



## NON-INTERVENTIONAL STATISTICAL ANALYSIS PLAN FOR SECONDARY DATA COLLECTION STUDY

### VERSION HISTORY

Version	Effective Date	Change Type (New, Revise, Admin)	Summary of Revisions
1.0	25 Januray 2019	New	
2.0	07 Januray 2021	Admin	<p>The purpose of changes is to further clarify and better present data. The vast majority of those changes are made related to appendix 4 of table shells. The changes do not impact data analyses or result generation.</p> <ul style="list-style-type: none"> <li>● In the body of the SAP: <ul style="list-style-type: none"> <li>○ Change “main cohort” to “main study”</li> <li>○ Change “prospective Cohort” or “prospective study” to “prospective cohort study”</li> <li>○ Change “Prevan13” to “13vPnC”</li> <li>○ Change “PCV13” to “13vPnC”</li> </ul> </li> <li>● For Appendix 1 and 2: <div style="background-color: black; width: 100px; height: 20px; margin: 5px 0;"></div> <div style="background-color: black; width: 100px; height: 20px; margin: 5px 0;"></div> </li> <li>● For the Table shell (Appendix 4): <ul style="list-style-type: none"> <li>○ Add tables 4.1.2, 4.1.5, 4.2.2, 4.2.5, 5.1.2, 5.1.5, 5.2.2, 5.2.5, and change the serial number for other tables accordingly (eg, 4.1.2 to 4.1.3..) – (Note: these tables were developed and included in the SAP version 1.0 but were left out accidentally at the time to attach them in the Table Shell, Appendix 4).</li> <li>○ Add variable “Febrile seizures” for tables 2.1, 4.1.1-4.2.6</li> <li>○ Drop variable “Highest temperature for each day fever is reported” for tables 5.1.1-5.2.6</li> <li>○ Add variable “Residential area” for table 1.1, 1.2, 3.1, 3.2</li> <li>○ Change “children” to “participants”</li> <li>○ Change “subjects” to “participants”</li> <li>○ Change “Safety Outcomes” to “Safety Outcomes of Interest”</li> <li>○ Format “0&lt;-2” as “0- ≤2”, “2&lt;-4” as “2- ≤4”, etc.</li> <li>○ Change “co administration” to “co-</li> </ul> </li> </ul>

			<p>administration”</p> <ul style="list-style-type: none"><li>○ Change “Seizures (including febrile seizures)” to “All Seizures”</li><li>○ Change “Seizures (NOT including febrile seizures)” to “All Seizures”</li><li>○ Other format changes include to change n to n (%) in the row titles, or drop n (%) in the column titles, and refine some footnotes.</li></ul>
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## **Non-Interventional Study Protocol**

**B1851193**

**An observational safety study for Prevenar 13 among  
Chinese children**

### **Statistical Analysis Plan (SAP)**

**Version:** <2.0>

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**Date:** 07 Januray 2021

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## 1. AMENDMENTS FROM PREVIOUS VERSION(S)

None.

## 2. INTRODUCTION

Pneumococcal disease is a leading cause of serious illness throughout the world.<sup>1</sup> It is an infection caused by *Streptococcus pneumoniae* bacteria (“pneumococcus”). These bacteria can result in both invasive diseases such as bacteremic pneumonia, septicemia, and meningitis, and non-invasive diseases, such as pneumonia, otitis media, and sinus infections. One of the key risk factors of pneumococcal diseases is age, with children younger than 2 years of age and the elderly being at the highest risk of developing pneumococcal-related infection.<sup>1</sup> Pneumococcal disease is estimated to be the leading cause of vaccine-preventable morbidity and mortality among children younger than 5 years both globally and in China.<sup>1</sup> At least 1 million children die of pneumococcal disease every year, most of these being young children in developing countries.<sup>2</sup> In China alone, approximately 30 thousand children in this age group die due to pneumococcal disease every year.<sup>3</sup>

Currently, several approved vaccines to prevent *S. pneumoniae* infections are available on the market, including the 10-, and 13-valent pneumococcal conjugate vaccines (10 vPnC; Synflorix, GlaxoSmithKline and 13vPnC; Prevnar 13, Pfizer, respectively), and the 23-valent pneumococcal polysaccharide vaccine (PPSV23; Pneumovax, SanofiPasteurMSD [in the US, Merck]). 13vPnC was approved in the European Union in December 2009 for the prevention of Invasive Pneumococcal Disease (IPD), pneumonia and acute otitis media caused by *S. pneumoniae* in infants, children and adolescents from 6 weeks to 17 years of age, and in the United States in February 2010 for the prevention of IPD and otitis media caused by *S. pneumoniae* in children 6 weeks through 5 years of age.

13vPnC is in use in the national childhood immunization programs in many countries and contains polysaccharides from the 7 serotypes included in the original 7vPnC (4, 6B, 9V, 14, 18C, 19F, and 23F) and an additional 6 serotypes (1, 3, 5, 6A, 7F, and 19A), all conjugated to cross-reactive material 197. It has been shown that the 6 additional serotypes in 13vPnC increase coverage for IPD prevention in children <5 years of age from 74% to 88% globally.<sup>4</sup> Importantly, the additional serotypes in 13vPnC are associated with a high percentage of pneumococcal disease in the developing world.<sup>5,6</sup>

In October 2016, 13vPnC was approved in China for the prevention of invasive disease (including bacteremic pneumonia, meningitis, septicemia, and bacteremia) caused by *Streptococcus pneumoniae* for infants and children aged 6 weeks to 15 months. 13vPnC is recommended as a series of four doses, one dose at each of these ages: 2 months; 4 months; 6 months; 12 through 15 months. Vaccines in China are classified into two categories. Type I vaccines are mandatory and provided for citizens by the government free of charge, and infants and children should get immunized according to the government’s regulations. These vaccines include tuberculosis (*Bacillus Calmette–Guérin*), diphtheria/tetanus/ pertussis, oral polio, measles/mumps/rubella, hepatitis B, hepatitis A, meningococcal, and Japanese encephalitis. Type II vaccines are ones

available on the private market for use on a voluntary base at the purchaser's expense. They consist of Haemophilus influenzae type b (Hib), pneumococcal conjugate, rotavirus (RV), inactivated polio (IPV), varicella, human papillomavirus, and influenza vaccines. In China, all type I and type II vaccines are administered at China Centers for Disease Control and Prevention (CDC) immunization clinics.

13vPnC has a favorable benefit-risk profile. Based on data from clinical trials and the worldwide safety experiences after authorization, convulsions/seizures, fever, apnea, and anaphylaxis/hypersensitivity are identified as known or potential risks associated with 13vPnC among young children.<sup>7,8</sup>

To monitor these known and potential risks for 13vPnC among Chinese children receiving 13vPnC in China, an observational study using a population-based electronic health record (EHR) database from May 1<sup>st</sup>, 2017 to July 31<sup>st</sup>, 2020 in Yinzhou district of Ningbo city in China will be conducted in a real world setting. Yinzhou is one of the largest districts in economically developed Ningbo city. Children exposed to 13vPnC in Yinzhou district are representative of those children likely receiving 13vPnC in China given that only families with sufficient financial resources can afford 13vPnC. In addition, the coverage for 7vPnC in Yinzhou district was similar to that in the published literature in China.<sup>9</sup> As a population-based database, Yinzhou EHR database consists of complete immunization records and healthcare data of all children in the district. This allows for the possibility of monitoring the safety of 13vPnC in the context of routine medical care from outpatient visits to inpatient care and provides greater generalizable findings.

This observational safety study is a post authorization commitment (PAC) to fulfill the key monitoring activity requirement of the National Medical Products Administration (NMPA) in China.

## 2.1. Study Objectives

The overall objective of this observational study is to expand the understanding of the safety profile of 13vPnC in Chinese pediatric populations.

Specific objectives of the study are to:

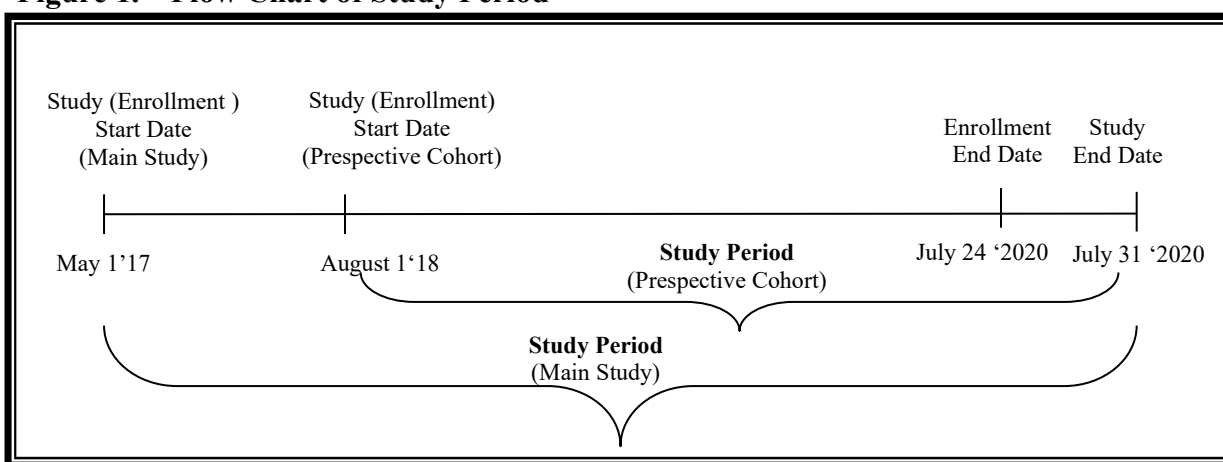
- Estimate incidence rates (per 1,000 person-days at risk and per 1,000 doses) of safety outcomes of interest (SOIs) including seizures (including febrile seizures), urticaria and angioedema, apnea, and fever for the periods of 0 through 3 days (with 0 indicating the day of vaccination), 4 through 7 days, and 0 through 7 days after the 13vPnC vaccination by all doses and by each dose in the main study based on Yinzhou EHR database between 1 May 2017 and 31 July 2020.
- Estimate the incidence rates (per 1,000 person-days at risk and per 1,000 doses) of the SOIs above after the 13vPnC vaccination by all doses and by each dose in a sub-population of the main study through a prospective cohort study between 1 August 2018 and 31 July 2020.

All SOIs are acute events and are likely to occur within 7 days post-vaccination based on the known safety profile of 13vPnC as well as biologic plausibility of these events occurring after vaccination.<sup>7,8</sup>

## 2.2. Study DESIGN

This is an observational study based on a population-based EHR database. In addition, a validation study including validation of ICD-10 codes or ICD-10 code based algorithm for identifying all SOIs and a prospective cohort study in a sub-population of the main study will be conducted in order to offset the potential biased results from the main study because of potential misclassification of the SOIs due to miscoding and/or undercoding of ICD-10 codes used to identify these safety outcomes in the EHR database.

**Figure 1. Flow Chart of Study Period**

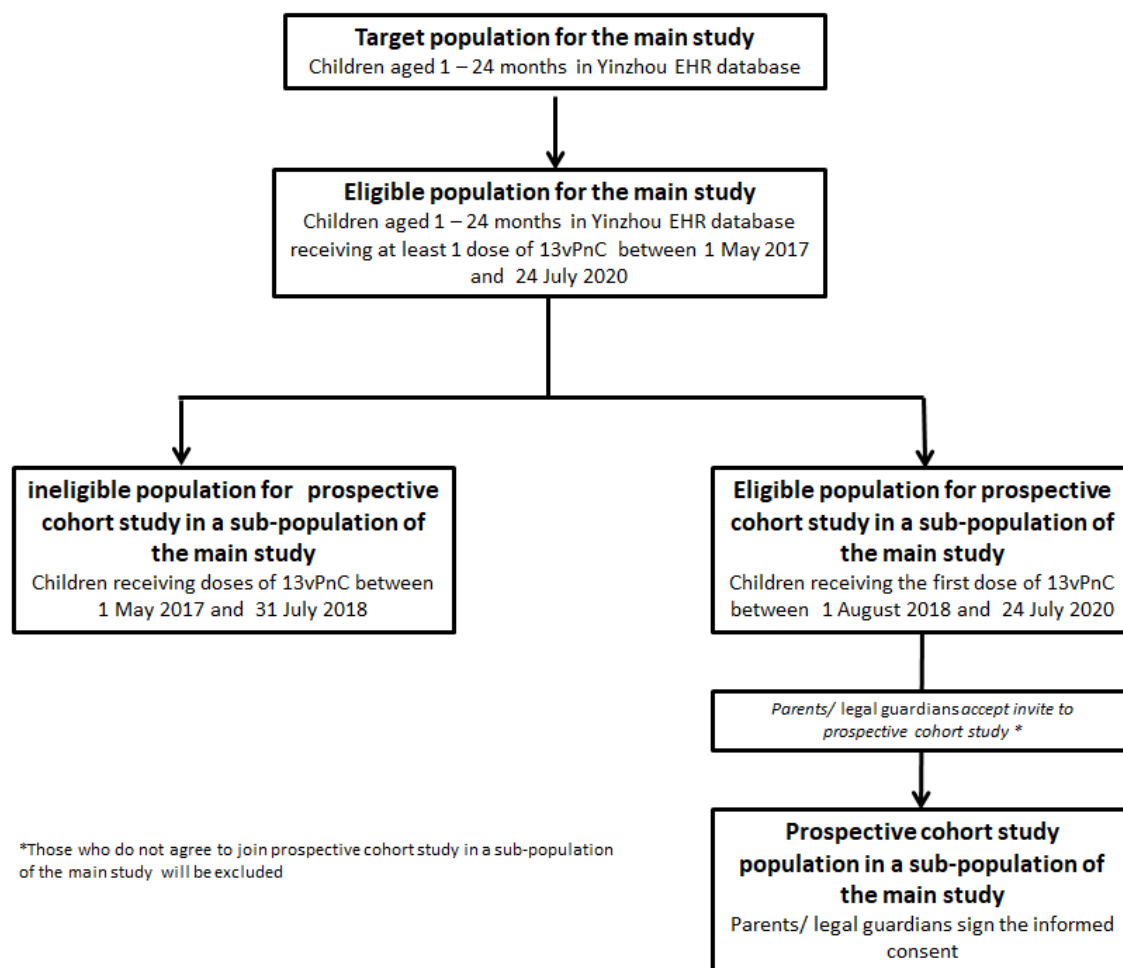


Note: The end of enrolment for both Prospective Cohort Study as well as the main study is the same-July 24, 2020 although we don't actively enroll patients in the main study. In other words, any doses received after July 24, 2020 won't be included. For both studies, we allow a 7-day follow up period for each dose. Thus, the study end date for both studies is July 31, 2020.

### 2.2.1. Study population

The main study population consists of eligible children aged 1-24 months receiving at least one dose of 13vPnC recorded in Yinzhou EHR database between 1 May 2017 and 24 July 2020 (i.e. one week prior to the end of the study) (Figure 2).



**Figure 2. Flow Chart for Study Populations**

### 2.2.2. Data Source

Since 2014, via collaboration with academic institutions in China, Pfizer has been evaluating various observational data sources in China and has determined that they provide potential value to post-marketing drug safety studies, particularly population-based EHRs.<sup>10</sup> Yinzhou EHR database is selected for this study because this population-based EHR database consists of complete immunization records and healthcare data of all children in the district.

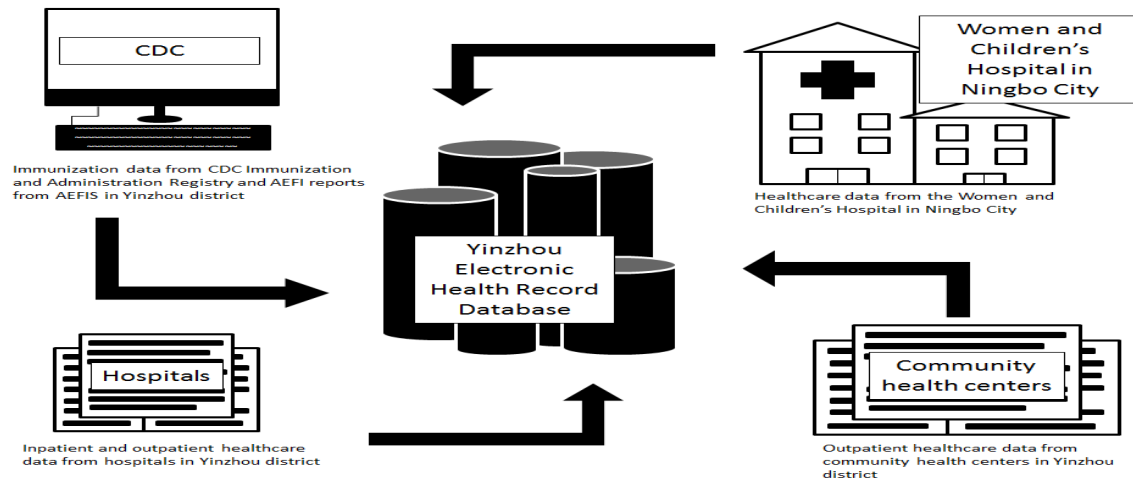
### 2.2.3. Yinzhou EHR Database

Yinzhou is one of the largest districts of economically developed Ningbo city in Zhejiang province, China and consists of approximately 1.6 million populations (740,000 permanent residents and 860,000 temporary residents). The Yinzhou EHRs include data from three main sources (Figure 3):

- Yinzhou CDC databases;

- Healthcare data including EMRs, claims and e-prescriptions from hospitals and community health centers within the district;
- Healthcare data including EMRs, claims and e-prescriptions from the Women and Children's hospital of Ningbo city.

**Figure 3. Components of Yinzhou EHR Database**



Data from these data sources are entered into Yinzhou EHR database in real time. These data sources are linked via each child's unique personal identification number (termed the national identification (NID) number) used by each resident throughout life in China. In a situation where children do not yet have a NID number, data of those children are matched by names of children, dates of birth, names of parents/legal guardians, or home addresses.

- Yinzhou CDC database:** There are two CDC databases (ie, Immunization Administration Registry and CDC AEFIS) in the district. The Immunization Administration Registry includes immunization data at CDC immunization clinics for both type I and type II vaccines for all children aged <7 years. The AEFIS is a passive surveillance system and collects AEFIs reports. All cases reported to AEFIS are to be investigated, with the exception of common adverse reactions that have a clear diagnosis (eg, fever, redness, and swelling on the injection site; induration).
- Healthcare data from hospitals and community health centers within the district:** Yinzhou district collect healthcare data of its residents from hospitals (3 tertiary general hospitals and 1 specialized hospital) and community health centers (20) within the district including inpatient and outpatient visits from all hospitals and outpatient visits from all community health centers within the district.

- c. **Healthcare data from the Women and Children's Hospital of Ningbo city:**  
The Women and Children's Hospital of Ningbo city is the only children hospital in the city. It is essential to have data from this hospital being part of Yinzhou EHR database because this hospital is very likely to be the hospital of choice if families would seek medical care for their children outside hospitals of Yinzhou district.

### 3. HYPOTHESES AND DECISION RULES

NA: This is a descriptive study

### 4. ANALYSIS SETS/POPULATIONS

An overall analysis population is defined in Figure 2, [Section 2.2](#).

#### 4.1. Analysis Set

##### 4.1.1. Inclusion Criteria

Children must meet all of the following inclusion criteria to be eligible for inclusion in the study:

- For main study, all children must be aged 1 to 24 months and receive at least one dose of 13vPnC between 1 May 2017 and 24 July 2020 where the first dose is received before or on 24 July 2020 since a 7-day post-vaccination follow-up for each dose in each child receiving 13vPnC is needed.
- The index date for this overall cohort of the main study is defined as the 1<sup>st</sup> date that an eligible child receives any dose of 13vPnC in the series between 1 May 2017 and 24 July 2020.

##### 4.1.2. Exclusion Criteria

There are no exclusion criteria for this study.

#### 4.2. Sub analysis set

For the prospective cohort study in a sub-population of the main study, eligible children must receive the first dose of 13vPnC between 1 August 2018 and 24 July 2020 and an informed consent must be obtained from parents/legal guardians (Figure 2).

- The index date for this prospective cohort study as a sub set of the main study is defined as the 1<sup>st</sup> date that an eligible child receives the 1<sup>st</sup> dose of 13vPnC in the series between 1 August 2018 and 24 July 2020

#### 4.3. Subgroups

Subgroup analysis may be considered, including but not limited to subgroup analyses by age, dosage, and follow-up length.

## 5. ENDPOINTS AND COVARIATES

Five safety outcomes will be evaluated in this study. ICD 10 codes and risk windows for these outcomes are described in details in section 5.1. As we are evaluating acute events after each dose among children aged 1-24 months, the risk windows are very short. The baseline period varies by each child and is defined as the period between the date entering the study (i.e. the enrolment data in the study dataset) and the 1<sup>st</sup> date receiving any available dose at age 1-24 months (main study). Demographic characteristics at time entering the study and age at the time receiving each dose of 13vPnC will be described (see [Section 7](#))

### 5.1. Safety Endpoints

Outcome*	Main Study	Perspective Cohort	Risk window for each dose and for all doses
Seizures (including febrile seizures)	Appendix 1 (ICD 10 code list for the Outcome of Interests)		0-3 days, 4-7 days, 0-7 days
Seizures (NOT including febrile seizures)		Reported Terms	0-3 days, 4-7 days, 0-7 days
Febrile seizures		Reported Terms	0-3 days, 4-7 days, 0-7 days
Urticaria and angioedema	Appendix 1 (ICD 10 code list for the Outcome of Interests)	Reported Terms	0-3 days, 4-7 days, 0-7 days
Apnea	Appendix 1 (ICD 10 code list for the Outcome of Interests)	Reported Terms	0-3 days, 4-7 days, 0-7 days
Fever	Appendix 1 (ICD 10 code list for the Outcome of Interests)	Reported Terms (≥38°C)	0-3 days, 4-7 days, 0-7 days
Highest temperature for each day fever		Reported Terms	0-3 days, 4-7 days, 0-7 days

\*Please note, ICD codes will be used to capture these events for the main study but reports of these events from parents will be used for the prospective cohort study.

### 5.2. Covariates

**Table 1. Variables and Roles**

Variable	Role	Operational definition
Age	Demographic	Age at index date, age at entering into study, age at 1 <sup>st</sup> diagnosis depending on the reporting purposes (see Table shell – Appendix 4)
Gender	Demographic	Female, Male
Residency Status	Demographic	Permanent residents, Temporal

		residents at time entering the study
Known allergies	Medical history	Only in prospective cohort study, reported during the 1 <sup>st</sup> visit (Yes/No)
Gestational Age	Medical history	Full term ( $\geq 37$ weeks), Preterm ( $< 37$ weeks) reported during the 1 <sup>st</sup> visit in prospective cohort; or diagnosis codes prior to the 1 <sup>st</sup> date of a dose available in the database
Birth weight	Medical history	Normal ( $\geq 2500$ g), Low birth weight ( $< 2500$ g) reported during the 1 <sup>st</sup> visit in prospective cohort study; or diagnosis codes prior to the 1 <sup>st</sup> date of a dose available in the database
Sickle cell disease	Medical history	In prospective cohort study, reported during the 1 <sup>st</sup> visit (Yes/No) In main study, look at the diagnosis codes prior to the 1 <sup>st</sup> date of a dose available in the database (Appendix 2– ICD 10 code list for the covariates)
History of febrile seizure	Medical history	In prospective cohort study, reported during the 1 <sup>st</sup> visit (Yes/No) In main study, look at the diagnosis codes prior to the 1 <sup>st</sup> date of a dose available in the database (Appendix 1)
History of other seizures	Medical history	In prospective cohort study, reported during the 1 <sup>st</sup> visit (Yes/No) In main study, look at the diagnosis codes prior to the 1 <sup>st</sup> date of a dose available in the database (Appendix 2- ICD 10 code list for the covariates)
History of urticaria	Medical history	In prospective cohort study, reported during the 1 <sup>st</sup> visit (Yes/No) In main study, look at the diagnosis codes prior to the 1 <sup>st</sup> date of a dose available in the database (Appendix 2- ICD 10 code list for the covariates)
History of angioedema	Medical history	In prospective cohort study, reported during the 1 <sup>st</sup> visit (Yes/No) In main study, look at the diagnosis codes prior to the 1 <sup>st</sup> date of a dose available in the database (Appendix 2- ICD 10

		code list for the covariates)
History of apnea	Medical history	In prospective cohort study, reported during the 1 <sup>st</sup> visit (Yes/No) In main study, look at the diagnosis codes prior to the 1 <sup>st</sup> date of a dose available in the database (Appendix 1)
Fever at the date prior to 13vPnC vaccination	Medical history	In prospective cohort study, reported during the 1 <sup>st</sup> visit (Yes/No) In main study, look at the diagnosis codes prior to the 1 <sup>st</sup> date of a dose available in the database (Appendix 1)
Smoking in the family	Covariate	Only in prospective cohort study, reported during the 1 <sup>st</sup> visit (Yes/No)
Season of diagnosis for each safety outcome of interest	Covariate	Date of diagnosis of outcome of interests
Hospitalization for each safety outcome of interest	Covariate	Admission to hospital for the outcome of the interests: 1). In prospective cohort study , (Yes/No), reported during each visit) 2). In main study, using admission or discharge diagnosis to be the outcome of interests
Use of antipyretics post-vaccination	Covariate	Only in prospective cohort study, (Yes/No), reported during each visit)
Date of each dose of 13vPnC vaccination (based on barcode scanning)	Exposure	Date of administration
Other vaccines administrated the same date with 13vPnC	Co-administration	Date of administration (Appendix 3- Other vaccines potentially administrated on the same date with 13vPnC )

## 6. HANDLING OF MISSING VALUES

No imputation for missing values will be performed.

## 7. STATISTICAL METHODOLOGY AND STATISTICAL ANALYSES

### 7.1. Descriptive Analysis

Means, medians, and standard deviations will be provided for continuous variables. Numbers and percentages will be provided for dichotomous variables or categorical variables. Frequency distributions of age at the time receiving each dose of 13vPnC, gender, residential status, birthweight, gestational age, year of 13vPnC vaccinations, co-administration of other vaccines at the same date, and medical history will be described (Appendix 4: Table shell). In addition, frequency distributions of the number of SOIs by age, gender, residential status, season of vaccination , hospitalization, and year of 13vPnC

vaccinations will also be described (Appendix 4: Table shell). The frequency distributions mentioned above will be tabulated for both the main study and the prospective cohort study in the sub-population of the main study.

The incidence rate and its 95% CI for each safety outcome will be calculated per 1,000 person-days at risk and per 1,000 doses. For the former, the incidence rate will be calculated as the number of children exposed to each dose who experience the event during the specified risk window (ie, 0-3 days, 4-7 days, and 0-7 days post-vaccination) divided by the observed time at risk, multiply by 1000 (i.e. IR per 1000 person-days at risk). For the latter, the incidence rate will be calculated as the number of children exposed to each dose who experience the event during the specified risk window (ie, 0-3 days, 4-7 days, and 0-7 days post-vaccination) divided by the number of child receiving this specific dose, multiply by 1000 (ie. IR per 1000 doses). The incidence rate for each safety outcome will also be stratified by potential risk factors such as age group, gender, residence status, co-administration of other vaccines on the same date, season of administration of 13vPnC (Appendix 4: Table shell). The incidence rates will be estimated for both the main study and the prospective cohort study in the sub-population of the main study.

## 7.2. Validation of ICD Codes

To evaluate the accuracy of the ICD-10 codes or ICD-10 codes based algorithm for identifying all SOIs in the main study, relevant medical records of children having the ICD codes for these events are going to be obtained from hospitals within Yinzhou district and Women and Children's hospital of Ningbo city and outpatient medical records from community health centers within the district by Yinzhou CDC. A data abstraction form will be used to abstract data from the medical records. The abstracted data will be sent to an adjudication committee to determine whether the identified potential case is a true case. Then the adjudicated outcomes will be entered into the validation study database for analyses. The procedures for the validation study is described in Figure 3. The following analyses of positive predicted value (PPV), sensitivity (SE), specificity (SP), positive percent of agreement (PPA), and negative percent of agreement (NPA) will be calculated for main study and prospective cohort study respective performed (Appendix 4: Table shell).

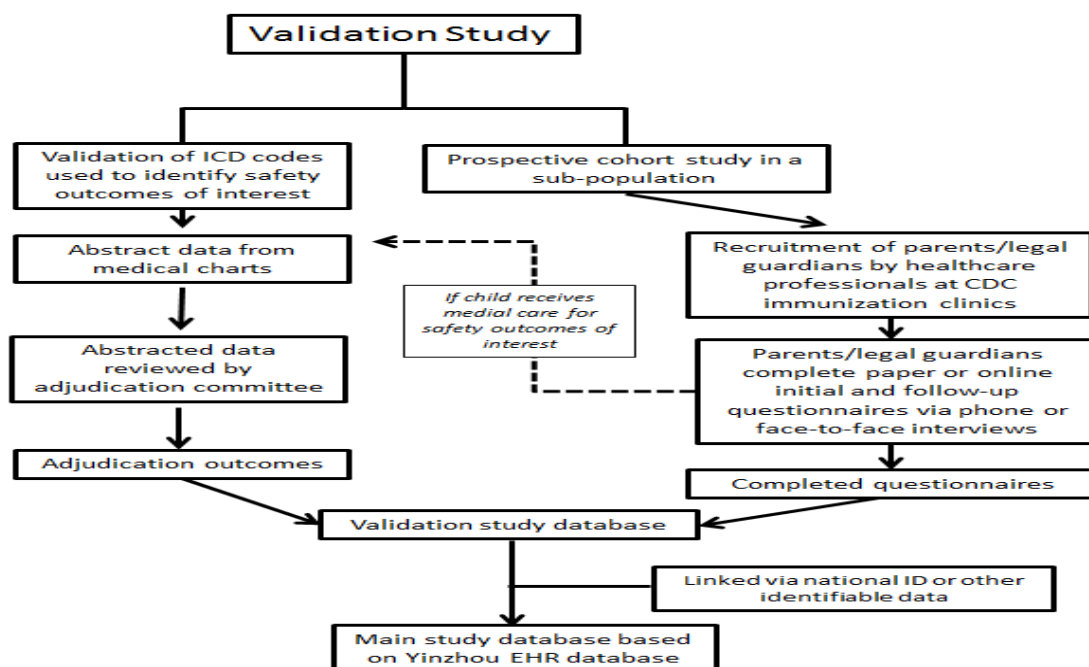
The PPV of an ICD-10 code or ICD-10 code based algorithm used to identify the SOIs against adjudicated outcomes based on medical records as a gold standard will be calculated for the validation of these codes in the main study.

- The PPV of a reported safety outcome of interest by parents/legal guardians that requires medical attentions against the adjudicated safety outcome based on medical records of children as a gold standard will be calculated in the prospective cohort study in the sub-population of the main study.
- Among children who participate in both the main study and the prospective cohort study, sensitivity and specificity of an ICD code or ICD-10 code based algorithm identifying seizures or apnea in the main study will be calculated using the adjudicated safety outcome in the prospective cohort study as a reference standard (ie, a gold standard).



- A positive percent of agreement and a negative percent of agreement will be estimated between an ICD code or ICD-10 code based algorithm identifying fever or urticaria and angioedema in the main study and the reported fever or urticaria and angioedema by parents/legal guardians in the prospective cohort study as a non-reference standard (ie, a non-gold standard).

**Figure 3. Procedures for the Validation Study**



All data analysis will be executed using statistical software SAS version 9.4 or later.

### 7.3. Summary of Analyses

	Analysis Set	Supports Protocol Objective Number	Subgroup	Statistical Method	Covariates/Strata	Missing Data
Characteristics of children	All enrolled children	1 and 2	NA	Descriptive analysis	NA	Included
Incidence rate	All enrolled children	1 and 2	Dose, age, gender, residence status, season, co-committant drugs	Descriptive analysis	Stratified by the subgroups	Excluded
ICD code validation	All cases where medical charts or data on medical charts are available	1 and 2	NA	PPV, SE, SP, PPA, NPA*	NA	Excluded

\*Positive predicted value (PPV), sensitivity (SE), specificity (SP), positive percent of agreement (PPA), and negative percent of agreement (NPA)

## 8. LIST OF TABLES AND TABLE SHELLS

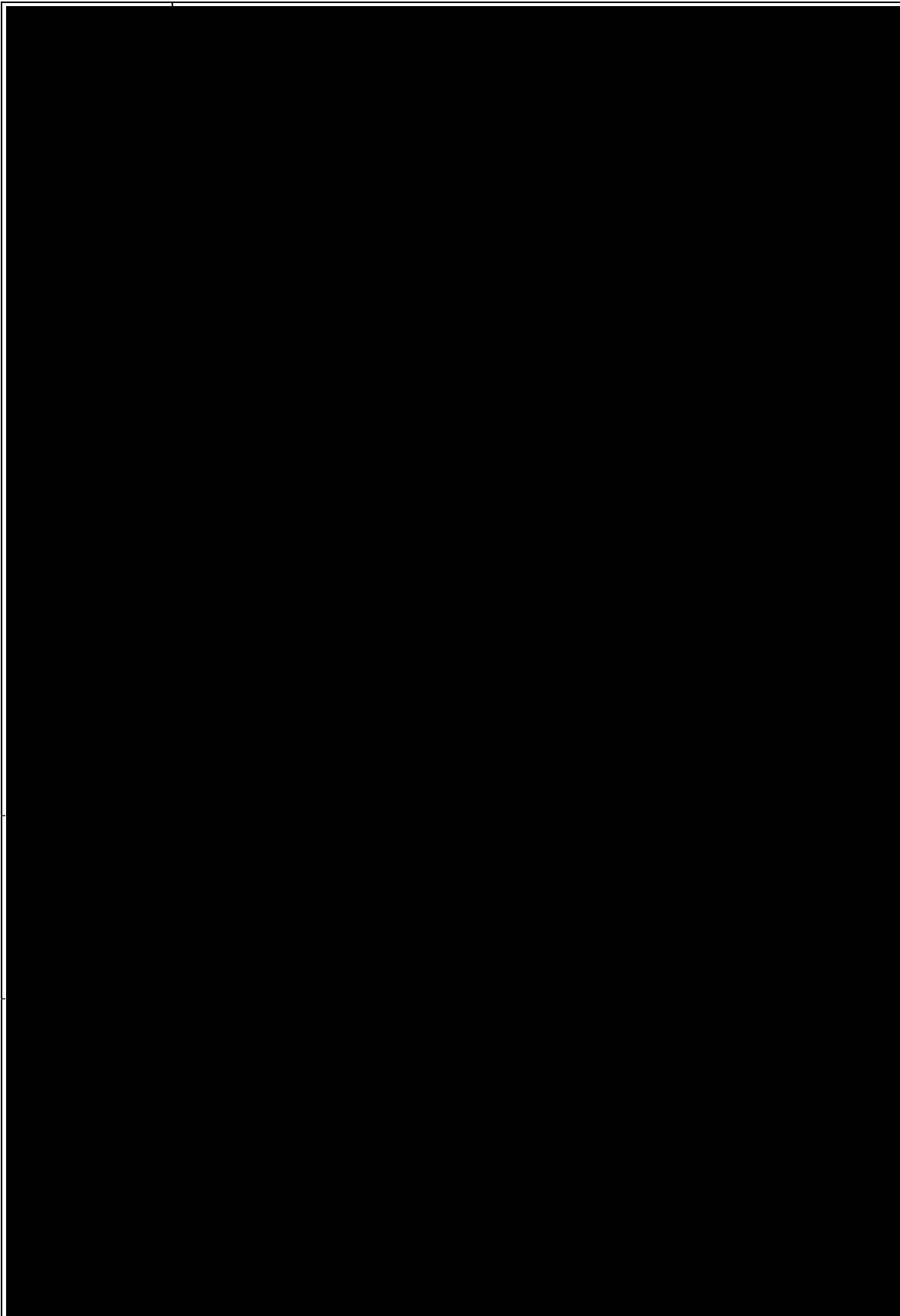
See Appendix 4.

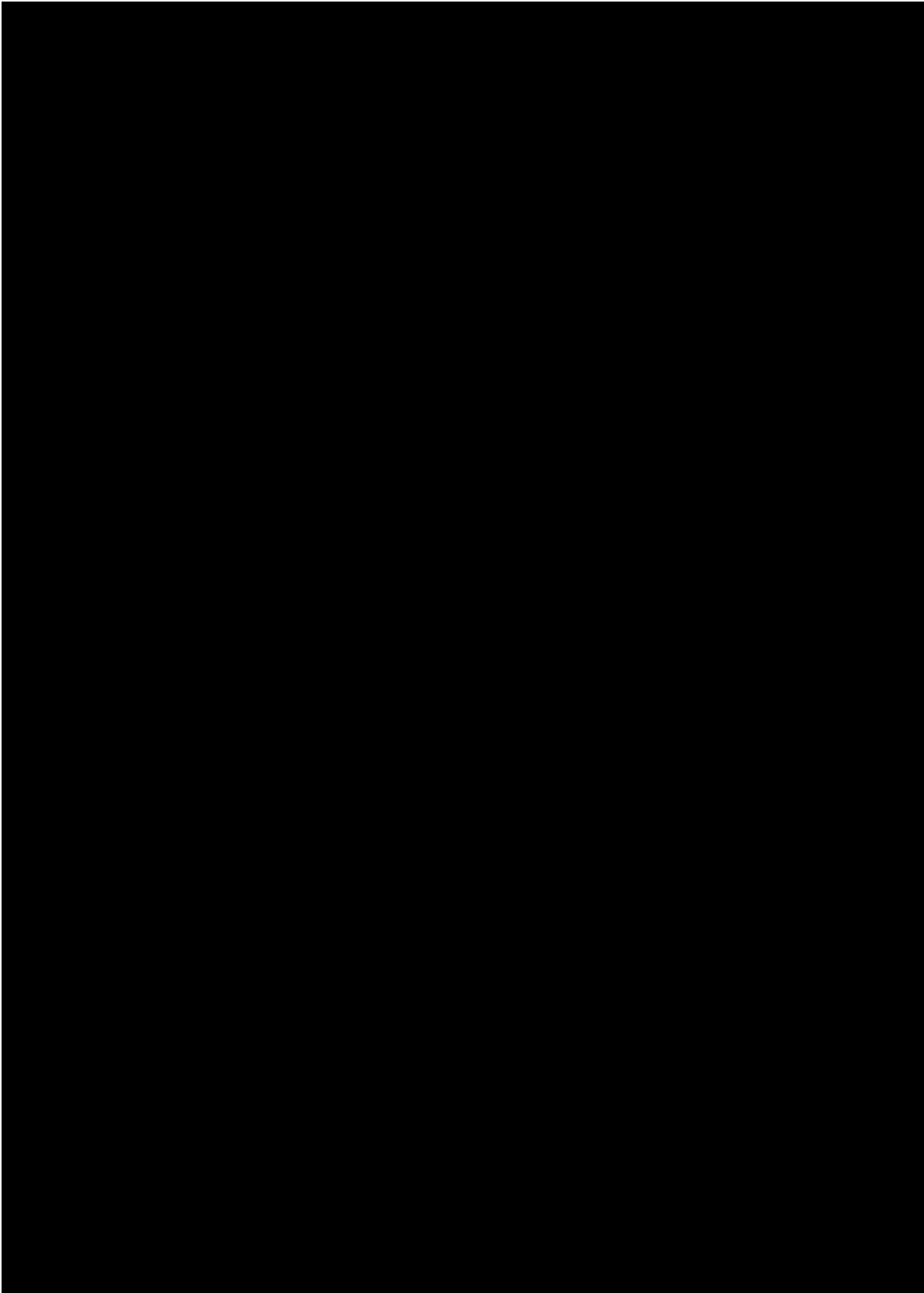
## 9. REFERENCES

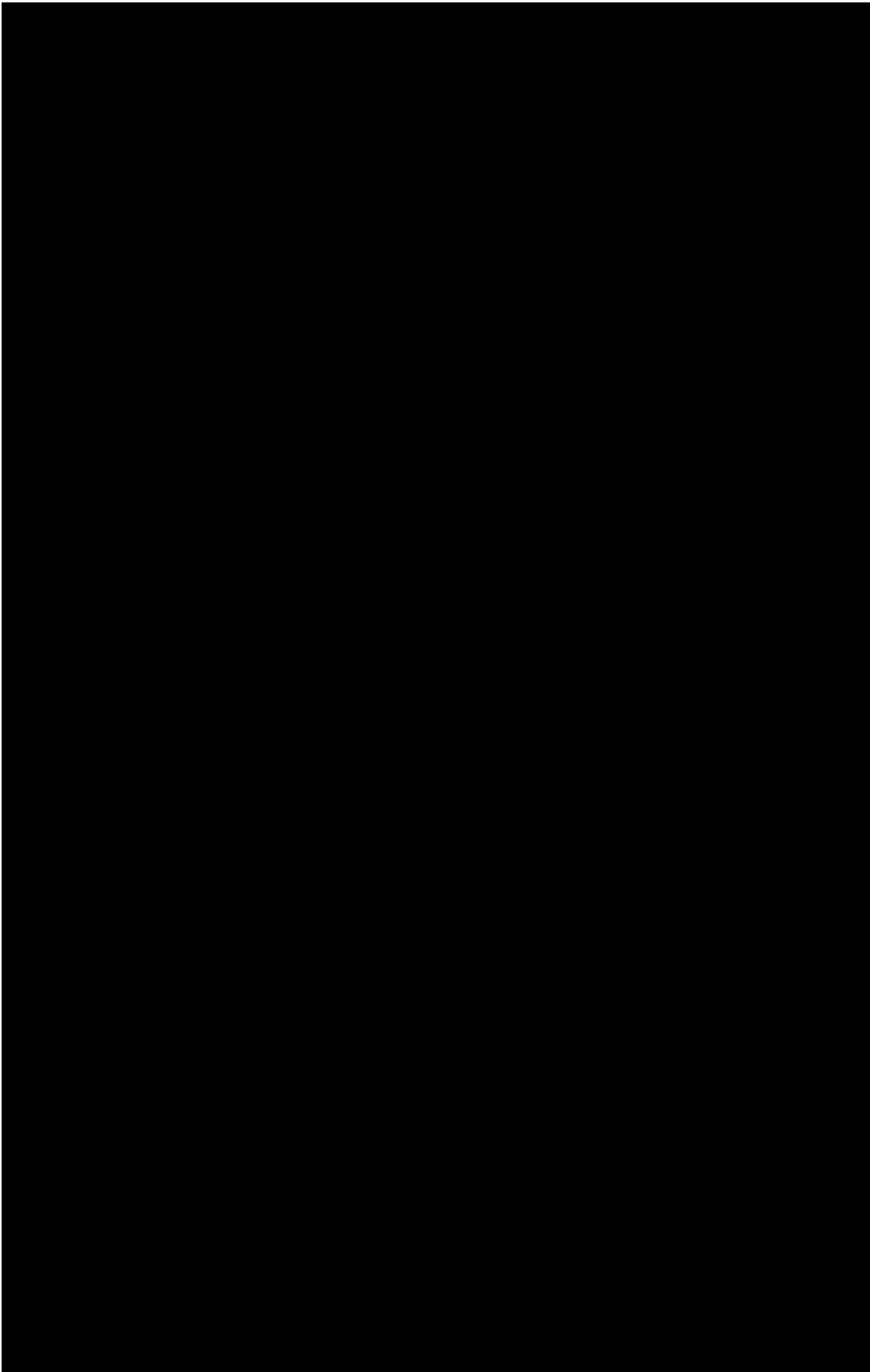
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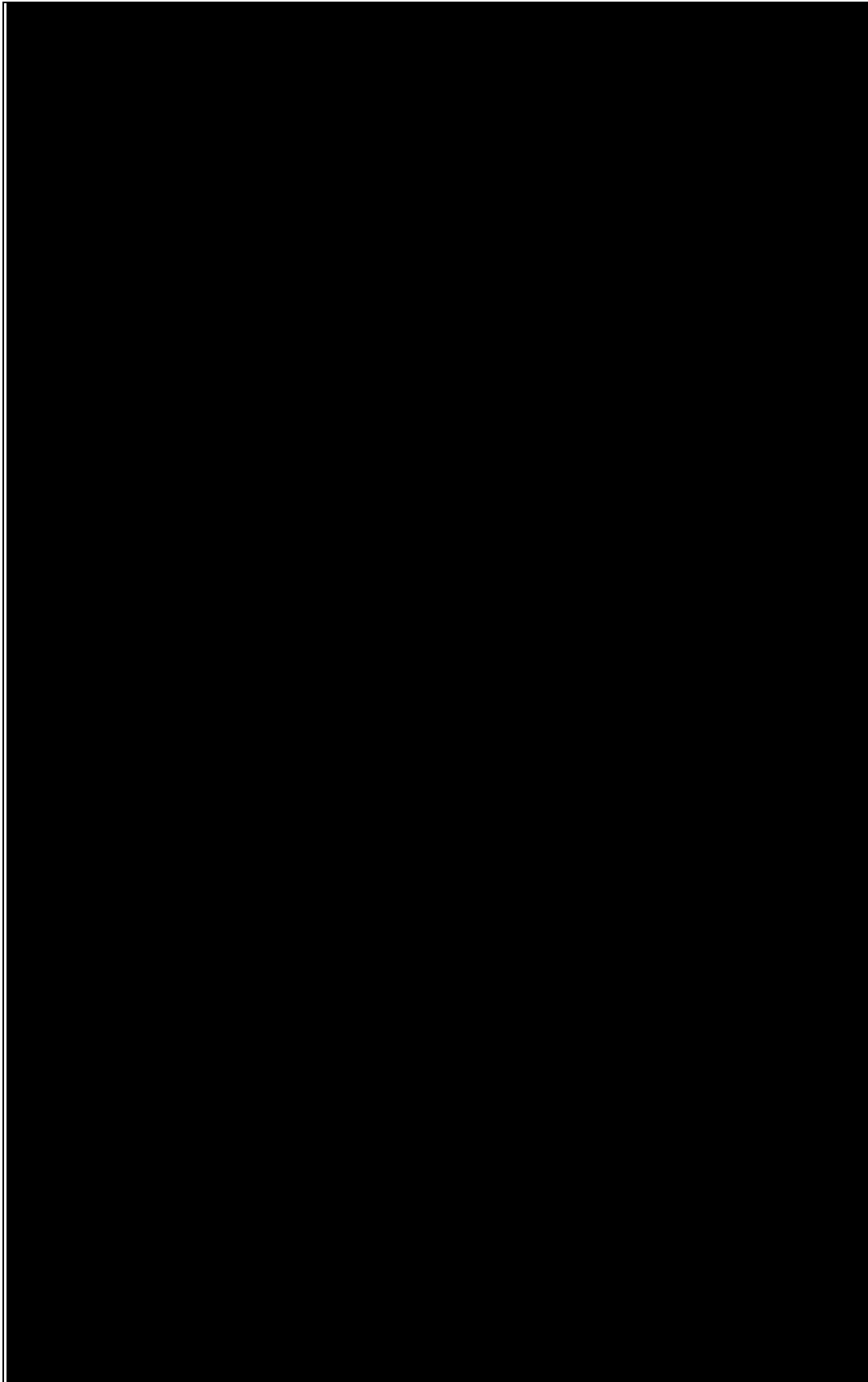
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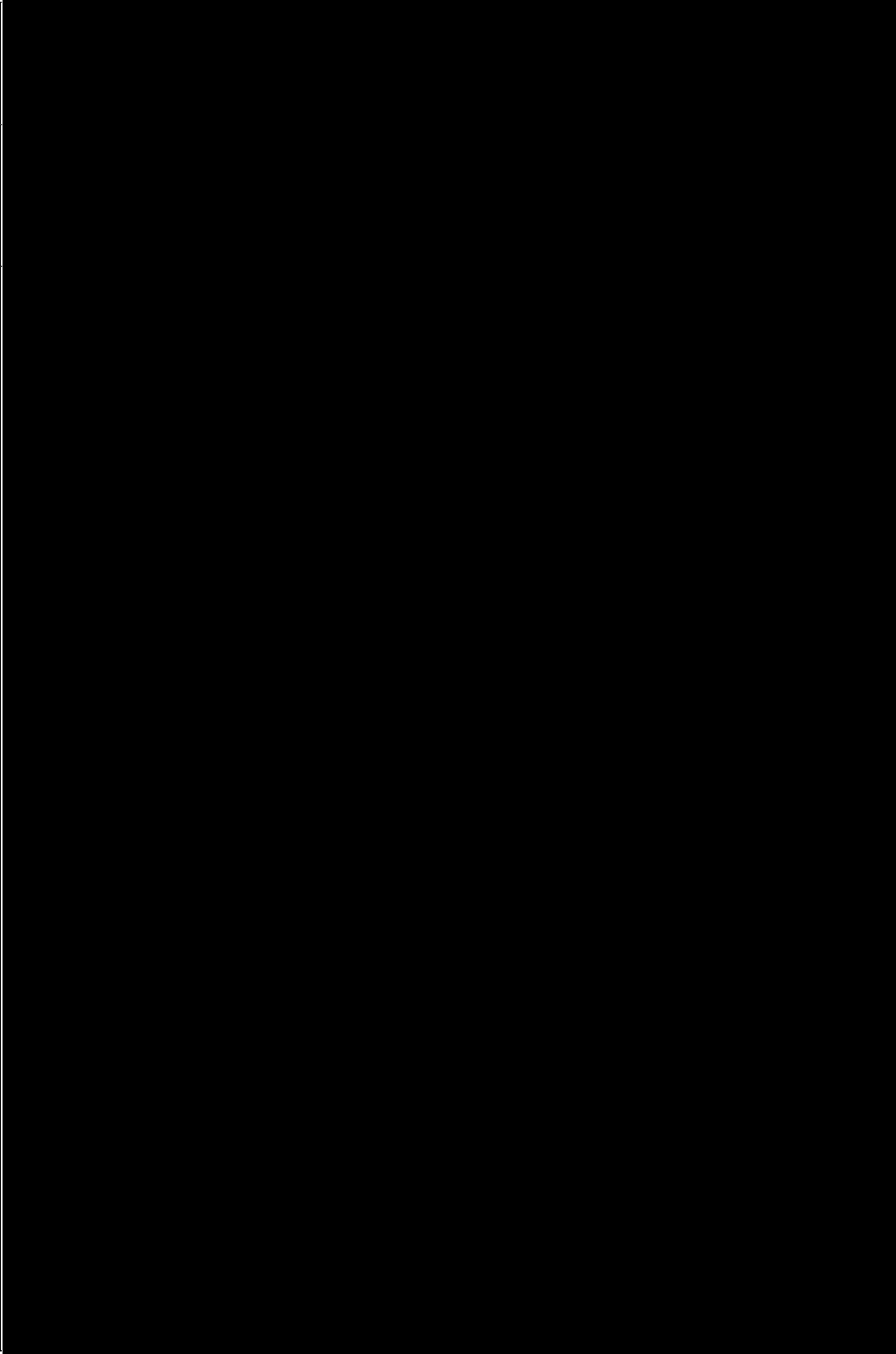














**Appendix 3. Other vaccines potentially administrated on the same date with 13vPnC - highlighted in the Table 1 and Table 2****Table 1. Immunization schedule for Type I vaccines for children aged 0-2 years in China**

Age/Vaccine	Bacillus Camette- Guerin	Hepatitis B	Polio	Diaphtheria/pertussis /Tetanus	Measles/ Mumps/ Rubella	Japanese Encephalitis	Meningococcal	Hepatitis A
Birth	B.C.G	HBV1						
1Month		HBV2						
2Months			OPV1					
3Months			OPV2	DPT1				
4Months			OPV3	DPT2				
5Months				DPT3				
6Months		HBV3						
6-18Months						JEV 2dose		
8Months					MMR			
10-22Months							MCV 2dose	
1-2 years			Booster	Booster		Booster		HAV1

**Table 2. Immunization schedule for Type II vaccines for children aged 0-2 years in China**

Age/Vaccines	Haemophilus Influenzae type b	Varicella	Rotavirus	Influenza	Pneumococcal	Pentaxim	IVP
Birth					1		
1Month							
2Months	Hib1		RV1		13vPnC-1	Pentaxim1	IPV1
3Months	Hib2		RV2			Pentaxim2	IPV2
4Months	Hib3		RV3		13vPnC-2	Pentaxim3	IPV3
5Months							
6Months					13vPnC-3		
12-15 Months					PCV Booster		
10-22Months	Hib Booster	Varicella1					
1-2 years				Influenza	Booster	Booster	Booster

**Appendix 4. Table Shell****Summary-TOC****Table 1.1 Participant Demographics and Clinical Characteristics at Baseline - Main Study****Table 1.2 Participant Demographics and Clinical Characteristics at Baseline - Prospective Cohort Study****Table 2.1 Administration of 13vPnC by Dose - Main Study****Table 2.2 Administration of 13vPnC by Dose - Prospective Cohort Study****Table 3.1 Distribution of Safety Outcomes of Interest - Main Study****Table 3.2 Distribution of Safety Outcomes of Interest - Prospective Cohort Study****Table 4.1.1 Incidence Rates (Per 1000 Person Days) of Safety Outcomes of Interest - Main Study (All Age: 0-24 months)****Table 4.1.2 Incidence Rates (Per 1000 Person Days) of Safety Outcomes of Interest - Main study (Age Stratification)****Table 4.1.3 Incidence Rates (Per 1000 Person Days) of Safety Outcomes of Interest - Main Study (by Gender)****Table 4.1.4 Incidence Rates (Per 1000 Person Days) of Safety Outcomes of Interest - Main Study (by Residence Status)****Table 4.1.5 Incidence Rates (Per 1000 Person Days) of Safety Outcomes of Interest - Main study (by Co-administration of other vaccines on the same date)****Table 4.1.6 Incidence Rates (Per 1000 Person Days) of Safety Outcomes of Interest - Main Study (by Season of administration of 13vPnC)****Table 4.2.1 Incidence Rates (Per 1000 Doses) of Safety Outcomes of Interest - Main Study (All Age: 0-24 months)****Table 4.2.2 Incidence Rates (Per 1000 Doses) of Safety Outcomes of Interest - Main study (Age Stratification)****Table 4.2.3 Incidence Rates (Per 1000 Doses) of Safety Outcomes of Interest - Main Study (by Gender)****Table 4.2.4 Incidence Rates (Per 1000 Doses) of Safety Outcomes of Interest - Main Study (by Residence Status)**

**Table 4.2.5 Incidence Rates (Per 1000 Doses) of Safety Outcomes of Interest - Main study (by Co-administration of other vaccines on the same date)**

**Table 4.2.6 Incidence Rates (Per 1000 Doses) of Safety Outcomes of Interest - Main Study (by Season of administration of 13vPnC)**

**Table 5.1.1 Incidence Rates (Per 1000 Person Days) of Safety Outcomes of Interest - Prospective Cohort Study (All Age: 0-24 months)**

**Table 5.1.2 Incidence Rates (Per 1000 Person Days) of Safety Outcomes of Interest - Prospective cohort study (Age Stratification)**

**Table 5.1.3 Incidence Rates (Per 1000 Person Days) of Safety Outcomes of Interest - Prospective Cohort Study (by Gender)**

**Table 5.1.4 Incidence Rates (Per 1000 Person Days) of Safety Outcomes of Interest - Prospective Cohort Study (by Residence Status)**

**Table 5.1.5 Incidence Rates (Per 1000 Person Days) of Safety Outcomes of Interest - Prospective cohort study (by Co-administration of other vaccines on the same date)**

**Table 5.1.6 Incidence Rates (Per 1000 Person Days) of Safety Outcomes of Interest - Prospective Cohort Study (by Season of administration of 13vPnC)**

**Table 5.2.1 Incidence Rates (Per 1000 Doses) of Safety Outcomes of Interest - Prospective Cohort Study (All Age: 0-24 months)**

**Table 5.2.2 Incidence Rates (Per 1000 Doses) of Safety Outcomes of Interest - Prospective cohort study (Age Stratification)**

**Table 5.2.3 Incidence Rates (Per 1000 Doses) of Safety Outcomes of Interest - Prospective Cohort Study (by Gender)**

**Table 5.2.4 Incidence Rates (Per 1000 Doses) of Safety Outcomes of Interest - Prospective Cohort Study (by Residence Status)**

**Table 5.2.5 Incidence Rates (Per 1000 Doses) of Safety Outcomes of Interest - Prospective cohort study (by Co-administration of other vaccines on the same date)**

**Table 5.2.6 Incidence Rates (Per 1000 Doses) of Safety Outcomes of Interest - Prospective Cohort Study (by Season of administration of 13vPnC)**

**Table 6 Validation of ICD code using adjudicated safety outcome based on medical records of children as gold standard: Positive Predictive Value (PPV)**

**Table 6.1.1 Validation of ICD code (Main Study): Seizures (including febrile seizures)**

**Table 6.1.2 Validation of ICD code (Main Study): Urticaria and angioedema**

**Table 6.1.3 Validation of ICD code (Main Study): Apnea**

**Table 6.1.4 Validation of ICD code (Main Study): Fever**

**Table 6.2.1 Validation of ICD code (Prospective Cohort Study): Seizures (including febrile seizures)**

**Table 6.2.2 Validation of ICD code (Prospective Cohort Study): Urticaria and angioedema**

**Table 6.2.3 Validation of ICD code (Prospective Cohort Study): Apnea**

**Table 6.2.4 Validation of ICD code (Prospective Cohort Study): Fever**

**Table 7 Validation of ICD code using adjudicated safety outcome in the Prospective Cohort Study as a reference standard: Sensitivity and Specificity**

**Table 7.1.1 Validation of ICD code using adjudicated safety outcome in the Prospective Cohort Study as a reference standard: Seizures (including febrile seizures)**

**Table 7.1.2 Validation of ICD code using adjudicated safety outcome in the Prospective Cohort Study as a reference standard: Apnea**

**Table 8 Validation of ICD code using the reported terms by parents/legal guardians in the Prospective Cohort Study as a non-reference standard: Positive Percentage Agreement (PPA) and Negative Percentage Agreement (NPA)**

**Table 8.1.1 Validation of ICD code using the reported terms by parents/legal guardians in the Prospective Cohort Study as a non-reference standard: Urticaria and angioedema**

**Table 8.1.2 Validation of ICD code using the reported terms by parents/legal guardians in the Prospective Cohort Study as a non-reference standard: Fever**

<b>Table 1.1 Participant Demographics and Clinical Characteristics at Baseline* - Main Study</b>	
	<b>Overall n (%)</b>
<b>Number of Participants</b>	XXX
<b>Age at entering the study [month]</b>	
Mean (SD)	XXX (XX.X)
Median	XXX
Minimum	XXX
Maximum	XXX
<b>Age groups at entering the study (month)</b>	
0- ≤2	XXX
2- ≤4	XXX
4- ≤6	XXX
6- ≤8	XXX
8- ≤10	XXX
10- ≤12	XXX
12- ≤14	XXX
14- ≤16	XXX
16- ≤18	XXX
18- ≤20	XXX
20- ≤22	XXX
22- ≤24	XXX
<b>Sex</b>	
Male	XXX (XX.X)
Female	XXX (XX.X)
<b>Residential area</b>	
Urban/suburban	XXX (XX.X)
Rural	XXX (XX.X)
Missing	XXX (XX.X)
<b>Residential status</b>	
Permanent residents	XXX (XX.X)
Temporary residents	XXX (XX.X)
Missing	XXX (XX.X)
<b>Birthweight [n (%)]</b>	
Normal	XXX (XX.X)
Low birth weight	XXX (XX.X)
high birth weight	XXX (XX.X)
Missing	XXX (XX.X)
<b>Gestational Age</b>	
Full term	XXX (XX.X)
Pre-mature	XXX (XX.X)
Post-mature	XXX (XX.X)
<b>Sickle cell disease</b>	



Yes	XXX (XX.X)
No	XXX (XX.X)
<b>History of other seizures</b>	
Yes	XXX (XX.X)
No	XXX (XX.X)
<b>History of febrile seizure</b>	
Yes	XXX (XX.X)
No	XXX (XX.X)
<b>History of urticaria</b>	
Yes	XXX (XX.X)
No	XXX (XX.X)
<b>History of angioedema</b>	
Yes	XXX (XX.X)
No	XXX (XX.X)
<b>History of apnea</b>	
Yes	XXX (XX.X)
No	XXX (XX.X)
<b>Fever at the date prior to 13vPnC vaccination</b>	
Yes	XXX (XX.X)
No	XXX (XX.X)

\*Definition of baseline: Period between the 1st date of healthcare record (combining EHR and vaccination data) during the study period and 1st date of available 13vPnC dose (index date) recorded

Table 1.2 Participant Demographics and Clinical Characteristics at Baseline* - Prospective Cohort Study	
	Overall n (%)
<b>Number of participants</b>	XXX
<b>Age at entering the study [month]</b>	
Mean (SD)	XXX (XX.X)
Median	XXX
Minimum	XXX
Maximum	XXX
<b>Age groups at entering the study (month)</b>	
0- ≤2	XXX
2- ≤4	XXX
4- ≤6	XXX
6- ≤8	XXX
8- ≤10	XXX
10- ≤12	XXX
12- ≤14	XXX
14- ≤16	XXX
16- ≤18	XXX
18- ≤20	XXX
20- ≤22	XXX
22- ≤24	XXX
<b>Sex [n (%)]</b>	
Male	XXX (XX.X)
Female	XXX (XX.X)
<b>Residential area</b>	
Urban/suburban	XXX (XX.X)
Rural	XXX (XX.X)
Missing	XXX (XX.X)
<b>Residential status</b>	
Permanent residents	XXX (XX.X)
Temporary residents	XXX (XX.X)
Missing	XXX (XX.X)
<b>Birthweight</b>	
Normal	XXX (XX.X)
Low birth weight	XXX (XX.X)
<b>Gestational Age</b>	
Full term	XXX (XX.X)
Pre-mature	XXX (XX.X)
<b>Known allergies</b>	

Yes	XXX (XX.X)
No	XXX (XX.X)
<b>Sickle cell disease</b>	
Yes	XXX (XX.X)
No	XXX (XX.X)
<b>History of other seizures</b>	
Yes	XXX (XX.X)
No	XXX (XX.X)
<b>History of febrile seizure</b>	
Yes	XXX (XX.X)
No	XXX (XX.X)
<b>History of urticaria</b>	
Yes	XXX (XX.X)
No	XXX (XX.X)
<b>History of angioedema</b>	
Yes	XXX (XX.X)
No	XXX (XX.X)
<b>History of apnea</b>	
Yes	XXX (XX.X)
No	XXX (XX.X)
<b>Fever at the date prior to 13vPnC vaccination</b>	
Yes	XXX (XX.X)
No	XXX (XX.X)
<b>Smoking in the family</b>	
Yes	XXX (XX.X)
No	XXX (XX.X)

\*Definition of baseline: Period between the 1st date of healthcare record (combining EHR and vaccination data) during the Prospective cohort study period and 1st 13vPnC dose date

<b>Table 2.1 Administration of 13vPnC by Dose - Main Study</b>				
	<b>Dose 1</b> n (%)	<b>Dose 2</b> n (%)	<b>Dose 3</b> n (%)	<b>Dose 4</b> n (%)
<b>Total number of Participants</b>	XXX	XXX	XXX	XXX
<b>Age at each dose [month]</b>				
0- ≤1	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
1- ≤2	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
2- ≤3	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
3- ≤4	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
4- ≤5	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
5- ≤6	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
6- ≤7	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
7- ≤8	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
8- ≤9	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
9- ≤10	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
10- ≤11	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
11- ≤12	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
12- ≤13	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
13- ≤14	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
14- ≤15	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
15- ≤16	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
16- ≤17	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
17- ≤18	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
18- ≤19	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
19- ≤20	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
20- ≤21	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
21- ≤22	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
22- ≤23	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
23- ≤24	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
<b>Outcome and hospitalization within 7 days of each dose</b>				
All seizures	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)

Hospitalized				
Yes	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
No	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Febrile seizures	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Hospitalized				
Yes	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
No	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Urticaria and angioedema	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Hospitalized				
Yes	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
No	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Apnea	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Hospitalized				
Yes	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
No	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Fever	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Hospitalized				
Yes	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
No	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
<b>Season of each dose</b>				
Winter (12/1-2/28)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Spring (3/1-5/31)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Summer (6/1-8/31)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Fall (9/1-11/30)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
<b>Year of administration</b>				
Year 1 (5/1/2017-4/30/2018)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Year 2 (5/1/2018-4/30/2019)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Year 3 (5/1/2019-7/24/2020)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
<b>Co-administration of other vaccines on the same date</b>				
Vaccine 1	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Vaccine 2	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)

Vaccine 3	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Vaccine 4	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Vaccine 5	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Vaccine 6	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
<b>Table 2.2 Administration of 13vPnC by Dose - Prospective Cohort Study</b>				
	<b>Dose 1</b> n (%)	<b>Dose 2</b> n (%)	<b>Dose 3</b> n (%)	<b>Dose 4</b> n (%)
<b>Total number of Participants</b>	XXX	XXX	XXX	XXX
<b>Age at each dose [month]</b>				
0- ≤1	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
1- ≤2	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
2- ≤3	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
3- ≤4	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
4- ≤5	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
5- ≤6	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
6- ≤7	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
7- ≤8	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
8- ≤9	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
9- ≤10	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
10- ≤11	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
11- ≤12	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
12- ≤13	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
13- ≤14	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
14- ≤15	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
15- ≤16	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
16- ≤17	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
17- ≤18	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
18- ≤19	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
19- ≤20	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
20- ≤21	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)

21- ≤22	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
22- ≤23	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
23- ≤24	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
<b>Safety outcomes of interest and Hospitalization within 7 days of each dose</b>				
All seizures	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Hospitalized				
Yes	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
No	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Febrile Seizures	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Hospitalized				
Yes	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
No	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Urticaria and angioedema	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Hospitalized				
Yes	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
No	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Apnea	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Hospitalized				
Yes	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
No	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Fever (≥38°C)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Hospitalized				
Yes	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
No	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Highest temperature for each day fever is reported				
Day 0	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Day 1	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Day 2	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Day 3	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)

Day 4				
Day 5	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Day 6	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Day 7	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Fever*	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
<b>Season of each dose</b>				
Winter (12/1-2/28)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Spring (3/1-5/31)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Summer (6/1-8/31)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Fall (9/1-11/30)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
<b>Year of administration of 13vPnC</b>				
Year 1 (7/1/2018-6/30/2019)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Year 2 (7/1/2019-7/24/2020)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
<b>Co-administration of other vaccines on the same date</b>				
Vaccine 1	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Vaccine 2	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Vaccine 3	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Vaccine 4	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Vaccine 5	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Vaccine 6	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
<b>Use of antipyretics post-vaccination within 7 days of each dose</b>				
Yes	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
No	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
<b>Use of concomitant drugs within 7 days of each dose</b>				
Yes	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
No	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)

\*Including those who had fever and reported temperature was greater than or equal to 38°C and those who had fever but not reported temperature

#Participants didn't respond to the follow-up questionnaire on the seventh day after vaccination



Table 3.1 Distribution of Safety Outcomes of Interest\* - Main Study

All Dose					Dose 1				Dose 2			
	All Seizures n (%)	Urticaria and angioedema n (%)	Apnea n (%)	Fever n (%)	All Seizures n (%)	Urticaria and angioedema n (%)	Apnea n (%)	Fever n (%)	All Seizures n (%)	Urticaria and angioedema n (%)	Apnea n (%)	Fever n (%)
Total number of Participants	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Age at 1st diagnosis [month]												
Mean (SD)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Median	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Minimum	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Maximum	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Age at 1st diagnosis [month]												
0- ≤2	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
2- ≤4	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
4- ≤6	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
6- ≤8	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
8- ≤10	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
10- ≤12	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
12- ≤14	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
14- ≤16	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
16- ≤18	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
18- ≤20	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
20- ≤22	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
22- ≤24	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Sex												
Male	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Female	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Residential area at study entry												
Urban/suburban	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)

Rural	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Residential status at study entry												
Permanent residents	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Temporary residents	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Hospitalization within 7 days of each dose <sup>#</sup>												
Yes	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
No	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Season of 1st diagnosis of each dose												
Winter (12/1-2/28)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Spring (3/1-5/31)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Summer (6/1-8/31)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Fall (9/1/-11/30)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Year of administration of 13vPnC associated with the 1st diagnosis of each dose												
Year 1 (5/1/2017-4/30/2018)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Year 2 (5/1/2018-4/30/2019)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Year 3 (5/1/2019-7/24/2020)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)

\*Each outcome is within 7 days on or after each dose  
<sup>#</sup>A patient could be hospitalized after each dose, but the patient count would be 1

Table 3.1 Distribution of Safety Outcomes of Interest - Main Study

Dose 3					Dose 4			
	All Seizures n (%)	Urticaria and angioedema n (%)	Apnea n (%)	Fever n (%)	All Seizures n (%)	Urticaria and angioedema n (%)	Apnea n (%)	Fever n (%)
Total number of Participants	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Age at 1st diagnosis [month]								
Mean (SD)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Median	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Minimum	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Maximum	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Age at 1st diagnosis [month]								
0- ≤2	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
2- ≤4	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
4- ≤6	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
6- ≤8	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
8- ≤10	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
10- ≤12	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
12- ≤14	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
14- ≤16	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
16- ≤18	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
18- ≤20	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
20- ≤22	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
22- ≤24	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Sex								
Male	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Female	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Residential area at study entry								
Urban/suburban	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)

Rural	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Residential status at study entry								
Permanent residents	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Temporary residents	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Hospitalization within 7 days of each dose <sup>#</sup>								
Yes	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
No	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Season of 1st diagnosis of each dose								
Winter (12/1-2/28)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Spring (3/1-5/31)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Summer (6/1-8/31)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Fall (9/1-11/30)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Year of administration of 13vPnC associated with the 1st diagnosis of each dose								
Year 1 (5/1/2017-4/30/2018)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Year 2 (5/1/2018-4/30/2019)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Year 3 (5/1/2019-7/24/2020)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)

\*Each outcome is within 7 days on or after each dose

<sup>#</sup>A patient could be hospitalized after each dose, but the patient count would be 1

Table 3.2 Distribution of Safety Outcomes of Interest\* - Prospective Cohort Study

All Dose							Dose 1						Dose 2					
	All seizures n (%)	Febrile seizures n (%)	Urticaria and angioedema n (%)	Apnea n (%)	Fever (≥38°C) n (%)	Highest temperature for each day fever is reported (≥39°C) n (%)	All seizures n (%)	Febrile seizures n (%)	Urticaria and angioedema n (%)	Apnea n (%)	Fever (≥38°C) n (%)	Highest temperature for each day fever is reported (≥39°C) n (%)	All seizures n (%)	Febrile seizures n (%)	Urticaria and angioedema n (%)	Apnea n (%)	Fever (≥38°C) n (%)	Highest temperature for each day fever is reported (≥39°C) n (%)
Total number of Participants	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Age at 1st diagnosis [month]																		
Mean (SD)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Median	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Minimum	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Maximum	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Age at 1st diagnosis [month]																		
0- ≤2	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
2- ≤4	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
4- ≤6	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
6- ≤8	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
8- ≤10	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
10- ≤12	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
12- ≤14	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
14- ≤16	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
16- ≤18	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
18- ≤20	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
20- ≤22	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
22- ≤24	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
Sex																		
Male	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Female	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Residential area at study entry																		

Urban/suburban	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Rural	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Residential status at study entry																			
Permanent residents	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Temporary residents	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Hospitalization within 7 days of each dose																			
Yes	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
No	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Season of 1st diagnosis of each dose																			
Winter (12/1-2/28)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Spring (3/1-5/31)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Summer (6/1-8/31)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Fall (9/1/-11/30)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Year of administration of 13vPnC associated with the 1st diagnosis of each dose																			
Year 1 (5/1/2017-4/30/2018)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Year 2 (5/1/2018-4/30/2019)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Year 3 (5/1/2019-7/24/2020)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)

\*Each outcome is within 7 days on or after each dose

Table 3.2 Distribution of Safety Outcomes of Interest\* - Prospective Cohort Study

Dose 3							Dose 4						
	All seizures n (%)	Febrile seizures n (%)	Urticaria and angioedema n (%)	Apnea n (%)	Fever (≥38°C) n (%)	Highest temperature for each day fever is reported (≥39°C) n (%)	All seizures n (%)	Febrile seizures n (%)	Urticaria and angioedema n (%)	Apnea n (%)	Fever (≥38°C) n (%)	Highest temperature for each day fever is reported (≥39°C) n (%)	
Total number of Participants	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	
Age at 1st diagnosis [month]													
Mean (SD)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	
Median	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	
Minimum	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	
Maximum	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	
Age at 1st diagnosis [month]													
0- ≤2	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	
2- ≤4	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	
4- ≤6	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	
6- ≤8	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	
8- ≤10	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	
10- ≤12	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	
12- ≤14	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	
14- ≤16	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	
16- ≤18	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	
18- ≤20	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	
20- ≤22	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	
22- ≤24	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	
Sex													
Male	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	
Female	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	
Residential area at study entry													

Urban/suburban	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Rural	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Residential status at study entry												
Permanent residents	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Temporary residents	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Hospitalization within 7 days of each dose												
Yes	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
No	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Season of 1st diagnosis of each dose												
Winter (12/1-2/28)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Spring (3/1-5/31)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Summer (6/1-8/31)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Fall (9/1-11/30)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Year of administration of 13vPnC associated with the 1st diagnosis of each dose												
Year 1 (5/1/2017-4/30/2018)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Year 2 (5/1/2018-4/30/2019)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
Year 3 (5/1/2019-7/24/2020)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)

\*Each outcome is within 7 days on or after each dose.



Table 4.1.1 Incidence Rates (Per 1000 Person Days) of Safety Outcomes of Interest - Main Cohort (All Age: 0-24 months)									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)

All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
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Table 4.1.2 Incidence Rates (Per 1000 person days) of Safety Outcomes of Interest - Main Study (Age Stratification)

Age 0- ≤2 months									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			

	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 2- ≤4 months									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Events	Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Events	All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 4- ≤6 months

Events	Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Events	Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Events	Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Events	Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)

All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

	All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 6- ≤8 months									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		



	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Age 8- ≤10 months									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Events	Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

	Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

	All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 10- ≤12 months

Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 3 (0-3 days)Dose 3 (4-7 days)Dose 3 (0-7 days)

	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 12- ≤14 months									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Events	Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Events	All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 14- ≤16 months									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Events	Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Events	Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Events	Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)



All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

	All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 16- ≤18 months									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		

	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Age 18- ≤20 months									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 20- ≤22 months

Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 3 (0-3 days)Dose 3 (4-7 days)Dose 3 (0-7 days)

	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 22- ≤24 months									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)



Table 4.1.3 Incidence Rates (Per 1000 Person Days) of Safety Outcomes of Interest - Main Study (by Gender)									
Male									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			

Events	Number of events (n)	Person months at risk (n)	Incidence Rate per 1,000 person months (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Female									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
	Number of events (n)	Person months at risk (n)	Incidence Rate per 1,000 person months (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
Events									
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
Events									
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
Events									
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Table 4.1.4 Incidence Rates ( <i>Per 1000 Person Days</i> ) of Safety Outcomes of Interest - Main Study (by Residence Status)									
Permanent residents									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		

Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Temporary residents									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)



Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
Events									
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
Events									
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
Events									
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Table 4.1.5 Incidence Rates (Per 1000 person days) of Safety Outcomes of Interest - Main Study (by Co-administration of other vaccines on the same date)

Co-administration of other vaccines on the same date (Yes)*									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Co-administration of other vaccines on the same date (No)

Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 3 (0-3 days)Dose 3 (4-7 days)Dose 3 (0-7 days)

	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

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\*Any dose of 13vPnC has been vaccinated on the same day as the other vaccines.

Table 4.1.6 Incidence Rates (Per 1000 Person Days) of Safety Outcomes of Interest - Main Study (by Season of administration of 13vPnC)									
Winter									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		

Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)



Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Spring									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)

All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Summer									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		

Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fall									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)



Table 4.2.1 Incidence Rates (Per 1000 Doses) of Safety Outcomes of Interest - Main Study (All Age: 0-24 months)									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
Events									
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
Events									
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
Events									

All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
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Table 4.2.2 Incidence Rates (Per 1000 Doses) of Safety Outcomes of Interest - Main Study (Age Stratification)

Age 0- ≤2 months									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		

	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 2- ≤4 months									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 4- ≤6 months

Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)

All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 6- ≤8 months									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		



	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Age 8- ≤10 months									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 10- ≤12 months

Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 3 (0-3 days)Dose 3 (4-7 days)Dose 3 (0-7 days)

Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 12- ≤14 months									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 14- ≤16 months

Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)



All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 16- ≤18 months									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		

	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Age 18- ≤20 months									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 20- ≤22 months

Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 3 (0-3 days)Dose 3 (4-7 days)Dose 3 (0-7 days)

	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 22- ≤24 months									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)



Table 4.2.3 Incidence Rates (Per 1000 Doses) of Safety Outcomes of Interest - Main Study (by Gender)									
Male									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			

Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Female									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Table 4.2.4 Incidence Rates ( <i>Per 1000 Doses</i> ) of Safety Outcomes of Interest - Main Study (by Residence Status)									
Permanent residents									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		

Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Temporary residents									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)



Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Table 4.2.5 Incidence Rates (Per 1000 Doses) of Safety Outcomes of Interest - Main Study (by Co-administration of other vaccines on the same date)

Co-administration of other vaccines on the same date (Yes)*									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Fever

XXX

XXX

XX.X (XX.X - XX.X)

XXX

XXX

XX.X (XX.X - XX.X)

XXX

XXX

XX.X (XX.X - XX.X)

Co-adminstration of other vaccines on the same date (No)									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

\*Any dose of 13vPnC has been vaccinated on the same day as the other vaccines.

Table 4.2.6 Incidence Rates (Per 1000 Doses) of Safety Outcomes of Interest - Main Study (by Season of administration of 13vPnC)									
Winter									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			



Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Spring									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)



Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	
Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)				
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	
	All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
	Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
	Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
	Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
	Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)				
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	
	All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
	Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
	Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
	Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
	Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)				

	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
Events									
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Summer									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
Events									
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)

All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fall									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			

	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
Events									
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
Events									
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
Events									
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Table 5.1.1 Incidence Rates (Per 1000 Person Days) of Safety Outcomes of Interest - Prospective Cohort Study (All Age: 0-24 months)									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
Events									
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
Events									
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)



Table 5.1.2 Incidence Rates (Per 1000 Person Days) of Safety Outcomes of Interest - Prospective cohort study (Age Stratification)

Age 0- ≤2 months									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 2- ≤4 months

Dose 1 (0-3 days)	Dose 1 (4-7 days)	Dose 1 (0-7 days)
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	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 4- ≤6 months

Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

	All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 6- ≤8 months									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		

	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Age 8- ≤10 months									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)



Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 10- ≤12 months

Dose 1 (0-3 days)Dose 1 (4-7 days)Dose 1 (0-7 days)

	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 2 (0-3 days)Dose 2 (4-7 days)Dose 2 (0-7 days)

	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 3 (0-3 days)Dose 3 (4-7 days)Dose 3 (0-7 days)

	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 12- ≤14 months									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Age 14- ≤16 months									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)

All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

	All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 16- ≤18 months										
Events	Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	
	All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
	Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
	Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
	Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
	Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)				

	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)



All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Age 18- ≤20 months									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 20- ≤22 months

Dose 1 (0-3 days)Dose 1 (4-7 days)Dose 1 (0-7 days)

	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 2 (0-3 days)Dose 2 (4-7 days)Dose 2 (0-7 days)

	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 3 (0-3 days)Dose 3 (4-7 days)Dose 3 (0-7 days)

	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)				Dose 4 (0-7 days)	
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)				All Doses (4-7 days)				All Doses (0-7 days)	
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 22- ≤24 months									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

	Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

	All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Table 5.1.3 Incidence Rates (Per 1000 Person Days) of Safety Outcomes of Interest - Prospective Cohort Study (by Gender)									
Male									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)

All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)



Female									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Table 5.1.4 Incidence Rates (Per 1000 Person Days) of Safety Outcomes of Interest - Prospective Cohort Study (by Residence Status)									
Permanent residents									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		

Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Temporary residents									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)

All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Table 5.1.5 Incidence Rates (Per 1000 Person Days) of Safety Outcomes of Interest - Prospective cohort study (by Co-administration of other vaccines on the same date)

Co-administration of other vaccines on the same date (Yes)*									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)



Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Events	Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

	All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Co-administration of other vaccines on the same date (No)									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			

	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1000 person days (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

\*Any dose of 13vPnC has been vaccinated on the same day as the other vaccines.

Table 5.1.6 Incidence Rates (Per 1000 Person Days) of Safety Outcomes of Interest - Prospective Cohort Study (by Season of administration of 13vPnC)									
Winter									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			

Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Spring									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)

All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Summer									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)



Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			

	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
Events									
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fall									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
Events									
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
Events									

All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
Events	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
Events									
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Table 5.2.1 Incidence Rates (Per 1000 Doses) of Safety Outcomes of Interest - Prospective Cohort Study (All Age: 0-24 months)									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)

All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Table 5.2.2 Incidence Rates (Per 1000 Doses) of Safety Outcomes of Interest - Prospective cohort study (Age Stratification)

Age 0- ≤2 months									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)



Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Events	Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

	All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 2- ≤4 months									
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Dose 1 (0-3 days)

Dose 1 (4-7 days)

Dose 1 (0-7 days)

	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Age 4- ≤6 months									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

	All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 6- ≤8 months									
Events	Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Events	Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)

	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Age 8- ≤10 months									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)



Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 10- ≤12 months

Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 3 (0-3 days)Dose 3 (4-7 days)Dose 3 (0-7 days)

	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 12- ≤14 months									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 14- ≤16 months

Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)

All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 16- ≤18 months									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		

	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Age 18- ≤20 months									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)



Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 20- ≤22 months

Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 3 (0-3 days)Dose 3 (4-7 days)Dose 3 (0-7 days)

	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Age 22- ≤24 months									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Table 5.2.3 Incidence Rates (Per 1000 Doses) of Safety Outcomes of Interest - Prospective Cohort Study (by Gender)									
Male									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		

Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Female									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)



Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)

All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Table 5.2.4 Incidence Rates (Per 1000 Doses) of Safety Outcomes of Interest - Prospective Cohort Study (by Residence Status)									
Permanent residents									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			

Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Temporary residents									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)

All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Table 5.2.5 Incidence Rates (Per 1000 Doses) of Safety Outcomes of Interest - Prospective cohort study (by Co-administration of other vaccines on the same date)

Co-administration of other vaccines on the same date (Yes)*									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)



Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Events	Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

	All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Co-administration of other vaccines on the same date (No)									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			

	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

	Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
	All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95% CI)
Events									
All seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

\*Any dose of 13vPnC has been vaccinated on the same day as the other vaccines.

Table 5.2.6 Incidence Rates (Per 1000 Doses) of Safety Outcomes of Interest - Prospective Cohort Study (by Season of administration of 13vPnC)									
Winter									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)				Dose 3 (4-7 days)			Dose 3 (0-7 days)		

	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
Events									
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)				Dose 4 (4-7 days)			Dose 4 (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
Events									
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)				All Doses (4-7 days)			All Doses (0-7 days)		
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
Events									

All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Spring									
Dose 1 (0-3 days)				Dose 1 (4-7 days)			Dose 1 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)				Dose 2 (4-7 days)			Dose 2 (0-7 days)		
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			

	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
Events									
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Summer									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
Events									
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			
	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
Events									



All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 3 (0-3 days)			Dose 3 (4-7 days)			Dose 3 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 4 (0-3 days)			Dose 4 (4-7 days)			Dose 4 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fall									
Dose 1 (0-3 days)			Dose 1 (4-7 days)			Dose 1 (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Dose 2 (0-3 days)			Dose 2 (4-7 days)			Dose 2 (0-7 days)			



All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
All Doses (0-3 days)			All Doses (4-7 days)			All Doses (0-7 days)			
Events	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Number of doses (n)	Incidence Rate per 1,000 doses (95%CI)	Number of events (n)	Person days at risk (n)	Incidence Rate per 1,000 person days (95%CI)
All Seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Febrile seizures	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Urticaria and angioedema	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Apnea	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)
Fever	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)	XXX	XXX	XX.X (XX.X - XX.X)

**Table 6. Validation of ICD code using adjudicated safety outcome based on medical records of children as gold standard: Positive Predictive Value (PPV)**

<b>Outcome</b>	<b>Main Study</b>	<b>Prospective Cohort Study</b>
Seizures (including febrile seizures)	a/n1 PPV (%)	a/n1 PPV (%)
Urticaria and angioedema	a/n1 PPV (%)	a/n1 PPV (%)
Apnea	a/n1 PPV (%)	a/n1 PPV (%)
Fever	a/n1 PPV (%)	a/n1 PPV (%)

Note: a= agreed outcome b/w cohort identified and adjudicated outcome  
n1=cohort identified outcome

**Table 6.1.1 Validation of ICD code (Main Study):  
Seizures (including febrile seizures)**

<b>Main Study Results</b>	<b>Adjudication Results</b>	
	Yes	No
<b>Yes</b>		
<b>No</b>		

**Table 6.1.2 Validation of ICD code (Main Study):  
Urticaria and angioedema**

<b>Main Study Results</b>	<b>Adjudication Results</b>	
	Yes	No
<b>Yes</b>		
<b>No</b>		

**Table 6.1.3 Validation of ICD code (Main Study): Apnea**

Main Study Results	Adjudication Results	
	Yes	No
Yes		
No		

**Table 6.1.4 Validation of ICD code (Main Study): Fever**

Main Study Results	Adjudication Results	
	Yes	No
Yes		
No		

**Table 6.2.1 Validation of ICD code (Prospective Study):  
Seizures (including febrile seizures)**

Prospective Study Results	Adjudication Results	
	Yes	No
Yes		
No		

**Table 6.2.2 Validation of ICD code (Prospective Study):  
Urticaria and angioedema**

Prospective Study Results	Adjudication Results	
	Yes	No
Yes		
No		

**Table 6.2.3 Validation of ICD code (Prospective Study): Apnea**

Prospective cohort study Results	Adjudication Results	
	Yes	No
Yes		
No		

**Table 6.2.4 Validation of ICD code (Prospective cohort study): Fever**

Prospective Study Results	Adjudication Results	
	Yes	No
Yes		
No		

**Table 7. Validation of ICD code using adjudicated safety outcome in the Prospective Cohort Study as a reference standard: Sensitivity and Specificity**

Outcome	Sensitivity	Specificity
Seizures (including febrile seizures)		
Apnea		

**Table 7.1.1 Validation of ICD code using adjudicated safety outcome in the Prospective Cohort Study as a reference standard: Seizures (including febrile seizures)**

Main Study Results	Adjudicated Prospective cohort study Results	
	Yes	No
Yes		

No		
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**Table 7.1.2 Validation of ICD code using adjudicated safety outcome in the Prospective Cohort Study as a reference standard: Apnea**

Main Study Results	Adjudicated Prospective cohort study Results	
	Yes	No
Yes		
No		

**Table 8. Validation of ICD code using the reported terms by parents/legal guardians in the Prospective Cohort Study as a non-reference standard: Positive Percentage Agreement (PPA) and Negative Percentage Agreement (NPA)**

Outcome	Positive Percentage Agreement (PPA)	Negative Percentage Agreement (NPA)
Urticaria and angioedema		
Fever		

**Table 8.1.1 Validation of ICD code using the reported terms by parents/legal guardians in the Prospective Cohort Study as a non-reference standard: Urticaria and angioedema**

Main Study Results	Reported Prospective cohort study Results	
	Yes	No
Yes		
No		



**Table 8.1.2 Validation of ICD code using the reported terms by parents/legal guardians in the Prospective Cohort Study as a non-reference standard: Fever**

Main Study Results	Reported Prospective cohort study Results	
	Yes	No
Yes		
No		

## Document Approval Record

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