Statistical Analysis Plan

Study Title

A Postmarketing, Phase 4, Multicentre, Prospective, Single- arm study to Assess the Safety of Fasenra® (Benralizumab) in Adult Patients of Severe Asthma with Eosinophilic Phenotype in India

Protocol/ Study Number :	D3250C00093
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LIST OF ABBREVIATION

Abbreviation	Term
ADA	antidrug antibody
ADR	adverse drug reaction
AE	adverse event
CI	confidence interval
COPD	chronic obstructive pulmonary disease
CRO	contract research organisation
ECG	electrocardiogram
EDC	electronic data capture
ER	Emergency Room
eCRF	electronic case report form
EOS	End of Study
FEV1	forced expiratory volume in 1 second
GCP	Good Clinical Practice
GINA	Global Initiative for Asthma
ICS	inhaled corticosteroid
ICF	informed consent form
ICH	International Council for Harmonisation
IEC	Independent Ethics Committee
IL-5	interleukin-5
IL-5Rα	interleukin-5 receptor alpha subunit
IMP	Investigational Medicinal Product
IRB	Institutional Review Board
KM	Kaplan–Meier
LABA	long-acting beta-agonist
OCS	8.1.Oral corticosteroid
PI	Package Insert
Pre-BD	prebronchodilator
Post-BD	postbronchodilator
SAE	serious adverse event
SD	standard deviation
SAP	statistical analysis plan
SmPC	Summary of product characteristics
SoA	schedule of activities
TEAE	treatment-emergent adverse event
USPI	United States Prescribing Information

1. INTRODUCTION

The purpose of this document is to provide a description of the statistical methods and procedures to be implemented for the analysis of data from D3250C00093 study. This document is based on protocol V 1.0, 09 Mar 2021. The statistical planning and conduct of analysis of the data from this study will follow the principles defined in relevant International Council on Harmonisation (ICH)-E9 guidelines. Any change from the planned analysis as described in the protocol, are detailed here, and any differences described here supersede the analysis as presented in the protocol.

2. Study Objective and Design

2.1 Study Objective

2.1.1 Primary Objective

- To Assess the safety and tolerability of Fasenra (Benralizumab) in adult patients of Severe asthma with eosinophilic phenotype over a period of 24 weeks.

2.1.2 Secondary Objective

- To assess the effectiveness of Fasenra (benralizumab) in adult patients of severe asthma with eosinophilic phenotype over a period of 24 weeks

2.2 Study Description

2.2.1 Study Design

This is a Phase 4, single-arm, prospective, multicentre, interventional study, designed to assess the safety, tolerability, and effectiveness of benralizumab in adult patients of severe asthma with eosinophilic phenotype in India. The study is planned to meet the post approval commitment as a regulatory requirement.

Ten centres across India will participate in this study. The investigators will be pulmonologists or chest physicians treating asthma patients. Informed consent will be obtained from all the patients at screening before any study-related procedures are performed. Adult patients of severe asthma with eosinophilic phenotype, who are prescribed benralizumab as an add-on therapy by the treating physician, will be enrolled in the study.

The total study duration will be 24 weeks, including 16 weeks of study treatment, and 8 weeks follow-up.

- Screening duration: 2 weeks
- Study period: 24 weeks
  - Treatment duration (4 doses): 16 weeks (Day 1, Week 4, Week 8, and Week 16)
  - Post-treatment follow-up duration: 8 weeks (Week 24)

Participants will be maintained on their currently prescribed therapies including ICS-LABA therapy(ies), throughout the study duration.

Study population will include adult (18 to 75 years of age) male or female patients who have severe asthma with eosinophilic phenotype requiring high dose of ICS and LABA.

Each participant should meet all the inclusion criteria and none of the exclusion criteria to be eligible for the study. Under no circumstances can there be exceptions to this rule. Participants who do not meet the entry requirements are screen failures

"Enrolled" means a participant's, or their legally acceptable representative's, agreement to participate in a clinical study after completion of the informed consent process. Prospective approval of protocol deviations to recruitment and enrolment criteria, also known as protocol waivers or exemptions, is not permitted.

This proposed Phase 4 single-arm study will fulfil the regulatory requirement as a postmarketing study to assess the safety of 30-mg benralizumab administered subcutaneously in Indian patients of severe asthma with eosinophilic phenotype who remain uncontrolled on high doses of ICS plus LABA. Owing to the recent marketing approval, there are no data available from real-life studies in the Indian population. Participants included in this study will be as per the indicated patient profile in the local prescribing information, specifically taking into consideration the contraindications, warnings, and special precautions for use.

The study will enrol patients who have been prescribed benralizumab as per the local prescribing information. The recommended dose is 30 mg administered once every 4 weeks for the first 3 doses, and then once every 8 weeks thereafter by subcutaneous injection into the upper arm, thigh, or abdomen by the study physician. Four doses of benralizumab will be administered as part of the study.

2.2.2 Inclusion Criteria

Patients are eligible to be included in the study only if all of the following criteria apply:

1. Male or female patients 18 to 75 years of age inclusive, at the time of signing the informed consent
2. Patients with physician's confirmed diagnosis of severe asthma with an eosinophilic phenotype, ie, diagnosis of severe asthma in preceding at least 12 months, with an eosinophil count of ≥300 cells/µL at screening, requiring treatment with high-dose ICS (>500 µg fluticasone propionate dry powder formulation, or >800 µg budesonide dry powder formulation, or equivalent total daily dose) and a LABA as maintenance treatment for at least 3 months prior to enrolment
3. A decreased lung function with prebronchodilator (Pre-BD) forced expiratory volume in 1 second (FEV1) of <80% predicted, demonstrated by spirometry at screening
4. At least 2 documented asthma exacerbations in the preceeding12 months, except in 30 days before the date of informed consent, that required the use of a systemic corticosteroid or temporary increase from the patient's usual maintenance dose of OCS

5. Documented postbronchodilator (post-BD) reversibility in FEV1 of ≥12% and ≥200 mL in FEV1 within 12 months before first dose. If historical documentation is not available, reversibility must be demonstrated and documented at screening or Day 1 before first dose
6. Benralizumab naive patients who have not previously received benralizumab prior to the start of this study
7. Patients who are willing and capable of giving signed informed consent as described in Appendix A, which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in this protocol.

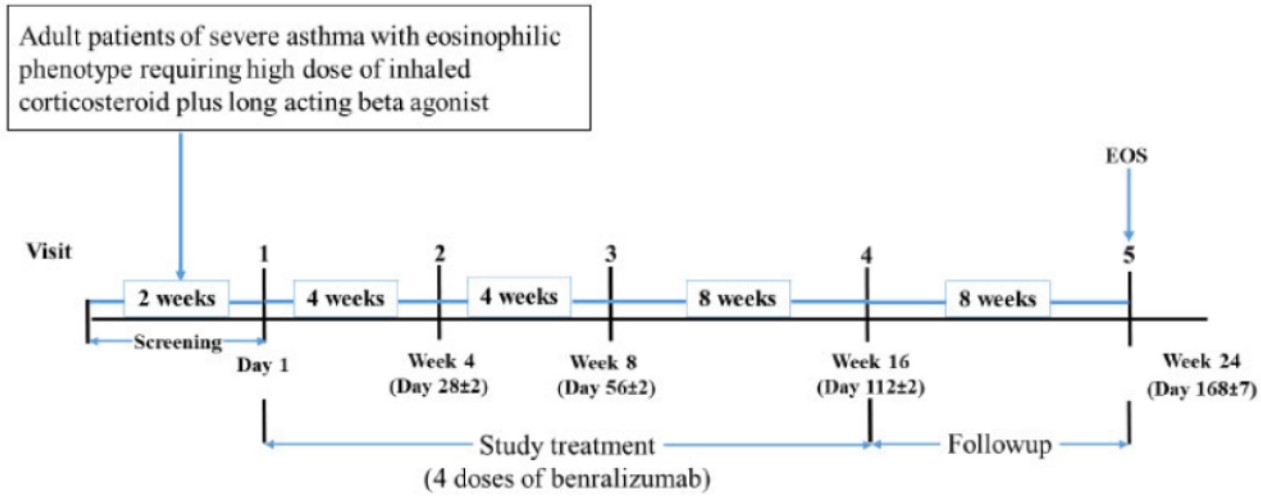
2.2.3 Exclusion Criteria

Patients will be excluded from the study if any of the following criteria apply:

1. Clinically important pulmonary disease other than asthma (eg, active lung infection, chronic obstructive pulmonary disease, bronchiectasis, pulmonary fibrosis, cystic fibrosis etc.) or ever been diagnosed with pulmonary or systemic disease, other than asthma, that are associated with elevated peripheral eosinophil counts (eg, allergic bronchopulmonary aspergillosis/mycosis, Churg-Strauss syndrome, hypereosinophilic syndrome), which can confound the outcome assessment
2. Patients currently enrolled in an interventional clinical study in parallel including those with any biologic treatment
3. Patients who have received any biologic within 30 days prior to the date of informed consent.
4. Known history of allergy or reaction to the benralizumab formulation or excipients (L-histidine, L-histidine hydrochloride monohydrate, α-trehalose dihydrate, polysorbate 20, water for injection)
5. History of anaphylaxis to any biologic therapy
6. A helminthic parasitic infection diagnosed within 24 weeks before the date informed consent is obtained that has not been treated with, or has failed to respond to, standard of care therapy
7. Acute asthma exacerbation 30 days before the date informed consent
8. Acute asthma exacerbation between screening and first dose of study dose administration.
9. Acute upper or lower respiratory infections requiring antibiotics or antiviral medication within 30 days before the date informed consent
10. Patients with malignancy within 5 years prior to enrolment, with the exception of adequately treated in-situ carcinoma of the cervix, uteri, basal, or squamous cell carcinoma or non-melanomatous skin cancer with active or recent malignancy

11. Any clinically significant abnormal findings in physical examination, vital signs, haematology, clinical chemistry, or urinalysis, which, in the opinion of the investigator, may put the participant at risk because of his/her participation in the study
12. History of current alcohol, drug, or chemical abuse or past abuse that would impair or risk the participant's full participation in the study, in the opinion of the investigator
13. Female patients who are pregnant or lactating or planning a family during the study period.

2.2.4 Study Flow chart



EOS = end of study

2.2.5 Study Plan

Procedure	Screening (Up to 14 Days Before Day 1)	Intervention Period				Follow-up
		Day 1	Week 4	Week 8	(Last Dose)Week 16	EOS Week 24
			Day 28±2	Day 56±2	Day 112±2	Day 168±7
Visit		1	2	3	4	5
Informed consent	X					
Inclusion and exclusion criteria[a]	X					
Demography, anthropometry including BMI	X					
Significant medical history	X					
Clinical safety laboratory assessments[b]	X					X
Serum/urine pregnancy test (WOCBP only)[c]	X	X	X	X	X	X
Vital signs[d]	X	X	X	X	X	X
ECG	X		X			X
Targeted physical examination	X	X	X	X	X	X
Blood eosinophil count	X		X		X	X
Prebronchodilator FEV1	X					
Postbronchodilator FEV1[e]	X					
Administration of benralizumab		X	X	X	X	
Recording Use of concomitant asthma medication (OCS/ICS/LABA)	X	X	X	X	X	X
Adverse events and Serious adverse events[f] (reported[g] and observed)	X	X	X	X	X	X
Assessment of asthma exacerbations	X	X	X	X	X	X

Abbreviations: BMI = body mass index; EOS = end of study; ECG= Electrocardiogram; FEV1 = forced expiratory volume in one second; ICS = inhaled corticosteroid; LABA = long-acting beta-agonist; OCS = oral corticosteroid; UPT = urine pregnancy test; WOCBP = women of childbearing potential (after menarche)

a. Recheck clinical status before first dose of benralizumab.

b. Clinical safety laboratory assessment will include clinical chemistry, haematology, and urinalysis. Clinical chemistry will include serum alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, gamma-glutamyl transferase, lactate dehydrogenase, total protein, total bilirubin, albumin, and serum creatinine. Haematology will include haematocrit, leucocyte count, leucocyte differential count (absolute count), platelet count, and haemoglobin. Urinalysis (dipstick) will assess urine haemoglobin/erythrocytes/blood, protein/albumin, and glucose.

c. Serum pregnancy test will be done at baseline and UPT will be done at Day 1,Week 4,8,16, 24.

d. The vital signs (pulse, blood pressure, respiration rate, and body temperature) will be taken before benralizumab administration, and, if possible, blood drawing and usual asthma controller medication. If it is

not logistically possible, sufficient time as per clinician discretion should be allotted between phlebotomy and vital signs assessment. For details, please refer to Section 8.1.3.

e. When historical proof of postbronchodilator reversibility in FEV1 is not documented within 12 months before Visit 1, the reversibility test by spirometry will need to be performed either during screening or on Day 1 before first dose.

f. While on study drug treatment and within 2 months after the end of study treatment/discontinuation of the study drug.

g. Participants will be provided a patient diary to record any undesirable health-related experience or adverse events occurring during the study. Adverse events and serious adverse events mentioned both in the patient diary and verbally communicated by the participant will be recorded.

2.3 Randomization

Not Applicable

2.4 Blinding and Un-Blinding

Not Applicable

2.5 Interim Analysis

No interim analyses is planned for this study.

3. Population Analysis Set

3.1 Enrolled Analysis Set

"Enrolled" means a participant's, or their legally authorised representative's, agreement by signing the ICF to participate in a clinical study following completion of the informed consent process.

3.2 Assigned to Study intervention Analysis Set

Potential participants who fulfil the eligibility criteria and are assigned with the study identification number.

3.3 Evaluable Analysis Set

All participants assigned to study intervention and receiving at least 1 dose of study intervention and provide at least one post baseline assessment.

3.4 Safety Analysis Set

All participants assigned to study intervention and who take at least 1 dose of study intervention.

4. Sample Size and Power Calculations

The primary objective of this study is to assess safety and tolerability of benralizumab in adult (18 to 75 years of age) male or female patients who have severe asthma with eosinophilic phenotype requiring high dose of ICS and LABA.

Based on the literature review, the below table is created for listing the key AEs (headache, pyrexia, pharyngitis and injection site reactions) and hypersensitivity reactions (e.g. anaphylaxis, angioedema, urticaria, urticaria papular, rash) which were included in the USPI, SmPC and the India PI, all in the range of 1% to 10%.

	Incidence Rate (%)		
Key AE Terms	SmPC/ India label	USPI	SIROCCO
Headache	Common (1%-10%)	8%	7%-9%
Pharyngitis		5%	4%-6%
Pyrexia		3%	3%-4%
Injection site reactions		2.2%	2%-4%
Hypersensitivity		3%	3%

Effectiveness $n = \frac{Z^2 P\,(1-P)}{d^2}$

where n = calculated sample size, Z = tabulated Z statistic value for α level of confidence, P = expected proportion of AEs and d = absolute precision level (half-width of the confidence interval [CI]).

Considering the maximum limit of the incidence rate of AEs to be 10%, approximately 139 evaluable participants will be required to present 95% CI around the estimated AE incidence rate with absolute precision level of 0.05. Considering dropout rate of 5%, a total of 147 participants will be required to be enrolled into the study.

5. Patient Characteristics and Study Conduct Summaries

5.1 General Considerations

Statistical Analysis will be performed using SAS (version 9.4 or higher) software (SAS Institute Inc USA). Categorical variables will be summarized with the frequency, percentage of Patients in each category and corresponding 95% CI (using Clopper-Pearson exact Method, where appropriate). Continuous variables will be summarized descriptively with the number of Patients, mean, standard deviation, median, 25th and 75th percentiles and minimum and maximum values.

5.2 Decimal Point

Unless otherwise noted, means, median, will be presented to one decimal place more than the measured value, the same decimal as the measured value, percentages, 25th and 75th percentiles and 95% confidence intervals will be presented to two decimal places and p-value will be presented to three decimal place. Percentages after zero counts will not be displayed and percentages equating to 100% will be presented as 100%, without any decimal places.

5.3 Disposition of Patients

Patient disposition table will be based on all Evaluable Analysis Set who consented to participate in the study. The following summaries will be included in the disposition table: total number of Patient Enrolled in the study, total

number of Patients screened in the study, number of Patients who failed screening, number and percentage of Patients who completed the study and number and percentage of Patients who discontinued from the study with reason for discontinuation.

5.4 Demographic and Baseline Characteristics

Demographic and baseline characteristics will be summarized based on the Evaluable Analysis Set.

Descriptive summaries will be provided for the demographic and baseline characteristics. Demographic characteristics and baseline characteristics such as age, Gender and Race, etc. will be summarized and tabulated for Evaluable Analysis Set.

All the continuous variables will be summarized by n, mean, standard deviation, median, 25th and 75th percentiles and minimum and maximum values. All the categorical variables will be summarized as frequency, percentage of Patients in each category and corresponding 95% CI (using Clopper-Pearson exact Method, where appropriate).

5.5 Covid-19 Vaccination

Covid-19 Vaccination will be summarized based on the Evaluable Population.

Descriptive summaries will be provided for the Covid-19 Vaccination.

All the continuous variables will be summarized by n, mean, standard deviation, median, 25th and 75th percentiles and minimum and maximum values. All the categorical variables will be summarized as frequency, percentage of Patients in each category and corresponding 95% CI (using Clopper-Pearson exact Method, where appropriate).

5.6 Medical History

Medical History will be summarized based on the Evaluable Population.

Descriptive summaries will be provided for the Medical History.

All the continuous variables will be summarized by n, mean, standard deviation, minimum, median and maximum values. All the categorical variables will be summarized as frequency, percentage of Patients in each category and corresponding 95% CI (using Clopper-Pearson exact Method, where appropriate).

5.7 Electrocardiogram (ECG)

Electrocardiogram will include Heart rate, QRS, PR, RR, QT, QTcB. Electrocardiogram will be summarized based on the Safety Analysis Set.

Descriptive summaries will be provided for the Electrocardiogram.

All the continuous variables will be summarized by n, mean, standard deviation, median, 25th and 75th percentiles and minimum and maximum values. All the categorical variables will be summarized as frequency, percentage of Patients in each category and corresponding 95% CI (using Clopper-Pearson exact Method, where appropriate).

6. Endpoints Analysis Strategy

6.1 Endpoints Analysis

6.1.1 Primary Endpoint

- Percentage of AEs, SAEs and TEAEs
- Nature, Incidence and Severity of AES, Including unexpected adverse drug reactions
- Percentage of patients with AEs that lead to Study treatment discontiuations or modifications

6.1.2 Secondary Endpoint

- Time to first asthma exacerbation
- Annualised exacerbation rate
- Overall investigators assessment on the outcome of the treatment: "well controlled", "Partly Controlled" and "Uncortolled"
- Change in blood eosinophil levels from baseline at week 4, 16 and 24.

6.2 Efficacy Hypothesis

There is no statistical hypothesis to be tested in this study.

6.3 Statstical Methods for Efficacy Analsysis

Statistical Analysis will be performed using SAS (version 9.4 or higher) software (SAS Institute Inc USA). Categorical variables will be summarized with the frequency and percentage of Patients in each category. Continuous variables will be summarized descriptively with the number of Patients, mean, standard deviation, 25th and 75th percentiles, minimum, median and maximum values.

6.3.1 Primary Endpoint Analysis

The primary analysis for primary endpoint will be based on Safety Analsysis Set.

Primary Endpoint evaluations will include Adverse Events (AEs), Serious Adverse Events (AEs), Treatment Emergent Adverse Event (TEAEs), Participants with unexpected Adverse Drug Reactions (ADRs) and Participants with AEs that lead to study treatment discontinuations or modifications.

Adverse Events (AEs), Serious Adverse Events (AEs), Treatment Emergent Adverse Event (TEAEs), Participants with unexpected Adverse Drug Reactions (ADRs) and Participants with AEs that lead to study treatment discontinuations or modifications will be summarized using Frequency, Percentages and 95% CIs (using Clopper-Pearson Exact method).

The AE profiles in participants will be presented as summaries showing the number of participants (n, %) along with number of events by System Organ Class and Preferred Terms assigned to the event by Medical Dictionary for Regulatory Activities (MedDRA) for the following:

- TEAEs
- SAEs
- Related and non-related TEAEs
- Serious and non-serious TEAEs
- TEAEs based on severity (Mild, Moderate, Severe)
- Unexpected ADRs based on severity (Mild, Moderate, Severe)

Physical Examination will include General Appearance, Respiratory system, Cardiovascular system, Abdomen, Skin, Head, Eye, Ear, Nose, Throat, Lymph node, Thyroid, Musculoskeletal system and Neurological System. Physical Examination will be summarized based on the Safety Analysis Set.

Descriptive summaries will be provided for the Physical Examination.

All the continuous variables will be summarized by n, mean, standard deviation, minimum, median and maximum values. All the categorical variables will be summarized as frequency, percentage of Patients in each category and corresponding 95% CI (using Clopper-Pearson exact Method, where appropriate).

Vital Signs will include Pulse rate, Respiratory rate, Systolic Blood Pressure, Diastolic Blood Pressure and Temperature. Vital Signs will be summarized based on the Safety Analysis Set.

Vital Signs will be will be summarised descriptively for actual values and change from baseline values for each visit using the number of observations, arithmetic mean, SD, median, 25th and 75th percentiles, and minimum and maximum values.

The Vital signs (Pulse rate, Respiratory rate, Systolic Blood Pressure, Diastolic Blood Pressure and Temperature) in this study is to evaluate the change from baseline to Post-baseline will be analysed using Paired t – test / Wilcoxon signed-rank test at 5% level of significance.

Change from baseline will be determined as:

Change from Baseline = (Post-baseline – Baseline)

Percent Change Change from Baseline = ([Post-baseline – Baseline] / Baseline) X 100

Clinical Safety laboratory Assessment will include clinical chemistry, haematology and urinalysis. Clinical Safety laboratory assessment will be summarized based on the Safety Analysis Set.

Clinical Safety laboratory Assessment will be summarised descriptively for actual values and change from baseline values for each visit using the number of observations, arithmetic mean, SD, median, 25th and 75th percentiles, and minimum and maximum values.

The Clinical Safety Laboratory (If available) in this study is to evaluate the change from baseline to Post-baseline will be analysed using Paired t – test / Wilcoxon signed-rank test at 5% level of significance.

Change from baseline will be determined as:

Change from Baseline = (Post-baseline – Baseline)

Percent Change Change from Baseline = ([Post-baseline – Baseline] / Baseline) X 100

6.3.2 Secondary Endpoint Analysis

All Secodary Endpoints will be summarized based on the Evaluable Analysis Set.

Descriptive summaries will be provided for the Asthma Exacerbation. All the continuous variables will be summarized by n, mean, standard deviation, minimum, median and maximum values. All the categorical variables will be summarized as frequency, percentage of Patients in each category and corresponding 95% CI (using Clopper-Pearson exact Method, where appropriate).

Time from first dose of study treatment to the first asthma exacerbation will be calculated as follows: Start Date of first asthma exacerbation minus Date of first dose of study treatment plus 1. The time to first asthma exacerbation for participants who do not experience an asthma exacerbation during the study period will be censored at 24 weeks, or at the time point after which an exacerbation could not be assessed (for lost-to-follow-up participants). The data will be summarised through median time to the first asthma exacerbation along with the 95% CI of median (as per availability of data) and displayed graphically using a KM plot.

Blood Eosinophils level will be summarized based on the Evaluable Analysis Set.

Blood Eosinophils will be summarised descriptively for actual values and change from baseline at week 4, 16, 24 using the number of observations, arithmetic mean, SD, median, 25th and 75th percentiles, and minimum and maximum values.

The Blood Eosinophils in this study is to evaluate the change from baseline to Post-baseline will be analysed using Paired t – test / Wilcoxon signed-rank test at 5% level of significance.

Change from baseline will be determined as:

Change from Baseline = (Post-baseline – Baseline)

Percent Change Change from Baseline = ([Post-baseline – Baseline] / Baseline) X 100

Overall Investigators Assessment will be summarized based on the Evaluable Analysis Set.

Descriptive summaries will be provided for the Overall Investigators Assessment.

All the categorical variables will be summarized as frequency, percentage of Patients in each category and corresponding 95% CI (using Clopper-Pearson exact Method, where appropriate).

7. References

1. ICH E3 Guideline_International Council for Harmonisation
2. ICH E9; STATISTICAL PRINCIPLES FOR CLINICAL TRIALS

8. Mock Tables

Table 14.1.1.1. Patient Disposition in the Study (Enrolled Analysis Set)

	N = xx n (%)
Patients Enrolled/ Screened	xx
Evaluable Analysis Set	xx
Screen Failures	xx
Patients Completed the study	xx (xx.xx)
Patients Discontinued the study	xx (xx.xx)
Reason for Discontinuation/ Withdrawal	
Patient Decision	xx (xx.xx)
Adverse Event	xx (xx.xx)
Severe non-compliance to Study protocol	xx (xx.xx)
Disease Progression	xx (xx.xx)
Pregnancy or intent to become pregnant	xx (xx.xx)
Lost to Follow-up	xx (xx.xx)
Other	xx (xx.xx)
Other 1	xx (xx.xx)
Other 2	xx (xx.xx)

- The Capital "N" in the column header represents the total number of Enrolled Analysis Set.
- The small "n" in summary statistics represents the total number of patients in the row category.
- Percentages in the “Patient completed the study” and “Patients Discontinued the study” rows are based on the total number of Enrolled Analysis Set.
- Percentages in the “Reasons for Discontinuation” rows are based on the number of Patients Discontinued study.
- There were 154 total enrolled/screened patients, 10 screen failures, 124 study completions, 20 trial discontinuations, however only 138 individuals were deemed eligible for analysis set because six patients meet the eligibility requirements but do not get the medication.
- Note: Screened Patients are those who signed the informed consent.
- Source: Listing 16.1.1.1 and Listing 16.1.1.3

Table 14.1.1.2. Summary of Patient Discontinuation of Study Intervention (Evaluable Analysis Set)

	N = xx
	n (%)
Study Treatment stopped permanently before the scheduled treatment period	
Yes	xx (xx.xx)
No	xx (xx.xx)
Patient continuing in the study	
Yes	xx (xx.xx)
No	xx (xx.xx)
Reason for Withdrawal	
Patient Decision	xx (xx.xx)
Development of any study-specific criteria for discontinuation	xx (xx.xx)
Anaphylactic reaction to benralizumab requiring administration of epinephrine	xx (xx.xx)
Development of helminth parasitic infestations requiring hospitalisation	xx (xx.xx)
Intensive care unit admission with prolonged intubation and mechanical ventilation for asthma-related event	xx (xx.xx)
Severe non-compliance to study protocol	xx (xx.xx)
Eligibility criteria not met	xx (xx.xx)
Pregnancy or intent to become pregnant	xx (xx.xx)
Lost to follow-up	xx (xx.xx)
Other	xx (xx.xx)
Other 1	xx (xx.xx)
Other 2	xx (xx.xx)

- The Capital "N" in the column header represents the total number of Evaluable Analysis Set.
- The small "n" in summary statistics represents the total number of patients in the row category.
- Percentages in the “Study treatment stopped permanently before the scheduled treatment period” rows are based on the total number of Evaluable Analysis Set.
- Percentages in the “Patient continuing in the study” and “Reason for Withdrawal” rows are based on the number of patients who stopped the study treatment permanently.
- Source: Listing 16.1.1.2

Table 14.1.1.3. Summary of Analysis Population (Enrolled Analysis Set)

	N = xx
	n (%)
Enrolled Analysis Set	xx (xx.xx)
Evaluable Analysis Set	xx (xx.xx)
Safety Analysis Set	xx (xx.xx)

- The Capital "N" in the column header represents the total number of Enrolled Analysis Set.
- The small "n" in summary statistics represents the total number of patients in the row category.
- Percentages in the "Safety Population" row is based on the total number of Enrolled Analysis Set.
- Enrolled Analysis Set: "Enrolled" means a participant, or his/her legally authorised representative, agreed by signing the ICF to participate in a clinical study following completion of the informed consent process.
- Evaluable analysis Set: All participants assigned to study intervention and receiving at least 1 dose of study intervention and provide at least one post baseline assessment.
- Safety Population: All participants assigned to study intervention and who take at least 1 dose of study intervention.
- Source: Listing 16.1.1.4

Table 14.1.2.1. Summary of Demographic and Baseline Characteristics (Evaluable Analysis Set)

Demographic and Baseline Variables	N = xx
Age (Years)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
(25^{th} percentiles, 75th percentiles)	(xx.xx, xx.xx)
Gender	
Male	xx (xx.xx)
Female	xx (xx.xx)
Missing	xx (xx.xx)
Female, Indicate childbearing potential	
Premenarchal	xx (xx.xx)
Premenopausal female	xx (xx.xx)
Postmenopausal female	xx (xx.xx)
Potentially able to bear children	xx (xx.xx)
Race	
Asian	xx (xx.xx)
Other	xx (xx.xx)
Other 1	xx (xx.xx)
Other n	xx (xx.xx)

- The Capital "N" in the column header represents the total number Evaluable Analysis Set.
- The small "n" in summary statistics represents the total number of patients.
- Percentages are based on number of Enrolled Analysis Set.
- SD = Standard Deviation, min=minimum, max=maximum
- Source: Listing 16.1.2.1

Table 14.1.2.2. Summary of Anthropometric Assessment (Evaluable Analysis Set)

	N = xx
Height (cm)	
n	xx
Missing	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
(25th percentiles, 75th percentiles)	(xx.xx, xx.xx)
Weight (Kg)	
n	xx
Missing	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
(25th percentiles, 75th percentiles)	(xx.xx, xx.xx)
Body Mass Index (Kg/m^2)	
n	xx
Missing	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
(25th percentiles, 75th percentiles)	(xx.xx, xx.xx)

- The Capital "N" in the column header represents the total number Evaluable Analysis Set.
- The small "n" in summary statistics represents the total number of patients.
- SD = Standard Deviation, min=minimum, max=maximum
- Source: Listing 16.1.2.2

Table 14.1.3. Summary of Significant Medical History (Evaluable Analysis Set)

System Organ Class /Preferred Term	N = xx
	n (%)
Patient with any medical history	xx (xx.xx)
System Organ Class 1	xx (xx.xx)
Preferred Term 1	xx (xx.xx)
Preferred Term 2	xx (xx.xx)
System Organ Class 2	xx (xx.xx)
Preferred Term 1	xx (xx.xx)
Preferred Term 2	xx (xx.xx)
System Organ Class 3	xx (xx.xx)
Preferred Term 1	xx (xx.xx)
Preferred Term 2	xx (xx.xx)
System Organ Class 4	xx (xx.xx)
Preferred Term 1	xx (xx.xx)
Preferred Term 2	xx (xx.xx)
System Organ Class 5	xx (xx.xx)
Preferred Term 1	xx (xx.xx)
Preferred Term 2	xx (xx.xx)

- The Capital "N" in the column header represents the total number of Evaluable Analysis Set.
- The small "n" in summary statistics represents the total number of patients in the row category.
- All Percentages rows are based on number of Evaluable Analysis Set.
- Medical histories were coded using MedDRA Ver24.1
- Source: Listing 16.1.3

Table 14.1.4. Summary of COVID-19 vaccination (Evaluable Analysis Set)

	N = xx
	n (%)
Patient received COVID-19 Vaccination	
Yes	xx (xx.xx)
No	xx (xx.xx)
Missing	xx (xx.xx)
If Vaccination	
1st Dose	xx (xx.xx)
2nd Dose	xx (xx.xx)
3rd Dose	xx (xx.xx)

- The Capital "N" in the column header represents the total number of Evaluable Analysis Set.
- The small "n" in summary statistics represents the total number of patients in the row category.
- Percentages in the "Patients received COVID-19 Vaccination" rows are based on the total number of Evaluable Analysis Set.
- Percentages in the "If Vaccination" rows are based on the total number of "Patient received covid-19 vaccination".
- Source: Listing 16.1.4

Table 14.1.5.1. Summary of Prior Asthma Therapy (Evaluable Analysis Set)

	N = xx
	n (%)
Patient take any prior asthma medication(s) other than oral/inhaled Corticosteroid	
Yes	xx (xx.xx)
No	xx (xx.xx)

- The Capital "N" in the column header represents the total number of Evaluable Analysis Set.
- The small "n" in summary statistics represents the total number of patients in the row category.
- Percentages in the "Patient take any prior asthma medication(s) other than oral/inhaled Corticosteroid" rows are based on the total number of Evaluable Analysis Set.
- Source: Listing 16.1.5.1

Table 14.1.5.2. Summary of oral/inhaled Corticosteroid (Evaluable Analysis Set)

	N = xx
	n (%)
Patient receive any prior oral/inhaled Corticosteroid	
Yes	xx (xx.xx)
No	xx (xx.xx)

- The Capital "N" in the column header represents the total number of Evaluable Analysis Set.
- The small "n" in summary statistics represents the total number of patients in the row category.
- Percentages in the "Patient receive any prior oral/inhaled Corticosteroid" rows are based on the total number of Evaluable Analysis Set.
-
- Source: Listing 16.1.5.2

Table 14.1.6. Patient Administration of Benralizumab (Evaluable Analysis Set)

	N = xx
	n (%)
Visit x	
Patient administer study Medication at this visit (N*=xxx)	
Yes	xx (xx.xx)
No	xx (xx.xx)

- The Capital "N" in the column header represents the total number of Evaluable Analysis Set.
- The small "n" in summary statistics represents the total number of patients in the row category.
- All percentages are based on N* i.e. the total number of patients of Evaluable Analysis set at the visit.
-
- Programmer Note: Visit x- Visit 1, Visit 2 and visit 3
- Source: Listing 16.1.6.1

Table 14.1.7. Summary of Overdose (Evaluable Analysis Set)

	N = xx
	n (%)
Overdose of study intervention recorded	
Yes	xx (xx.xx)
No	xx (xx.xx)
Missing	xx (xx.xx)
Adverse Event occurred due to overdose	
Yes	xx (xx.xx)
No	xx (xx.xx)
Missing	xx (xx.xx)
Overdose Accidental	
Yes	xx (xx.xx)
No	xx (xx.xx)
Missing	xx (xx.xx)

- The Capital "N" in the column header represents the total number of Evaluable Analysis Set.
- The small "n" in summary statistics represents the total number of patients in the row category.
- All percentages are based on the Evaluable Analysis set.
- Source: Listing 16.1.6.2

Table 14.1.8. Summary of Pulmonary Function Test (Evaluable Analysis Set)

	N = xx
Pulmonary function test using Spirometer performed	
Yes	xx (xx.xx)
No	xx (xx.xx)
Missing	xx (xx.xx)
Pre-Bronchodilator Assessment	
Forced Expiratory Volume in 1 second (L)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
(25^{th} percentiles, 75th percentiles)	(xx.xx, xx.xx)
Predicted Normal FEV1 (%)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
(25^{th} percentiles, 75th percentiles)	(xx.xx, xx.xx)
Forced Vital Capacity (L)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
(25^{th} percentiles, 75th percentiles)	(xx.xx, xx.xx)
Patient have historical proof of Post-Bronchodilator reversibility within 12 months	
Yes	xx (xx.xx)
No	xx (xx.xx)
Missing	xx (xx.xx)
Forced expiratory volume in 1 Second (L)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
(25^{th} percentiles, 75th percentiles)	(xx.xx, xx.xx)
Reversibility FEV1 (%)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
(25^{th} percentiles, 75th percentiles)	(xx.xx, xx.xx)
FEV1 Reversibility (mL)	
n	Xx

Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
(25th percentiles, 75th percentiles)	(xx.xx, xx.xx)

- The Capital "N" in the column header represents the total number Evaluable Analysis Set.
- The small "n" in summary statistics represents the total number of patients.
- Percentages are based on number of Evaluable Analysis Set.
- SD = Standard Deviation, min=minimum, max=maximum
- Source: Listing 16.1.7

Table 14.2.1.1. Summary of Asthma and Exacerbation (Evaluable Analysis Set)

	N = xx	
	n (%)	95% CI
Visit 1		
Significant History of Asthma with Eosinophilic Phenotype		
Yes	xx (xx.xx)	(xx.xx, xx.xx)
No	xx (xx.xx)	(xx.xx, xx.xx)
Missing	xx (xx.xx)	(xx.xx, xx.xx)
Disease Duration (months)		
n	Xx	
Missing	Xx	
Mean (SD)	xx.x (xx.xx)	
Median	xx.x	
(min, max)	(xx.xx, xx.xx)	
(25th percentiles, 75th percentiles)	(xx.xx, xx.xx)	
Patient Experience Exacerbation in the previous 12 months		
Yes	xx (xx.xx)	(xx.xx, xx.xx)
No	xx (xx.xx)	(xx.xx, xx.xx)
Missing	xx (xx.xx)	(xx.xx, xx.xx)
Visit x		
Patient Experience any new Exacerbation or change in existing Exacerbation since last visit		
Yes	xx (xx.xx)	(xx.xx, xx.xx)
No	xx (xx.xx)	(xx.xx, xx.xx)
Missing	xx (xx.xx)	(xx.xx, xx.xx)

- The Capital "N" in the column header represents the total number of Evaluable Analysis Set.
- The small "n" in summary statistics represents the total number of patients.
- All Percentages rows are based on the total number of Evaluable Analysis Set.
- 95% CI calculate will be using Clopper-Pearson Exact method.
- Programmer Note: Visit x- Visit 2, Visit 3, Visit 4 and Visit 5
- Source: Listing 16.2.1.1 and Listing 16.2.1.2

Table 14.2.1.2. Summary of Exacerbation (Evaluable Analysis Set)

	N = xx	
	n (%)	95% CI
Outcome		
Resolved	xx (xx.xx)	(xx.xx, xx.xx)
Fatal	xx (xx.xx)	(xx.xx, xx.xx)
Not Resolved	xx (xx.xx)	(xx.xx, xx.xx)
Patient withdrawn due to exacerbation		
Yes	xx (xx.xx)	(xx.xx, xx.xx)
No	xx (xx.xx)	(xx.xx, xx.xx)
Exacerbation is Clinical Significance		
Yes	xx (xx.xx)	(xx.xx, xx.xx)
No	xx (xx.xx)	(xx.xx, xx.xx)
Patient visit the Emergency room due to this Exacerbation		
Yes	xx (xx.xx)	(xx.xx, xx.xx)
No	xx (xx.xx)	(xx.xx, xx.xx)
If Yes, Number of Telephone calls		
n	Xx	
Missing	Xx	
Mean (SD)	xx.x (xx.xx)	
Median	xx.x	
(min, max)	(xx.xx, xx.xx)	
(25^{th} percentiles, 75th percentiles)	(xx.xx, xx.xx)	
Patient Hospitalisation due to this Exacerbation		
Yes	xx (xx.xx)	(xx.xx, xx.xx)
No	xx (xx.xx)	(xx.xx, xx.xx)
Patient visit to clinic as out-patient		
Yes	xx (xx.xx)	(xx.xx, xx.xx)
No	xx (xx.xx)	(xx.xx, xx.xx)
Oral/Inhaled Corticosteroids taken for the Exacerbation		
Yes	xx (xx.xx)	(xx.xx, xx.xx)
No	xx (xx.xx)	(xx.xx, xx.xx)
Patient intubated for this exacerbation		
Yes	xx (xx.xx)	(xx.xx, xx.xx)
No	xx (xx.xx)	(xx.xx, xx.xx)
Exacerbation medications other than oral/inhaled Corticosteroids taken		
Yes	xx (xx.xx)	(xx.xx, xx.xx)
No	xx (xx.xx)	(xx.xx, xx.xx)

- The Capital "N" in the column header represents the total number of Evaluable Analysis Set.
- The small "n" in summary statistics represents the total number of Events.
- Percentages are based on the number of Evaluable Analysis Set
- 95% CI calculate will be using Clopper-Pearson Exact method.
- ***Patient 09021 is counted under both 'Yes' and 'No'. The patient had 4 exacerbation events. It had visited the emergency room for 1 exacerbation event but not visited the emergency room for other 3 events.**
- Source: Listing 16.2.2.1, Listing 16.2.2.2 and Listing 16.2.2.3

Table 14.2.1.3. Summary of Before and After Treatment Exacerbation (Evaluable Analysis Set)

	N = xx
Exacerbation before study	
N	xx
Missing	xx
Mean (SD)	x.x (x.xx)
Median	x.x
(min, max)	(x,x)
(25th Percentile, 75th Percentile)	(x.xx, x.xx)
Exacerbation at end of study	
n	xx
Missing	xx
Mean (SD)	x.x (x.xx)
Median	x.x
(min, max)	(x,x)
(25th Percentile, 75th Percentile)	(x.xx, x.xx)
P-value	x.xxxx
Annualized exacerbation rate	x.xx

- The column header's capital "N" denotes the total number of Evaluable Analysis Sets.
- The modest "n" in the number of patients suffering from exacerbation.
- The annual rate for each patient was calculated by dividing the total number of exacerbations by the number of days participated in the study and multiplying by 365.
- Source: Listing 16.2.2.1, Listing 16.2.2.2 and Listing 16.2.2.3

Table 14.2.2. Summary of Time to first Exacerbation (Evaluable Analysis Set)

	N=xxx
Patient Asthma Exacerbation, n (%)	
Yes	xx(xx.xx)
No	xx(xx.xx)
Duration of Patient First Asthma Exacerbation (Days)	
n	Xx
missing	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min , max)	(xx.xx, xx.xx)
(25^{th} Percentile, 75^{th} Percentile)	(xx.xx, xx.xx)
Estimate for Time to Response (Days)	
Median	xx.x
95 % CI	(xx.xx, xx.xx)

- The Capital "N" in the column header represents the total number of Evaluable Analysis Set.
- The small “n” in summary statistics represents the total number of patients
- Estimate for Time to Response using Kaplan-Meier method.
- Start date of first asthma exacerbation minus Date of First dose of study treatment Plus 1.
- Source: Listing 16.2.2.1, Listing 16.2.2.2 and Listing 16.2.2.3

Table 14.2.3. Analysis of change in Blood Eosinophils count from baseline to Visit 2, Visit 4 and Visit 5 (Evaluable Analysis Set)

	Observed value (N = xx)	Change from Baseline (N = xx)	% Change from Baseline (N = xx)
Absolute Eosinophil			
Baseline (Screening Visit)			
n	xx		
Missing	xx		
Mean (SD)	xx.x (xx.xx)		
Median	xx.x		
(min, max)	(xx.xx, xx.xx)		
(25th percentiles, 75th percentiles)	(xx.xx, xx.xx)		
Visit x			
n	xx	xx	xx
Missing	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
(25th percentiles, 75th percentiles)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
p-value		x.xxx	x.xxx

- The Capital "N" in the column header represents the total number of Patients in Safety Analysis Set.
- The small "n" in summary statistics represents the total number of patients.
- SD = Standard deviation, min=minimum, max=maximum
- Change from Baseline= Post-Baseline - Baseline
- % Change from Baseline = (Post-Baseline - Baseline / Baseline) X 100
- p-value calculate using paired t – test.
- Programmer Note: Visit x: Visit 2, Visit 4 and Visit 5
- Source: Listing 16.2.3

Table 14.2.4 Summary of Overall Investigators Assessment (Evaluable Analysis Set)

	N = xx	
	n (%)	95% CI
Overall Investigators Assessment performed		
Yes	xx (xx.xx)	(xx.xx, xx.xx)
No	xx (xx.xx)	(xx.xx, xx.xx)
If yes		
Well Controlled	xx (xx.xx)	(xx.xx, xx.xx)
Partly Controlled	xx (xx.xx)	(xx.xx, xx.xx)
Uncotrolled	xx (xx.xx)	(xx.xx, xx.xx)

- The Capital "N" in the column header represents the total number of Evaluable Analysis Set.
- The small "n" in summary statistics represents the total number of patients.
- Percentages in the "Overall Investigators Assessment performed" rows are based on the total number of Evaluable Analysis Set.
- Percentages in the "If Yes" rows are based on the total number of "Patient Performed overall Investigation Assessment".
- 95% CI calculate will be using Clopper-Pearson Exact method.
- Source: Listing 16.2.4

Table 14.3.1.1. Overall Summary of Adverse Events (Safety Analysis Set)

	(N=xx)
	n (%) E
Patient with at least one AE	xx (xx.xx) xx
Patients with at least one Serious AE	xx (xx.xx) xx
Patient with at least one TEAE	xx (xx.xx) xx
Patients with at least one Serious TEAE	xx (xx.xx) xx
Subjects with at least drug related TEAE	xx (xx.xx) xx
Patients with any TEAE Leading to discontinuation	xx (xx.xx) xx
Patients with any TEAE Leading to death	xx (xx.xx) xx

- TEAE = treatment-emergent adverse event; N = number of Patients in the Safety Analysis Set
- n = number of patients in row category.
- TEAE are those adverse events which occurred after first dose of study medication.
- All Percentage rows are based on the Safety Analysis Set.
- Note: Adverse events were coded using MedDRA version 24.1 If a Patient has multiple occurrences of an AE, the Patient is presented only once in the respective patient count column (n) for the corresponding AE. Events are counted each time in the event (E) column.
- Source: Listing 16.3.1.2, Listing 16.3.2.1 and Listing 16.3.2.2

Table 14.3.1.2. Summary of Treatment Emergent Adverse Events (Safety Analysis Set)

	(N=xx) n (%) E	95% CI
Adverse Events		
Patient with any TEAE	xx (xx.xx) xx	(xx.xx, xx.xx)
Patient with any Serious TEAE	xx (xx.xx) xx	(xx.xx, xx.xx)
Adverse Events by Intensity grade		
Mild	xx (xx.xx) xx	(xx.xx, xx.xx)
Moderate	xx (xx.xx) xx	(xx.xx, xx.xx)
Severe	xx (xx.xx) xx	(xx.xx, xx.xx)
Action Taken		
None	xx (xx.xx) xx	(xx.xx, xx.xx)
None-drug treatment required	xx (xx.xx) xx	(xx.xx, xx.xx)
Hostpitalisation/prolonged hostpitalisation	xx (xx.xx) xx	(xx.xx, xx.xx)
Diagnostic or clinical test conducted	xx (xx.xx) xx	(xx.xx, xx.xx)
Drug withdrawn	xx (xx.xx) xx	(xx.xx, xx.xx)
TEAE by outcome		
Recovered without sequelae	xx (xx.xx) xx	(xx.xx, xx.xx)
Recovered with Sequelae	xx (xx.xx) xx	(xx.xx, xx.xx)
Not recovered/Not resolved	xx (xx.xx) xx	(xx.xx, xx.xx)
Recovering/Resolving	xx (xx.xx) xx	(xx.xx, xx.xx)
Unknown	xx (xx.xx) xx	(xx.xx, xx.xx)
Fatal	xx (xx.xx) xx	(xx.xx, xx.xx)
Investigators causality rating against the Investigational Product		
Yes	xx (xx.xx) xx	(xx.xx, xx.xx)
No	xx (xx.xx) xx	(xx.xx, xx.xx)
Patient Withdrawn		
Yes	xx (xx.xx) xx	(xx.xx, xx.xx)
No	xx (xx.xx) xx	(xx.xx, xx.xx)
Non-Study Medication Teatment taken		
Yes	xx (xx.xx) xx	(xx.xx, xx.xx)
No	xx (xx.xx) xx	(xx.xx, xx.xx)

- TEAE = treatment-emergent adverse event; N = number of Patients in the Safety Analysis
- n = number of patients in row category, E = number of TEAE.
- TEAE are those adverse events which occurred after first dose of study medication.
- All Percentages rows are based on the total number of patients in the Safety Analysis Set
- 95% CI calculate will be using Clopper-Pearson Exact method.
- Source: Listing 16.3.1.2

Table 14.3.1.3.1 Summary of Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set)

	(N=xx)
System Organ Class/Preferred Term	n (%) E
Patient with at least one TEAE	xx (xx.xx) xx
System Organ Class	xx (xx.xx) xx
Preferred Term 1	xx (xx.xx) xx
Preferred Term 2	xx (xx.xx) xx
System Organ Class	xx (xx.xx) xx
Preferred Term 1	xx (xx.xx) xx
Preferred Term 2	xx (xx.xx) xx

- TEAE = treatment-emergent adverse event; N = number of Patients in the Safety Analysis Set
- n = number of patients in row category; E = number of TEAE
- TEAE are those adverse events which occurred after first dose of study medication.
- All Percentages ros are based on the total number of patients in the Safety Analysis Set .
- System Organ classes was sorted by descending frequency. Preferred terms are sorted by descending frequency within system organ class.
- Adverse events were coded using MedDRA version 24.1 If a patient has multiple occurrences of an AE, the patient is presented only once in the respective patient count column (n) for the corresponding AE. Events are counted each time in the event column.
- Source: Listing 16.3.1.2, Listing 16.3.2.1 and Listing 16.3.2.2

Table 14.3.1.3.2 Summary of Serious Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set)

	(N=xx)
System Organ Class/Preferred Term	n (%) E
Patient with at least one Serious TEAE	xx (xx.xx) xx
System Organ Class	xx (xx.xx) xx
Preferred Term 1	xx (xx.xx) xx
Preferred Term 2	xx (xx.xx) xx
System Organ Class	xx (xx.xx) xx
Preferred Term 1	xx (xx.xx) xx
Preferred Term 2	xx (xx.xx) xx

- TEAE = treatment-emergent adverse event; N = number of Patients in the Safety Analysis Set
- n = number of patients in row category; E = number of TEAE
- TEAE are those adverse events which occurred after first dose of study medication.
- All Percentages ros are based on the total number of patients in the Safety Analysis Set .
- System Organ classes was sorted by descending frequency. Preferred terms are sorted by descending frequency within system organ class.
- Adverse events were coded using MedDRA version 24.1 If a patient has multiple occurrences of an AE, the patient is presented only once in the respective patient count column (n) for the corresponding AE. Events are counted each time in the event column.
- Source: Listing 16.3.1.2, Listing 16.3.2.1 and Listing 16.3.2.2

Table 14.3.1.4. Summary of TEAE related to the Investigational Product by System Organ Class and Preferred Term (Safety Analysis Set)

	(N=xx)
System Organ Class/Preferred Term	n (%) E
Patient with any TEAE related to the IP	xx (xx.xx) xx
System Organ Class	xx (xx.xx) xx
Preferred Term 1	xx (xx.xx) xx
Preferred Term 2	xx (xx.xx) xx
System Organ Class	xx (xx.xx) xx
Preferred Term 1	xx (xx.xx) xx
Preferred Term 2	xx (xx.xx) xx

- TEAE = treatment-emergent adverse event; N = number of patients in Safety Analysis Set
- n = number of Patients in row category; E = number of TEAE
- IP=Investigational product
- TEAE are those adverse events which occurred after first dose of study medication.
- All Percentage rows are based on the total number of patients in the Safety Analysis Set.
- System organ classes are sorted by descending frequency. Preferred terms are sorted by descending frequency within system organ class. Related includes possible and probable
- Adverse events were coded using MedDRA version 24.1. If a patient has multiple occurrences of an AE, the patient is presented only once in the respective patient count column (n) for the corresponding AE. Events are counted each time in the event € column.
- Source: Listing 16.3.1.2, Listing 16.3.2.1 and Listing 16.3.2.2

Table 14.3.1.5. Summary of TEAE leading to discontinuation by System Organ Class and Preferred Term (Safety Analysis Set)

	(N=xx)	
System Organ Class/Preferred Term	n (%) E	95% CI
Patient with any TEAE leading to discontinuation	xx (xx.xx) xx	(xx.xx, xx.xx)
System Organ Class	xx (xx.xx) xx	(xx.xx, xx.xx)
Preferred Term 1	xx (xx.xx) xx	(xx.xx, xx.xx)
Preferred Term 2	xx (xx.xx) xx	(xx.xx, xx.xx)
System Organ Class	xx (xx.xx) xx	(xx.xx, xx.xx)
Preferred Term 1	xx (xx.xx) xx	(xx.xx, xx.xx)
Preferred Term 2	xx (xx.xx) xx	(xx.xx, xx.xx)

- TEAE = treatment-emergent adverse event; N = number of patients in Safety Analysis Set; n = number of patients in row category; E = number of TEAE
- IP Investigartional product
- TEAE are those adverse events which occurred after first dose of study medication.
- All Percentages roes are based on the total number of patients in the Safety Analysis Set.
- System organ classes are sorted by descending frequency. Preferred terms are sorted by descending frequency overall within system organ class.
- Adverse events will be using MedRA version 24.1. If a patient has multiple occurrences of an AE, the patient is presented only once in the respective patient count column (n) for the corresponding AE. Events are counted each time in the event E column.
- 95% CI calculate will be using Clopper-Pearson Exact method.
- Source: Listing 16.1.4, Listing 16.3.1.2, Listing 16.3.2.1 and Listing 16.3.2.2

Table 14.3.1.6. Summary of Serious TEAE by System Organ Class and Preferred Term (Safety Analysis Set)

	(N=xx)
System Organ Class/Preferred Term	n (%) E
Patient with at least one serious TEAE	xx (xx.xx) xx
System Organ Class	xx (xx.xx) xx
Preferred Term 1	xx (xx.xx) xx
Preferred Term 2	xx (xx.xx) xx
System Organ Class	xx (xx.xx) xx
Preferred Term 1	xx (xx.xx) xx
Preferred Term 2	xx (xx.xx) xx

- TEAE = treatment-emergent adverse event; N = number of patients in Safety Analysis Set;
- n = number of Patients in row category; E = number of serious TEAE
- TEAE are those adverse events which occurred after first dose of study medication.
- All Percentages rows are based on the total number of patients in the Safety Analysis Set.
- System Organ classes was sorted by descending frequency. Preferred terms are sorted by descending frequency within system orgen class.
- Adverse events were coded using MedDRA version 24.1 If a patient has multiple occurrences of an AE, the patient is presented only once in the respective patient count column (n) for the corresponding AE. Events are counted each time in the event € column.
- Source: Listing 16.3.1.2,Listing 16.3.2.1 and Listing 16.3.2.2

Table 14.3.2.1. Analysis of change in Haematology parameters from baseline to Week 24. (Safety Analysis Set)

	Observed value (N = xx)	Change from Baseline (N = xx)	% Change from Baseline (N = xx)
Haematology parameter x			
Baseline (Screening Visit)			
n	xx		
Missing	xx		
Mean (SD)	xx.x (xx.xx)		
Median	xx.x		
(min, max)	(xx.xx, xx.xx)		
(25^{th} percentiles, 75^{th} percentiles)	(xx.xx, xx.xx)		
Week 24			
n	xx	xx	xx
Missing	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
(25^{th} percentiles, 75^{th} percentiles)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
p-value		x.xxx	x.xxx

- The Capital "N" in the column header represents the total number of patients in Safety Analysis Set.
- The small "n" in summary statistics represents the total number of patients.
- SD = Standard deviation, min=minimum, max=maximum
- Change from Baseline= Post-Baseline – Baseline
- % Change from Baseline = (Post-Baseline – Baseline / Baseline) X 100
- p-value calculate using paired t – test.
- Programmer Note: Haematology parameter x: Haematocrit (%), Haemoglobin(g/DL), Absolute Neutrophils (mm^3), Absolute Basophils(mm^3), Absolute Eosinophils(mm^3), Absolute Monocytes(mm^3), Absolute Lymphocytes(mm^3), Platelet count (/µL) and Total leukocyte count(/µL)
- Source: Listing 16.3.3.1

Table 14.3.2.2. Analysis of change in Biochemistry parameters from baseline to Week 24 (Safety Analysis Set)

	Observed value (N = xx)	Change from Baseline (N = xx)	% Change from Baseline (N = xx)
Biochemistry parameter x			
Baseline (Screening Visit)			
n	xx		
Missing	xx		
Mean (SD)	xx.x (xx.xx)		
Median	xx.x		
(min, max)	(xx.xx, xx.xx)		
(25^{th} percentiles, 75^{th} percentiles)	(xx.xx, xx.xx)		
Week 24			
n	Xx	Xx	xx
Missing	Xx	Xx	Xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
(25^{th} percentiles, 75^{th} percentiles)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
p-value		x.xxx	x.xxx

- The Capital "N" in the column header represents the total number of patients in Safety Analysis Set.
- The small "n" in summary statistics represents the total number of patients.
- SD = Standard deviation, min=minimum, max=maximum
- Change from Baseline= Post-Baseline – Baseline
- % Change from Baseline = (Post-Baseline – Baseline / Baseline) X 100
- p-value calculate using paired t – test.
- Programmer Note: Biochemistry parameter x: Serum Alkaline phosphatase (IU/L), Alanine aminotransferase(U/L), Aspartate aminotransferase (U/L), Gamma- glutamyl transferase(U/L), Lactate dehydrogenase(U/L), Total Protein (g/dL), Total bilirubin (mg/dL), Albumin (g/dL), Serum Creatinine (mg/dL).
- Source: Listing 16.3.3.2

Table 14.3.3. Analysis of change in Vital Sign parameters from baseline to Visit 1, Visit 2, Visit 3, Visit 4 and Visit 5 (Safety Analysis Set)

	Observed value (N = xx)	Change from Baseline (N = xx)	% Change from Baseline (N = xx)
Vital Sign parameter x			
Baseline (Screening Visit)			
n	xx		
Missing	xx		
Mean (SD)	xx.x (xx.xx)		
Median	xx.x		
(min, max)	(xx.xx, xx.xx)		
(25^{th} percentiles, 75^{th} percentiles)	(xx.xx, xx.xx)		
Visit x			
n	Xx	Xx	xx
Missing	Xx	Xx	Xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
(25^{th} percentiles, 75^{th} percentiles)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
p-value		x.xxx	x.xxx

- The Capital "N" in the column header represents the total number of patients in Safety Analysis Set.
- The small "n" in summary statistics represents the total number of patients.
- SD = Standard deviation, min=minimum, max=maximum
- Change from Baseline= Post-Baseline – Baseline
- % Change from Baseline = (Post-Baseline – Baseline / Baseline) X 100
- p-value calculate using paired t – test.
- Programmer Note: Vital Signs parameter x: Pulse rate (beats/min), Respiratory rate (breaths/min), Systolic blood pressure (mmHg), Diastolic blood pressure (mmHg) and Temperature(^{0}F).
- Programmer Note: Visit x: Visit 1, Visit 2, Visit 3, Visit 4 and Visit 5
- Source: Listing 16.3.4

Table 14.3.4. Summary of Electrocardiogram (Safety Analysis Set)

	N = xx
Visit x	
ECG performed	
Yes	xx (xx.xx)
No	xx (xx.xx)
Heart Rate (beats/min)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
(25^{th} percentiles, 75^{th} percentiles)	(xx.xx, xx.xx)
QRS (ms)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
(25^{th} percentiles, 75^{th} percentiles)	(xx.xx, xx.xx)
PR (ms)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
(25^{th} percentiles, 75^{th} percentiles)	(xx.xx, xx.xx)
RR (ms)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
(25^{th} percentiles, 75^{th} percentiles)	(xx.xx, xx.xx)
QT (ms)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
(25^{th} percentiles, 75^{th} percentiles)	(xx.xx, xx.xx)
QTcB (ms)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)

(25th percentiles, 75th percentiles) (xx.xx, xx.xx)

- The Capital "N" in the column header represents the total number of patients in Safety Analysis Set.
- The small "n" in summary statistics represents the total number of patients.
- Percentages are based on number of Safety Analysis Set.
- SD = Standard Deviation, min=minimum, max=maximum
- Programmer Note: Visit x: Screening Visit, Visit 2 and Visit 5
- Source: Listing 16.3.5

Table 14.3.5. Summary of Targeted Physical Examination (Safety Analysis Set)

	N = xx n (%)
Visit x	
Physical Examination Performed	
Yes	xx (xx.xx)
No	xx (xx.xx)
General Appearance	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
Abnormal CS	xx (xx.xx)
Abnormal NCS	xx (xx.xx)
Respiratory System	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
Abnormal CS	xx (xx.xx)
Abnormal NCS	xx (xx.xx)
Cardiovascular System	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
Abnormal CS	xx (xx.xx)
Abnormal NCS	xx (xx.xx)
Abdomen	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
Abnormal CS	xx (xx.xx)
Abnormal NCS	xx (xx.xx)
Skin	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
Abnormal CS	xx (xx.xx)
Abnormal NCS	xx (xx.xx)
Head, Eye, Ear, Nose, Throat	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
Abnormal CS	xx (xx.xx)
Abnormal NCS	xx (xx.xx)
Lymph Node	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
Abnormal CS	xx (xx.xx)
Abnormal NCS	xx (xx.xx)
Thyroid	
Normal	xx (xx.xx)

Abnormal	xx (xx.xx)
If Abnormal	
Abnormal CS	xx (xx.xx)
Abnormal NCS	xx (xx.xx)
Musculoskeletal System	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
Abnormal CS	xx (xx.xx)
Abnormal NCS	xx (xx.xx)
Neurological System	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
Abnormal CS	xx (xx.xx)
Abnormal NCS	xx (xx.xx)
Other	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
Abnormal CS	xx (xx.xx)
Abnormal NCS	xx (xx.xx)

- The Capital "N" in the column header represents the total number of patients in Safety Analysis Set.
- The small "n" in summary statistics represents the total number of patients.
- All Percentages rows are based on the total number of Safety Analysis Set.
- Programmer note: Visit x: Screening Visit, Visit 1, Visit 2, Visit 3, Visit 4 and Visit 5.
- Source: Listing 16.3.6

Table 14.3.6.1. Summary of Serum Pregnancy Test (Safety Analysis Set)

	N = xx
	n (%)
Serum Pregnancy test performed	
Yes	xx (xx.xx)
No	xx (xx.xx)
Result	
Positive	xx (xx.xx)
Negative	xx (xx.xx)

- The Capital "N" in the column header represents the total number of Safety Analysis Set.
- The small "n" in summary statistics represents the total number of patients.
- All Percentages rows are based on the total number of Safety Analysis Set.
- Source: Listing 16.3.3.4

Table 14.3.6.2. Summary of Urine Pregnancy Test (Safety Analysis Set)

	N = xx
	n (%)
Visit x	
Urine Pregnancy test performed	
Yes	xx (xx.xx)
No	xx (xx.xx)
Result	
Positive	xx (xx.xx)
Negative	xx (xx.xx)

- The Capital "N" in the column header represents the total number of Safety Analysis Set.
- The small "n" in summary statistics represents the total number of patients.
- All Percentages rows are based on the total number of Safety Analysis Set.
- Programmer note: Visit x- Visit 1, Visit 2, Visit 3, Visit 4 and Visit 5
- Source: Listing 16.3.7

Listing 16.1.1.1. Listing of Patient Informed consent

Patient No	Informed Consent Obtained	Date of Informed Consent obtained	Time of Informed Consent obtained
xx-xxx	Yes/No	DD-MMM-YYYY	HH:MM
xx-xxx	Yes/No	DD-MMM-YYYY	HH:MM
xx-xxx	Yes/No	DD-MMM-YYYY	HH:MM
xx-xxx	Yes/No	DD-MMM-YYYY	HH:MM
xx-xxx	Yes/No	DD-MMM-YYYY	HH:MM

Listing 16.1.1.2. Listing of Patient Discontinuation of Study Intervention

Patient No	Study Treatment stopped permanently before the scheduled end of treatment period	Patient Continue in the Study	Date of Last Dose	Primary reason for withdrawal	If Other, Specify
xx-xxx	Yes/No	Yes/No	DD-MMM-YYYY	Xxxx	Xxxx
xx-xxx	Yes/No	Yes/No	DD-MMM-YYYY	Xxxx	Xxxx
xx-xxx	Yes/No	Yes/No	DD-MMM-YYYY	Xxxx	Xxxx
xx-xxx	Yes/No	Yes/No	DD-MMM-YYYY	Xxxx	Xxxx
xx-xxx	Yes/No	Yes/No	DD-MMM-YYYY	xxxx	xxxx

Listing 16.1.1.3. Listing of Patient Study Completion

Patient No	Patient complete the study	Date of Completion/ Discontinuation	Primary reason for withdrawal	If Other, Specify
xx-xxx	Yes/No	DD-MMM-YYYY	Xxxx	Xxxx
xx-xxx	Yes/No	DD-MMM-YYYY	Xxxx	Xxxx
xx-xxx	Yes/No	DD-MMM-YYYY	Xxxx	Xxxx
xx-xxx	Yes/No	DD-MMM-YYYY	Xxxx	Xxxx
xx-xxx	Yes/No	DD-MMM-YYYY	xxxx	xxxx

Listing 16.1.1.4. Listing of Patient Analysis Set

Patient No	Enrolled Analysis Set	Assigned to study intervention Analysis Set	Evaluable Analysis Set	Safety Analysis Set
xx-xxx	Yes/No	Yes/No	Yes/No	Yes/No
xx-xxx	Yes/No	Yes/No	Yes/No	Yes/No
xx-xxx	Yes/No	Yes/No	Yes/No	Yes/No
xx-xxx	Yes/No	Yes/No	Yes/No	Yes/No
xx-xxx	Yes/No	Yes/No	Yes/No	Yes/No

Listing 16.1.2.1. Listing of Patient Demographics Information

Patient No	Date of Birth	Age (Years)	Gender	Indicate child-bearing potential	Date of last menses	Race	Other Specify
xx-xxx	DD-MMM-YYYY	Xx	Male/Female	xxxx	DD-MMM-YYYY	Asian/Other	xxxx
xx-xxx	DD-MMM-YYYY	Xx	Male/Female	xxxx	DD-MMM-YYYY	Asian/Other	xxxx
xx-xxx	DD-MMM-YYYY	Xx	Male/Female	xxxx	DD-MMM-YYYY	Asian/Other	xxxx
xx-xxx	DD-MMM-YYYY	Xx	Male/Female	xxxx	DD-MMM-YYYY	Asian/Other	xxxx
xx-xxx	DD-MMM-YYYY	xx	Male/Female	xxxx	DD-MMM-YYYY	Asian/Other	xxxx

Listing 16.1.2.2. Listing of Patient Anthropometry

Patient No	Height (cm)	Weight (Kg)	Body Mass Index (Kg/m^2)
xx-xxx	xxx	xxx	xxx
xx-xxx	xxx	xxx	xxx
xx-xxx	xxx	xxx	xxx
xx-xxx	xxx	xxx	xxx
xx-xxx	xxx	xxx	xxx

Listing 16.1.3. Listing of Patient Significant Medical History

Patient No	Patient have any medical/surgical History	Seq. No.	Medical/Surgical Description	Start Date	End Date	Ongoing	Received Treatment
xx-xxx	Yes/No	Xx	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	Yes/No
xx-xxx	Yes/No	Xx	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	Yes/No
xx-xxx	Yes/No	Xx	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	Yes/No
xx-xxx	Yes/No	Xx	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	Yes/No
xx-xxx	Yes/No	xx	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	Yes/No

Listing 16.1.4. Listing of Patient COVID-19 Vaccination

Patient No	Patient received COVID-19 vaccine	Date of 1st Dose	Date of 2nd Dose	Date of 3rd Dose
xx-xxx	Yes/No	DD-MMM-YYYY/NA	DD-MMM-YYYY/NA	DD-MMM-YYYY/NA
xx-xxx	Yes/No	DD-MMM-YYYY/NA	DD-MMM-YYYY/NA	DD-MMM-YYYY/NA
xx-xxx	Yes/No	DD-MMM-YYYY/NA	DD-MMM-YYYY/NA	DD-MMM-YYYY/NA
xx-xxx	Yes/No	DD-MMM-YYYY/NA	DD-MMM-YYYY/NA	DD-MMM-YYYY/NA
xx-xxx	Yes/No	DD-MMM-YYYY/NA	DD-MMM-YYYY/NA	DD-MMM-YYYY/NA

Listing 16.1.5.1. Listing of Patient Prior Asthma Therapy

Patient No	Patient take any prior asthma medication other than oral/Inhaled Corticosteroid	Seq. No.	Drug name	Start Date	Stop Date	Ongoing	Total Daily Dose	Units	Frequency	Route
xx-xxx	Yes/No	Xx	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	xxxx	xxxx	xxxx	xxxx
xx-xxx	Yes/No	Xx	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	xxxx	xxxx	xxxx	xxxx
xx-xxx	Yes/No	Xx	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	xxxx	xxxx	xxxx	xxxx
xx-xxx	Yes/No	Xx	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	xxxx	xxxx	xxxx	xxxx
xx-xxx	Yes/No	xx	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	xxxx	xxxx	xxxx	xxxx

Listing 16.1.5.2. Listing of Patient Prior Oral/Inhaled Corticosteroid Therapy

Patient No	Patient receive any oral/Inhaled Corticosteroid therapy	Seq. No.	Drug name	Start Date	Stop Date	Ongoing	Duration (Years: Months)	Total Daily Dose	Units	Frequency	Route
xx-xxx	Yes/No	xx	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	xx : xx	xxxx	xxxx	xxxx	xxxx
xx-xxx	Yes/No	xx	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	xx : xx	xxxx	xxxx	xxxx	xxxx
xx-xxx	Yes/No	xx	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	xx : xx	xxxx	xxxx	xxxx	xxxx
xx-xxx	Yes/No	xx	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	xx : xx	xxxx	xxxx	xxxx	xxxx
xx-xxx	Yes/No	xx	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	xx : xx	xxxx	xxxx	xxxx	xxxx

Listing 16.1.6.1. Listing of Patient Administration of Benralizumab

Patient No	Visit	Patient administer Study Medication at this visit	Dose	Date and time of Medication Administration
xx-xxx	Xxxx	Yes/No	30 mg/mL	DD-MMM-YYYY/HH:MM
xx-xxx	Xxxx	Yes/No	30 mg/mL	DD-MMM-YYYY/HH:MM
xx-xxx	Xxxx	Yes/No	30 mg/mL	DD-MMM-YYYY/HH:MM
xx-xxx	Xxxx	Yes/No	30 mg/mL	DD-MMM-YYYY/HH:MM
xx-xxx	Xxxx	Yes/No	30 mg/mL	DD-MMM-YYYY/HH:MM

Listing 16.1.6.2. Listing of Patient Overdose

Patient No	Any Overdose of study interventional recorded	Any Adverse Event Occurred due to Overdose	Seq. of AE	Date of Overdose	Visit of Overdose	Overdose Accidental	Possible Cause
xx-xxx	Yes/No	Yes/No	Xx	DD-MMM-YYYY	Xx	Yes/No	Xxxx
xx-xxx	Yes/No	Yes/No	Xx	DD-MMM-YYYY	Xx	Yes/No	Xxxx
xx-xxx	Yes/No	Yes/No	Xx	DD-MMM-YYYY	Xx	Yes/No	Xxxx
xx-xxx	Yes/No	Yes/No	Xx	DD-MMM-YYYY	Xx	Yes/No	Xxxx
xx-xxx	Yes/No	Yes/No	xx	DD-MMM-YYYY	xx	Yes/No	Xxxx

Listing 16.1.7. Listing of Patient Pulmonary Function Test

Patient No	Pulmonary function test using Spirometer performed	Date and Time of Assessment	Pre-Bronchodilator of Assessment	Unit	Result	Patient have any historical proof of Post- Bronchodilator reversibility within 12 months	Date of Assessment	Post-Bronchodilator of Assessment	Unit	Result
xx-xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxxx	Xxxx	Xxxx	Yes/No	Xxxx	Xxxx	Xxxx	Xxxx
xx-xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxxx	Xxxx	Xxxx	Yes/No	Xxxx	Xxxx	Xxxx	Xxxx
xx-xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxxx	Xxxx	Xxxx	Yes/No	Xxxx	Xxxx	Xxxx	Xxxx
xx-xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxxx	Xxxx	Xxxx	Yes/No	Xxxx	Xxxx	Xxxx	Xxxx
xx-xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxxx	Xxxx	Xxxx	Yes/No	Xxxx	Xxxx	Xxxx	Xxxx

Listing 16.2.1.1. Listing of Patient Asthma and Exacerbation History

Patient No	Significant history of Asthma with Eosinophilic	Date of Diagnosis	Disease Duration (Years: Months)	Patient Experience exacerbation in the previous 12 months
xx-xxx	Yes/No	DD-MMM-YYYY	YY:MM	Yes/No
xx-xxx	Yes/No	DD-MMM-YYYY	YY:MM	Yes/No
xx-xxx	Yes/No	DD-MMM-YYYY	YY:MM	Yes/No
xx-xxx	Yes/No	DD-MMM-YYYY	YY:MM	Yes/No
xx-xxx	Yes/No	DD-MMM-YYYY	YY:MM	Yes/No

Listing 16.2.1.2. Listing of Patient Assessment of Asthma and Exacerbation

Patient No	Visit	Patient Experience any new exacerbation or change in exacerbation since last visit
xx-xxx	xxxx	Yes/No
xx-xxx	xxxx	Yes/No
xx-xxx	xxxx	Yes/No
xx-xxx	xxxx	Yes/No
xx-xxx	xxxx	Yes/No

Listing 16.2.2.1. Listing of Patient Exacerbation (Part 1)

Patient No	Seq. No	Date of Onset	Outcome	Date of Resolution	Date of Death	Primary Cause of Exacerbation	Patient withdrawn due to this Exacerbation	Exacerbation Clinical Significant
xx-xxx	Xx	DD-MMM-YYYY	Xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Xxxx	Yes/No	Yes/No
xx-xxx	Xx	DD-MMM-YYYY	Xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Xxxx	Yes/No	Yes/No
xx-xxx	Xx	DD-MMM-YYYY	Xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Xxxx	Yes/No	Yes/No
xx-xxx	Xx	DD-MMM-YYYY	Xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Xxxx	Yes/No	Yes/No
xx-xxx	xx	DD-MMM-YYYY	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	xxxx	Yes/No	Yes/No

Listing 16.2.2.2. Listing of Patient Exacerbation (Part 2)

Patient No	Patient visit the emergency room due to this Exacerbation	Number of Telephone Call	Patient Hospitalizations due to this Exacerbation	ICU (Days)	General ward (Days)	Patient visit to clinic as out-patient	Visit (days)	No. of Emergency Room Visit (days)
xx-xxx	Yes/No	Xx	Yes/No	Xx	Xx	Yes/No	Xx	Yes/No
xx-xxx	Yes/No	Xx	Yes/No	Xx	Xx	Yes/No	Xx	Yes/No
xx-xxx	Yes/No	Xx	Yes/No	Xx	Xx	Yes/No	Xx	Yes/No
xx-xxx	Yes/No	Xx	Yes/No	Xx	Xx	Yes/No	Xx	Yes/No
xx-xxx	Yes/No	xx	Yes/No	xx	xx	Yes/No	xx	Yes/No

Listing 16.2.2.3. Listing of Patient Exacerbation (Part 3)

Patient No	Oral/Inhaled Corticosteroids taken for the Exacerbation	Patient intubated for this Exacerbation	Exacerbation medication other than oral/Inhaled corticosteroids taken
xx-xxx	Yes/No	Yes/No	Yes/No
xx-xxx	Yes/No	Yes/No	Yes/No
xx-xxx	Yes/No	Yes/No	Yes/No
xx-xxx	Yes/No	Yes/No	Yes/No
xx-xxx	Yes/No	Yes/No	Yes/No

Listing 16.2.3. Listing of Patient Blood Eosinophils count

Patient No	Visit	Blood Sample Collected	Date and Time of Blood Sample Collected	Parameter	Result	Unit	Reference Range	Assessment	If Abnormal CS
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	Xxxx	Xxxx	Xxxx	Xxxx	Normal/Abnormal	Xxxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	Xxxx	Xxxx	Xxxx	Xxxx	Normal/Abnormal	Xxxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	Xxxx	Xxxx	Xxxx	Xxxx	Normal/Abnormal	Xxxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	Xxxx	Xxxx	Xxxx	Xxxx	Normal/Abnormal	Xxxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	xxxx	Normal/Abnormal	xxxx

Listing 16.2.4. Listing of Overall Investigators Assessment

Patient No	Visit	Overall Investigators Assessment performed	If Yes
xx-xxx	xxxx	Yes/No	Well controlled/Partly controlled/Uncontrolled
xx-xxx	xxxx	Yes/No	Well controlled/Partly controlled/Uncontrolled
xx-xxx	xxxx	Yes/No	Well controlled/Partly controlled/Uncontrolled
xx-xxx	xxxx	Yes/No	Well controlled/Partly controlled/Uncontrolled
xx-xxx	xxxx	Yes/No	Well controlled/Partly controlled/Uncontrolled

Listing 16.3.1.1. Listing of Patient Adverse Event Assessment

Patient No	Visit	Patient Experience any adverse event since ICF obtained	Patient Experience any new adverse event or change in existing adverse event since ICF obtained
xx-xxx	xxxx	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No

Listing 16.3.1.2. Listing of Patient Adverse Events

Patient No	Patient Experience any Adverse Event	Seq. No.	Event Description	Start Date/ Stop Date	Ongoing	Intensity	Investigators causality rating against the Investigational Product	Action taken	Patient Withdrawn	Treatment taken	Outcome	SAE
xx-xxx	Yes/No	Xx	Xxxx	DD-MMM-YYYY/ DD-MMM-YYYY	Xxxx	Xxxx	Yes/No	Xxxx	Yes/No	Xxxx	Xxxx	Yes/No
xx-xxx	Yes/No	Xx	Xxxx	DD-MMM-YYYY/ DD-MMM-YYYY	Xxxx	Xxxx	Yes/No	Xxxx	Yes/No	Xxxx	Xxxx	Yes/No
xx-xxx	Yes/No	Xx	Xxxx	DD-MMM-YYYY/ DD-MMM-YYYY	Xxxx	Xxxx	Yes/No	Xxxx	Yes/No	Xxxx	Xxxx	Yes/No
xx-xxx	Yes/No	Xx	Xxxx	DD-MMM-YYYY/ DD-MMM-YYYY	Xxxx	Xxxx	Yes/No	Xxxx	Yes/No	Xxxx	Xxxx	Yes/No
xx-xxx	Yes/No	xx	Xxxx	DD-MMM-YYYY/ DD-MMM-YYYY	Xxxx	Xxxx	Yes/No	Xxxx	Yes/No	Xxxx	Xxxx	Yes/No

Listing 16.3.2.1. Listing of Patient Serious Adverse Events (Part 1)

Patient No	Age	Gender	SAE term	Date of AE met criteria for SAE	Date of Investigator became aware of Serious AE	Patient Hospitalized due to SAE	Date of Hospitalized	Date of Discharge	Seriousness Criteria	Date of Event Onset
xx-xxx	Xx	Xx	Xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	DD-MMM-YYYY	DD-MMM-YYYY	Xxxx	DD-MMM-YYYY
xx-xxx	Xx	Xx	Xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	DD-MMM-YYYY	DD-MMM-YYYY	Xxxx	DD-MMM-YYYY
xx-xxx	Xx	Xx	Xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	DD-MMM-YYYY	DD-MMM-YYYY	Xxxx	DD-MMM-YYYY
xx-xxx	Xx	Xx	Xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	DD-MMM-YYYY	DD-MMM-YYYY	Xxxx	DD-MMM-YYYY
xx-xxx	xx	xx	Xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	DD-MMM-YYYY	DD-MMM-YYYY	Xxxx	DD-MMM-YYYY

Listing 16.3.2.2. Listing of Patient Serious Adverse Events (Part 2)

Patient No	Causality assessment in relation to study Procedure	Causality assessment in relation to other medication	Outcome	Recovered with sequelae date	Probable Cause of Death	Autopsy Performed	Date of Autopsy
xx-xxx	Yes/No	Yes/No	Xxxx	DD-MMM-YYYY	xxxx	Yes/No	DD-MMM-YYYY
xx-xxx	Yes/No	Yes/No	Xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	DD-MMM-YYYY
xx-xxx	Yes/No	Yes/No	Xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	DD-MMM-YYYY
xx-xxx	Yes/No	Yes/No	Xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	DD-MMM-YYYY
xx-xxx	Yes/No	Yes/No	Xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	DD-MMM-YYYY

Listing 16.3.3.1. Listing of Patient Haematology Parameters

Patient No	Visit	Blood Sample Collected	Date and Time of Blood sample	Parameter	Result	Unit	Reference Range	Clinical Significance	If Abnormal CS/NCS
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	xxxx	Normal / Abnormal	xxxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	xxxx	Normal / Abnormal	xxxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	xxxx	Normal / Abnormal	xxxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	xxxx	Normal / Abnormal	xxxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	xxxx	Normal / Abnormal	xxxx

Listing 16.3.3.2. Listing of Patient Biochemistry Parameters

Patient No	Visit	Blood Sample Collected	Date and Time of Blood sample	Parameter	Result	Unit	Reference Range	Clinical Significance	If Abnormal CS/NCS
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	xxxx	Normal / Abnormal	Xxxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	xxxx	Normal / Abnormal	Xxxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	xxxx	Normal / Abnormal	Xxxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	xxxx	Normal / Abnormal	Xxxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	xxxx	Normal / Abnormal	xxxx

Listing 16.3.3.3. Listing of Patient Urinalysis Parameters

Patient No	Visit	Blood Sample Collected	Date and Time of Urine sample	Parameter	Result	Unit	Reference Range	Clinical Significance	If Abnormal CS/NCS
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	xxxx	Normal / Abnormal	Xxxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	xxxx	Normal / Abnormal	xxxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	xxxx	Normal / Abnormal	xxxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	xxxx	Normal / Abnormal	xxxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	xxxx	Normal / Abnormal	xxxx

Listing 16.3.3.4. Listing of Patient Serum Pregnancy Test

Patient No	Visit	Serum Pregnancy test performed	Date and Time of Assessment	Result
xx-xxx	xx-xxx	Yes/No	DD-MMM-YYYY/HH:MM	Positive/Negative
xx-xxx	xx-xxx	Yes/No	DD-MMM-YYYY/HH:MM	Positive/Negative
xx-xxx	xx-xxx	Yes/No	DD-MMM-YYYY/HH:MM	Positive/Negative
xx-xxx	xx-xxx	Yes/No	DD-MMM-YYYY/HH:MM	Positive/Negative
xx-xxx	xx-xxx	Yes/No	DD-MMM-YYYY/HH:MM	Positive/Negative

Listing 16.3.4. Listing of Patient Vital Signs

Patient No	Visit	Vital signs collected	If No, Specify reason	Parameter	Result	Unit	Assessment	If Abnormal CS/NCS
xx-xxx	xxxx	Yes/No	Xxxx	Xxxx	Xxxx	Xxxx	Normal/Abnormal	Xxxx
xx-xxx	xxxx	Yes/No	Xxxx	Xxxx	Xxxx	Xxxx	Normal/Abnormal	Xxxx
xx-xxx	xxxx	Yes/No	Xxxx	Xxxx	Xxxx	Xxxx	Normal/Abnormal	Xxxx
xx-xxx	xxxx	Yes/No	Xxxx	Xxxx	Xxxx	Xxxx	Normal/Abnormal	Xxxx
xx-xxx	xxxx	Yes/No	xxxx	xxxx	xxxx	xxxx	Normal/Abnormal	xxxx

Listing 16.3.5. Listing of Patient Electrocardiogram (ECG)

Patient No	Visit	ECG Performed	If No, Specify reason	Parameter	Result	Unit	Assessment	If Abnormal CS/NCS
xx-xxx	xxxx	Yes/No	Xxxx	Xxxx	Xxxx	Xxxx	Normal/Abnormal	Xxxx
xx-xxx	xxxx	Yes/No	Xxxx	Xxxx	Xxxx	Xxxx	Normal/Abnormal	Xxxx
xx-xxx	xxxx	Yes/No	Xxxx	Xxxx	Xxxx	Xxxx	Normal/Abnormal	Xxxx
xx-xxx	xxxx	Yes/No	Xxxx	Xxxx	Xxxx	Xxxx	Normal/Abnormal	Xxxx
xx-xxx	xxxx	Yes/No	xxxx	xxxx	xxxx	Xxxx	Normal/Abnormal	xxxx

Listing 16.3.6. Listing of Patient Targeted Physical Examination

Patient No	Visit	Physical Examination performed	If No, Specify reason	Date of Physical Examination	Seq. No	System	Assessment	If Abnormal CS/NCS
xx-xxx	xxxx	Yes/No	Xxxx	DD-MMM-YYYY	Xxxx	Xxxx	Normal/Abnormal	Xxxx
xx-xxx	xxxx	Yes/No	Xxxx	DD-MMM-YYYY	Xxxx	Xxxx	Normal/Abnormal	Xxxx
xx-xxx	xxxx	Yes/No	Xxxx	DD-MMM-YYYY	Xxxx	Xxxx	Normal/Abnormal	Xxxx
xx-xxx	xxxx	Yes/No	Xxxx	DD-MMM-YYYY	Xxxx	Xxxx	Normal/Abnormal	Xxxx
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY	xxxx	xxxx	Normal/Abnormal	xxxx

Listing 16.3.7. Listing of Patient Urinalysis Pregnancy test

Patient No	Visit	Urine Pregnancy Test performed	Date and Time of Assessment	Result
xx-xxx	Xxxx	Yes/No	DD-MMM-YYYY/HH:MM	Positive/Negative
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	Positive/Negative
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	Positive/Negative
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	Positive/Negative
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	Positive/Negative

Listing 16.3.8. Listing of Patient Pregnancy Form

Patient No	Date Pregnancy was confirmed	Date of Last Menstrual Period	Date of Estimated delivery	Outcome of Pregnancy	Live Birth Date	Pregnancy Status	Elective abortion Date	Spontaneous/ misses Date	Ectopic abortion Date
xx-xxx	DD-MMM-YYYY	DD-MMM-YYYY	DD-MMM-YYYY	Xxxx	DD-MMM-YYYY	Xxxx	DD-MMM-YYYY	DD-MMM-YYYY	DD-MMM-YYYY
xx-xxx	DD-MMM-YYYY	DD-MMM-YYYY	DD-MMM-YYYY	Xxxx	DD-MMM-YYYY	Xxxx	DD-MMM-YYYY	DD-MMM-YYYY	DD-MMM-YYYY
xx-xxx	DD-MMM-YYYY	DD-MMM-YYYY	DD-MMM-YYYY	Xxxx	DD-MMM-YYYY	Xxxx	DD-MMM-YYYY	DD-MMM-YYYY	DD-MMM-YYYY
xx-xxx	DD-MMM-YYYY	DD-MMM-YYYY	DD-MMM-YYYY	Xxxx	DD-MMM-YYYY	Xxxx	DD-MMM-YYYY	DD-MMM-YYYY	DD-MMM-YYYY
xx-xxx	DD-MMM-YYYY	DD-MMM-YYYY	DD-MMM-YYYY	Xxxx	DD-MMM-YYYY	Xxxx	DD-MMM-YYYY	DD-MMM-YYYY	DD-MMM-YYYY

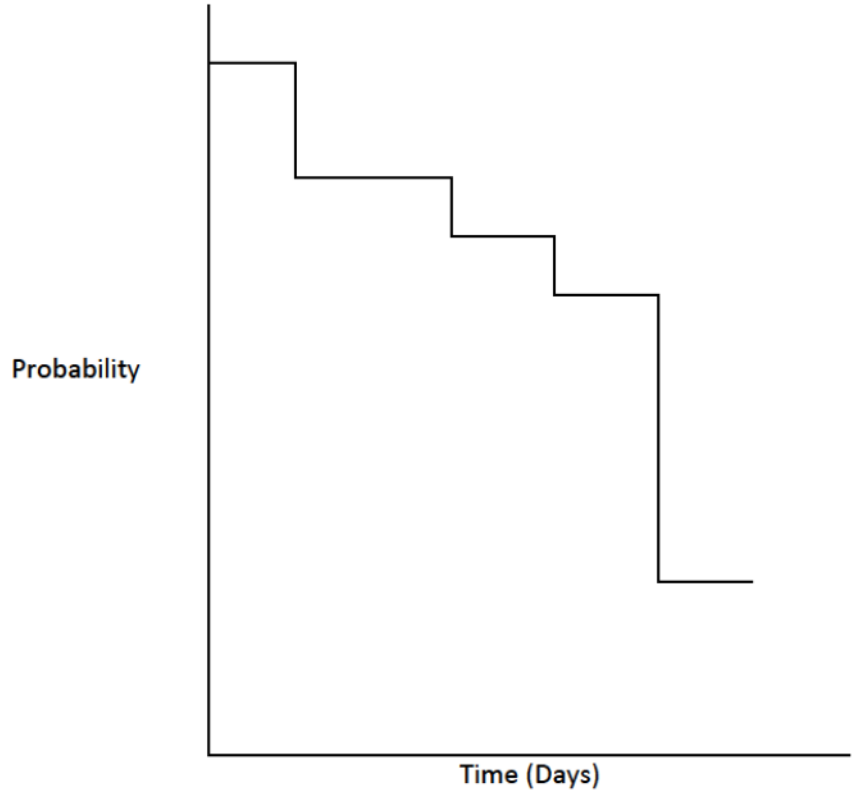
Listing 16.3.9.1. Listing of Patient Concomitant Medication

Patient No	Visit	Patient have any other concomitant medication during visit	Aby changes in concomitant or taking new medication since last visit
xx-xxx	xxxx	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No

Listing 16.3.9.2. Listing of Patient Prior and Concomitant Medication

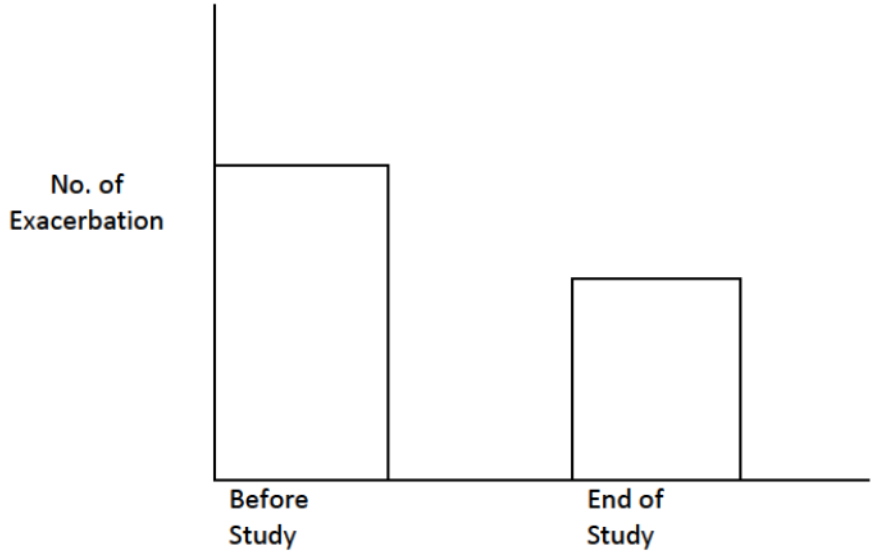
Patient No	Patient receive any Prior or concomitant medications	Seq. No.	Medication Name	Start Date/ Stop Date	Ongoing	Indication	Indication Description	Dosage Form	Dose	Unit	Route	Frequency
xx-xxx	Yes/No	Xx	Xxxx	DD-MMM-YYYY/ DD-MMM-YYYY	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
xx-xxx	Yes/No	Xx	Xxxx	DD-MMM-YYYY/ DD-MMM-YYYY	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
xx-xxx	Yes/No	Xx	Xxxx	DD-MMM-YYYY/ DD-MMM-YYYY	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
xx-xxx	Yes/No	Xx	Xxxx	DD-MMM-YYYY/ DD-MMM-YYYY	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
xx-xxx	Yes/No	xx	Xxxx	DD-MMM-YYYY/ DD-MMM-YYYY	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx

Figure 14.2.1. Figure of Time to first Asthma Exacerbation



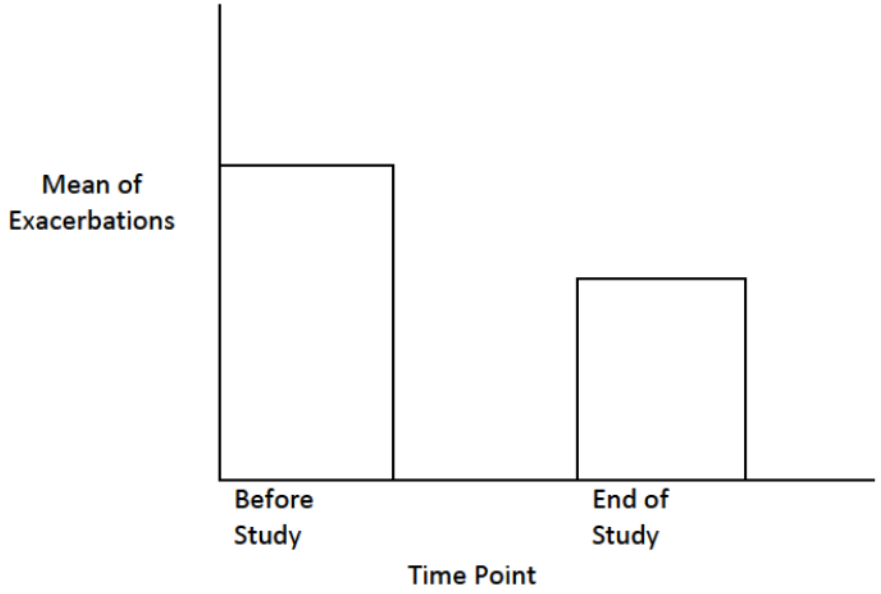
Programmer Note: Kaplan-Meier Curve format will change.; X-axis= Time (Days) and y- axis=Probability

Figure 14.2.2. Figure of Number of Exacerbation



Programmer Note: X-axis= Time point and y- axis= No. of Excerbations

Figure 14.2.3. Figure of Mean of Exacerbation



Programmer Note: X-axis= Time point and y- axis= Mean of Excerbations