GlaxoSmithKline	**Statistical Analysis Plan**
Detailed Title:	A Phase IIIB, non-randomized, open-label, multi-country, multi-centric cross-vaccination study to evaluate the safety of GSK Biologicals' Herpes Zoster subunit (HZ/su) vaccine when administered intramuscularly on a two-dose schedule to subjects who previously received placebo in ZOSTER-006 and ZOSTER-022 studies.
eTrack study number and Abbreviated Title	204486 (ZOSTER-056)
Scope:	All data pertaining to the above study.
Date of Statistical Analysis Plan	Final: 26-Feb-2019
Co-ordinating author:	PPD (Expert Biostatistician), PPD (Expert Statistician)
Reviewed by:	PPD (Clinical and Epidemiology Project Lead) PPD (Clinical Research and Development Lead) PPD (Clinical Research and Development Lead) PPD (Lead statistician) PPD (Lead statistical analyst) PPD (Scientific writer) PPD (Regulatory Affairs) PPD (SERM Scientist) PPD (Public disclosure representative)
Approved by:	PPD (Clinical and Epidemiology Project Lead) PPD (Clinical Research and Development Lead) PPD (Lead statistician) PPD (Lead statistical analyst) PPD (Scientific writer)

APP 9000058193 Statistical Analysis Plan Template (Effective date: 14 April 2017)

TABLE OF CONTENTS

PAGE

LIST OF TABLES

PAGE

LIST OF TEMPLATES

PAGE

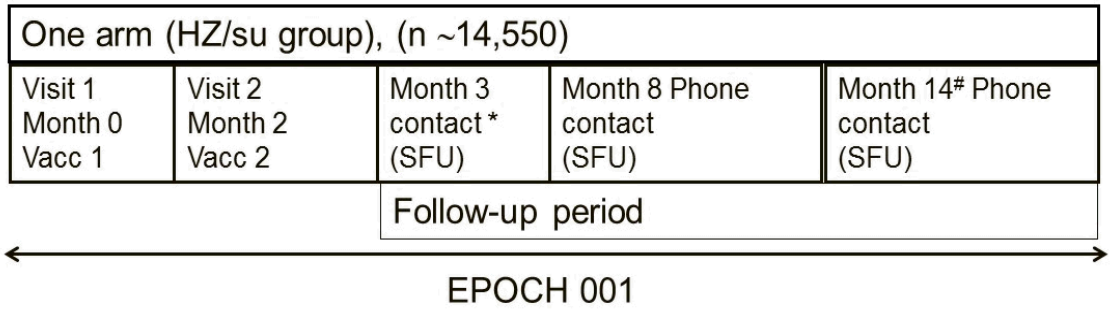
LIST OF ABBREVIATIONS

AE	Adverse event
CI	Confidence Interval
CRF	Case Report Form
CSR	Clinical Study Report
CTRS	Clinical Trial Registry Summary
HZ	Herpes Zoster
LL	Lower Limit of the confidence interval
MedDRA	Medical Dictionary for Regulatory Activities
pIMD	Potential Immune-Mediated Disease
SAE	Serious adverse event
SAP	Statistical Analysis Plan
SD	Standard Deviation
Su	Subunit
TFL	Tables Figures and Listings
TOC	Table of Content
TVC	Total Vaccinated Cohort
UL	Upper Limit of the confidence interval
YOA	Years of age

1. DOCUMENT HISTORY

Date	Description	Protocol Version
26-FEB-2019	Final version Please note: As the SAP has been started long back (19Dec2017) and reviewed also but was not finalized due to study team change and delay in the outcome of the Shingrix After Action Review (AAR) post Type C meeting with CBER which was required to be implemented in this SAP, the old template of the SAP has been used. This has been agreed by Lead Statistician.	Amendment 3 Final: 30-MAY-2017

2. STUDY DESIGN



*Could be a visit or a phone contact.
i.e. 12 months post dose 2
n: number of subjects
Vacc: vaccination
SFU: Safety follow-up

- Experimental design: Phase IIIB open-label, non-randomised, multi-centric, multi-country cross-vaccination study, with a single group.
- Duration of the study: Approximately 14 months. Each subject will be followed for safety approximately 12 months after the second vaccine dose
  - Epoch 001: Primary starting at Visit 1 (Month 0) and ending at final phone contact (Month 14, i.e. 12 months post dose 2)
- Study groups:

Table 1 Study groups and epochs foreseen in the study

Study Groups	Number of subjects	Age (Min – Max)	Epochs
			Epoch 001
HZ/su Group	max 14,550	> 50 YOA	x

Table 2 Study groups and treatment foreseen in the study

Treatment name	Vaccine/Product name	Study Groups
HZ/su	VZV gE	HZ/su Group
	$AS01_B$	

- Control: uncontrolled.
- Vaccination schedule: 0, 2 months.
- Treatment allocation: non-randomised.
- Blinding: open-label.

Table 3 Blinding of study epochs

Study Epochs	Blinding
Epoch 001	open

- Sampling schedule: no sampling.
- Type of study: self-contained.
- Data collection: electronic Case Report Form (eCRF).

3. OBJECTIVES

3.1. Primary objective

- To evaluate the safety, in terms of unsolicited Adverse Events (AEs), Serious Adverse Events (SAEs) and pIMD in all subjects, following administration of each dose of the HZ/su vaccine.

3.2. Secondary objective

- To evaluate the incidence of suspected HZ episodes (self-reported or medically diagnosed) during the entire study period.

4. ENDPOINTS

4.1. Primary endpoints

- Occurrence of unsolicited AEs.
  - Occurrence, intensity and relationship to vaccination of unsolicited AEs during 30 days (Days 0-29) after each vaccination, according to the Medical Dictionary for Regulatory Activities (MedDRA) classification.
- Occurrence of SAEs.
  - Occurrence and relationship to vaccination of all SAEs from Month 0 until study end (Month 14, i.e. 12 months post dose 2).
- Occurrence of AEs of special interest.
  - Occurrence of any pIMDs from Month 0 until study end (Month 14, i.e. 12 months post dose 2).

4.2. Secondary endpoints

- Occurrence of suspected HZ cases.
  - Occurrence of suspected HZ cases from Month 0 to study end.

5. ANALYSIS SETS

5.1. Definition

5.1.1. Total Vaccinated Cohort

This study will collect only safety data. The statistical analysis of the safety endpoints will be based on the Total Vaccinated Cohort (TVC); hence no according to protocol (ATP) cohorts are defined for the purpose of statistical analysis.

The Total vaccinated cohort will include all subjects with at least one HZ/su vaccine administration documented for whom data are available:

- A safety analysis based on the Total vaccinated cohort will include all vaccinated subjects.

5.2. Criteria for eliminating data from Analysis Sets

5.2.1. Elimination from Total Vaccinated Cohort (TVC)

Code 900 (invalid informed consent or fraud data) and code 1030 (Study vaccine not administered at all) will be used for identifying subjects eliminated from Total Vaccinated Cohort.

5.2.1.1. Excluded subjects

A subject will be excluded from the TVC analysis under the following conditions:

Code	Condition under which the code is used
900	Invalid informed consent and fraud data *(Subjects receiving a code 900 should not receive any other elimination codes)*
1030	Study vaccine not administered at all *(Subjects receiving a code 1030 should not receive any other elimination codes)*

6. STATISTICAL ANALYSES

Note that standard data derivation rules and statistical methods are described in Section 11 and will not be repeated below.

6.1. Demography

6.1.1. Analysis of demographics/baseline characteristics planned in the protocol

Demographic characteristics (age at first study vaccination in years, gender), withdrawal status will be summarised using descriptive statistics:

- Frequency tables will be generated for categorical variable such as centre.
- Mean, median, standard deviation will be provided for continuous data such as age, in Years, at vaccination in the current study.

6.1.2. Additional considerations

- Demographic characteristics will also be tabulated by age sub-group at vaccination in the ZOSTER-056 (50-59, 60-69, 70-79 and ≥80 YOA).
- List of subjects withdrawn from vaccination with reason for withdrawal will be presented.
- The following table will be performed for web-disclosure:
  - Percentage of Enrolled subjects by country will be tabulated,
  - Percentage of Enrolled subjects in the following age categories ≤64, 65-84, ≥85 will be tabulated.

6.2. Exposure

6.2.1. Analysis of exposure planned in the protocol

Not applicable.

6.2.2. Additional considerations

The number of doses administered will be tabulated overall and by age sub-group at vaccination in the ZOSTER-56 (50-59, 60-69, 70-79 and ≥80 YOA).

6.3. Analysis of safety

6.3.1. Analysis of safety planned in the protocol

The analysis for safety will be based on the TVC.

All analysis will be performed overall and by age sub-group at vaccination in the ZOSTER-056 (50-59, 60-69, 70-79 and ≥80 YOA).

When appropriate, tabulations will be presented overall and by time of occurrence related to last vaccination (e.g. using windows such as Days 0-29 and more than 30 days post-vaccination.

The results for the analysis of safety will be tabulated as follows:

- The proportion of subjects with at least one report of an unsolicited AE during the 30-day (Days 0–29) follow-up period after each vaccination classified according to the MedDRA System Organ Class and Preferred Terms will be tabulated, with exact 95% CI.
- The same tabulation will be performed for grade 3 unsolicited AEs (including SAEs) and for unsolicited AEs with a relationship to vaccination. The proportion of AEs resulting in a medically attended visit will also be tabulated.
- Total number/percentages of doses (per dose and overall) followed by AEs during the 30 days (Days 0-29) follow-up period after each vaccination classified according to the MedDRA System Organ Class and Preferred Terms will be tabulated.
- SAEs will be described in detail in listing for the entire study period.
- Withdrawal due to AE(s) and SAE will be described in detail in listing for the entire study period.
- Number of subjects with pIMDs will be tabulated according to the MedDRA System Organ Class and Preferred Terms for the period during first vaccination up to 30 days post second vaccine dose, after 30 days post second vaccine dose to study end and from first vaccination to study end.

6.3.2. Additional considerations

Following additional analyses will be performed:-

1. Number and percentage of subjects with at least one report of a grade 3 non-serious unsolicited AE during the 30-day (Days 0–29) follow-up period after each vaccination classified according to the MedDRA System Organ Class and Preferred Terms will be tabulated, with exact 95% CI.

2. Number and percentage of subjects reporting at least one SAE/ pIMD classified according to the MedDRA System Organ Class and Preferred Terms will be tabulated, with exact 95% CI with onset day of SAE during the time interval during study start to 30 days post 2nd vaccine dose, after 30 days post 2nd vaccine dose till study end and from study start till study end.
3. Number and percentage of subjects with fatal SAEs, classified by MedDRA Primary System Organ Class and Preferred Term will be presented with exact 95% CI in two ways:-
   - With onset of fatal SAE during the period starting from first vaccination to 30 days post last vaccination dose, after 30 days post last vaccination dose to study end and from first vaccination to study end
   - Who died during the period starting from first vaccination to 30 days post last vaccination dose, after 30 days post last vaccination dose to study end and entire study period.
4. Number and percentage of subjects reporting the occurrence of unsolicited adverse events classified by MedDRA Primary System Organ Class and Preferred Term within the 30-day (Days 0-29) post-vaccination period will also be presented, overall and by age sub-group with exact 95% CI on Total Vaccinated Cohort considering only subjects with a confirmed HZ episode during Zoster-006/022. The same tabulation will be performed for grade 3 unsolicited AEs and for unsolicited AEs with a relationship to vaccination.
5. Number and percentage of subjects reporting the occurrence of serious adverse event and pIMD, classified by MedDRA Primary System Organ Class and Preferred Term from first vaccination until study end will also be presented with exact 95% CI on Total Vaccinated Cohort considering only subjects with a confirmed HZ episode during Zoster-006/022.
6. List of subjects withdrawn from vaccination with reason for withdrawal will be presented from first vaccination until study end.
7. Listing of potential Immune-Mediated Diseases (pIMDs) reported as identified by predefined list of preferred terms and/or by investigator assessment from first vaccination until study end will be presented. Listing of the subjects who died will also be generated for the entire study period.
8. The unsolicited adverse events experienced within 30 days (Day 0-29) by subjects post receipt of only adjuvant will be presented in the listing.
9. Number and percentage of subjects with Past/Current pre-existing medical conditions by SOC and PT will be presented.

6.4. Analysis of suspected HZ incidence

6.4.1. Analysis of suspected HZ incidence planned in Protocol

1. The number of suspected HZ cases will be tabulated on TVC.

6.4.2. Additional consideration

1. The analysis will also be performed on subjects having confirmed HZ episode from Zoster-006/022.
2. Listing for all the suspected HZ episodes will be presented.

7. ANALYSIS INTERPRETATION

All analyses are descriptive.

8. CONDUCT OF ANALYSES

8.1. Sequence of analyses

Description	Analysis ID	Disclosure Purpose (CTRS=public posting, SR=study report, internal)	Dry run review needed (Y/N)	*Study Headline Summary (SHS)*requiring expedited communication to upper management (Yes/No)	Reference for TFL
End of study	E1_01	Study report	Y	Yes	Section 13 of the SAP and TOC dated 26-FEB-19

8.2. Statistical considerations for interim analyses

All analyses will be conducted on final data and therefore no statistical adjustment for interim analyses is required.

9. CHANGES FROM PLANNED ANALYSES

Following are the changes from the planned analysis:-

1. As per protocol, it was mentioned that 'all analyses may be performed by age group at vaccination in the ZOSTER-006/022 (50-59, 60-69 and ≥70 YOA). However, team felt it is more reasonable to present the analysis based on age (by Year of birth) at first vaccination in current study. As the ≥ 80 YOA population in current study has increased in number because the cohort has aged, so the sub-group considered for the analysis has also been modified by dividing ≥70 YOA sub-group, further, into two (70-79 and ≥80 YOA) looking at the frequency of the subjects in these age groups (70-79 YOA = 3349 and ≥80 YOA = 2109). The age sub-group to be considered now will be (50-59, 60-69, 70-79 and ≥80 YOA)' based on the age (by Year of birth) at first vaccination in current study.
2. Table on presentation of fatal SAE has been added under additional consideration for safety analysis based on CBER feedback following Shingrix After Action Review (AAR) post Type C meeting with CBER.

3. Safety analysis by previous confirmed HZ episode (HZ episodes from Zoster-006/022 study) has been added.
4. Suspected HZ episodes in this study will also be presented on confirmed previous HZ episodes from Zoster-006/022 study.

10. LIST OF FINAL REPORT TABLES, LISTINGS AND FIGURES

The TFL TOC provides the list of tables/listings and figures needed for the study report. It also identifies the tables eligible for the analysis and their role (synopsis, in-text, post-text, SHS, web disclosure). Note that all TFL aimed to be included as post-text are noted as post-text even if these are tabulation of individual data such as listing of SAE. The post-text material contains all source material for the study report and accordingly a post-text table may be redundant with an in-text table.

The following group name will be used in the TFLs:

Group order in tables	Group label in tables	Group definition for footnote	Pooled Groups label in tables	Pooled definition for footnote
1	HZ/su	Herpes Zoster subunit vaccine	NA	NA

NA=Not applicable

The following sub-group names will be used in the TFLs:

Sub-group order in tables	Sub-group label in tables	Sub-group definition for footnote
1	50-59YOA	Subjects aged 50-59 years*
2	60-69YOA	Subjects aged 60-69 years*
3	70-79YOA	Subjects aged 70-79 years
4	≥80YOA	Subjects aged 80 years and over *

*age at first vaccination in Zoster-056 study

11. ANNEX 1 STANDARD DATA DERIVATION RULES AND STATISTICAL METHODS

11.1. Statistical Method References

The exact two-sided 95% CIs for a proportion within a group will be the Clopper-Pearson exact CI [Clopper CJ, Pearson ES. The use of confidence or fiducial limits illustrated in the case of binomial. *Biometrika*. 1934;26:404-413].

11.2. Standard data derivation

11.2.1. Date derivation

- SAS date derived from a character date: In case day is missing, 15 is used. In case day and month are missing, 30 June is used.
- Onset day for an event (AE, medication, vaccination, …): The onset day is the number of days between the last study vaccination and the onset/start date of the event. This is 0 for an event starting on the same day as a vaccination. See SAS date derived in case the start date of the event is incomplete.
- Duration: Duration of an event is expressed in days. It is the number of days between the start and the stop dates + 1. Therefore duration is 1 day for an event starting and ending on the same day.

11.2.2. Dose number

- The study dose number is defined in reference to the number of study visits at which vaccination occurred. More specifically dose 1 refers to all vaccines administered at the first vaccination visit while dose 2 corresponds to all vaccinations administered at the second vaccination visit even if this is the first time a product is administered to the subject.
- Associated dose: the associated dose for an event (AE, medication,…) is the most recent study dose given before an event. In case the event takes place on the day a study dose is given, the associated dose will be that of the study dose, even if the event actually took place before vaccination. For instance, if an adverse event begins on the day of the study vaccination but prior to administration of the vaccine, it will be assigned to this dose. In case a study dose is not administered and an event occurs after the subsequent study dose (e.g. 2nd study dose), the associated dose of the event will be study dose associated to the subsequent study dose (e.g. dose 2).
- The number of doses for a product is the number of times the product was administered to a subject.
- The incidence per dose is the number of visits with vaccine administered at which an event was reported among all visits with vaccine administered.

11.2.3. Demography

- For computation of age, following rule will be applied:-
  - Age will be calculated as the number of years between the date of birth and the date of first vaccination.
  - To ensure that the collection of date of birth will not jeopardise the privacy of Personally Identifiable Information (PII), only a partial date of birth (YYYY) will be collected. For calculation of age, as the date and month is not collected, the date will be replaced by the June 30th of the year. Accordingly, the age estimated using the middle of the year may differ by one year with the exact age.

11.2.4. Safety

- For analysis of unsolicited adverse events, such as serious and non-serious adverse events by primary MedDRA term, and for the analysis of concomitant medications; all vaccinated subjects will be considered. Subjects who did not report any adverse event or any concomitant medication will be considered as subjects without an adverse event or concomitant medication respectively.
- HZ cases: Suspected HZ cases:
  - A suspected HZ episode is defined as a new rash characteristic of HZ (e.g., unilateral, dermatomal and accompanied by pain broadly defined to include allodynia, pruritus or other sensations).
  - Suspected HZ episode has to be confirmed by the investigator or the delegate judgement.

11.3. Number of Decimals

The following decimal description from the decision rules will be used for the demography and safety analysis.

Display Table	Parameters	Number of decimal digits
Demographic characteristics	Mean, median age	1
Demographic characteristics	SD (age)	1
All summaries	% of count, including LL & UL of CI	1

12. ANNEX 2: SUMMARY ON ELIMINATION CODES

Refer to section 5.

13. ANNEX 3: STUDY SPECIFIC MOCK TFL

The following mock TFLs will be used.

The title and footnote are for illustration purpose and will be adapted to the study specificity as indicated in the TFL TOC.

Note that there may be few changes between the study specific SAP mock TFL and the final TFLs. These editorial/minor changes will not lead to a SAP amendment.

13.1. Template of Tables and Figures

Template 1 Study population (Total Vaccinated Cohort)

Number of subjects	**HZ/su**
Planned, N	
Vaccinated, N (Total Vaccinated Cohort)	
Completed, n (%)	
Demographics	**HZ/su**
N (Total Vaccinated Cohort)	
Females:Males	
Mean Age, years (SD)	
Median Age, years (minimum, maximum)	
<Most frequent category of race>, n (%)	
<Second most frequent category of race>, n (%)	
<Third most frequent category of race>, n (%)	

HZ/su = Herpes Zoster subunit vaccine
Completed = number of subjects who completed phone contact Month14

Template 2 Number of subjects vaccinated, completed and withdrawn with reason for withdrawal (Total Vaccinated Cohort)

	HZ/su	
	N	%
Number of subjects vaccinated		
Number of subjects completed		
Number of subjects withdrawn		
Reasons for withdrawal :		
Serious Adverse Event		
Non-Serious Adverse Event		
Protocol violation		
Consent withdrawal (not due to an adverse event)		
Migrated/moved from study area		
Lost to follow-up (subjects with incomplete vaccination course)		
Lost to follow-up (subjects with complete vaccination course)		
Sponsor study termination		
Suspected HZ episode		
Others		

HZ/su = Herpes Zoster subunit vaccine
Vaccinated = number of subjects who were vaccinated in the study
Completed = number of subjects who completed last phone contact
Withdrawn = number of subjects who did not complete all visits up to last phone contact
n = number of subjects in a given category
% = (n / Number of subjects vaccinated) x 100

Template 3 Summary of demographic characteristics (Total Vaccinated Cohort)

		HZ/su N =	
Characteristics	**Parameters or Categories**	**Value or n**	**%**
Age (years) at vaccination dose : 1	Mean		
	SD		
	Median		
	Minimum		
	Maximum		
Gender	Female		
	Male		
Geographic Ancestry	African Heritage / African American		
	American Indian or Alaskan Native		
	Asian - Central/South Asian Heritage		
	Asian - East Asian Heritage		
	Asian - Japanese Heritage		
	Asian - South East Asian Heritage		
	Native Hawaiian or Other Pacific Islander		
	White - Arabic / North African Heritage		
	White - Caucasian / European Heritage		
	Other		

HZ/su = Herpes Zoster subunit vaccine
N = total number of subjects
n/% = number / percentage of subjects in a given category
Value = value of the considered parameter
SD = standard deviation

Template 4 Number of subjects by center (Total Vaccinated Cohort)

	HZ/su	
Center	**N**	**%**
<each center>		
All		

HZ/su = Herpes Zoster subunit vaccine
n = number of subjects for a given center or for all centers
All = sum of all subjects in total
% = n/All x 100
Center = GSK Biologicals assigned center number

Template 5 Number of subjects enrolled into the study as well as the number excluded from TVC analysis with reasons for exclusion

	Total			HZ/su		
Title	**n**	**s**	**%**	**n**	**s**	**%**
Total enrolled cohort						
Invalid informed consent and fraud data (code 900)						
Total effective cohort						
Study vaccine dose not administrated but subject number allocated (code 1030)						
Total vaccinated cohort						

HZ/su = Herpes Zoster subunit vaccine
Note: Subjects may have more than one elimination code assigned
n = number of subjects with the elimination code assigned excluding subjects who have been assigned a lower elimination code number
s = number of subjects with the elimination code assigned
% = percentage of subjects (n) relative to the Total vaccinated cohort

Template 6 Number of subjects at each visit and list of withdrawn subjects (Total Vaccinated Cohort)

Group	VISIT	N (%)	Withdrawn Subject numbers	Reason for withdrawal
HZ/su	VISIT 1			
	VISIT 2			
	VISIT 3 \ PHC M3			
	PHONE CONT M8			
	PHONE CONT M14			

HZ/su = Herpes Zoster subunit vaccine
N = Number of subjects who are still in the study up to the visit
Withdrawn = Subject who did not return after the visit
PHC = Phone contact

Template 7 List of subjects withdrawn from vaccination with reason for withdrawal (Total Vaccinated Cohort)

Group	Age	Subject number	Dose	Decision	Reason	Comment
HZ/su						

HZ/su = Herpes Zoster subunit vaccine

Template 8 Deviations from specifications for intervals between study visits (Total Vaccinated Cohort)

		VISIT 1 – VISIT 2	VISIT 2 - VISIT 3\PHC M3	VISIT 2 – PHONE CONT M8	VISIT 2 – PHONE CONT M14
Group		**Protocol**	**Protocol**	**Protocol**	**Protocol**
		from 49 to 83 days	from 30 to 48 days	from 180 to 240 days	from 335 to 395 days
HZ/su	N				
	n				
	%				
	range				

HZ/su = Herpes Zoster subunit vaccine
N = total number of subjects with available results
n/% = number / percentage of subjects with results outside of the interval
range = minimum-maximum for intervals
PHC = Phone contact

Template 9 Number of enrolled subjects by country

		HZ/su N =
Characteristics	**Categories**	**n**
Country	<each country>	

HZ/su = Herpes Zoster subunit vaccine
N = Number of enrolled subjects
n= number of enrolled subjects for a given country or for all countries

Template 10 Number of enrolled subjects by age category

		HZ/su N =
Characteristics	**Categories**	**N**
Age category	Adults (18-64 years)	
	From 65-84 years	
	85 years and over	
	Missing	

HZ/su = Herpes Zoster subunit vaccine
N = Number of enrolled subjects
n= number of enrolled subjects included for a given age category or for all age categories
Missing = Subjects enrolled in the study but did not receive the first vaccine dose at Month 0

Template 11 Minimum and maximum activity dates (Total Vaccinated Cohort)

Group	Activity number	Activity Description	Minimum date	Maximum date
HZ/su	110	VISIT 1		
	120	VISIT 2		
	210	VISIT 3 \ PHC M3		
	220	PHONE CONT M8		
	230	PHONE CONT M14		

HZ/su = Herpes Zoster subunit vaccine
PHC = Phone contact

Template 12 Study population – by age sub-group (Total Vaccinated Cohort)

Number of subjects	**[each age sub-group]**
Planned, N	-
Randomised, N (Total Vaccinated Cohort)	
Completed, n (%)	
Demographics	**[each age sub-group]**
N (Total Vaccinated Cohort)	
Females:Males	
Mean Age, years (SD)	
Median Age, years (minimum, maximum)	
<Most frequent category of race>, n (%)	
<Second most frequent category of race>, n (%)	
<Third most frequent category of race>, n (%)	

Age sub-group is based on subject's age at first vaccination
50-59YOA = Subjects aged 50-59 years
60-69YOA = Subjects aged 60-69 years
70-79YOA = Subjects aged 70-79 years
≥80YOA = Subjects aged 80 years and over
HZ/su = Herpes Zoster subunit vaccine
Completed = number of subjects who completed last phone contact

Template 13 Number of subjects vaccinated, completed and withdrawn with reason for withdrawal – by age sub-group (Total Vaccinated Cohort)

	[each age sub-group]		**Total**	
	n	**%**	**n**	**%**
Number of subjects vaccinated				
Number of subjects completed				
Number of subjects withdrawn				
Reasons for withdrawal :				
Serious Adverse Event				
Non-Serious Adverse Event				
Protocol violation				
Consent withdrawal (not due to an adverse event)				
Migrated/moved from study area				
Lost to follow-up (subjects with incomplete vaccination course)				
Lost to follow-up (subjects with complete vaccination course)				
Sponsor study termination				
Suspected HZ episode				
Others				

*Age sub-group is based on subject's age at first vaccination
50-59YOA = Subjects aged 50-59 years
60-69YOA = Subjects aged 60-69 years
70-79YOA = Subjects aged 70-79 years
≥80YOA = Subjects aged 80 years and over
HZ/su = Herpes Zoster subunit vaccine
Vaccinated = number of subjects who were vaccinated in the study
Completed = number of subjects who completed last phone contact
Withdrawn = number of subjects who did not complete all visits up to last phone contact
n = number of subjects in a given category
% = (n / Number of subjects vaccinated) x 100

Template 14 Summary of demographic characteristics - by age sub-group (Total Vaccinated Cohort)

		[each age sub-group] N =		Total N =	
Characteristics	**Parameters or Categories**	**Value or n**	**%**	**Value or n**	**%**
Age (years) at vaccination dose : 1	Mean				
	SD				
	Median				
	Minimum				
	Maximum				
Gender	Female				
	Male				
Geographic Ancestry	African Heritage / African American				
	American Indian or Alaskan Native				
	Asian - Central/South Asian Heritage				
	Asian - East Asian Heritage				
	Asian - Japanese Heritage				
	Asian - South East Asian Heritage				
	Native Hawaiian or Other Pacific Islander				
	White - Arabic / North African Heritage				
	White - Caucasian / European Heritage				
	Other				

*Age sub-group is based on subject's age at first vaccination
50-59YOA = Subjects aged 50-59 years
60-69YOA = Subjects aged 60-69 years
70-79YOA = Subjects aged 70-79 years
≥80YOA = Subjects aged 80 years and over
HZ/su = Herpes Zoster subunit vaccine
N = total number of subjects
n/% = number / percentage of subjects in a given category
Value = value of the considered parameter
SD = standard deviation
Note that the exact age is unknown since only the year of date of birth is recorded. Accordingly, the age estimated using the middle of the year may differ by one year with the exact age

Template 15 Number of subjects by center - by age sub-group (Total Vaccinated Cohort)

	[each subgroup]	Total	
Center	**N**	**N**	**%**
<each center>			
All			

*Age sub-group is based on subject's age at first vaccination
50-59YOA = Subjects aged 50-59 years
60-69YOA = Subjects aged 60-69 years
70-79YOA = Subjects aged 70-79 years
≥80YOA = Subjects aged 80 years and over
HZ/su = Herpes Zoster subunit vaccine
n = number of subjects for a given center or for all centers
All = sum of all subjects in total
% = n/All x 100
Center = GSK Biologicals assigned center number

Template 16 Number of subjects at each visit and list of withdrawn subjects by - age sub-group (Total Vaccinated Cohort)

[each age sub-group]	Group	VISIT	N (%)	Withdrawn Subject numbers	Reason for withdrawal
	HZ/su	VISIT 1			
		VISIT 2			
		VISIT 3 \ PHC M3			
		PHONE CONT M8			
		PHONE CONT M14			

*Age sub-group is based on subject's age at first vaccination
50-59YOA = Subjects aged 50-59 years
60-69YOA = Subjects aged 60-69 years
70-79YOA = Subjects aged 70-79 years
≥80YOA = Subjects aged 80 years and over
HZ/su = Herpes Zoster subunit vaccine
N = Number of subjects who are still in the study up to the visit
Withdrawn = Subject who did not return after the visit
PHC = Phone contact

Template 17 Number and percentage of subjects who received study vaccine doses (Total Vaccinated Cohort)

	HZ/su N =	
Total number of doses received	**N**	**%**
1		
2		
Any		

HZ/su = Herpes Zoster subunit vaccine
N = number of subjects in the group or in total included in the considered cohort
n/% = number/percentage of subjects receiving the specified total number of doses
Any = number and percentage of subjects receiving at least one dose

Template 18 Number and percentage of subjects reporting the occurrence of <grade 3> <non-serious><unsolicited adverse events> classified by MedDRA Primary System Organ Class and Preferred Term <with causal relationship to vaccination> <with medically attended visit> within the 30-day (Days 0-29) post-vaccination period (<Total Vaccinated Cohort, Total Vaccinated Cohort - confirmed HZ episode during Zoster-006/022>)

		HZ/su N =			
				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**
At least one symptom					
Each SOC	At least one PT related to the corresponding SOC				
	Each PT				

HZ/su = Herpes Zoster subunit vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/%= number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Template 19 Number and percentage of doses with <grade 3> unsolicited adverse events classified by MedDRA Primary System Organ Class and Preferred Term <with causal relationship to vaccination> <with medically attended visit> within the 30-day (Days 0-29) post-vaccination period (Total Vaccinated Cohort)

		HZ/su N =			
				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**
At least one symptom					
Each SOC	At least one PT related to the corresponding SOC				
	Each PT				

HZ/su = Herpes Zoster subunit vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of administered doses
n/% = number/percentage of doses with the symptom
95% CI= exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Template 20 Global summary of <grade 3> <non-serious><unsolicited adverse events> <with causal relationship to vaccination> <with medically attended visit> reported within the 30-day (Days 0-29) post-vaccination period (Total Vaccinated Cohort)

	HZ/su
Number of subjects with at least one unsolicited symptom reported	
Number of doses followed by at least one unsolicited symptom	
Number of unsolicited symptoms classified by MedDRA Preferred Term*	
Number of unsolicited symptoms reported**	

HZ/su = Herpes Zoster subunit vaccine
* Symptoms reported by a subject after a given dose and classified by the same Preferred Term are counted once
** Symptoms reported by a subject after a given dose and classified by the same Preferred Term and the same start date of the event, are counted once

Template 21 Number and percentage of subjects reporting the occurrence of <potential Immune-Mediated Diseases> <serious adverse events> classified by MedDRA Primary System Organ Class and Preferred Term <with causal relationship to vaccination> reported <from first vaccination up to 30 days post last vaccination dose> <after 30 days post last vaccination dose up to study end><from first vaccination until study end > (<Total Vaccinated Cohort, Total Vaccinated Cohort - confirmed HZ episode during Zoster-006/022>)

		HZ/su N =				
					95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n***	**n**	**%**	**LL**	**UL**
At least one symptom						
Each SOC	At least one PT related to the corresponding SOC					
	Each PT					

HZ/su = Herpes Zoster subunit vaccine group
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/%= number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit
n* = number of events reported (only required for CTRS posting)

Template 22 Number and percentage of subjects <with><experiencing> fatal SAEs classified by MedDRA Primary System Organ Class and Preferred Term <who died> <with onset of fatal SAE> <during the period starting> <from first vaccination up to 30 days post last vaccination dose> <after 30 days post last vaccination dose up to study end><from first vaccination to study end ><during the entire study period> (<Total Vaccinated Cohort, Total Vaccinated Cohort - confirmed HZ episode during Zoster-006/022>)

		HZ/su N =			
				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**
At least one symptom					
Each SOC	At least one PT related to the corresponding SOC				
	Each PT				

HZ/su = Herpes Zoster subunit vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/%= number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Template 23 Number and percentage of subjects with <past><current> pre-existing medical conditions by SOC and PT (Total Vaccinated Cohort)

		HZ/su N =	
SOC (CODE)	**PT (CODE)**	**n**	**%**
At least one condition			
Blood and lymphatic system disorders (10005329)	Any condition		
	Anaemia (10002034)		
Cardiac disorders (10007541)	Any condition		
	Angina pectoris (10002383)		
	Arrhythmia (10003119)		
	Atrial fibrillation (10003658)		
	Cardiac failure (10007554)		
	Coronary artery disease (10011078)		
	Hypertensive heart disease (10020823)		
	Myocardial ischaemia (10028600)		
Each SOC (CODE)	Any condition		
	Each PT (CODE)		

HZ/su = Herpes Zoster subunit vaccine
N = total number of subjects
n/% = number / percentage of subjects reporting the condition at least once

Template 24 Number and percentage of subjects who received study vaccine doses - by age sub-group (Total Vaccinated Cohort)

	[each age sub-group]*		Total	
Total number of doses received	**N**	**%**	**N**	**%**
1				
2				
Any				

*Age sub-group is based on subject's age at first dose of vaccination in Zoster-056
50-59YOA = Subjects aged 50-59 years
60-69YOA = Subjects aged 60-69 years
70-79YOA = Subjects aged 70-79 years
≥80YOA = Subjects aged 80 years and over
HZ/su = Herpes Zoster subunit vaccine
N = number of subjects in each sub-group or in total included in the considered cohort
n/% = number/percentage of subjects receiving the specified total number of doses
Any = number and percentage of subjects receiving at least one dose

Template 25 Number and percentage of subjects reporting the occurrence of <grade 3> <non-serious> <unsolicited adverse events> classified by MedDRA Primary System Organ Class and Preferred Term <with causal relationship to vaccination> <with medically attended visit> within the 30-day (Days 0-29) post-vaccination period - by age sub-group (<Total Vaccinated Cohort, Total Vaccinated Cohort - confirmed HZ episode during Zoster-006/022>)

		[each age sub-group]			
		HZ/su N =			
				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**
At least one symptom					
Each SOC	At least one PT related to the corresponding SOC				
	Each PT				

*Age sub-group is based on subject's age at first vaccination
50-59YOA = Subjects aged 50-59 years
60-69YOA = Subjects aged 60-69 years
70-79YOA = Subjects aged 70-79 years
≥80YOA = Subjects aged 80 years and over
HZ/su = Herpes Zoster subunit vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/%= number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Template 26 Number and percentage of doses with <grade 3> unsolicited adverse events classified by MedDRA Primary System Organ Class and Preferred Term <with causal relationship to vaccination> <with medically attended visit> within the 30-day (Days 0-29) post-vaccination period - by age sub-group (Total Vaccinated Cohort)

		[each age sub-group]			
		HZ/su N =			
				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**
At least one symptom					
Each SOC	At least one PT related to the corresponding SOC				
	Each PT				

*Age sub-group is based on subject's age at first vaccination
50-59YOA = Subjects aged 50-59 years
60-69YOA = Subjects aged 60-69 years
70-79YOA = Subjects aged 70-79 years
≥80YOA = Subjects aged 80 years and over
HZ/su = Herpes Zoster subunit vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of administered doses
n/% = number/percentage of doses with the symptom
95% CI= exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Template 27 Global summary of <grade 3> <non-serious><unsolicited adverse events> <with causal relationship to vaccination> <with medically attended visit> reported <within the 30-day (Days 0-29) post-vaccination period> - by age sub-group (Total Vaccinated Cohort)

	[each age sub-group]*	All
Number of subjects with at least one unsolicited symptom reported		
Number of doses followed by at least one unsolicited symptom		
Number of unsolicited symptoms classified by MedDRA Preferred Term*		
Number of unsolicited symptoms reported**		

*Age sub-group is based on subject's age at first vaccination
50-59YOA = Subjects aged 50-59 years
60-69YOA = Subjects aged 60-69 years
70-79YOA = Subjects aged 70-79 years
≥80YOA = Subjects aged 80 years and over
HZ/su = Herpes Zoster subunit vaccine
* Symptoms reported by a subject after a given dose and classified by the same Preferred Term are counted once
** Symptoms reported by a subject after a given dose and classified by the same Preferred Term and the same start date of the event, are counted once

Template 28 Number and percentage of subjects reporting the occurrence of <potential Immune-Mediated Diseases> <serious adverse events> classified by MedDRA Primary System Organ Class <with causal relationship to vaccination> reported <from first vaccination up to 30 days post last vaccination dose><after 30 days post last vaccination dose up to study end> <from first vaccination until study end > - by age sub-group (<Total Vaccinated Cohort, Total Vaccinated Cohort - confirmed HZ episode during Zoster-006/022>)

		[each age sub-group]* N=			
				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**N**	**%**	**LL**	**UL**
At least one symptom					
Each SOC	At least one PT related to the corresponding SOC				
	Each PT				

*Age sub-group is based on subject's age at first vaccination
50-59YOA = Subjects aged 50-59 years
60-69YOA = Subjects aged 60-69 years
70-79YOA = Subjects aged 70-79 years
≥80YOA = Subjects aged 80 years and over
HZ/su = Herpes Zoster subunit vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/%= number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Template 29 Number and percentage of subjects <with><experiencing> fatal SAEs classified by MedDRA Primary System Organ Class and Preferred Term <who died><with onset of fatal SAE> <during the period starting> <from first vaccination up to 30 days post last vaccination dose> <after 30 days post last vaccination dose up to study end><from first vaccination until the study end><during the entire study period> by age sub-group (<Total Vaccinated Cohort, Total Vaccinated Cohort - confirmed HZ episode during Zoster-006/022>)

		[each age sub-group]* N=			
				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**
At least one symptom					
Each SOC	At least one PT related to the corresponding SOC				
	Each PT				

*Age sub-group is based on subject's age at first vaccination
50-59YOA = Subjects aged 50-59 years
60-69YOA = Subjects aged 60-69 years
70-79YOA = Subjects aged 70-79 years
≥80YOA = Subjects aged 80 years and over
HZ/su = Herpes Zoster subunit vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/%= number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit
Please note this table will be generated only based on final feedback and agreement with CBER

Template 30 Number and percentage of subjects with <past><current> pre-existing medical conditions by SOC and PT – by age sub-group (Total Vaccinated Cohort)

		[each age sub-group]* N=		Total N=	
SOC (CODE)	**PT (CODE)**	**N**	**%**	**N**	**%**
At least one condition					
Blood and lymphatic system disorders (10005329)	Any condition				
	Anaemia (10002034)				
Cardiac disorders (10007541)	Any condition				
	Angina pectoris (10002383)				
	Arrhythmia (10003119)				
	Atrial fibrillation (10003658)				
	Cardiac failure (10007554)				
	Coronary artery disease (10011078)				
	Hypertensive heart disease (10020823)				
	Myocardial ischaemia (10028600)				
Each SOC (CODE)	Any condition				
	Each PT (CODE)				

*Age sub-group is based on subject's age at first vaccination
50-59YOA = Subjects aged 50-59 years
60-69YOA = Subjects aged 60-69 years
70-79YOA = Subjects aged 70-79 years
≥80YOA = Subjects aged 80 years and over
HZ/su = Herpes Zoster subunit vaccine group
N = total number of subjects
n/% = number / percentage of subjects reporting the condition at least once

Template 31 Listing of all SAEs from first vaccination until study end - by age sub-group (Total Vaccinated Cohort)

Goup	Sub-group *	Sub.No.	Age at onset (Year)	Sex	Verbatim	Preferred term	System Organ Class	MED type	Dose	Day of onset	Duration	Intensity	Causality	Outcome
[HZ/su	[each age sub-group]													

*Age sub-group is based on subject's age at first vaccination
50-59YOA = Subjects aged 50-59 years
60-69YOA = Subjects aged 60-69 years
70-79YOA = Subjects aged 70-79 years
≥80YOA = Subjects aged 80 years and over
HZ/su = Herpes Zoster subunit vaccine group
MED = Medically attended visit
HO = Hospitalization,
MD = medical personnel
Please note this listing will also include the SAE related to only adjuvants which subject has received

Template 32 Listing of potential immune-mediated diseases (pIMDs) reported as identified by predefined list of preferred terms and/or by investigator assessment from first vaccination until study end - by age sub-group (Total Vaccinated Cohort)

Group	Sub-group	Patient ID	Country	Age at onset (Y)	Gender	Race	Primary System Organ Class	Preferred term
HZ/su	[each age sub-group]							

Group	Sub-group*	Dose	Day of onset	Relation	Serious pIMD based on Investigator?	SAE (Y/N)	Outcome	pIMD Source
HZ/su	[each age sub-group]							

*Age sub-group is based on subject's age at first vaccination
50-59YOA = Subjects aged 50-59 years
60-69YOA = Subjects aged 60-69 years
70-79YOA = Subjects aged 70-79 years
≥80YOA = Subjects aged 80 years and over
HZ/su = Herpes Zoster subunit vaccine

Template 33 Listing of dropouts due to AEs and SAEs from first vaccination until study end - by age sub-group (Total Vaccinated Cohort)

Group	Sub-group*	Study-Subject No.	Country	Gender	Race	AE Description	SAE	Causality	Outcome	Type of discontinuation
HZ/su	[each age sub-group]									

*Age sub-group is based on subject's age at first vaccination
50-59YOA = Subjects aged 50-59 years
60-69YOA = Subjects aged 60-69 years
70-79YOA = Subjects aged 70-79 years
≥80YOA = Subjects aged 80 years and over
HZ/su = Herpes Zoster subunit vaccine
Type of discontinuation = discontinuation from study or from treatment

Template 34 Listing of subjects who died during the entire study period – by age group (Total Enrolled Cohort)

Group	Sub. No.	Sex	Country	Race	Age at Onset (Year)	Verbatim	Preferred term	Primary System Organ Class	MED type	Dose prior to onset of fatal SAE	Days between onset of fatal SAE and previous dose	Dose prior to death	Days between death and previous dose	SAE Duration	SAE Causality
HZ/su	X1								HO						
	X2								HO						
	X3								HO						

HZ/su = Herpes Zoster subunit vaccine
No Group= Enrolled not vaccinated
MED = Medical Advice type (HO: hospitalisation, ER: emergency room visit, MD: medical practice visit)

Template 35 Unsolicited adverse events classified by MedDRA Primary System Organ Class and Preferred Term within the 30-day (Days 0-29) post-vaccination period including number of events - SAE excluded (Total Vaccinated Cohort)

		HZ/su N =		
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n***	**N**	**%**
At least one symptom				
<each SOC>	<each PT term>			

HZ/su = Herpes Zoster subunit vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one administered dose
n* = number of events reported
n/% = number/percentage of subjects reporting the symptom at least once

Template 36 Number (%) of subjects with serious adverse events from first vaccination until study end including number of events reported (Total Vaccinated Cohort)

			HZ/su N =		
Type of Event	**Primary System Organ Class**	**Preferred Term (CODE)**	**n***	**N**	**%**
SAE	At least one symptom				
	<each SOC>	<each PT term>			
Related SAE	At least one symptom				
	<each SOC>	<each PT term>			
Fatal SAE	At least one symptom				
	<each SOC>	<each PT term>			
Related fatal SAE	At least one symptom				
	<each SOC>	<each PT term>			

HZ/su = Herpes Zoster subunit vaccine group
N = number of subjects with the administered dose
n* = number of events reported
n/% = number/percentage of subjects reporting the event at least once

Template 37 Number and percentage of suspected HZ episodes (Total Vaccinated Cohort)

	HZ/su N =	
Categories	**n**	**%**
HZ episode		
Suspected HZ episode only		
Confirmed HZ episode		

HZ/su = Herpes Zoster subunit vaccine
N = total number of subjects
n/% = number / percentage of subjects in a given category
HZ episode: number of subjects with at least one suspected episode
Suspected HZ episode only: Suspected HZ episode not confirmed by the Investigator/Delegate
Confirmed HZ episode: Suspected HZ episode confirmed by the Investigator/Delegate

Template 38 Number and percentage of suspected HZ episodes considering only subjects who had a confirmed HZ episode during Zoster-006/022 (Total Vaccinated Cohort)

	HZ/su N =	
Categories	**n**	**%**
HZ episode		
Suspected HZ episode only		
Confirmed HZ episode		

HZ/su = Herpes Zoster subunit vaccine
N = total number of placebo subjects from Zoster-006/022 (TVC) with a confirmed HZ episode during Zoster-006/022 vaccinated in this study
n/% = number / percentage of subjects in a given category
HZ episode: number of subjects with at least one suspected episode
Suspected HZ episode only: Suspected HZ episode not confirmed by the Investigator/Delegate
Confirmed HZ episode: Suspected HZ episode confirmed by the Investigator/Delegate

Template 39 Number and percentage of suspected HZ episodes - by age sub-group (Total Vaccinated Cohort)

	[each age sub-group]* N=		Total N =	
Categories	**n**	**%**	**N**	**%**
HZ episode				
Suspected HZ episode only				
Confirmed HZ episode				

*Age sub-group is based on subject's age at first vaccination
50-59YOA = Subjects aged 50-59 years
60-69YOA = Subjects aged 60-69 years
70-79YOA = Subjects aged 70-79 years
≥80YOA = Subjects aged 80years and over
HZ/su = Herpes Zoster subunit vaccine
N = total number of subjects
n/% = number / percentage of subjects in a given category
HZ episode: number of subjects with at least one suspected episode
Suspected HZ episode only: Suspected HZ episode not confirmed by the Investigator/Delegate
Confirmed HZ episode: Suspected HZ episode confirmed by the Investigator/Delegate

Template 40 Number and percentage of suspected HZ episodes considering only subjects who had a confirmed HZ episode during Zoster-006/022 - by age sub-group (Total Vaccinated Cohort)

	[each age sub-group]* N=		Total N=	
Categories	**n**	**%**	**N**	**%**
HZ episode				
Suspected HZ episode only				
Confirmed HZ episode				

*Age sub-group is based on subject's age at first vaccination
50-59YOA = Subjects aged 50-59 years
60-69YOA = Subjects aged 60-69 years
70-79YOA = Subjects aged 70-79 years
≥80YOA = Subjects aged 80years and over
HZ/su = Herpes Zoster subunit vaccine

N = total number of placebo subjects from Zoster-006/022 (TVC) with a confirmed HZ episode during Zoster-006/022 and vaccinated in this study
n/% = number / percentage of subjects in a given category
HZ episode: number of subjects with at least one suspected episode
Suspected HZ episode only: Suspected HZ episode not confirmed by the Investigator/Delegate
Confirmed HZ episode: Suspected HZ episode confirmed by the Investigator/Delegate

Template 41 Listing of subjects with a suspected HZ episode - by age sub-group (Total Vaccinated Cohort)

Group	Sub-group*	Patient ID	Country	Center	Age at first vaccination in Zoster-056	HZ episode number	Rash start date	Start date of pain/itching/abnormal sensation at rash site
HZ/su	[each age sub-group]							

Group	Sub-group	Confirmed by INV/DEL	Date of first vaccination in Zoster-056	Date of second vaccination in Zoster-056	Previous dose	Day of onset	HZ_P30D2	Rash end date	End date of pain/itching/abnormal sensation at rash site	Confirmed HZ episode during Zoster-006/022
HZ/su	[each age sub-group]									

*Age sub-group is based on subject's age at first vaccination
50-59YOA = Subjects aged 50-59 years
60-69YOA = Subjects aged 60-69 years
70-79YOA = Subjects aged 70-79 years
≥80YOA = Subjects aged 80 years and over
HZ/su = Herpes Zoster subunit vaccine
INV/DEL = Investigator/Delegate
HZ_P30D2 = flag for suspected HZ episode occurring after 30 days post-Dose 2

Template 42 Listing of unsolicited adverse event within 30 days (Day 0-29) post receipt of only adjuvant - by age sub-group (Total Vaccinated Cohort)

Goup	Sub-group *	Sub. No.	Age at onset (Year)	Sex	Verbatim	Preferred term	System Organ Class	MED type	Dose	Day of onset	Duration	Intensity	Causality	Outcome
[HZ/su	[each age sub-group]													

*Age sub-group is based on subject's age at first vaccination
50-59YOA = Subjects aged 50-59 years
60-69YOA = Subjects aged 60-69 years
70-79YOA = Subjects aged 70-79 years
≥80YOA = Subjects aged 80 years and over
HZ/su = Herpes Zoster subunit vaccine group
MED = Medically attended visit
HO = Hospitalization,
MD = medical personnel