Statistical Analysis Plan

Study ID: 213749

Official Title of Study: A Phase 1/2 randomized, observer-blinded, multi-country study to evaluate safety and immunogenicity of investigational adjuvanted human papillomavirus vaccine in females (16 to 26 years of age)

NCT number: NCT05496231

Date of Document: 08 FEB 2024

STATISTICAL ANALYSIS PLAN

213749 (HPV9-AS04-001)

A Phase 1/2 randomized, observer-blinded, multi-country study to evaluate safety and immunogenicity of investigational adjuvanted human papillomavirus vaccine in females (16 to 26 years of age)

AUTHOR: PPD

VERSION NUMBER AND DATE: V3.0, 02FEB2024

STATISTICAL ANALYSIS PLAN SIGNATURE PAGE

Statistical Analysis Plan V3.0 (Dated 02FEB2024) for Protocol 213749 (HPV9-AS04-001)

	Name	Signature	Date (DDMmmYYYY)
Author:	PPD	Refe PPD	ebruary 6, 2024
Position:	PPD		
Company:	IQVIA		

Upon review of this document, the undersigned approves this version of the Statistical Analysis Plan, authorizing that the content is acceptable for the reporting of this study.

	Name	Signature	Date (DDMmmYYYY)
Approved By:	PPD	PPD	uary 8, 2024
Position:	Senior Biostatistician		
Company:	IQVIA		
Approved By:	PPD	PPD	bruary 5, 2024
Position:	Project Statistician		
Company:	GSK		

MODIFICATION HISTORY

Unique Identifier for this Version	Date of the Document Version	Author	Significant Changes from Previous Authorized Version
1.0	25APR2022	PPD	Not Applicable – First Version
2.0	21JUL2023	PPD	Update the visit window for visit 5 following protocol amendment 3. SRT meetings to occur quarterly after all participants complete one-month post dose 2. SRC meetings on an ad-hoc basis. Changes following SRT and iSRC output review including percentages for solicited and unsolicited summaries to be out of the number of participants with a dose in each period update to the age categories and include summary for grade 2. Remove summaries for BMI, height and weight in the demography outputs. Update summary of the exposure output. Updates to the estimands section. Include extra detail on the Deming's regression model. CCI [redacted]
3.0	02FEB2024	PPD	Include analysis of the duration of solicited events. Include the summary of the number of immunogenicity records to be imputed. Include immune concordance analysis.

TABLE OF CONTENTS

1. LIST OF ABBREVIATIONS

AE	Adverse Event
AESI	Adverse Event of Special Interest
ALT	Alanine Aminotransferase
ANOVA	Analysis of variance
AST	Aspartate Aminotransferase
ATC	Anatomical Therapeutic Chemical
BMI	Body Mass Index
BUN	Blood Urea Nitrogen
CD	Cluster of Differentiation
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
CCI [redacted]	
COVID-19	Coronavirus disease 2019
CSR	Clinical Study Report
DMC	Data Monitoring Committee
eCRF	Electronic Case Report Form
ECL	Electrochemiluminescence assay
ENR	Enrolled Set
ES	Exposed Set
GCP	Good Clinical Practice

GMC	Geometric Mean Concentration
GMT	Geometric Mean Titer
HPV	Human Papillomavirus
ICE	Intercurrent Events
IgG	Immunoglobulin G
IM	Intramuscularly
iSRC	internal Safety Review Committee
LLOQ	Lower Limit Of Quantification
MedDRA	Medical Dictionary for Regulatory Activities
PBNA	pseudovirion-based neutralization assay
PD	Protocol Deviation
PDMP	Protocol Deviations Management Plan
pIMD	Potential immune-mediated disease
PPS	Per Protocol Set
PT	Preferred Term
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SOC	System Organ Class
TEAE	Treatment Emergent Adverse Event
TFL	Table, Figures and Listing

ULOQ	Upper Limit Of Quantification
WBC	White Blood Cells

2. INTRODUCTION

This Statistical Analysis Plan (SAP) describes the rules and conventions to be used in the presentation and analysis of immunogenicity and safety data for Protocol 213749 (HPV9-AS04-001). It describes the data to be summarized and analyzed, including specifics of the statistical analyses to be performed.

This SAP is based on protocol amendment 3, dated 8th June 2023.

3. STUDY OBJECTIVES AND ESTIMANDS

3.1. Primary Objective

The primary objectives are:

- to evaluate the safety and reactogenicity of GSK's investigational adjuvanted human papillomavirus (HPV) vaccine formulations
- to evaluate the immune response to GSK's investigational adjuvated HPV vaccine formulations.

3.2. Secondary Objectives

The secondary objectives are:

- To evaluate the safety and reactogenicity of GSK's investigational adjuvanted HPV vaccine formulations
- To evaluate the immune response for all HPV vaccine types for all vaccines

3.3. Tertiary Objectives

CCI

[redacted]

3.4. Estimands

The primary and secondary estimands to support regulatory decisions are described in the following table:

Table A: Objectives and Estimands

Estimand	Attributes					
	Treatment	Population	Variable (or endpoint)	Intercurrent events (ICEs)		Population level summary
				Description	Handling strategy	
Primary	Randomized HPV dose (High, Medium or Low) or *Gardasil 9*	Female participants between 16 and 26 years old	Each grade 3 solicited administration site event within 7 days after each vaccine dose	1. eDiary not completed on each day	1. Missing data won't be imputed. All data collected will be included in the summaries (treatment policy).	Percentage of participants with event with exact 95% Confidence Interval (CI)
Primary	Randomized HPV dose (High, Medium or Low) or *Gardasil 9*	Female participants between 16 and 26 years old	Each grade 3 solicited systemic event within 7 days after each vaccine dose	1. eDiary not completed on each day	1. Missing data won't be imputed. All data collected will be included in the summaries (treatment policy).	Percentage of participants with event with exact 95% CI
Primary	Randomized HPV dose (High, Medium or Low) or *Gardasil 9*	Female participants between 16 and 26 years old	Each grade 3 unsolicited adverse event within 28 days after each vaccine dose	1. Permanently discontinuation from study treatment due to any reasons	1. Missing data won't be imputed. All data collected will be included in the summaries (treatment policy).	Percentage of participants with event with exact 95% CI
Primary	Randomized HPV dose (High, Medium or Low) or *Gardasil 9*	Female participants between 16 and 26 years old	Serious Adverse Events from first vaccination up to study end	1. Permanently discontinuation from study treatment due to any reasons	1. Missing data won't be imputed. All data collected will be included in the summaries (treatment policy).	Percentage of participants with event with exact 95% CI

Estimand	Attributes					
	Treatment	Population	Variable (or endpoint)	Intercurrent events (ICEs)		Population level summary
				Description	Handling strategy	
Primary	Randomized HPV dose (High, Medium or Low) or *Gardasil 9*	Female participants between 18 and 26 years old	Clinically relevant abnormalities in each biochemical and hematological parameter at Day 7 post-dose 1	1. Permanently discontinuation from study treatment due to any reasons	1. Missing data won't be imputed. All data collected will be included in the summaries (treatment policy).	Percentage of participants in Step 1 with event with exact 95% CI
Primary	Randomized HPV dose (High, Medium or Low) or *Gardasil 9*	Female participants between 16 and 26 years old	Anti-HPV immunoglobulin G (IgG) antibody 1 month after third dose (Month 7)	1. Permanently discontinuation from study treatment due to any reasons 2. Study vaccine not administered per protocol 3. Prohibited medication or intercurrent medical condition 4. Vaccine or blood sample taken out of window 5. No post-vaccine immunogenicity result available	1. Missing data won't be imputed. 2. Participant excluded from the immunogenicity analysis. 3. Participant excluded from the immunogenicity analysis. 4. Participant excluded from the immunogenicity analysis. 5. Participant excluded from the immunogenicity analysis.	Antibody GMC with exact 95% CI .
Secondary	Randomized HPV dose (High,	Female participants between 16 and 26	Each solicited administration site	1. eDiary not completed on each	1. Missing data won't be imputed. All data	Percentage of participants with event with exact 95% CI

Estimand	Attributes					
	Treatment	Population	Variable (or endpoint)	Intercurrent events (ICEs)		Population level summary
				Description	Handling strategy	
	Medium or Low) or *Gardasil 9*	years old	event within 7 days after each vaccine dose	day	collected will be included in the summaries (treatment policy).	
Secondary	Randomized HPV dose (High, Medium or Low) or *Gardasil 9*	Female participants between 16 and 26 years old	Each solicited systemic event within 7 days after each vaccine dose	1. eDiary not completed on each day	1. Missing data won't be imputed. All data collected will be included in the summaries (treatment policy).	Percentage of participants with event with exact 95% CI
Secondary	Randomized HPV dose (High, Medium or Low) or *Gardasil 9*	Female participants between 16 and 26 years old	Unsolicited adverse event within 28 days after each vaccine dose	1. Permanently discontinuation from study treatment due to any reasons	1. Missing data won't be imputed. All data collected will be included in the summaries (treatment policy).	Percentage of participants with event with exact 95% CI
Secondary	Randomized HPV dose (High, Medium or Low) or *Gardasil 9*	Female participants between 16 and 26 years old	Potential immune-mediated disease (pIMDs) from first vaccination up to study end	1. Permanently discontinuation from study treatment due to any reasons	1. Missing data won't be imputed. All data collected will be included in the summaries (treatment policy).	Percentage of participants with event with exact 95% CI
Secondary	Randomized HPV dose (High, Medium or Low) or *Gardasil 9*	Female participants between 16 and 26 years old	Experienced pregnancy and their outcomes from Day 1 of pregnancy up to study end	1. Permanently discontinuation from study treatment due to any reasons	1. Missing data won't be imputed. All data collected will be included in the summaries (treatment policy).	Percentage of participants who experienced pregnancy and their outcomes
Secondary	Randomized HPV dose (High, Medium or Low) or *Gardasil 9*	Female participants between 16 and 26 years old	Anti-HPV IgG antibody concentration at Day 1, Month 2, Month 3,	1. Permanently discontinuation from study treatment due to	1. Missing data won't be imputed. 2. Participant excluded from the immunogenicity	Antibody GMC and 2-sided 95% CI at each timepoint. GMC ratio at Month 3 and Month 7

Estimand	Attributes					
	Treatment	Population	Variable (or endpoint)	Intercurrent events (ICEs)		Population level summary
				Description	Handling strategy	
			Month 6, Month 7 and Month 12	any reasons 2. Study vaccine not administered per protocol 3. Prohibited medication or intercurrent medical condition 4. Vaccine or blood sample taken out of window 5. No post-vaccine immunogenicity result available	analysis. 3. Participant excluded from the immunogenicity analysis. 4. Participant excluded from the immunogenicity analysis. 5. Participant excluded from the immunogenicity analysis.	
Secondary	Randomized HPV dose (High, Medium or Low) or *Gardasil 9*	Female participants between 16 and 26 years old	Anti-HPV IgG antibody seroconversion at Month 2, Month 3, Month 6, Month 7 and Month 12	1. Permanently discontinuation from study treatment due to any reasons 2. Study vaccine not administered per protocol 3. Prohibited medication or intercurrent medical condition 4. Vaccine or blood	1. Missing data won't be imputed. 2. Participant excluded from the immunogenicity analysis. 3. Participant excluded from the immunogenicity analysis. 4. Participant excluded from the immunogenicity analysis. 5. Participant excluded from the immunogenicity	Seroconversion and seropositivity rates for each antigen with exact 95% CI. Difference in seroconversion rate at Month 3 and Month 7 with exact 95% CI.

Estimand	Attributes					
	Treatment	Population	Variable (or endpoint)	Intercurrent events (ICEs)		Population level summary
				Description	Handling strategy	
				sample taken out of window 5. No post-vaccine immunogenicity result available	analysis.	
Secondary	Randomized HPV dose (High, Medium or Low) or *Gardasil 9*	Female participants between 16 and 26 years old	Anti-HPV neutralizing antibody titers at Day 1, Month 3 and Month 7 (at least 150 participants in each group) and Month 2 in a subset of participants	1. Permanently discontinuation from study treatment due to any reasons 2. Study vaccine not administered per protocol 3. Prohibited medication or intercurrent medical condition 4. Vaccine or blood sample taken out of window 5. No post-vaccine immunogenicity result available	1. Missing data won't be imputed. 2. Participant excluded from the immunogenicity analysis. 3. Participant excluded from the immunogenicity analysis. 4. Participant excluded from the immunogenicity analysis. 5. Participant excluded from the immunogenicity analysis.	Antibody Geometric Mean Titer (GMT) with exact 95% CI at each timepoint and GMT ratio at Month 3 and Month 7.
Secondary	Randomized HPV dose (High, Medium or Low) or *Gardasil 9*	Female participants between 16 and 26 years old	Anti-HPV neutralizing antibody seroconversion at Month 3 and Month 7	1. Permanently discontinuation from study treatment due to	1. Missing data won't be imputed. 2. Participant excluded from the immunogenicity	Seroconversion and seropositivity rates for each antigen with exact 95% CI. Difference in seroconversion

Estimand	Attributes					
	Treatment	Population	Variable (or endpoint)	Intercurrent events (ICEs)		Population level summary
				Description	Handling strategy	
				any reasons 2. Study vaccine not administered per protocol 3. Prohibited medication or intercurrent medical condition 4. Vaccine or blood sample taken out of window 5. No post-vaccine immunogenicity result available	analysis. 3. Participant excluded from the immunogenicity analysis. 4. Participant excluded from the immunogenicity analysis. 5. Participant excluded from the immunogenicity analysis.	rate at Month 3 and Month 7 with exact 95% CI.
Secondary	Randomized HPV dose (High, Medium or Low) or *Gardasil 9*	Female participants between 16 and 26 years old	anti-HPV IgG antibody concentration and anti-HPV neutralizing antibody titers at Day 1, Month 2, Month 3 and Month 7	1. Permanently discontinuation from study treatment due to any reasons 2. Study vaccine not administered per protocol 3. Prohibited medication or intercurrent medical condition 4. Vaccine or blood	1. Missing data won't be imputed. 2. Participant excluded from the immunogenicity analysis. 3. Participant excluded from the immunogenicity analysis. 4. Participant excluded from the immunogenicity analysis. 5. Participant excluded from the immunogenicity	Correlation between anti-HPV IgG antibody concentration and anti-HPV neutralizing antibody titers for each timepoint. Functional relationship between each pair of assay methods. A qualitative summary between ECL and PBNA for each timepoint.

Estimand	Attributes					
	Treatment	Population	Variable (or endpoint)	Intercurrent events (ICEs)		Population level summary
				Description	Handling strategy	
				sample taken out of window 5. No post-vaccine immunogenicity result available	analysis.	

4. STUDY DESIGN

4.1. General Description

This is a phase 1/2 randomized, observer-blind, multi-country study with 4 groups of females 16-26 years of age at the time of vaccine administration. Participants will be randomized in a 1:1:1:1 ratio to receive a series of 3 investigational adjuvanted intervention doses (3 different potencies [a high, medium, low potency]) or a series of the *Gardasil 9* vaccine.

The investigational adjuvanted intervention or *Gardasil 9* vaccine will be administered intramuscularly (IM) at Day 1 (Month 0), Month 2, and Month 6. Blood sampling will be performed on Day 1, Month 2, Month 3, Month 6, Month 7, and Month 12 to assess for immunological response.

This study is organized into 2 steps. Forty-eight participants (12 per group) of the study Step 1 (sentinel participants) will receive the initial assigned dose prior to participants in Step 2 of the study, and sentinel participants will have an additional blood sampling visit at Day 7 to assess for biochemical and hematological parameters. The internal Safety Review Committee (iSRC) will review the accumulated safety data up to 7 days post-dose 1 for the sentinel participants to determine whether any of the pre-defined holding rules have been met. If no safety concerns were observed and no holding rules were met, the sentinel participants will continue with study visits and dosing as scheduled, and the Step 2 participants will be initiated.

CCI [redacted]

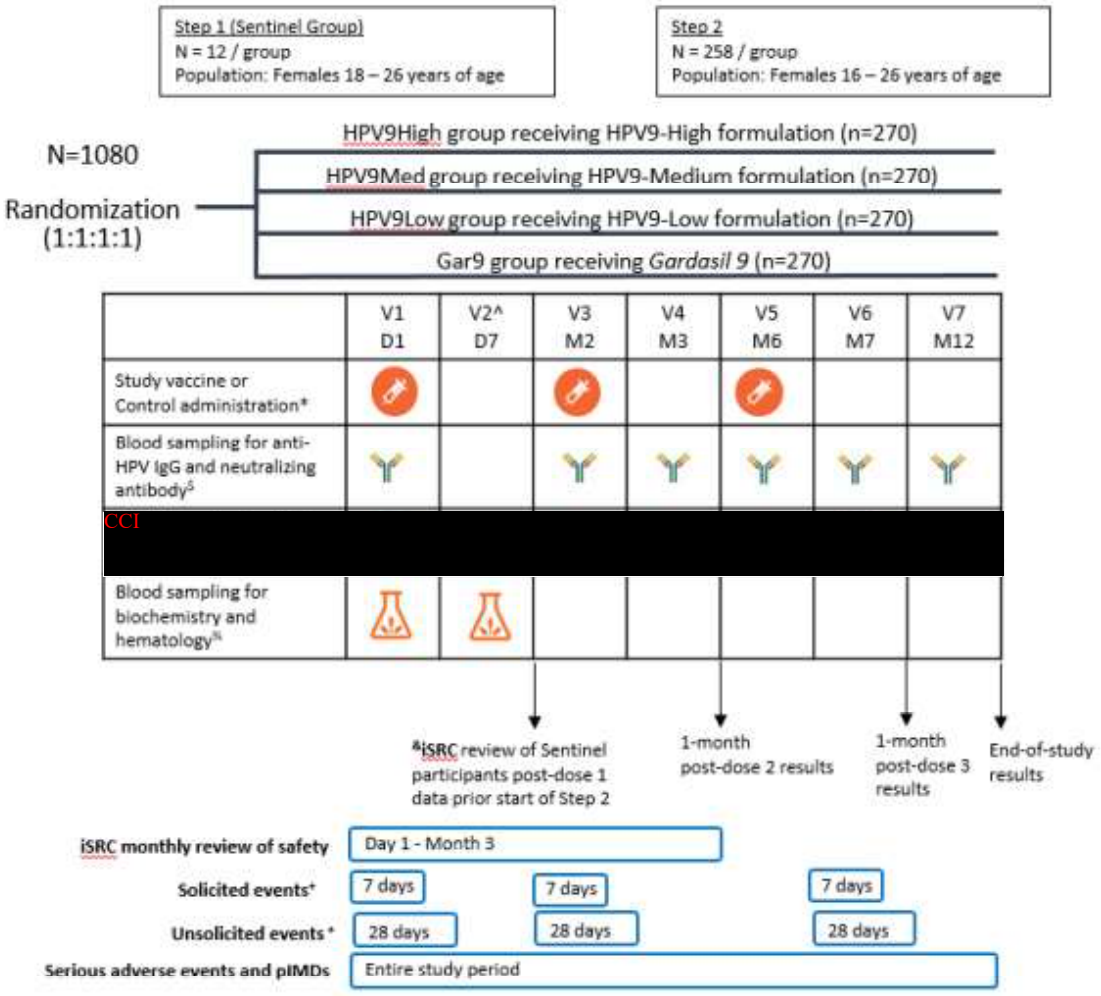
Approximately 1080 participants will be randomly assigned to the 4 study groups to provide approximately 270 participants per study group.

Table B: Study intervention Groups

Study Group	Study Interventions	Number of Participants
HPV9High	HPV9-High	270
HPV9Med	HPV9-Medium	270
HPV9Low	HPV9-Low	270
Gar9	Gardasil 9	270

The duration of the intervention will be approximately 6 months. Participants will be monitored until Month 12. Monitoring of pregnancies (if any) can be beyond 12 months.

Figure 1 Study Design Overview



D = day; iSRC = internal Safety Review Committee; M = month; IgG = immunoglobulin G; CCI [redacted] pIMD = potential immune-mediated disease; V = visit

^V2 is only for Step 1 participants

*Pregnancy test before study vaccine administration

$ Pseudovirion-based neutralization assays at D1, M2 (subset), M3 and M7

CCI [redacted]

+Post study vaccine administration

&iSRC reviews Sentinel participants post-dose 1 safety data, then iSRC reviews the data on monthly basis until one month post-dose 2 for all participants and one-month post dose 3 for Step 1 participants are reviewed Safety data review will occur then on a quarterly basis till the end of the study.
%Blood sampling for biochemistry and hematology is only for Step 1 participants.

4.2. Schedule of Events

Schedule of events can be found in Table 1 of the protocol.

4.3. Changes to Analysis from Protocol

- Differences in the seroconversion rates between study groups are to be summarized for the anti-HPV IgG Antibody and the anti-HPV Neutralizing Antibody
- Sensitivity analysis of the anti-HPV IgG Antibody and the anti-HPV Neutralizing Antibody included where the values above the Upper Limit of Quantification (ULOQ) are not imputed.

5. PLANNED ANALYSES

The following analyses will be performed for this study:

- Analyses for iSRC review
- Two Interim Analyses
- Final Analysis

5.1. Data Monitoring Committee (DMC)

Safety monitoring review will be performed by the iSRC.

5.1.1. iSRC review

An iSRC will be reviewing the unblinded accumulated safety data up to 7 days post-dose 1 for the sentinel participants to determine whether any of the pre-defined holding rules have been met in order to proceed with study schedule of activities. Then iSRC will review the safety data on a monthly basis until safety data from one-month

post-dose 2 for all participants and data from one-month post dose 3 for Step 1 participants are reviewed. The iSRT will then review the safety data on a quarterly basis until the end of the study. Further details on this analysis will be provided in a separate analysis plan.

5.2. Interim Analysis

Two interim analyses will take place for this study.

The first will be performed on all data available for the primary and secondary endpoints up to Month 3 (1 month post-dose 2). This includes all safety data up to 1-month post-dose 2 for all participants, anti-HPV IgG data up to 1-month post-dose 2 for all participants* and anti-HPV neutralizing titers data up to 1-month post-dose 2 with at least 150* participants/group for 1-month post-dose 2 timepoint. Unblinded analysis will also be provided with the study groups unblinded, no individual unblinding information will be shared. Listings will be provided in a blinded manner. Summary analysis might lead to accidental unblinding.

The second will be performed on all available data for primary and secondary endpoints up to Month 7 (1 month post-dose 3). This includes all safety data up to 1-month post-dose 3 for all participants, anti-HPV IgG data up to 1-month post-dose 3 for all participants and anti-HPV neutralizing titers data up to 1-month post-dose 3 with at least 150* participants/group for 1-month post-dose 3 timepoint. Unblinded analysis will also be provided with the study groups unblinded, no individual unblinding information will be shared. Listings will be provided in a blinded manner. Summary analysis might lead to accidental unblinding.
*In case of visit delay, analysis may be performed for as many participants as possible with data available at the time of the analysis. Analysis for remaining participants will be performed at the time of the next analysis.

The results of these will be based on the unblinded treatment groups. See section 9.5 of the protocol for more details.

Derivations and definitions for the interim analysis will be based on those required for the final analysis contained in this analysis plan unless deviations are stated within the text. The list of outputs provided with the full set of output templates (planned for the final analysis) will highlight which of these outputs will also be provided for the interim analysis.

The IQVIA study team, including those responsible for creating the programs to produce the outputs for the Interim

Analysis, will remain blinded. Once the programs have been produced by the IQVIA study team, these programs will be sent to an independent statistician who will apply the randomization schedule and provide a set of unblinded outputs.

5.3. Final Analysis

All final, planned analyses identified in this SAP will be performed by IQVIA Biostatistics following Sponsor Authorization of this Statistical Analysis Plan, Database Lock, Sponsor Authorization of Analysis Sets and Unblinding of intervention group.

This SAP is focused/limited to planned interim and final analyses. Outputs required for the interim analyses will be flagged in the Table, Figures and Listings (TFL) mock shells document.

6. ANALYSIS SETS

Agreement and authorization of subjects included/excluded from each analysis set will be conducted prior to the unblinding of the study.

6.1. Process for Analysis Set Assignment

- Definitions for analysis sets are provided below.
- Prior to database lock, a transfer of raw data from the electronic Case Report Form (eCRF) will occur, and participants will be assigned to analysis sets in accordance with the definitions in this SAP and the available data at that time. However, the protocol deviations will be monitored continuously throughout the study.
- Listings presenting participants excluded from each preliminary analysis set and reasons for exclusion will be prepared for sponsor review ahead of database lock in order to allow appropriate related data queries to be issued.
- Listings presenting participants excluded from each final analysis set and reasons for exclusion will be prepared for sponsor review ahead of unblinding for a final review and approval. However, for deviations that can only be assessed after unblinding such as vaccination errors these will be reviewed after unblinding.
- A Data Review meeting will be held to confirm analysis set assignment for each participant and any changes will be recorded. Changes will be implemented, and an updated analysis set assignment will be approved by the sponsor.

- Sponsor authorization of the analysis sets will be necessary to unblind the data after the final database lock. Once approved, the study will be unblinded, analysis sets will be finalized including additional eliminations requiring unblinding, and the database will be locked.
- After database lock, the final analysis sets will be derived using the final study data, i.e., clinical database (eCRF), external vendor data (immunogenicity results), protocol deviations log and blinded data report.

6.2. Enrolled Set [ENR]

All eligible participants who received a study vaccine or had a blood draw before study vaccine administration or were randomized. Note that as per Good Clinical Practice (GCP) enrolled participants should have completed the informed consent process and participants should be eligible before initiating any study procedure.

6.3. Exposed Set [ES]

All participants who received a study intervention. Analysis per group is based on the study vaccine administered

6.4. Per Protocol Set [PPS]

A per-protocol set (PPS) will be defined for all participants in the ES at each visit that meet the following criteria:

- Meeting all eligibility criteria
- For whom the administration route of the vaccine was as according to protocol
- For whom the study vaccine was administered per protocol
- Who did not receive a concomitant medication/product/vaccine leading to exclusion from a PP analysis, as described in the protocol
- Who did not present with an intercurrent medical condition leading to exclusion from a PP analysis, as described in the protocol
- Who complied with the vaccination schedule
- Who complied with the timings of the post-vaccination blood sampling for immune response evaluation
- For whom post-vaccination immunogenicity results are available for at least one antigen at the corresponding time points

The eliminations for the PPS will be adapted as per the timepoint analysis, e.g., for month 3 analysis only violations up to month 3 will be excluded.

7. GENERAL CONSIDERATIONS

Data will be summarized descriptively (frequency and percentage for categorical data and mean, standard deviation [SD] and range for continuous data, unless specified otherwise). In summary tables for categorical data for which categories are defined on the eCRF, all categories will be presented as specified, even if the participant count within that category is zero.

Unless otherwise specified, all data collected during the trial will be presented in listings for the ENR.

7.1. Reference Start Date and Study Day

Study Day will be calculated from the reference start date and will be used to show start/stop day of assessments and events.

Reference start date is defined as the day of the most recent dose of study vaccination and will appear in every listing where an assessment date or event date appears.

If the date of the event is on or after the date of vaccination then:
Study Day = (date of event – date of vaccination) + 1.

If the date of the event is prior to the date of vaccination then:
Study Day = (date of event – date of vaccination).

In the situation where the event date is partial or missing, Study Day, and any corresponding durations will appear partial or missing in the listings.

7.2. Baseline

Unless otherwise specified, baseline is defined as the last non-missing measurement taken prior to reference start date (including unscheduled assessments). In the case where the last non-missing measurement and the reference start date coincide, that measurement will be considered baseline if the assessment is planned per protocol to take place prior to first study vaccination administration. Adverse Events (AEs) and medications commencing on the reference start date will be considered post-baseline unless otherwise indicated based on available start date/time

combination or collected eCRF information that identifies the individual event/medication as starting prior to first study vaccination administration.

7.3. Retests, Unscheduled Visits and Early Termination Data

In general, for by-visit summaries, data recorded at the nominal visit will be presented. Unscheduled measurements will not occur for this study.

Listings will include all scheduled, and early termination discontinuation data.

7.4. Windowing Conventions

Allowed time window for each visit will be performed as mentioned in "Schedule of Activities", section 1.3 of protocol.

Table C: Intervals Between Study Visits

Interval	Planned Visit Interval*	Allowed Interval Range
Visit 1 → Visit 2	**7 days**	**7 – 12 days**
Visit 1 → Visit 3	60 days	56 – 74 days
Visit 3 → Visit 4	28 days	28 – 44 days
Visit 1 → Visit 5 (visit 5 occurring before protocol amendment 2 [08JUN2023])	180 days	180 – 194 days
Visit 1 → Visit 5 (visit 5 occurring on or after protocol amendment 2 [08JUN2023])	180 days	166 – 194 days
Visit 5 → Visit 6	28 days	28 – 44 days
Visit 1 → Visit 7	360 days	346 – 374 days

- * = Number of days between the visits

Table D: Window Convention

Assigned Study Day	Visit Label as per Protocol	Visit Assigned
Day 1	**Visit 1**	**Visit 1**
Day 7 (Day 1 + 7 to 12 days)	Visit 2	Visit 2
Day 60 (Day 1 + 56 to 74 days)	Visit 3	Visit 3
Day 88 (Day 1 + 84 to 118 days)	Visit 4	Visit 4
Day 180 (Day 1 + 180 to 194 days) (visit 5 occurring before protocol amendment 2 [08JUN2023])	Visit 5	Visit 5
Day 180 (Day 1 + 166 to 194 days) (visit 5 occurring on or after protocol amendment 2 [08JUN2023])	Visit 5	Visit 5
Day 208 (Day 1 + 208 to 238 days)	Visit 6	Visit 6
Day 360 (Day 1 + 346 to 374 days)	Visit 7	Visit 7

7.5. Statistical Tests

The default significant level will be 5%; CIs will be 95% and all tests will be two-sided, unless otherwise specified in the description of the analyses.

7.6. Common Calculations

Geometric Mean Concentration/Titer (GMC/GMT):

Distributions of antibodies are generally skewed to the right (Nauta, 2010). Therefore, prior to any statistical analysis that assumes normally distributed observations, antibody concentrations or titers will be log10-transformed. GMC/GMTs and their 95% CI are computed by exponentiating (base 10) the least squares mean and 95% CI of the log10 titers.

The GMC/GMT will be calculated using the following formula:

$$10^{\left(\frac{\sum_{i=1}^{n}\log 10(t_i)}{n}\right)}$$

Where $t_1, t_2, \ldots, t_n$ are n observed immunogenicity concentrations/titer.

Concentration below assay cut-off (i.e., <lower limit of quantification or < LLOQ) will be replaced by half the assay cut-off (LLOQ/2) for the purpose of GMC computation. Any concentrations above the upper limit of quantification (or ULOQ) will be set to the ULOQ value. No imputation for ULOQ will be performed for the sensitivity analysis of GMC/GMT and for the correlations and Deming's regression.

Seroconversion:
Defined as the appearance of antibodies (i.e., concentrations/titers greater than or equal to the cut-off value) in the serum of participants seronegative before vaccination.

For quantitative measurements, change from baseline will be calculated as:

- Test Value at Visit X – Baseline Value

7.7. Software Version

All analyses will be conducted using SAS version 9.4 or higher.

8. STATISTICAL CONSIDERATIONS

8.1. Adjustments for Covariates and Factors to be Included in Analyses

For details on the factors to be used in the analysis refer to section 17.1 and 17.2. The model will include all groups and country as fixed categorical effects in the ANOVA model.

8.2. Multicenter Studies

This study will be conducted by multiple investigators at multiple centers. The participants will be randomized to one of the 4 groups (refer to Table B in section 4.1) which will be performed in a 1:1:1:1 ratio prior to intervention to provide approximately 270 enrolled participants per group.

8.3. Missing Data

Missing data (missing, incomplete, or partial dates, AE measurement (including missing AE severity and relationship), prior and concomitant medications and death date) will be handled as per APPENDIX 2 of this analysis plan.

Missing immunogenicity data will not be imputed.

8.4. Examination of Subgroups

No subgroup analyses will be performed for this study.

9. OUTPUT PRESENTATIONS

APPENDIX 1 shows conventions for presentation of data in outputs.

The templates provided with this SAP describe the presentations for this study and therefore the format and content of the summary tables, figures, and listings to be provided by IQVIA Biostatistics. Statistical output numbering will follow 'ICH E3 Structure and Content of Clinical Study Reports'.

10. DISPOSITION AND WITHDRAWALS

All participants who are enrolled in the study (those who received a study intervention or were randomized) will be accounted for in this study.

10.1. Disposition

Participant disposition, withdrawals, and reasons for exclusion from each analysis set, including inclusion as well as exclusion criteria will be presented for the ENR. Specifically, the number of participants, vaccinated, completed the study, discontinuing the study and the reason for discontinuation will be summarized by study group for the ENR. Additionally, the number of participants returning for each visit for the ES will be presented. The number of participants enrolled by age category (preterm newborn – gestational age < 37 weeks, newborn (0-27 days), infant and toddler (28 days to 23 months), children (2-11 years), adolescents (12-17 years), 18-64 years, 65-84 years and >=85 years) will be summarized by study group.

A listing of the disposition for all participants with early withdrawal or discontinuation due to having Coronavirus Disease 2019 (COVID-19) or COVID-19 related issues information will be provided. The number of participants who discontinue the study due to COVID-19 will also be summarized by study group.

10.2. Protocol Deviations

During the study, Protocol Deviations (PDs) will be collected in a PD log, as detailed in the Protocol Deviations Management Plan (PDMP). All PDs will be assessed as either important or non-important. PDs will be reviewed by the sponsor, and their status confirmed by the time that all data are cleaned for the Final Analysis. A summary table presenting the number and percentage of participants with important PDs (i.e, those PDs associated to elimination from PPS) will be presented for participants in the ES. A listing of all PDs including an indicator of those excluded from the PPS and an indicator of COVID-19 causality will be provided.

10.2.1. Protocol Deviations Related to Study Conduct

A PD is any non-compliance with the clinical trial protocol, GCP, or protocol deviation guidelines requirements. The non-compliance may be either on the part of the participant, the site investigator, the study site staff or the sponsor.

10.2.2. Protocol Deviations Related to Immunogenicity Analysis

Changes to the procedures or events, which may impact the quality of the immunogenicity data, will be considered important PDs and will be described within the Clinical Study Report (CSR). This includes any circumstances that

could alter the evaluation of the immunogenicity results such as sample processing errors that lead to inaccurate immunogenicity results, and/or inaccurate dosing which could exclude them from the PPS. In addition, participants may also be eliminated from the PPS based on usage of certain concomitant therapies or vaccines as described in Section 5.2.2 of the Protocol.

11. DEMOGRAPHIC AND OTHER BASELINE CHARACTERISTICS

Demographic data and other baseline characteristics will be presented for the ES and each of the PPS. No statistical testing will be carried out for demographic or other baseline characteristics. The following demographic and other baseline characteristics will be reported for this study:

- Age (years) - calculated relative to date of first vaccination
- Age category – <18 and >=18
- Race (as per Clinical Data Interchange Standards Consortium [CDISC] categories)
- Ethnicity

12. GENERAL MEDICAL HISTORY AND EXAMINATIONS

Medical/Vaccination History information will be presented for the ENR.

- Medical History will be coded using Medical Dictionary for Regulatory Activities (MedDRA) central coding dictionary, Version 26.0 or higher.
- Data captured on the "Medical History" page of the eCRF will be presented by System Organ Class (SOC) and Preferred Term (PT). Medical occurrences that begin before the start of study intervention but after obtaining informed consent will be recorded on the Medical History section of the eCRF, not the AE section.

Data will be presented in table summaries for general medical/vaccination history for the ENR and in listings.

13. PRIOR AND CONCOMITANT VACCINATIONS

Prior and concomitant and co-administered vaccination will be coded with the current version of the WHO drug dictionary.

- Prior vaccinations are vaccinations per protocol given to participants prior to the dosing of study intervention and are recorded on the eCRF.

• Concomitant vaccinations are defined as any vaccine that the participant is receiving as of the time of enrolment or receives during the study (other than study interventions) as recorded on the "Concomitant Medications/Vaccination" page of the eCRF, under the "Concomitant Vaccination" category.

Data will be presented in table summaries for concomitant vaccinations for the ES and in listings.

14. MEDICATIONS

The percentage of participants who started medications after study vaccination will be presented by intervention group for the ES.

See APPENDIX 2 for handling of partial dates for medications, in the case where it is not possible to define a medication as prior or concomitant, the medication will be classified by the worst case; i.e., concomitant.

• 'Prior' medications are medications which started prior to the dose of study vaccination.

• 'Concomitant' medications are medications which started on or after the day of the administration of study vaccination

Further details are in Section 6.8 of the Protocol. Concomitant medications during the study will be presented in table summaries (Any, any antipyretic, any prophylactic antipyretic, any antibiotic) and in listings for all medications.

15. STUDY VACCINATION EXPOSURE

Exposure to study vaccine will be presented for the ES. Summaries will include the number of participants with exactly 1 dose, exactly 2 doses, exactly 3 doses, at least 1 dose and at least 2 doses. The date and time of study vaccine administration will be taken from the eCRF "Exposure" form. For dosing instructions and route, refer to Table 6 of the Protocol.

Data will also be presented in listings.

16. IMMUNOGENICITY OUTCOMES

16.1. Primary Immunogenicity

16.1.1. Primary Immunogenicity Variables & Derivations

The primary immunogenicity endpoint is:

- Anti-HPV immunoglobulin G (IgG) antibody geometric mean concentrations (GMCs), 1 month after the third dose (Month 7) for each antigen. For the derivation of GMC refer to section 7.6.

16.1.2. Intercurrent Event Handling and Data Imputation for Primary Immunogenicity Variable(s)

See Table A: and section 8.3.

16.1.3. Primary Analysis of Primary Immunogenicity Variables

The primary immunogenicity analysis will be performed for the PPS. If the number of participants excluded from the PPS is >5% when compared with the ES, then the analysis will also be performed for the ES.

The primary immunogenicity endpoint GMCs of anti-HPV IgG antibody concentration at Month 7 will be summarized by study group for each antigen with their 95% CI summarised for the pre-vaccination status of seronegative, seropositive and total. Anti-HPV IgG antibody concentration will be graphically presented by reverse cumulative curves per study group.

16.2. Secondary Immunogenicity

The secondary immunogenicity analyses will be performed for the PPS.

16.2.1. Secondary Immunogenicity Variables & Derivations

16.2.1.1. ANTI-HPV IGG ANTIBODY CONCENTRATION

Anti-HPV IgG antibody concentration at Day 1, Month 2, Month 3, Month 6, and Month 12 for each antigen.

16.2.1.2. ANTI-HPV IGG ANTIBODY SEROCONVERSION AND SEROPOSITIVITY RATE

Anti-HPV IgG antibody seroconversion and seropositivity rates at Day 1 (for seropositivity only), Month 2, Month 3, Month 6, Month 7 and Month 12 for each antigen.

Seroconversion is defined as the appearance of antibodies (i.e, concentrations greater than or equal to the cut-off value) in the serum of participants seronegative before vaccination.

Seropositivity is defined as the appearance of antibodies (i.e, concentrations greater than or equal to the cut-off value) in the serum of participants.

16.2.1.3. ANTI-HPV NEUTRALIZING ANTIBODY TITERS

Anti-HPV neutralizing antibody titers at Day 1, Month 3 and Month 7 (at least 150 participants in each group) and Month 2 in a subset of 384 participants (at least 96 in each group) for each antigen.

16.2.1.4. ANTI-HPV NEUTRALIZING ANTIBODY SEROCONVERSION AND SEROPOSITIVITY RATE

Anti-HPV neutralizing antibody seroconversion and seropositivity rates at Day 1 (seropositivity only), Month 3 and Month 7 (at least 150 participants in each group) and Month 2 in a subset of 384 participants (at least 96 in each group) for each antigen.

Seroconversion is defined as the appearance of antibodies (i.e, titer greater than or equal to the cut-off value) in the serum of participants seronegative before vaccination.

Seropositivity is defined as the appearance of antibodies (i.e, titer greater than or equal to the cut-off value) in the serum of participants.

16.2.1.5. CORRELATION BETWEEN ANTI-HPV IGG ANTIBODY CONCENTRATION AND ANTI-HPV NEUTRALIZING ANTIBODY TITERS

Correlation between anti-HPV IgG antibody concentrations and anti-HPV neutralizing antibody titers at Day 1, Month 2, Month 3, Month 7 and overall for each antigen.

16.2.2. Intercurrent Event Handling and Data Imputation for Secondary Immunogenicity Variable(s)

See Table A: and section 8.3.

16.2.3. Analysis of Secondary Immunogenicity Variables

16.2.3.1. Anti-HPV IgG antibody concentration

The immunogenicity endpoint GMCs of anti-HPV IgG antibody concentration will be summarized for each antigen at Day 1, Month 2, Month 3, Month 6, and Month 12 by study group with their 95% CI derived considering log10-transformed antibody concentrations are normally distributed with unknown variance, summarised for the pre-vaccination status of seronegative, seropositive and total. The concentration below the assay cut-off will be assigned to half the cut-off for the purpose of GMC computation. The number of records above the ULOQ will be summarised at each visit for the pre-vaccination status of seronegative (except Day 1), seropositive and total.

Anti-HPV IgG antibody concentration will be graphically presented by reverse cumulative curves per antigen, timepoint and study group.

16.2.3.2. Anti-HPV IgG antibody seroconversion and seropositivity rate

The percentage of participants with a seroconversion and seropositivity for each antigen will be summarized for each antigen at Day 1 (for seropositivity only), Month 2, Month 3, Month 6, Month 7 and Month 12 by study group and corresponding 2-sided 95% CI will be reported based on Clopper and Pearson method.

16.2.3.3. Anti-HPV neutralizing antibody titers

The anti-HPV neutralizing antibody titers will be summarized for each antigen at Day 1, Month 3 and Month 7 (at least 150 participants in each group) and Month 2 in a subset of participants by study group with their 95% CI derived considering log10-transformed antibody titers are normally distributed with unknown variance, summarised for the pre-vaccination status of seronegative, seropositive and total. Anti-HPV neutralizing antibody titers will be graphically presented by reverse cumulative curves per antigen, timepoint and study group. The concentration below the assay cut-off will be assigned to half the cut-off for the purpose of GMT computation. The number of records above the ULOQ will be summarised at each visit for the pre-vaccination status of seronegative (except day 1), seropositive and total.

16.2.3.4. ANTI-HPV NEUTRALIZING ANTIBODY SEROCONVERSION AND SEROPOSITIVITY RATE

The percentage of participants with a seroconversion and seropositivity for each antigen will be summarized at Day 1 (seropositivity only), Month 3 and Month 7 and Month 2 in a subset of 384 participants (at least 96 in each group) by study group and corresponding 2-sided 95% CI will be reported based on Clopper and Pearson method.

16.2.3.5. CORRELATION BETWEEN ANTI-HPV IGG ANTIBODY CONCENTRATION AND ANTI-HPV NEUTRALIZING ANTIBODY TITERS

The Pearson coefficient of correlation between anti-HPV IgG antibody concentration and anti-HPV neutralizing antibody titers with associated p-value will be calculated for each investigational adjuvanted vaccine groups and *Gardasil 9* group for each antigen at Day 1, Month 2, Month 3, Month 7 and overall. The Pearson correlation will be computed by the log10-transformation of specific antibody concentrations.

For each HPV type, the functional relationship between the pair of assay methods (pseudovirion-based neutralization assay [PBNA] verses electrochemiluminescence assay [ECL]) will be estimated by timepoint at Day 1, Month 2, Month 3 and Month 7 and overall using the Deming's regression model.

The Deming's regression will consider the following:

- Anti-HPV Neutralizing titers (from PBNA) with errors ϵ_i

1.1 $x_i = X_i + \epsilon_i$

- Anti-HPV IgG antibody concentrations (from ECL) with errors δ_{i_i}

1.2 $y_i = Y_i + \delta_i$

where X_i and Y_i are the measurements of Anti-HPV Neutralizing titers and Anti-HPV IgG antibody concentrations.

The Deming's regression model to be fitted is

$$Y = \beta_0 + \beta_1 X$$

The following terms will be fitted in the model:
Response (Y): log transformed anti-HPV IgG antibody concentration (from ECL)
Covariate (X): log transformed anti-HPV Neutralizing titers (from PBNA)
β_0 is the Y-intercept and β_1 is the coefficient (slope) associated with the Anti-HPV Neutralizing titers from PBNA.

Assumption: Error ratio: $V(\epsilon_i) / V(\delta_i) = 1$

The model will be fitted for each antigen and study group separately.

The intercept and the slope estimates and corresponding 95% CI (only for slope) will be presented. Note that a slope ≈ 1 implies a favorable outcome, i.e. both the assays (ECL and PBNA) are in strong agreement and have a similar performance.

Graphs representing the scatterplot of the Anti-HPV Neutralizing titers and Anti-HPV IgG antibody concentration will be presented for all timepoints with the Deming's regression line for each antigen and each study group. LLOQ and ULOQ values of the ECL and PBNA will also be presented in the same graph.

16.2.4. Exploratory Immunogenicity Variables

The exploratory immunogenicity analyses will be performed for the Month 3 and Month 7 PPS.

16.2.4.1. Anti-HPV IgG antibody concentration between group assessment

Anti-HPV IgG antibody concentration at Month 3 and Month 7 for each antigen.

For each antigen an adjusted GMC and GMC ratio with 2-sided 95% CI for intervention group which is derived from an ANOVA model on log10 transformed concentration will be tabulated for anti-HPV IgG antibody concentration adjusted for country effect. The analysis will be performed at Month 3 and at Month 7, summarised for the pre-vaccination status of seronegative, seropositive and total. The model will be based on the data from all groups, will include study group and country as a fixed effect and will be based on the PPS. The non-inferiority of different vaccine formulations to the control group will be assessed if the lower limit of the 2-sided 95% CI is not less than the defined non-inferiority limit. The non-inferiority between different vaccine formulations will also be assessed.

16.2.4.2. Anti-HPV IgG antibody seroconversion rate

The differences in the seroconversion rate at Month 3 and Month 7 will be summarized for each antigen between each HPV9 study group (High, Medium and Low) against Gardasil 9 along with the corresponding 2-sided 95% CI will be reported. The differences in the seroconversion rate at Month 3 and Month 7 between each antigen and HPV9 study group will also be assessed.

16.2.4.3. ANTI-HPV NEUTRALIZING ANTIBODY TITERS BETWEEN GROUP ASSESSMENT

Anti-HPV neutralizing antibody titers at Month 3 and Month 7 (at least 150 participants in each group) for each antigen.

For each antigen an adjusted GMT and GMT ratio with 2-sided 95% CI for intervention group which is derived from an ANOVA model on log10 transformed titer will be tabulated for anti-HPV neutralizing antibody titer adjusted for country effect. The analysis will be performed at Month 3 and at Month 7, summarised for the pre-vaccination status of seronegative, seropositive and total. The model will be based on the data from all groups, will include study group and country as a fixed effect and will be based on the PPS. The non-inferiority of different vaccine formulations to the control group will be assessed if the lower limit of the 2-sided 95% CI is not less than the defined non-inferiority limit. The non-inferiority between different vaccine formulations will also be assessed.

16.2.4.4. ANTI-HPV NEUTRALIZING ANTIBODY SEROCONVERSION RATE

The differences in the seroconversion rate at Month 3 and Month 7 will be summarized for each antigen between each HPV9 study group (High, Medium and Low) against Gardasil 9 along with the corresponding 2-sided 95% CI will be reported. The differences in the seroconversion rate at Month 3 and Month 7 between each antigen and HPV9 study group will also be assessed.

16.2.4.5. COMPARISON OF ANTI-HPV IGG ANTIBODY CONCENTRATION AND ANTI-HPV NEUTRALIZING ANTIBODY TITERS

A qualitative comparison between the ant-HPV IgG antibody concentration and the anti-HPV neutralizing antibody titers will be performed for each antigen by timepoint on all the PPS (except Month 6 and Month 12). This will be performed on each timepoint and antigen where both the anti-HPV IgG antibody concentration and the anti-HPV neutralizing antibody titer will be available. The agreement rate of the 2 results will be summarized and presented along with the kappa and the kappa p-value. The larger the kappa value (close to 1) the better the agreement between the two tests. The McNemar p-value will also be summarized.

16.3. Tertiary Immunogenicity

CCI

CCI

[redacted]

16.4. Sensitivity Immunogenicity Variables & Derivations

Sensitivity analysis will be performed on the PPS only.

The analysis for anti-HPV IgG antibody concentration (section 16.2.3.1), anti-HPV neutralizing antibody titers between group assessment (section 16.2.4.1), anti-HPV neutralizing antibody titers (section 16.2.3.3), anti-HPV neutralizing antibody titers between group assessment (section 16.2.4.3) and the correlation between anti-HPV IgG antibody concentration and anti-HPV neutralizing antibody titers (section **Error! Reference source not found.**) will all be performed for the sensitivity analysis. The corresponding figures will also be presented for the sensitivity analysis.

The concentration/titer below the assay cut-off will be assigned to half the cut-off for the purpose of GMC/GMT computation. Concentration/titer above the ULOQ will not be imputed. Concentration below the ULOQ for the RCC will not be imputed for the ECL

17. SAFETY AND REACTOGENICITY OUTCOMES

17.1. Primary Safety and Reactogenicity

17.1.1. Primary Safety and Reactogenicity Variables & Derivations

The primary safety and reactogenicity endpoints are:

- Solicited events:
  - Percentage of participants reporting each solicited administration site event assessed as Grade 3 in terms of intensity within 7 days (Day 1 – Day 7) after each vaccine dose
  - Percentage of participants reporting each solicited systemic event assessed as Grade 3 in terms of intensity within 7 days (Day 1 – Day 7) after each vaccine dose
- Unsolicited adverse events:
  - Percentage of participants reporting unsolicited adverse event assessed as Grade 3 in terms of intensity classified by MedDRA within 28 days (Day 1 – Day 28) after each vaccine dose
- Serious adverse events (SAEs):
  - Percentage of participants reporting SAEs classified by MedDRA from first vaccination up to study end
- Safety laboratory parameters (Step 1 participants):
  - Percentage of participants presenting clinically relevant abnormalities in each biochemical and hematological parameter at Day 7 post-dose 1.

17.1.2. Intercurrent Event Handling and Data Imputation for Primary Efficacy Variable(s)

See Table A:.

17.1.3. Primary Analysis of Primary Safety and Reactogenicity Variables

The primary safety and reactogenicity analysis will be performed for the ES.

17.1.3.1. SOLICITED EVENTS

For each study group and overall and each solicited event, the incidence rate (frequencies and percentages) of vaccinated participants with solicited administration site events (pain at injection site, redness at injection site and swelling at injection site) and systemic events (fever, headache, myalgia, arthralgia and fatigue) assessed as Grade 3 in intensity within 7 days after each vaccine administration will be summarized over the whole vaccination course with the exact 95% CI. The number of solicited events will be summarized at the maximum severity per participant. Each solicited event will be counted once regardless of the number of days the event occurred. The percentages will be out of the number of participants in the ES for each period (after first vaccine dose, after second vaccine dose, after third vaccine dose, overall (dose) and overall (participant)) except the overall dose. The overall dose will be out of the total number of doses in the ES.

Intensity scales for solicited events will be assessed as follows:

Adverse Event	MedDRA Preferred Term	Intensity Grade	Parameter
Pain at Injection Site	Administration site pain (10058049)	1	Mild: Any pain neither interfering with nor preventing normal everyday activities
		2	Moderate: Painful when limb is moved and interferes with everyday activities
		3	Severe: Significant pain at rest. Prevents normal everyday activities.
Redness at Injection Site	Administration site erythema (10074796)	1	Mild: > 0 - ≤ 20 mm
		2	Moderate: > 20 - ≤ 50 mm
		3	Severe: > 50 mm

Adverse Event	MedDRA Preferred Term	Intensity Grade	Parameter
Swelling at Injection Site	Administration site swelling (10075107)	1	Mild: > 0 - ≤ 20 mm
		2	Moderate: > 20 - ≤ 50 mm
		3	Severe: > 50 mm
Temperature	Pyrexia (10037660)	1	Mild: ≥ 37.5°C (≥99.5°F) - ≤ 38.0°C (≥100.4°F)
		2	Moderate: > 38.0°C (≥100.4°F) - ≤ 39.0°C (≥102.2°F)
		3	Severe: > 39.0°C (≥ 102.2°F)
Headache	Headache (10019211)	1	Mild: Headache that is easily tolerated
		2	Moderate: Headache that interferes with normal activity
		3	Severe: Headache that prevents normal activity
Fatigue	Fatigue (10016256)	1	Mild: Fatigue that is easily tolerated
		2	Moderate: Fatigue that interferes with normal activity
		3	Severe: Fatigue that prevents normal activity
Arthralgia	Arthralgia (10003239)	1	Mild: Arthralgia that is easily tolerated
		2	Moderate: Arthralgia that interferes with normal activity
		3	Severe: Arthralgia that prevents normal activity
Myalgia	Myalgia (10028411)	1	Mild: Myalgia that is easily tolerated
		2	Moderate: Myalgia that interferes with normal activity
		3	Severe: Myalgia that prevents normal activity

17.1.3.2. UNSOLICITED EVENTS

For each study group and overall, the incidence rates (frequencies and percentages) of participants/events with unsolicited AEs, assessed as Grade 3 and Grade 3 related in intensity assessed by MedDRA occurring within 28-days (Days 1-28) after each vaccine administration will be summarized by SOC and PT over the whole vaccination course with the exact 95% CI. The percentages will be out of the number of participants in the ES for each vaccine dose (after first vaccine dose, after second vaccine dose, after third vaccine dose, overall (dose) and overall (participant)) expect the overall dose. The overall dose will be out of the total number of doses in the ES.

Unsolicited events will be coded using MedDRA central coding dictionary, version 26.0 or higher. Unsolicited events will be described using frequency and percentage.

Unsolicited events will be grouped by SOC and PT and summarized by intervention at time of onset of the event. The summary tables will present the number and percentage of total participants and number of events, by SOC and by PT for each intervention group.

For the summaries of unsolicited events, participants who experience the same AE (in terms of the MedDRA SOC and PT) more than once will only be counted once for that event in the number of participants but all occurrences of the same event will be counted in the number of events.

17.1.3.3. SERIOUS ADVERSE EVENTS

For each study group and overall, the incidence rates (frequencies and percentages) of participants/events with SAEs from first vaccination up to Month 12 will be summarized by SOC and PT over the whole vaccination course with the exact 95% CI. The incidence rates (frequencies and percentages) of participants with SAEs causally related to study vaccine, fatal SAEs and causally related fatal SAEs occurring post-dose of study interventions will also be presented. Serious AEs will be recorded on the “Expedited Adverse Events” page of the eCRF.

17.1.3.4. LABORATORY PARAMETERS OUTSIDE NORMAL RANGE

For each study group and overall, the percentage of participants in Step 1 outside the defined normal ranges for each biochemical and hematological parameter measured in the study at Day 7 after the first vaccination will be tabulated with exact 95% CI.

17.2. Secondary Safety and Reactogenicity

The secondary safety and reactogenicity analyses will be performed for the ES.

17.2.1. Secondary Safety and Reactogenicity Variables & Derivations

The secondary safety and reactogenicity endpoints are:

- Solicited events:
  - Percentage of participants reporting each solicited administration site event within 7 days (Day 1 – Day 7) after each vaccine dose
  - Percentage of participants reporting each solicited systemic event within 7 days (Day 1 – Day 7) after each vaccine dose
- Unsolicited adverse events:
  - Percentage of participants reporting unsolicited adverse event within 28 days (Day 1 – Day 28) after each vaccine dose
- Potential immune-mediated disease (pIMDs)
  - Percentage of participants reporting pIMDs from first vaccination up to study end. A pIMD is an Adverse Event of Special Interest (AESI)
- Pregnancy outcomes
  - Percentage of participants who experienced pregnancy and their outcomes from Day 1 of pregnancy up to study end.

17.2.2. Intercurrent Event Handling and Data Imputation for Secondary Safety and Reactogenicity Variable(s)

See Table A:.

17.2.3. Analysis of Secondary Safety and Reactogenicity Variables

17.2.3.1. SOLICITED EVENTS

For each study group and overall and each solicited event, the incidence rate (frequencies and percentages) of vaccinated participants with solicited administration site events (pain at injection site, redness at injection site and swelling at injection site) and systemic events (fever, headache, myalgia, arthralgia and fatigue) within 7 days after

each vaccine administration will be summarized (any, leading to medical advice) over the whole vaccination course with the exact 95% CI. The completeness defined as the percentage of vaccinated participants who documented presence/absence of each event as well as the daily prevalence of each symptom among vaccinated participants who documented presence /absence of the event on that day will be provided. The percentages will be out of the number of participants who have at least one documented event (either present or absent). The number of solicited events will be summarized at the maximum severity per participant. Each solicited event will be counted once regardless of the number of days the event occurred. The number of solicited events will also be summarized by severity. The percentages will be out of the number of participants in the ES for each period (after first vaccine dose, after second vaccine dose, after third vaccine dose, overall (dose) and overall (participant)) expect the overall dose. The overall dose will be out of the total number of doses in the ES.

The duration of each Grade 3 solicited event (split between solicited administration events and systemic events) will be summarized. The duration of the event is defined as the number of days that a participant had an event, for example if an event occurs on day 2 and 4 but the event did not occur on day 3 (or was not captured in the eDiary) then the duration is considered as 2 days. The duration will be summarized numerically (with n, mean, STD, median, minimum and maximum) and also the frequency (the number of events that had a duration of 1, 2, 3,4, >=5 days).

17.2.3.2. UNSOLICITED EVENTS

For each study group and overall, the incidence rates (frequencies and percentages) of participants/events with unsolicited AEs (any, related, leading to medical attention), occurring within 28-days (Days 1-28) after each vaccine administration and overall will be summarized by SOC and PT with the exact 95% CI. The number of unsolicited events will also be summarized by severity. The percentages will be out of the number of participants in the ES for each period (after first vaccine dose, after second vaccine dose, after third vaccine dose, overall (dose) and overall (participant)) expect the overall dose. The overall dose will be out of the total number of doses in the ES.

Causality, as indicated by the Investigator is classed as “related” and “not related” to HPV vaccine. A “related” AE is defined as an AE with a relationship to study intervention as “related”. If a participant reports the same AE more than once within that SOC/ PT, the AE with the worst-case relationship to study intervention will be used in the corresponding relationship summaries for each vaccination group.

Unsolicited events will be coded using MedDRA central coding dictionary, version 26.0 or higher. Unsolicited events will be described using frequency and percentage.

Unsolicited events will be grouped by SOC and PT and summarized by intervention at time of onset of the event. The summary tables will present the number and percentage of total participants and number of events, by SOC and by PT for each intervention group.

For the summaries of unsolicited events, participants who experience the same AE (in terms of the MedDRA SOC and PT) more than once will only be counted once for that event in the number of participants but all occurrences of the same event will be counted in the number of events.

17.2.3.3. POTENTIAL IMMUNE-MEDIATED DISEASE

For each study group and overall, the incidence rates (frequencies and percentages) of participants/events with pIMDs and pIMDs causally related to study vaccine from first vaccination up to study end will be summarized (any and related) over the whole vaccination course with the exact 95% CI.

17.2.3.4. PREGNANCY

For each study group and overall, the percentage of participants who experienced pregnancy during the entire study and around each vaccination (30 days before and 45 days after each vaccination) will be summarized along with their outcomes.

17.3. Laboratory Parameters

Scheduled clinical safety laboratory parameters will be summarized at each visit by grade (grade 0, 1, 2, 3 and 4) according to Table 13 of the protocol. These include:

- Hematology: hemoglobin, hemoglobin change from baseline, White Blood Cell (WBC) increase, WBC decrease, lymphocyte decrease, neutrophils decrease, eosinophils and platelet decrease
- Chemistry: Blood Urea Nitrogen (BUN), Aspartate Aminotransferase (AST) and Alanine Aminotransferase (ALT)

Box plots of the above summary will be presented for the iSRC analysis.

18. DATA NOT SUMMARIZED OR PRESENTED

The other variables and/or domains not summarized or presented are:

- Physical examination
- Vital signs
- Body temperature

These domains and/or variables will not be summarized or presented, but will be available in the clinical study database, SDTM and/or ADaM datasets. Vital signs and body temperature will be presented in a listing.

19. REFERENCES

Clopper CJ, Pearson ES. The use of confidential or fiducial limits illustrated in the case of the binomial. Biometrika 1934; 26:404-413

Nauta J. Statistics in Clinical Vaccine Trials. 2010. Heidelberg: Springer.

Brown et all. Concordance assessment between a multiplexed competitive Luminex immunoassay, a multiplexed IgG Luminex immunoassay, and a pseudovirion-based neutralization assay for detection of human papillomaviruse types 16 and 18. 2014.

APPENDIX 1. PROGRAMMING CONVENTIONS FOR OUTPUTS

IQVIA Output Conventions

Outputs will be presented according to the following IQVIA Output Conventions

Document Headers
All TFL is to include the following header:

GSK Vaccines
Vaccine: HPV
Study 213749 (HPV9) - DELIVERY DESIGNATION

where delivery designation is the name of the current delivery, e.g., DRY-RUN, FINAL ANALYSIS REPORT, etc

Dates & Times

Depending on data available, dates and times will take the form yyyy-mm-ddThh:mm:ss.

Spelling Format

English US

Presentation of Treatment Groups

For outputs, treatment groups will be represented as follows and in the given order:

Treatment Group	For Tables and Figures	For Listings (include if different to tables)
HPV9High	HPV9 High	HPV9 High

Treatment Group	For Tables and Figures	For Listings (include if different to tables)
HPV9Med	HPV9 Med	HPV9 Medium
HPV9Low	HPV9 Low	HPV Low
Gar9	Gardasil 9	Gardasil 9

Presentation of Visits

For outputs, visits will be represented as follows and in that order:

Long Name (default)	Short Name
Visit 1 (Day 1)	Day 1
Visit 2 (Day 7)	Day 7
Visit 3 (Month 2)	Month 2
Visit 4 (Month 3)	Month 3
Visit 5 (Month 6)	Month 6
Visit 6 (Month 7)	Month 7
Visit 7 (Month 12)	Month 12

Listings

All listings will be ordered by the following (unless otherwise indicated in the template):

- Randomized treatment group (or treatment received if it's a safety output), first by HPV9High then HPV9Med, then HPV9Low and then Gardasil9
- Center-subject ID,
- Date (where applicable),
-

DECIMAL PLACES

Decimal places for categorical data

- For percentages one decimal will be displayed
- Differences in percentages and their corresponding confidence limits will be displayed with one more decimal than the maximum number used to display the individual percentages, for example the difference between two percentages displayed with one decimal will be displayed with two decimals.

Decimal places for Demographic and baseline characteristics will be as follows:

The mean, median, and SD for continuous baseline characteristics (age) will be presented with one decimal.

Serological Summary Statistics

The number of decimals used when displaying geometric mean concentrations (GMC) and their confidence limits is shown in the following table:

GMC value	Number of decimals
<0.1	3
>=0.1 and <10	2
>=10 and <1000	1
>=1000	0

When multiple categories of GMC values are present in the same table, the number of decimals displayed should match that of the smallest category (i.e. the one with the higher number of decimals). For example, if GMC values of <0.1 appear in the same table as values of >=0.1 and <10 3 decimals should be displayed for both.

GMC ratios and their confidence limits will be displayed with 2 decimals regardless of the actual values.

APPENDIX 2. PARTIAL DATE CONVENTIONS

Imputed dates will NOT be presented in the listings.

When partially completed dates (i.e. with missing day or month) are used in calculations, the following standard rules will be applied:

- A missing day will be replaced by 15
- A missing day and month will be replaced by June 30th.

The following exceptions apply:

- Adverse event start dates with missing day:
  - If the event starts in the same month as the study intervention, the contents of AE.AESTRTPT (the flag indicating if the event occurred before or after vaccination) will be used to complete the date. If 'after vaccination' is selected, the imputed start date will match study dose given during that month. If 'before vaccination' is selected, the imputed date will be one day before the study intervention given during that month.
- Adverse event start dates with missing day and month:
  - If the event starts in the same year as study intervention, the contents of AE.AESTRTPT (the flag indicating if the event occurred before or after vaccination) will be used to complete the date. If 'after vaccination' is selected, the imputed start date will match the study intervention given during that year. If 'before vaccination' is selected, the imputed date will be one day before the) study intervention given during that year.

All other cases of incomplete AE or concomitant medication/vaccination start date will follow the standard rules above.

Algorithm for Prior / Concomitant Medications:

START DATE	STOP DATE	ACTION
Known	Known	If stop date < study med start date, assign as prior If stop date >= study med start date and start date <= study med end date, assign as concomitant

START DATE	STOP DATE	ACTION
	Partial	Impute stop date as latest possible date (i.e. last day of month if day unknown or 31st December if day and month are unknown), then: If stop date < study med start date, assign as prior If stop date >= study med start date and start date <= study med end date, assign as concomitant
	Missing	If stop date is missing could never be assumed a prior medication If start date <= study med end date, assign as concomitant
Partial	Known	Impute start date as earliest possible date (i.e. first day of month if day unknown or 1st January if day and month are unknown), then: If stop date < study med start date, assign as prior If stop date >= study med start date and start date <= study med end date, assign as concomitant
	Partial	Impute start date as earliest possible date (i.e. first day of month if day unknown or 1st January if day and month are unknown) and impute stop date as latest possible date (i.e. last day of month if day unknown or 31st December if day and month are unknown), then: If stop date < study med start date, assign as prior If stop date >= study med start date and start date <= study med end date, assign as concomitant
	Missing	Impute start date as earliest possible date (i.e. first day of month if day unknown or 1st January if day and month are unknown), then: If stop date is missing could never be assumed a prior medication If start date <= study med end date, assign as concomitant
Missing	Known	If stop date < study med start date, assign as prior If stop date >= study med start date, assign as concomitant

START DATE	STOP DATE	ACTION
	Partial	Impute stop date as latest possible date (i.e. last day of month if day unknown or 31st December if day and month are unknown), then: If stop date < study med start date, assign as prior If stop date >= study med start date, assign as concomitant
	Missing	Assign as concomitant

TABLE, FIGURES AND LISTINGS SHELLS

213749 (HPV9-AS04-001)

A Phase 1/2 randomized, observer-blinded, multi-country study to evaluate safety and immunogenicity of investigational adjuvanted human papillomavirus vaccine in females (16 to 26 years of age)

AUTHOR: PPD

VERSION NUMBER AND DATE: V3.0, 05FEB2024

TABLE, LISTINGS AND FIGURES SHELLS SIGNATURE PAGE

Table, listing and Figures Shells V3.0 (Dated 05FEB2024) for Protocol 213749 (HPV9-AS04-001)

	Name	Signature	Date (DDMmmYYYY)
Author:	PPD	Refer to e PPD	uary 6, 2024
Position:	Associate Director Biostatistics		
Company:	IQVIA		

Upon review of this document, the undersigned approves this version of the Statistical Analysis Plan, authorizing that the content is acceptable for the reporting of this study.

	Name	Signature	Date (DDMmmYYYY)
Approved By:	PPD	PPD	bruary 8, 2024
Position:	Senior Biostatistician		
Company:	IQVIA		
Approved By:	PPD	PPD	February 5, 2024
Position:	Project Statistician		
Company:	GSK		

MODIFICATION HISTORY

Unique Identifier for this Version	Date of the Document Version	Author	Significant Changes from Previous Authorized Version
1.0	03AUG2022	PPD	Not Applicable – First Version
2.0	21JUL2023	PPD	Updates based on Statistical Analysis Plan V2.0. Including list of outputs required for the interim analysis and the headline results
3.0	05FEB2024	PPD	Updates following the first interim analysis. New outputs – demography tables for each of the Per Protocol Sets, concordance analysis table and duration of grade 3 solicited events tables

CCI

List of Outputs Required for Interim Analysis

The below file contains the ToC of the outputs that are required for the iSAC, and whether they are synopsis tables or intext tables. It also displays which outputs will also be created separately for the sensitivity analysis.

TFL_Shells ToC Version 2.xlsx

Table 14.1.1.1: Summary of Participant Disposition (Enrolled Set)

Table 14.1.1.1
Summary of Participant Disposition
Enrolled Set

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Number of participants enrolled	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Number of participants enrolled but not vaccinated	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Number of participants vaccinated	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Participants who completed the study	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Participants who discontinued the study	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Reason for discontinuing the study						
Adverse event requiring expedited reporting	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Pregnancy	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Unsolicited AE	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Solicited AE	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Withdrawal by participant	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Migrated/moved from the study area	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Lost to follow up	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Study termination	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Withdrew due to COVID-19 pandemic	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Other	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. AE = Adverse Event. COVID-19 = Coronavirus Disease 2019.
N is the number of participants in the Enrolled Set.
n is the number of participants in each category.
Percentages are calculated as 100 * n/N.
A participant is considered to have completed the study if he/she returns for the last visit/contact or is available for the last scheduled procedure/contact as described in the protocol

Table 14.1.1.1
Summary of Participant Disposition
Enrolled Set

	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)

Programming Notes

Output ID: DS0001
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.1.1.2: Number of Participants at each visit (Exposed Set)

Study 213749 - DELIVERY DESIGNATION

Table 14.1.1.2
Number of Participants at each visit
Exposed Set

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Participants attending each visit:						
Visit 1 (Day 1)	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Visit 2 (Day 7)*	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Visit 3 (Month 2)	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Visit 4 (Month 3)	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Visit 5 (Month 6)	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Visit 6 (Month 7)	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Visit 7 (Month 12)	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus.
N is the number of participants in the Exposed Set.
n is the number of participants in each category.
Percentages are calculated as 100 * n/N.
* = Step 1 participants only

Programming Notes

Output ID: DS0002
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.1.1.3: Number and Percentage of Participants Discontinued due to COVID-19 (Exposed Set)

Study 213749 - DELIVERY DESIGNATION

Table 14.1.1.3
Number and Percentage of Participants Discontinued due to COVID-19
Exposed Set

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Participants discontinued/withdrew from the study due to COVID-19	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Participants missed visit due to COVID-19	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Visit 1 (Day 1)	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Visit 2 (Day 7)*	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Visit 3 (Month 2)	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Visit 4 (Month 3)	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Visit 5 (Month 6)	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Visit 6 (Month 7)	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Visit 7 (Month 12)	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. COVID-19 = Coronavirus disease 2019.
N is the number of participants in the Exposed Set.
n is the number of participants in each category.
Percentages are calculated as 100 * n/N.
* = Step 1 participants only

Programming Notes

Output ID: DS0003
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.1.1.4: Number of Participants Enrolled by Age Category (Exposed Set)

Table 14.1.1.4
Number of Participants Enrolled by Age Category
Enrolled Set

Characteristic		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Age category						
Preterm newborn - gestational age < 37 weeks	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Newborn (0-27 days)	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Infant and toddlers (28 days to 23 months)	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Children (2-11 years)	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Adolescents (12-17 years)	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
From 18 - 64 years	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
From 65 - 84 years	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Over 85 years	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus.
N is the number of participants in the Enrolled Set.
n is the number of participants in each category.
Percentages are calculated as 100 * n/N.

Programming Notes

Output ID: DS0004
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.1.2: Summary of Protocol Deviations Leading to Elimination from Per Protocol Set (Exposed Set)

Table 14.1.2
Summary of Protocol Deviations Leading to Elimination from Per Protocol Set
Exposed Set

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Withdrawals at Day 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
AE requiring expedited reporting	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Pregnancy	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Unsolicited AE (non-serious)	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Solicited AE	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Not willing to be vaccinated	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Discontinued study treatment due to COVID-19 pandemic	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Other	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Eliminations at Day 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Informed consent criteria	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Inclusion criteria	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Exclusion criteria	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Concomitant medication	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)

Table 14.1.2
Summary of Protocol Deviations Leading to Elimination from Per Protocol Set
Exposed Set

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Laboratory assessment	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Study procedure	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Safety	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Randomization	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Visit schedule	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
IP conditions	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
IP preparation	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
IP administration	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Subject IP compliance	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Efficacy	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Subject discontinuation	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Blinding	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Patient Reported Outcomes	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Other	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Number of participants included in the Per Protocol Set at Day 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
…						

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus.
N is the number of participants in the Exposed Set.

Table 14.1.2
Summary of Protocol Deviations Leading to Elimination from Per Protocol Set
Exposed Set

	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)

n is the number of participants in each category.
Percentages are calculated as 100 * n/N.
Participants with both a withdrawal and an elimination at the timepoint are summarized in the withdrawals only

Programming Notes
Continue for the following visits: Month 2, Month 3, Month 7 and Month 12
Only present categories which do occur.

Output ID: PD0001
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.1.3: Summary of Analysis Sets (Enrolled Set)

Study 213749 - DELIVERY DESIGNATION

Table 14.1.3
Summary of Analysis Sets
Enrolled Set

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Number of participants in enrolled set	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Number of participants in exposed set	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Number of participants in per protocol set at day 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Number of participants in per protocol set at month 2	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Number of participants in per protocol set at month 3	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Number of participants in per protocol set at month 7	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Number of participants in per protocol set at month 12	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Number of participants in CCI [redacted]	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. CCI [redacted]
N is the number of participants in the Enrolled Set.
n is the number of participants in each category.
Percentages are calculated as 100 * n/N.

Programming Notes

Output ID: AS0001
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.1.4.1.1: Summary of Demographic and Baseline Characteristics (Exposed Set)

Study 213749 - DELIVERY DESIGNATION

Table 14.1.4.1.1
Summary of Demographic and Baseline Characteristics
Exposed Set

Characteristic	Statistic	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Age (years) at time of first vaccination	n	x	x	x	x	x
	Mean (SD)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)
	Median	x.x	x.x	x.x	x.x	x.x
	Min - Max	x - x	x - x	x - x	x - x	x - x
Age category (years						
<18	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
>=18	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Race						
Black or African American	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
American Indian or Alaska Native	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Asian	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Native Hawaiian or other Pacific Islander	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
White	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Other*	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Missing	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Ethnicity						
Hispanic or Latino	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Not Hispanic nor Latino	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus.
N is the number of participants in the Exposed Set.

Table 14.1.4.1.1
Summary of Demographic and Baseline Characteristics
Exposed Set

Characteristic	Statistic	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)

n is the number of participants in each category.
Percentages are calculated as 100 * n/N.
* Other includes participants with multiple race categories.

Programming Notes
Missing row only included if 1 or more participant have missing information

Output ID: DM0001
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.1.4.1.2: Summary of Demographic and Baseline Characteristics (Per Protocol Set at Day 1)

Table 14.1.4.1.2
Summary of Demographic and Baseline Characteristics
Per Protocol Set at Day 1

DM0002: This output uses shell DM0001 [Table 14.1.4.1.1]

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus.
N is the number of participants in the Per Protocol Set at Day 1.
n is the number of participants in each category.
Percentages are calculated as 100 * n/N.
* Other includes participants with multiple race categories.

Programming Notes
• Replace footnotes in original shell with those listed above
Missing row only included if 1 or more participant have missing information

Table 14.1.4.1.3: Summary of Demographic and Baseline Characteristics (Per Protocol Set at Month 2)

Table 14.1.4.1.3
Summary of Demographic and Baseline Characteristics
Per Protocol Set at Month 2

DM0002: This output uses shell DM0001 [Table 14.1.4.1.1]

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus.
N is the number of participants in the Per Protocol Set at Month 2.
n is the number of participants in each category.
Percentages are calculated as 100 * n/N.
* Other includes participants with multiple race categories.

Programming Notes
• Replace footnotes in original shell with those listed above
Missing row only included if 1 or more participant have missing information

Table 14.1.4.1.4: Summary of Demographic and Baseline Characteristics (Per Protocol Set at Month 3)

Table 14.1.4.1.4
Summary of Demographic and Baseline Characteristics
Per Protocol Set at Month 3

DM0002: This output uses shell DM0001 [Table 14.1.4.1.1]

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus.
N is the number of participants in the Per Protocol Set at Month 3.
n is the number of participants in each category.
Percentages are calculated as 100 * n/N.
* Other includes participants with multiple race categories.

Programming Notes
• Replace footnotes in original shell with those listed above
Missing row only included if 1 or more participant have missing information

Table 14.1.4.1.5: Summary of Demographic and Baseline Characteristics (Per Protocol Set at Month 6)

Table 14.1.4.1.5
Summary of Demographic and Baseline Characteristics
Per Protocol Set at Month 6

DM0002: This output uses shell DM0001 [Table 14.1.4.1.1]

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus.
N is the number of participants in the Per Protocol Set at Month 6.
n is the number of participants in each category.
Percentages are calculated as 100 * n/N.
* Other includes participants with multiple race categories.

Programming Notes
• Replace footnotes in original shell with those listed above
Missing row only included if 1 or more participant have missing information

Table 14.1.4.1.6: Summary of Demographic and Baseline Characteristics (Per Protocol Set at Month 7)

Table 14.1.4.1.6
Summary of Demographic and Baseline Characteristics
Per Protocol Set at Month 7

DM0002: This output uses shell DM0001 [Table 14.1.4.1.1]

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus.
N is the number of participants in the Per Protocol Set at Month 7.
n is the number of participants in each category.
Percentages are calculated as 100 * n/N.
* Other includes participants with multiple race categories.

Programming Notes
• Replace footnotes in original shell with those listed above
Missing row only included if 1 or more participant have missing information

Table 14.1.4.1.7: Summary of Demographic and Baseline Characteristics (Per Protocol Set at Month 12)

Table 14.1.4.1.7
Summary of Demographic and Baseline Characteristics
Per Protocol Set at Month 12

DM0002: This output uses shell DM0001 [Table 14.1.4.1.1]

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus.
N is the number of participants in the Per Protocol Set at Month 12.
n is the number of participants in each category.
Percentages are calculated as 100 * n/N.
* Other includes participants with multiple race categories.

Programming Notes
• Replace footnotes in original shell with those listed above
Missing row only included if 1 or more participant have missing information

Table 14.1.4.2: Summary of Medical History (Exposed Set)

Study 213749 - DELIVERY DESIGNATION

Table 14.1.4.2
Summary of Medical History
Enrolled Set

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Participants with medical/vaccination history	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
System Organ Class 1						
Preferred term 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Preferred term 2	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Preferred term 3	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
System Organ Class 2						
Preferred term 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Preferred term 2	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
…						

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus.
Medical history coded using MedDRA version xx.x
N is the number of participants in the Enrolled Set.
n is the number of participants in each category.
Percentages are calculated as 100 * n/N.

Programming Notes

Output ID: MH0001
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.1.4.3: Summary of Concomitant Vaccinations (Exposed Set)

Study 213749 - DELIVERY DESIGNATION

Table 14.1.4.3
Summary of Concomitant Vaccinations
Exposed Set

ATC Preferred Term		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Participants with concomitant vaccinations	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
xxxxxxxxxx	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
xxxxxxxxxx	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
xxxxxxxxxx	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
xxxxxxxxxxx	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
…						

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. ATC = Anatomical therapeutic chemical.
N is the number of participants in the Exposed Set.
n is the number of participants in each category.
Percentages are calculated as 100 * n/N.
Concomitant vaccinations coded using WHO drug dictionary version x.x.
Concomitant vaccinations are any vaccines that the participant received at the time of enrolment or received during the study.

Programming Notes

Output ID: CM0001
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.1.4.4: Summary of Participants starting a Concomitant Medication within 30 days following each dose and overall (Exposed Set)

Table 14.1.4.4
Summary of Participants starting a Concomitant Medication within 30 days following each dose and overall
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Any medications	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Any antipyretic	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Any prophylactic antipyretic	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Any antibiotic	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. CI = Confidence Interval.
N is the number of participants in the Exposed Set for each period except Overall dose, where N is the total number of doses in the Exposed Set.
n is the number of participants with an event in the Exposed Set for each period except Overall dose, where n is the total number of doses in the Exposed Set where an event occurs.
Percentages are calculated as 100 * n/N.
95% CI are based on Clopper-Pearson

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.1.5: Study Vaccine Administration (Exposed Set)

GSK Vaccines

Study 213749 - DELIVERY DESIGNATION

Table 14.1.5
Study Vaccine Exposure
Exposed Set

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Exactly 1 dose	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Exactly 2 doses	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Exactly 3 doses	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
At least 1 dose	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
At least 2 doses	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus.
N is the number of participants in the Exposed Set.
n is the number of participants in each category.
Percentages are calculated as 100 * n/N.
Exactly x dose(s) categories are mutually exclusive.

Programming Notes

Output ID: EX0001
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.1.6: Summary of Important Protocol Deviations Leading to Elimination from any analyses (Enrolled Set)

Study 213749 - DELIVERY DESIGNATION

Table 14.1.6
Summary of Important Protocol Deviations Leading to Elimination from any analyses
Enrolled Set

Category Sub category		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
At least one important protocol deviation	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
<Each category>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
<Each sub category>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus.
N is the number of participants in the enrolled set.
n is the number of participants in each category.
Percentages are calculated as 100 * n/N.

Programming Notes

Output ID: AS0001
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.2.1.1: Summary of anti-HPV IgG Antibody GMCs and seropositivity for each antigen at Day 1, Month 2, Month 3, Month 6, Month 7 and Month 12 (Per Protocol Set)

Study 213749 - DELIVERY DESIGNATION

Table 14.2.1.1
Summary of anti-HPV IgG Antibody GMCs and seropositivity for each antigen at Day 1, Month 2, Month 3, Month 6, Month 7 and Month 12
Per Protocol Set

Antigen: xxx (LLOQ = xx; ULOQ = xx; Unit = xx)

Visit	Pre-vaccination status		HPV9 High	HPV9 Medium	HPV9 Low	Gardasil 9
Day 1	Seronegative	N	xxx	xxx	xxx	xxx
		n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		95% CI seropositivity	x.x - x.x	x.x - x.x	x.x - x.x	x.x - x.x
		GMC (GSD)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)
		Median	x.x	x.x	x.x	x.x
		Min - Max	x - x	x - x	x - x	x - x
		95% CI GMC	x.x - x.x	x.x - x.x	x.x - x.x	x.x - x.x
	Seropositive	N	xxx	xxx	xxx	xxx
		n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		95% CI seropositivity	x.x - x.x	x.x - x.x	x.x - x.x	x.x - x.x
		GMC (GSD)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)
		Median	x.x	x.x	x.x	x.x
		Min - Max	x - x	x - x	x - x	x - x
		95% CI GMC	x.x - x.x	x.x - x.x	x.x - x.x	x.x - x.x
		n > ULOQ	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	N	xxx	xxx	xxx	xxx
		n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		95% CI seropositivity	x.x - x.x	x.x - x.x	x.x - x.x	x.x - x.x
		GMC (GSD)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)
		Median	x.x	x.x	x.x	x.x
		Min - Max	x - x	x - x	x - x	x - x
		95% CI GMC	x.x - x.x	x.x - x.x	x.x - x.x	x.x - x.x

Table 14.2.1.1
Summary of anti-HPV IgG Antibody GMCs and seropositivity for each antigen at Day 1, Month 2, Month 3, Month 6, Month 7 and Month 12
Per Protocol Set

Antigen: xxx (LLOQ = xx; ULOQ = xx; Unit = xx)

Visit	Pre-vaccination status		HPV9 High	HPV9 Medium	HPV9 Low	Gardasil 9
		n > ULOQ	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Month 2	Seronegative	N	x	x	x	x
		n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		95% CI seropositivity	x.x - x.x	x.x - x.x	x.x - x.x	x.x - x.x
		GMC (GSD)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)
		Median	x.x	x.x	x.x	x.x
		Min - Max	x - x	x - x	x - x	x - x
		95% CI GMC	x.x - x.x	x.x - x.x	x.x - x.x	x.x - x.x
		n > ULOQ	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.						

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. GMC = Geometric Mean Concentration. GSD = Geometric Standard Deviation. LLOQ = Lower Limit of Quantification. ULOQ = Upper Limit of Quantification.
N = number of participants in the Per Protocol Set at each visit and pre-vaccination status.
n (%) = number/percentage of participants with concentration equal or above LLOQ.
95% CI GMC = 95% confidence interval derived using the log10-transformed antibody concentration.
Seronegative is defined as the situation where antibodies are not elevated (i.e, concentrations less than the LLOQ) in the serum of participants.
Seropositive is defined as the appearance of antibodies (i.e, concentrations greater than or equal to the LLOQ) in the serum of participants.

The concentration below the LLOQ will be replaced by half the LLOQ (LLOQ/2). Concentration above the ULOQ will be replaced by the ULOQ.

Programming Notes

Output ID: IM0001
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.2.1.2: Summary of anti-HPV IgG Antibody GMCs and seropositivity for each antigen at Day 1, Month 2, Month 3, Month 6, Month 7 and Month 12 (Exposed Set)

Table 14.2.1.2
Summary of anti-HPV IgG Antibody GMCs and seropositivity for each antigen at Day 1, Month 2, Month 3, Month 6, Month 7 and Month 12
Exposed Set

IM0002: This output uses shell IM0001 [Table 14.2.1.1]

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. GMC = Geometric Mean Concentration. GSD = Geometric Standard Deviation. LLOQ = Lower Limit of Quantification. ULOQ = Upper Limit of Quantification.
N = number of participants in the Exposed Set at each visit and pre-vaccination status.
n (%) = number/percentage of participants with concentration equal or above LLOQ.
95% CI = 95% confidence interval derived using the log10-transformed antibody concentration.
Seronegative is defined as the situation where antibodies are not elevated (i.e, concentrations less than the LLOQ) in the serum of participants.
Seropositive is defined as the appearance of antibodies (i.e, concentrations greater than or equal to the LLOQ) in the serum of participants.

The concentration below the assay LLOQ will be replaced by half the LLOQ (LLOQ/2). Concentration above the ULOQ will be replaced by the ULOQ.

Programming Notes
- *Replace footnotes in original shell with those listed above*

- *Table is only required when >5% of participants have been excluded from the PPS when compared with the ES*

Table 14.2.2.1.1: Ratio of anti-HPV IgG Antibody GMCs for each antigen at Month 3 and Month 7 between Groups (HPV group [different potencies - Low, Med, High] divided by Gardasil 9 group) (Per Protocol Set)

Study 213749 - DELIVERY DESIGNATION

Table 14.2.2.1.1
Ratio of anti-HPV IgG Antibody GMCs for each antigen at Month 3 and Month 7 between Groups (HPV group [different potencies - Low, Med, High] divided by Gardasil 9 group)
Per Protocol Set

Antigen: xxx (LLOQ = xx; ULOQ = xx; Unit = xx)

Pre-vaccination status		HPV9 Group N	HPV9 Group Adjusted GMC	Gardasil 9 Group N	Gardasil 9 Group Adjusted GMC	Group GMC Ratio Value	Group GMC Ratio 95% CI
Seronegative	anti-HPV IgG concentration at Month 3						
	HPV9 High / Gardasil 9	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 Medium / Gardasil 9	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 Low / Gardasil 9	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
Seropositive	anti-HPV IgG concentration at Month 3						
	HPV9 High / Gardasil 9	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 Medium / Gardasil 9	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 Low / Gardasil 9	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
Total	anti-HPV IgG concentration at Month 3						
	HPV9 High / Gardasil 9	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 Medium / Gardasil 9	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 Low / Gardasil 9	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
Seronegative	anti-HPV IgG concentration at Month 7						
	HPV9 High / Gardasil 9	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 Medium / Gardasil 9	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 Low / Gardasil 9	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x

…

Table 14.2.2.1.1
Ratio of anti-HPV IgG Antibody GMCs for each antigen at Month 3 and Month 7 between Groups (HPV group [different potencies - Low, Med, High] divided by Gardasil 9 group)
Per Protocol Set

Antigen: xxx (LLOQ = xx; ULOQ = xx; Unit = xx)

Pre-vaccination status	HPV9 Group		Gardasil 9 Group		Group GMC Ratio	
	N	Adjusted GMC	N	Adjusted GMC	Value	95% CI

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. GMC = Geometric Mean Concentration.
N = Number of participants with available results
The analysis is based on ANOVA model with log10 transformed anti-gE antibody concentration values as response variable and the study group and country as fixed effects.
Seronegative is defined as the situation where antibodies are not elevated (i.e, concentrations less than the LLOQ) in the serum of participants.
Seropositive is defined as the appearance of antibodies (i.e, concentrations greater than or equal to the LLOQ) in the serum of participants.
95% CI GMC = 95% confidence interval derived using the log-transformed antibody concentration.
The concentration below the assay cut-off will be replaced by half the cut-off (LLOQ/2). Concentration above the ULOQ will be replaced by the ULOQ
Programming Notes

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM
Output ID: IM0003

Table 14.2.2.1.2: Ratio of anti-HPV IgG Antibody GMCs for each antigen at Month 3 and Month 7 between HPV Groups (Per Protocol Set)

Study 213749 - DELIVERY DESIGNATION

Table 14.2.2.1.2
Ratio of anti-HPV IgG Antibody GMCs for each antigen at Month 3 and Month 7 between HPV Groups
Per Protocol Set

Antigen: xxx (LLOQ = xx; ULOQ = xx; Unit = xx)

Pre-vaccination status		First Group N	First Group Adjusted GMC	Second Group N	Second Group Adjusted GMC	Group GMC Ratio Value	Group GMC Ratio 95% CI
Seronegative	anti-HPV IgG concentration at Month 3						
	HPV9 High / HPV9 Medium	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 Medium / HPV9 Low	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 High / HPV9 Low	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
Seropositive	anti-HPV IgG concentration at Month 3						
	HPV9 High / HPV9 Medium	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 Medium / HPV9 Low	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 High / HPV9 Low	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
Total	anti-HPV IgG concentration at Month 3						
	HPV9 High / HPV9 Medium	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 Medium / HPV9 Low	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 High / HPV9 Low	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
Seronegative	anti-HPV IgG concentration at Month 7						
	HPV9 High / HPV9 Medium	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 Medium / HPV9 Low	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 High / HPV9 Low	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x

…

Table 14.2.2.1.2
Ratio of anti-HPV IgG Antibody GMCs for each antigen at Month 3 and Month 7 between HPV Groups
Per Protocol Set

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. GMC = Geometric Mean Concentration.
N = Number of participants with available results
The analysis is based on ANOVA model with log10 transformed anti-gE antibody concentration values effect as response variable and the study group and country as fixed effects.
Seronegative is defined as the situation where antibodies are not elevated (i.e, concentrations less than the LLOQ) in the serum of participants.
Seropositive is defined as the appearance of antibodies (i.e, concentrations greater than or equal to the LLOQ) in the serum of participants.
95% CI = 95% confidence interval derived using the log-transformed antibody concentration.
The concentration below the assay cut-off will be replaced by half the cut-off (LLOQ/2). Concentration above the ULOQ will be replaced by the ULOQ
Programming Notes

Programming Notes

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM
Output ID: IM0003

Table 14.2.2.2: Differences of anti-HPV IgG Antibody Seroconversion Rate for each antigen at Month 3 and Month 7 between Groups (HPV group [different potencies - Low, Med, High] and Gardasil9 group) (Per Protocol Set)

Study 213749 - DELIVERY DESIGNATION

Table 14.2.2.2
Differences of anti-HPV IgG Antibody Seroconversion Rate for each antigen at Month 3 and Month 7 between Groups (HPV group [different potencies - [Low, Med, High] and Gardasil9 group]
Per Protocol Set

Antigen: xxx (LLOQ = xx; ULOQ = xx; Unit = xx)

	First Study Group		Second Study Group		Difference	
	N	n (%)	N	n (%)	%	95% CI
Seroconversion Rate at Month 3						
HPV9 High - Gardasil 9	xx	xx (xx.x)	xx	xx (xx.x)	xx.x	xx.x; xx.x
HPV9 Medium - Gardasil 9	xx	xx (xx.x)	xx	xx (xx.x)	xx.x	xx.x; xx.x
HPV9 Low - Gardasil 9	xx	xx (xx.x)	xx	xx (xx.x)	xx.x	xx.x; xx.x
HPV9 High - HPV9 Low	xx	xx (xx.x)	xx	xx (xx.x)	xx.x	xx.x; xx.x
HPV9 Medium - HPV9 Low	xx	xx (xx.x)	xx	xx (xx.x)	xx.x	xx.x; xx.x
HPV9 High - HPV9 Medium	xx	xx (xx.x)	xx	xx (xx.x)	xx.x	xx.x; xx.x
Seroconversion Rate at Month 7						
HPV9 High - Gardasil 9	xx	xx (xx.x)	xx	xx (xx.x)	xx.x	xx.x; xx.x
HPV9 Medium - Gardasil 9	xx	xx (xx.x)	xx	xx (xx.x)	xx.x	xx.x; xx.x
HPV9 Low - Gardasil 9	xx	xx (xx.x)	xx	xx (xx.x)	xx.x	xx.x; xx.x
HPV9 High - HPV9 Low	xx	xx (xx.x)	xx	xx (xx.x)	xx.x	xx.x; xx.x
HPV9 Medium - HPV9 Low	xx	xx (xx.x)	xx	xx (xx.x)	xx.x	xx.x; xx.x
HPV9 High - HPV9 Medium	xx	xx (xx.x)	xx	xx (xx.x)	xx.x	xx.x; xx.x

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus.
N = Number of participants with available results who were seronegative (i.e, concentrations less than the LLOQ) at baseline.
n (%) = number/percentage of participants with concentration equal or above specified value.
Seroconversion is defined as the appearance of antibodies (i.e, concentrations greater than or equal to the LLOQ) in the serum of participants seronegative before vaccination

Table 14.2.2.2
Differences of anti-HPV IgG Antibody Seroconversion Rate for each antigen at Month 3 and Month 7 between Groups (HPV group [different potencies - [Low, Med, High] and Gardasil9 group]
Per Protocol Set

Antigen: xxx (LLOQ = xx; ULOQ = xx; Unit = xx)

	First Study Group		Second Study Group		Difference	
	N	n (%)	N	n (%)	%	95% CI

95% CI = 95% confidence interval computed based on Miettinen and Nurminen method.
The concentration below the assay cut-off will be replaced by half the cut-off (LLOQ/2). Concentration above the ULOQ will be replaced by the ULOQ
Programming Notes

Table 14.2.2.3: Summary of anti-HPV Neutralizing Antibody GMTs and seropositivity for each antigen at Day 1, Month 2, Month 3 and Month 7 (Per Protocol Set)

Study 213749 - DELIVERY DESIGNATION

Table 14.2.2.3
Summary of anti-HPV Neutralizing Antibody GMTs and seropositivity for each antigen at Day 1, Month 2, Month 3 and Month 7
Per Protocol Set

Antigen: xxx (LLOQ = xx; ULOQ = xx; Unit = xx)

Visit	Pre-vaccination status		HPV9 High	HPV9 Medium	HPV9 Low	Gardasil 9
Day 1	Seronegative	N	xxx	xxx	xxx	xxx
		n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		95% CI seropositivity	x.x - x.x	x.x - x.x	x.x - x.x	x.x - x.x
		GMT (GSD)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)
		Median	x.x	x.x	x.x	x.x
		Min - Max	x - x	x - x	x - x	x - x
		95% CI GMT	x.x - x.x	x.x - x.x	x.x - x.x	x.x - x.x
	Seropositive	N	xxx	xxx	xxx	xxx
		n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		95% CI seropositivity	x.x - x.x	x.x - x.x	x.x - x.x	x.x - x.x
		GMT (GSD)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)
		Median	x.x	x.x	x.x	x.x
		Min - Max	x - x	x - x	x - x	x - x
		95% CI GMT	x.x - x.x	x.x - x.x	x.x - x.x	x.x - x.x
		n > ULOQ	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	N	xxx	xxx	xxx	xxx
		n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		95% CI seropositivity	x.x - x.x	x.x - x.x	x.x - x.x	x.x - x.x
		GMT (GSD)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)
		Median	x.x	x.x	x.x	x.x
		Min - Max	x - x	x - x	x - x	x - x
		95% CI GMT	x.x - x.x	x.x - x.x	x.x - x.x	x.x - x.x
		n > ULOQ	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Table 14.2.2.3
Summary of anti-HPV Neutralizing Antibody GMTs and seropositivity for each antigen at Day 1, Month 2, Month 3 and Month 7
Per Protocol Set

Antigen: xxx (LLOQ = xx; ULOQ = xx; Unit = xx)

Visit	Pre-vaccination status		HPV9 High	HPV9 Medium	HPV9 Low	Gardasil 9
Month 2	Seronegative	N	x	x	x	x
		n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		95% CI seropositivity	x.x - x.x	x.x - x.x	x.x - x.x	x.x - x.x
		GMT (GSD)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)
		Median	x.x	x.x	x.x	x.x
		Min - Max	x - x	x - x	x - x	x - x
		95% CI GMT	x.x - x.x	x.x - x.x	x.x - x.x	x.x - x.x
		n > ULOQ	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.						

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. GMT = Geometric Mean Titer. GSD = Geometric Standard Deviation. LLOQ = Lower Limit of Quantification. ULOQ = Upper Limit of Quantification.
N = number of participants in the Per Protocol Set at each visit and pre-vaccination status.
n (%) = number/percentage of participants with titer equal or above LLOQ.
95% CI GMT = 95% confidence interval derived using the log10-transformed antibody titers.
Seronegative is defined as the situation where antibodies are not elevated (i.e, titers less than the LLOQ) in the serum of participants.
Seropositive is defined as the appearance of antibodies (i.e, titers greater than or equal to the LLOQ) in the serum of participants.

The titer below the LLOQ will be replaced by half the LLOQ (LLOQ/2). Titer above the ULOQ will be replaced by the ULOQ.

Programming Notes

Programming Notes

Output ID: IM0005
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.2.2.4.1: Ratio of anti-HPV Neutralizing Antibody GMTs for each antigen at Month 3 and Month 7 between Groups (HPV group [different potencies - Low, Med, High] divided by Gardasil 9 group) (Per Protocol Set)

Table 14.2.2.4.1
Ratio of anti-HPV Neutralizing Antibody GMTs for each antigen at Month 3 and Month 7 between Groups (HPV group [different potencies - Low, Med, High] divided by Gardasil 9 group)
Per Protocol Set

Antigen: xxx (LLOQ = xx; ULOQ = xx; Unit = xx)

Pre-vaccination status		HPV9 Group N	HPV9 Group Adjusted GMT	Gardasil 9 Group N	Gardasil 9 Group Adjusted GMT	Group GMT Ratio Value	Group GMT Ratio 95% CI
Seronegative	anti-HPV Neutralizing titer at Month 3						
	HPV9 High / Gardasil 9	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 Medium / Gardasil 9	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 Low / Gardasil 9	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
Seropositive	anti-HPV Neutralizing titer at Month 3						
	HPV9 High / Gardasil 9	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 Medium / Gardasil 9	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 Low / Gardasil 9	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
Total	anti-HPV Neutralizing titer at Month 3						
	HPV9 High / Gardasil 9	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 Medium / Gardasil 9	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 Low / Gardasil 9	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
Seronegative	anti-HPV Neutralizing titer at Month 7						
	HPV9 High / Gardasil 9	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 Medium / Gardasil 9	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 Low / Gardasil 9	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x

…

Table 14.2.2.4.1
Ratio of anti-HPV Neutralizing Antibody GMTs for each antigen at Month 3 and Month 7 between Groups (HPV group [different potencies - Low, Med, High] divided by Gardasil 9 group)
Per Protocol Set

Antigen: xxx (LLOQ = xx; ULOQ = xx; Unit = xx)

Pre-vaccination status	HPV9 Group		Gardasil 9 Group		Group GMT Ratio	
	N	Adjusted GMT	N	Adjusted GMT	Value	95% CI

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. GMT = Geometric Mean Titer.
N = Number of participants with available results
The analysis is based on ANOVA model with log10 transformed anti-gE antibody titers values as response variable and the study group and country as fixed effects.
Seronegative is defined as the situation where antibodies are not elevated (i.e, titers less than the LLOQ) in the serum of participants.
Seropositive is defined as the appearance of antibodies (i.e, titers greater than or equal to the LLOQ) in the serum of participants.
95% CI GMT = 95% confidence interval derived using the log-transformed antibody titers.
The titer below the LLOQ will be replaced by half the LLOQ (LLOQ/2). Titer above the ULOQ will be replaced by the ULOQ.
Programming Notes

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM
Output ID: IM0003

Table 14.2.2.4.2: Ratio of anti-HPV Neutralizing Antibody GMTs for each antigen at Month 3 and Month 7 between HPV Groups (Per Protocol Set)

Table 14.2.2.4.2
Ratio of anti-HPV Neutralizing Antibody GMTs for each antigen at Month 3 and Month 7 between HPV Groups
Per Protocol Set

Antigen: xxx (LLOQ = xx; ULOQ = xx; Unit = xx)

Pre-vaccination status		First Group N	First Group Adjusted GMT	Second Group N	Second Group Adjusted GMT	Group GMT Ratio Value	Group GMT Ratio 95% CI
Seronegative	anti-HPV Neutralizing titer at Month 3						
	HPV9 High / HPV9 Medium	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 Medium / HPV9 Low	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 High / HPV9 Low	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
Seropositive	anti-HPV Neutralizing titer at Month 3						
	HPV9 High / HPV9 Medium	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 Medium / HPV9 Low	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 High / HPV9 Low	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
Total	anti-HPV Neutralizing titer at Month 3						
	HPV9 High / HPV9 Medium	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 Medium / HPV9 Low	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 High / HPV9 Low	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
Seronegative	anti-HPV Neutralizing titer at Month 7						
	HPV9 High / HPV9 Medium	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 Medium / HPV9 Low	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x
	HPV9 High / HPV9 Low	xx	xx.x	xx	xx.x	xx.x	xx.x; xx.x

…

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. GMT = Geometric Mean Titer.
N = Number of participants with available results

The analysis is based on ANOVA model with log10 transformed anti-gE antibody titers values as response variable and the study group and country as fixed effect.
Seronegative is defined as the situation where antibodies are not elevated (i.e, titers less than the LLOQ) in the serum of participants.
Seropositive is defined as the appearance of antibodies (i.e, titers greater than or equal to the LLOQ) in the serum of participants.
95% CI GMT = 95% confidence interval derived using the log-transformed antibody titers.
The titer below the LLOQ will be replaced by half the LLOQ (LLOQ/2). Titer above the ULOQ will be replaced by the ULOQ.
Programming Notes

Programming Notes

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM
Output ID: IM0013

Table 14.2.2.5: Differences of anti-HPV Neutralizing Antibody Seroconversion Rate for each antigen at Month 3 and Month 7 between Groups (HPV group [different potencies - Low, Med, High] and Gardasil9 group) (Per Protocol Set)

Study 213749 - DELIVERY DESIGNATION

Table 14.2.2.5
Differences of anti-HPV Neutralizing Antibody Seroconversion Rate for each antigen at Month 3 and Month 7 between Groups (HPV group [different potencies - Low, Med, High] and Gardasil9 group)
Per Protocol Set

Antigen: xxx (LLOQ = xx; ULOQ = xx; Unit = xx)

	First Study Group		Second Study Group		Difference	
	N	n (%)	N	n (%)	%	95% CI
Seroconversion Rate at Month 3						
HPV9 High - Gardasil 9	xx	xx (xx.x)	xx	xx (xx.x)	xx.x	xx.x; xx.x
HPV9 Medium - Gardasil 9	xx	xx (xx.x)	xx	xx (xx.x)	xx.x	xx.x; xx.x
HPV9 Low - Gardasil 9	xx	xx (xx.x)	xx	xx (xx.x)	xx.x	xx.x; xx.x
HPV9 High - HPV9 Low	xx	xx (xx.x)	xx	xx (xx.x)	xx.x	xx.x; xx.x
HPV9 Medium - HPV9 Low	xx	xx (xx.x)	xx	xx (xx.x)	xx.x	xx.x; xx.x
HPV9 High - HPV9 Medium	xx	xx (xx.x)	xx	xx (xx.x)	xx.x	xx.x; xx.x
Seroconversion Rate at Month 7						
HPV9 High - Gardasil 9	xx	xx (xx.x)	xx	xx (xx.x)	xx.x	xx.x; xx.x
HPV9 Medium - Gardasil 9	xx	xx (xx.x)	xx	xx (xx.x)	xx.x	xx.x; xx.x
HPV9 Low - Gardasil 9	xx	xx (xx.x)	xx	xx (xx.x)	xx.x	xx.x; xx.x
HPV9 High - HPV9 Low	xx	xx (xx.x)	xx	xx (xx.x)	xx.x	xx.x; xx.x
HPV9 Medium - HPV9 Low	xx	xx (xx.x)	xx	xx (xx.x)	xx.x	xx.x; xx.x
HPV9 High - HPV9 Medium	xx	xx (xx.x)	xx	xx (xx.x)	xx.x	xx.x; xx.x

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus.
N = Number of participants with available results who were seronegative (i.e, concentrations less than the LLOQ) at baseline.
n (%) = number/percentage of participants with concentration equal or above specified value.
Seroconversion is defined as the appearance of antibodies (i.e, titers greater than or equal to the LLOQ) in the serum of participants seronegative before vaccination

Table 14.2.2.5
Differences of anti-HPV Neutralizing Antibody Seroconversion Rate for each antigen at Month 3 and Month 7 between Groups (HPV group [different potencies - Low, Med, High] and Gardasil9 group)
Per Protocol Set

Antigen: xxx (LLOQ = xx; ULOQ = xx; Unit = xx)

	First Study Group		Second Study Group		Difference	
	N	n (%)	N	n (%)	%	95% CI

95% CI = 95% CI computed based on Miettinen and Nurminen method.
The titer below the LLOQ will be replaced by half the LLOQ (LLOQ/2). Titer above the ULOQ will be replaced by the ULOQ.
Programming Notes

Table 14.2.2.6: Correlation between anti-HPV Immunoglobulin Antibody Concentration and anti-HPV Neutralizing Antibody Titers for each antigen at Day 1, Month 2, Month 3 and Month 7 (Per Protocol Set)

GSK Vaccines Page X of Y

Study 213749 - DELIVERY DESIGNATION

Table 14.2.2.6
Correlation between anti-HPV Immunoglobulin Antibody Concentration and anti-HPV Neutralizing Antibody Titers for each antigen at Day 1, Month 2, Month 3 and Month 7
Per Protocol Set

Antigen: xxx

Study Dose	Visit	n	Pearson coefficient of correlation	p-value
HPV9 High	Day 1	xx	x.xxx	0.xxx
	Month 2	xx	x.xxx	0.xxx
	Month 3	xx	x.xxx	0.xxx
	Month 7	xx	x.xxx	0.xxx
	Overall	xx	x.xxx	0.xxx
HPV9 Medium	Day 1	xx	x.xxx	0.xxx
	Month 2	xx	x.xxx	0.xxx
	Month 3	xx	x.xxx	0.xxx
	Month 7	xx	x.xxx	0.xxx
	Overall	xx	x.xxx	0.xxx
…				

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus.
n is the number of samples with both concentration and titer values.

Pearson correlation will be computed by the log10-transformation of the antibody concentration.
Samples testing below the LLOQ or above the ULOQ in either assay were excluded from the analysis.

Programming Notes

```
Output ID: IM0007
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749
(HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM
```

Table 14.2.2.7: Functional Relationship between the Assay Methods for each antigen (Per Protocol Set)

Study 213749 - DELIVERY DESIGNATION

Table 14.2.2.7
Functional Relationship between the Assay Methods for each antigen
Per Protocol Set

Antigen: xxx

Study Dose	Visit	n	Intercept (95% CI for Intercept)	Slope (95% CI for slope)
HPV9-High	Day 1	xxx	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)
	Month 2	xxx	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)
	Month 3	xxx	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)
	Month 7	xxx	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)
	Overall	xxx	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)
HPV9-Medium	Day 1	xxx	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)
	Month 2	xxx	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)
	Month 3	xxx	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)
	Month 7	xxx	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)
	Overall	xxx	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)
HPV9-Low		xxx	xx.xx (xx.xx, xx.xx)	xx.xx (xx.xx, xx.xx)
Gardasil 9				

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. ECL = Electrochemiluminescence assay. PBNA = Pseudovirion-Based Neutralization Assay
n is the number of samples with both concentration and titer values.
Deming's regression model is fitted to the Anti-HPV IgG antibody concentration (ECL) with Anti-HPV Neutralizing titers (PBNA) as a covariate.
Deming's regression will be computed by the log10-transformation of the antibody concentration and neutralizing titer.
Samples testing below the LLOQ or above the ULOQ in either assay were excluded from the assay.

Table 14.2.2.7
Functional Relationship between the Assay Methods for each antigen
Per Protocol Set

Antigen: xxx

Study Dose	Visit	n	Intercept (95% CI for Intercept)	Slope (95% CI for slope)

Programming Notes

Output ID: IM0008
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.2.2.8 Summary of qualitative comparison between ECL and PBNA for each antigen by time point (Per Protocol Set)

Table 14.2.2.8
Summary of qualitative comparison between ECL and PBNA for each antigen by time point
Per Protocol Set

Antigen: xxx

Study dose	Visit	n	Pos/ Pos	Neg/ Neg	Pos/ Neg	Neg/ Pos	IgG % +ve	Neutralizing titers % +ve	Agreement rate %	Kappa	McNema p-value	Kappa p-value
HPV9-High	Day 1	xx	xx	xx	xx	xx	xx	xx	xx	xx	0.xxx	0.xxx
	Month 2	xx	xx	xx	xx	xx	xx	xx	xx	xx	0.xxx	0.xxx
	Month 3	xx	xx	xx	xx	xx	xx	xx	xx	xx	0.xxx	0.xxx
	Month 7	xx	xx	xx	xx	xx	xx	xx	xx	xx	0.xxx	0.xxx
	Overall	xx	xx	xx	xx	xx	xx	xx	xx	xx	0.xxx	0.xxx
HPV9-Medium	Day 1	xx	xx	xx	xx	xx	xx	xx	xx	xx	0.xxx	0.xxx
	Month 2	xx	xx	xx	xx	xx	xx	xx	xx	xx	0.xxx	0.xxx
	Month 3	xx	xx	xx	xx	xx	xx	xx	xx	xx	0.xxx	0.xxx
	Month 7	xx	xx	xx	xx	xx	xx	xx	xx	xx	0.xxx	0.xxx
	Overall	xx	xx	xx	xx	xx	xx	xx	xx	xx	0.xxx	0.xxx
HPV9-Low												
Gardasil 9												
Total												

Abbreviations: HPV = Human Papillomavirus. ECL = Electrochemiluminescence assay. PBNA = pseudovirion-based neutralization assay.
n is the number of samples with both concentration and titer values are available.
Percentages are based on n.
Pos/Pos is the number of participants seropositive with both ECL and PBNA.
Neg/Neg is the number of participants seronegative with both ECL and PBNA.
Pos/Neg is the number of participants seropositive with ECL and seronegative with PBNA.
Neg/Pos is the number of participants seronegative with ECL and seropositive with PBNA.
Seronegative is defined as the situation where antibodies are not elevated (i.e, concentrations less than the LLOQ) in the serum of participants.

Table 14.2.2.8
Summary of qualitative comparison between ECL and PBNA for each antigen by time point
Per Protocol Set

Antigen: xxx

Study dose	Visit	n	Pos/ Pos	Neg/ Neg	Pos/ Neg	Neg/ Pos	IgG % +ve	Neutralizing titers % +ve	Agreement rate %	Kappa	McNema p-value	Kappa p-value

Seropositive is defined as the appearance of antibodies (i.e, concentrations greater than or equal to the LLOQ) in the serum of participants.

Programming Notes

Output ID: LS0014
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

CCI

[redacted]


CCI

Table 14.3.1.1: Overall Summary of Grade 3 Solicited Administration Site Events and Solicited Systemic Events Reported within 7 days (Days 1-7) after each vaccine dose and overall (Exposed Set)

GSK Vaccines

Study 213749 - DELIVERY DESIGNATION

Table 14.3.1.1
Overall Summary of Grade 3 Solicited Administration Site Events and Solicited Systemic Events Reported within 7 days (Days 1-7) after each vaccine dose and overall
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Any grade 3 solicited event	n (%) [95% CI] e	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x
Any grade 3 solicited administration site event	n (%) [95% CI] e	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x
Any grade 3 solicited systemic event	n (%) [95% CI] e	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. CI = Confidence Interval.
N is the number of participants in the Exposed Set for each period except Overall dose, where N is the total number of doses in the Exposed Set.
n is the number of participants with an event in the Exposed Set for each period except Overall dose, where n is the total number of doses in the Exposed Set where an event occurs.
Percentages are calculated as 100 * n/N.
95% CI are based on Clopper-Pearson

e is the number of events; participants with events in more than one preferred term are counted once in each of those preferred terms.
Includes AEs with an onset date on or after the date of first vaccine up to Data Lock Point.

MedDRA version xx.x.

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Output ID: SE0001
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.3.1.2.1: Number and Percentage of Participants of each Grade 3 Solicited Administration Site Events Reported within 7 days (Days 1-7) after each vaccine dose and overall (Exposed Set)

Table 14.3.1.2.1
Number and Percentage of Participants of each Grade 3 Solicited Administration Site Events Reported within 7 days (Days 1-7) after each vaccine dose and overall
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
At least one grade 3 solicited administration site event	n (%) [95% CI] e	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x
Injection site pain	n (%) [95% CI]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]
Redness at injection site	n (%) [95% CI]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]
Swelling at injection site	n (%) [95% CI]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]
At least one grade 3 solicited administration site event leading to medical attention	n (%) [95% CI] e	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x
Injection site pain	n (%) [95% CI]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]
Redness at injection site	n (%) [95% CI]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]
Swelling at injection site	n (%) [95% CI]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. CI = Confidence Interval.

Table 14.3.1.2.1
Number and Percentage of Participants of each Grade 3 Solicited Administration Site Events Reported within 7 days (Days 1-7) after each vaccine dose and overall
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)

N is the number of participants in the Exposed Set for each period except Overall dose, where N is the total number of doses in the Exposed Set.
n is the number of participants with an event in the Exposed Set for each period except Overall dose, where n is the total number of doses in the Exposed Set where an event occurs.
e is the number of events.
Percentages are calculated as 100 * n/N.

95% CI are based on Clopper-Pearson

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.3.1.2.2: Summary of duration of Grade 3 Solicited Administration Site Events Reported within 7 days (Days 1-7) after each vaccine dose and overall (Exposed Set)

Study 213749 - DELIVERY DESIGNATION

Table 14.3.1.2.2
Summary of duration of Grade 3 Solicited Administration Site Events Reported within 7 days (Days 1-7) after each vaccine dose and overall
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose)

Event	Statistic	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Injection Site Pain	n	x	x	x	x	x
	Mean (SD)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)
	Median	x.x	x.x	x.x	x.x	x.x
	Q1 - Q3	x - x	x - x	x - x	x - x	x - x
	Min - Max	x - x	x - x	x - x	x - x	x - x
Redness at Injection Site	n	x	x	x	x	x
	Mean (SD)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)
	Median	x.x	x.x	x.x	x.x	x.x
	Q1 - Q3	x - x	x - x	x - x	x - x	x - x
	Min - Max	x - x	x - x	x - x	x - x	x - x
Swelling at Injection Site	n	x	x	x	x	x
	Mean (SD)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)
	Median	x.x	x.x	x.x	x.x	x.x
	Q1 - Q3	x - x	x - x	x - x	x - x	x - x
	Min - Max	x - x	x - x	x - x	x - x	x - x

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus.
N is the number of participants in the Exposed Set for each period except Overall dose, where N is the total number of doses in the Exposed Set.
n is the number of participants with an event in the Exposed Set for each period except Overall dose, where n is the total number of doses in the Exposed Set where an event occurs.

Table 14.3.1.2.2
Summary of duration of Grade 3 Solicited Administration Site Events Reported within 7 days (Days 1-7) after each vaccine dose and overall
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose)

Event	Statistic	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)

Programming Notes

Output ID: DUR0001
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.3.1.2.3: Number and percentage of participants with Grade 3 Solicited Administration Site Events Reported within 7 days (Days 1-7) after each vaccine dose and overall by days of duration (Exposed Set)

Table 14.3.1.2.3
Number and percentage of participants with Grade 3 Solicited Administration Site Events Reported within 7 days (Days 1-7) after each vaccine dose and overall by days of duration
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Injection Site Pain						
N*		x	x	x	x	x
1 day	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
2 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
3 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
4 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
>=5 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Redness at Injection Site						
N*		x	x	x	x	x
1 day	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
2 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
3 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
4 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
>=5 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Swelling at Injection Site						
N*		x	x	x	x	x
1 day	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
2 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
3 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
4 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
>=5 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)

Table 14.3.1.2.3
Number and percentage of participants with Grade 3 Solicited Administration Site Events Reported within 7 days (Days 1-7) after each vaccine dose and overall by days of duration
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (participant)

	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus.
N is the number of participants in the Exposed Set for each period except Overall dose, where N is the total number of doses in the Exposed Set.
N* is the number of participants with an event in the Exposed Set for each period except Overall dose, where n is the total number of doses in the Exposed Set where an event occurs
n is the number of participants with a specified duration of an event
Percentages are calculated as 100 * n/N*.

Table 14.3.1.3.1: Number and Percentage of Participants of each Grade 3 Solicited Systemic Events Reported within 7 days (Days 1-7) after each vaccine dose and overall (Exposed Set)

Table 14.3.1.3.1
Number and Percentage of Participants of each Grade 3 Solicited Systemic Events Reported within 7 days (Days 1-7) after each vaccine dose and overall
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
At least one grade 3 solicited systemic event	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
Fever	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Headache	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Myalgia	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Arthralgia	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Fatigue	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
At least one grade 3 solicited systemic event leading to medical attention	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
Fever	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Headache	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Myalgia	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Arthralgia	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)

Table 14.3.1.3.1
Number and Percentage of Participants of each Grade 3 Solicited Systemic Events Reported within 7 days (Days 1-7) after each vaccine dose and overall
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Fatigue	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. CI = Confidence Interval.
N is the number of participants in the Exposed Set for each period except Overall dose, where N is the total number of doses in the Exposed Set.
n is the number of participants with an event in the Exposed Set for each period except Overall dose, where n is the total number of doses in the Exposed Set where an event occurs.
e is the number of events.
Percentages are calculated as 100 * n/N.

95% CI are based on Clopper-Pearson

Table 14.3.1.3.2: Summary of duration of Grade 3 Solicited Systemic Events Reported within 7 days (Days 1-7) after each vaccine dose and overall (Exposed Set)

Study 213749 - DELIVERY DESIGNATION

Table 14.3.1.3.2
Summary of duration of Grade 3 Solicited Systemic Events Reported within 7 days (Days 1-7) after each vaccine dose and overall
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose)

Event	Statistic	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Fever	n	x	x	x	x	x
	Mean (SD)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)
	Median	x.x	x.x	x.x	x.x	x.x
	Q1 - Q3	x - x	x - x	x - x	x - x	x - x
	Min - Max	x - x	x - x	x - x	x - x	x - x
Headache	n	x	x	x	x	x
	Mean (SD)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)
	Median	x.x	x.x	x.x	x.x	x.x
	Q1 - Q3	x - x	x - x	x - x	x - x	x - x
	Min - Max	x - x	x - x	x - x	x - x	x - x
Myalgia	n	x	x	x	x	x
	Mean (SD)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)
	Median	x.x	x.x	x.x	x.x	x.x
	Q1 - Q3	x - x	x - x	x - x	x - x	x - x
	Min - Max	x - x	x - x	x - x	x - x	x - x
Arthralgia	n	x	x	x	x	x
	Mean (SD)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)
	Median	x.x	x.x	x.x	x.x	x.x
	Q1 - Q3	x - x	x - x	x - x	x - x	x - x
	Min - Max	x - x	x - x	x - x	x - x	x - x
Fatigue	n	x	x	x	x	x
	Mean (SD)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)	x.x (x.xx)

Table 14.3.1.3.2
Summary of duration of Grade 3 Solicited Systemic Events Reported within 7 days (Days 1-7) after each vaccine dose and overall
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose)

Event	Statistic	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
	Median	x.x	x.x	x.x	x.x	x.x
	Q1 - Q3	x - x	x - x	x - x	x - x	x - x
	Min - Max	x - x	x - x	x - x	x - x	x - x

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus.
N is the number of participants in the Exposed Set for each period except Overall dose, where N is the total number of doses in the Exposed Set.
n is the number of participants with an event in the Exposed Set for each period except Overall dose, where n is the total number of doses in the Exposed Set where an event occurs.

Programming Notes

Output ID: DUR0001
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.3.1.3.3: Number and percentage of participants with Grade 3 Solicited Systemic Events Reported within 7 days (Days 1-7) after each vaccine dose and overall by days of duration (Exposed Set)

Table 14.3.1.3.3
Number and percentage of participants with Grade 3 Solicited Systemic Events Reported within 7 days (Days 1-7) after each vaccine dose and overall by days of duration
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Fever						
N*		x	x	x	x	x
1 day	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
2 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
3 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
4 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
>=5 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Headache						
N*		x	x	x	x	x
1 day	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
2 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
3 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
4 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
>=5 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Myalgia						
N*		x	x	x	x	x
1 day	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
2 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
3 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
4 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
>=5 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)

Table 14.3.1.3.3
Number and percentage of participants with Grade 3 Solicited Systemic Events Reported within 7 days (Days 1-7) after each vaccine dose and overall by days of duration
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Arthalgia						
N*		x	x	x	x	x
1 day	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
2 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
3 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
4 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
>=5 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Fatigue						
N*		x	x	x	x	x
1 day	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
2 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
3 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
4 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
>=5 days	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus.
N is the number of participants in the Exposed Set for each period except Overall dose, where N is the total number of doses in the Exposed Set.
N* is the number of participants with an event in the Exposed Set for each period except Overall dose, where n is the total number of doses in the Exposed Set where an event occurs
n is the number of participants with a specified duration of an event
Percentages are calculated as 100 * n/N*.

Table 14.3.1.4: Summary of Participants with any Grade 3 Unsolicited Events and Serious Adverse Events (Exposed Set)

Table 14.3.1.4
Summary of Participants with any Grade 3 Unsolicited Events and Serious Adverse Events
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
At least one Grade 3 Unsolicited Adverse Event	n (%) [95% CI] e	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x
At least one causally related Grade 3 Unsolicited Adverse Event	n (%) [95% CI] e	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x
At least one Serious Adverse Event	n (%) [95% CI] e	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x
At least one causally related Serious Adverse Event	n (%) [95% CI] e	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x
At least one fatal Serious Adverse Event	n (%) [95% CI] e	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x
At least one causally related fatal Serious Adverse Event	n (%) [95% CI] e	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. CI = Confidence Interval.

Table 14.3.1.4
Summary of Participants with any Grade 3 Unsolicited Events and Serious Adverse Events
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)

N is the number of participants in the Exposed Set for each period except Overall dose, where N is the total number of doses in the Exposed Set.
n is the number of participants included in each category.
Percentages are calculated as 100 * n/N.
e is the number of events.
Includes AEs with an onset date on or after the date of first vaccine up to Study End.
95% CI are based on Clopper-Pearson
Causally related events are those that are related to HPV vaccine according to the investigator.
The unsolicited adverse event summaries include events that are reported within 28 days (Day 1 – 28) after each vaccine dose. The serious adverse event summaries include events that are reported upto Study End.
MedDRA version xx.x.

Table 14.3.1.5: Number and Percentage of Participants of each Grade 3 Unsolicited Adverse Events Reported within 28 days (Days 1-28) after each vaccine dose and overall by System Organ Class and Preferred Term (Exposed Set)

Table 14.3.1.5
Number and Percentage of Participants of each Grade 3 Unsolicited Adverse Events Reported within 28 days (Days 1-28) after each vaccine dose and overall by System Organ Class and Preferred Term
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
At least one grade 3 unsolicited adverse event	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<System organ class 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x]x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 2>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<System organ class 2>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 2>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. CI = Confidence Interval. MedDRA = Medical dictionary for regulatory activities
N is the number of participants in the Exposed Set for each period except Overall dose, where N is the total number of doses in the Exposed Set.

Table 14.3.1.5
Number and Percentage of Participants of each Grade 3 Unsolicited Adverse Events Reported within 28 days (Days 1-28) after each vaccine dose and overall by System Organ Class and Preferred Term
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)

n is the number of participants with an event in the Exposed Set for each period except Overall dose, where n is the total number of doses in the Exposed Set where an event occurs.
Percentages are calculated as 100 * n/N.
Participants with multiple events in the same preferred term are counted only once in that preferred term.
e is the number of events; participants with events in more than one preferred term are counted once in each of those preferred terms.
Unsolicited AEs include serious AEs.
MedDRA version xx.x.
95% CI are based on Clopper-Pearson

Table 14.3.1.6: Number and Percentage of Participants of causally related Grade 3 Unsolicited Adverse Events Reported within 28 days (Days 1-28) after each vaccine dose and overall by System Organ Class and Preferred Term (Exposed Set)

Table 14.3.1.6
Number and Percentage of Participants of causally related Grade 3 Unsolicited Adverse Events Reported within 28 days (Days 1-28) after each vaccine dose and overall by System Organ Class and Preferred Term
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
At least one causally related grade 3 unsolicited adverse event	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<System organ class 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x]x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 2>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<System organ class 2>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 2>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. CI = Confidence Interval. MedDRA = Medical dictionary for regulatory activities
N is the number of participants in the Exposed Set for each period except Overall dose, where N is the total number of doses in the Exposed Set.

Table 14.3.1.6
Number and Percentage of Participants of causally related Grade 3 Unsolicited Adverse Events Reported within 28 days (Days 1-28) after each vaccine dose and overall by System Organ Class and Preferred Term
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)

n is the number of participants with an event in the Exposed Set for each period except Overall dose, where n is the total number of doses in the Exposed Set where an event occurs.
Percentages are calculated as 100 * n/N.
Participants with multiple events in the same preferred term are counted only once in that preferred term.
e is the number of events; participants with events in more than one preferred term are counted once in each of those preferred terms.
Unsolicited AEs include serious AEs.
MedDRA version xx.x.
95% CI are based on Clopper-Pearson

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYY

Table 14.3.1.7: Number and Percentage of Participants of Serious Adverse Events Reported up to Study End by System Organ Class and Preferred Term (Exposed Set)

Table 14.3.1.7
Number and Percentage of Participants of Serious Adverse Events Reported up to Study End by System Organ Class and Preferred Term
Exposed Set

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
At least one serious adverse event	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<System organ class 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 2>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<System organ class 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. CI = Confidence Interval. MedDRA = Medical dictionary for regulatory activities
N is the number of participants in the Exposed Set.
n is the number of participants included in each category.
Percentages are calculated as 100 * n/N.
Participants with multiple events in the same preferred term are counted only once in that preferred term.
e is the number of events; participants with events in more than one preferred term are counted once in each of those preferred terms.
Includes AEs with an onset date on or after the date of first vaccine up to Data Lock Point.
95% CI are based on Clopper-Pearson

Table 14.3.1.7
Number and Percentage of Participants of Serious Adverse Events Reported up to Study End by System Organ Class and Preferred Term
Exposed Set

	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)

MedDRA version xx.x.

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.3.1.8: Number and Percentage of Participants of causally related Serious Adverse Events Reported up to Study End by System Organ Class and Preferred Term (Exposed Set)

Study 213749 - DELIVERY DESIGNATION

Table 14.3.1.8
Number and Percentage of Participants of causally related Serious Adverse Events Reported up to Study End by System Organ Class and Preferred Term
Exposed Set

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
At least one causally related serious adverse event	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<System organ class 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 2>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<System organ class 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. CI = Confidence Interval. MedDRA = Medical dictionary for regulatory activities
N is the number of participants in the Exposed Set.
n is the number of participants included in each category.
Percentages are calculated as 100 * n/N.
Participants with multiple events in the same preferred term are counted only once in that preferred term.
e is the number of events; participants with events in more than one preferred term are counted once in each of those preferred terms.
Includes AEs with an onset date on or after the date of first vaccine up to Study End.

Table 14.3.1.8
Number and Percentage of Participants of causally related Serious Adverse Events Reported up to Study End by System Organ Class and Preferred Term
Exposed Set

	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)

95% CI are based on Clopper-Pearson
Causally related events are those that are related to HPV vaccine according to the investigator.
MedDRA version xx.x.

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.3.1.9: Number and Percentage of Participants of fatal Serious Adverse Events Reported up to Study End by System Organ Class and Preferred Term (Exposed Set)

Table 14.3.1.9
Number and Percentage of Participants of fatal Serious Adverse Events Reported up to Study End by System Organ Class and Preferred Term
Exposed Set

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
At least one fatal serious adverse event	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<System organ class 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 2>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<System organ class 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. CI = Confidence Interval. MedDRA = Medical dictionary for regulatory activities
N is the number of participants in the Exposed Set.
n is the number of participants included in each category.
Percentages are calculated as 100 * n/N.
Participants with multiple events in the same preferred term are counted only once in that preferred term.
e is the number of events; participants with events in more than one preferred term are counted once in each of those preferred terms.
Includes AEs with an onset date on or after the date of first vaccine up to Study End.
95% CI are based on Clopper-Pearson

Table 14.3.1.9
Number and Percentage of Participants of fatal Serious Adverse Events Reported up to Study End by System Organ Class and Preferred Term
Exposed Set

	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)

MedDRA version xx.x.

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.3.1.10: Number and Percentage of Participants of causally related fatal Serious Adverse Events Reported up to Study End by System Organ Class and Preferred Term (Exposed Set)

Table 14.3.1.10
Number and Percentage of Participants of causally related fatal Serious Adverse Events Reported up to Study End by System Organ Class and Preferred Term
Exposed Set

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
At least one causally related fatal serious adverse event	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<System organ class 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 2>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<System organ class 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. CI = Confidence Interval. MedDRA = Medical dictionary for regulatory activities
N is the number of participants in the Exposed Set.
n is the number of participants included in each category.
Percentages are calculated as 100 * n/N.
Participants with multiple events in the same preferred term are counted only once in that preferred term.
e is the number of events; participants with events in more than one preferred term are counted once in each of those preferred terms.

Table 14.3.1.10
Number and Percentage of Participants of causally related fatal Serious Adverse Events Reported up to Study End by System Organ Class and Preferred Term
Exposed Set

	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)

Includes AEs with an onset date on or after the date of first vaccine up to Study End.
95% CI are based on Clopper-Pearson
Causally related events are those that are related to HPV vaccine according to the investigator.
MedDRA version xx.x.

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.3.1.11: Number and Percentage of Participants of Laboratory Parameters Outside normal range at Day 7 after the first vaccine dose (Exposed Set)

Study 213749 - DELIVERY DESIGNATION

Table 14.3.1.11
Number and Percentage of Participants of Laboratory Parameters Outside normal range at Day 7 after the first vaccine dose - Step 1 Participants
Exposed Set

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Biochemical						
<<Lab parameter 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
<<Lab parameter 2>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
<<Lab parameter 3>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Hematological						
<<Lab parameter 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. CI = Confidence Interval.
Percentages are calculated as 100 * n/N.
95% CI are based on Clopper-Pearson

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.3.2.1: Overall Summary of Solicited Administration Site Events and Solicited Systemic Events Reported within 7 days (Days 1-7) after each vaccine dose and overall (Exposed Set)

GSK Vaccines

Study 213749 - DELIVERY DESIGNATION

Table 14.3.2.1
Overall Summary of Solicited Administration Site Events and Solicited Systemic Events Reported within 7 days (Days 1-7) after each vaccine dose and overall
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Any solicited event	n (%) [95% CI] e	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x
Any solicited administration site event	n (%) [95% CI] e	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x
Any solicited systemic event	n (%) [95% CI] e	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. CI = Confidence Interval.
N is the number of participants in the Exposed Set for each period except Overall dose, where N is the total number of doses in the Exposed Set.
n is the number of participants with an event in the Exposed Set for each period except Overall dose, where n is the total number of doses in the Exposed Set where an event occurs.
Percentages are calculated as 100 * n/N.
95% CI are based on Clopper-Pearson

e is the number of events; participants with events in more than one preferred term are counted once in each of those preferred terms.
Includes AEs with an onset date on or after the date of first vaccine up to Data Lock Point.

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.3.2.2: Number and Percentage of Participants of Solicited Administration Site Events Reported within 7 days (Days 1-7) after each vaccine dose and overall (Exposed Set)

Table 14.3.2.2
Number and Percentage of Participants of each Solicited Administration Site Events Reported within 7 days (Days 1-7) after each vaccine dose and overall
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
At least one solicited administration site event	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
Injection site pain	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Redness at injection site	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Swelling at injection site	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
At least one solicited administration site event leading to medical attention	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
Injection site pain	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Redness at injection site	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Swelling at injection site	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. CI = Confidence Interval.
N is the number of participants in the Exposed Set for each period except Overall dose, where N is the total number of doses in the Exposed Set.

Table 14.3.2.2
Number and Percentage of Participants of each Solicited Administration Site Events Reported within 7 days (Days 1-7) after each vaccine dose and overall
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)

n is the number of participants with an event in the Exposed Set for each period except Overall dose, where n is the total number of doses in the Exposed Set where an event occurs.
e is the number of events.
Percentages are calculated as 100 * n/N.

95% CI are based on Clopper-Pearson

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.3.2.3: Number and Percentage of Participants of Solicited Systemic Events Reported within 7 days (Days 1-7) after each vaccine dose and overall (Exposed Set)

Table 14.3.2.3
Number and Percentage of Participants of Solicited Systemic Events Reported within 7 days (Days 1-7) after each vaccine dose and overall
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
At least one solicited administration site event	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
Fever	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Headache	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Myalgia	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Arthralgia	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Fatigue	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
At least one solicited administration site event leading to medical attention	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
Fever	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Headache	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Myalgia	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Arthralgia	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]

Table 14.3.2.3
Number and Percentage of Participants of Solicited Systemic Events Reported within 7 days (Days 1-7) after each vaccine dose and overall
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Fatigue	n (%) [95% CI]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]	x (x.x) [xx.x, xx.x]

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. CI = Confidence Interval.
N is the number of participants in the Exposed Set for each period except Overall dose, where N is the total number of doses in the Exposed Set.
n is the number of participants with an event in the Exposed Set for each period except Overall dose, where n is the total number of doses in the Exposed Set where an event occurs.
e is the number of events.
Percentages are calculated as 100 * n/N.

95% CI are based on Clopper-Pearson

Table 14.3.2.4: Number and Percentage of Participants of Solicited Administration Site Events Reported within 7 days (Days 1-7) after each vaccine dose and overall by Severity (Exposed Set)

Table 14.3.2.4
Number and Percentage of Participants of each Solicited Administration Site Events Reported within 7 days (Days 1-7) after each vaccine dose and overall by Severity
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
At least one solicited administration site event	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
Injection site pain	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 2	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 3	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Redness at injection site	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 2	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 3	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Swelling at injection site	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 2	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]

Table 14.3.2.4
Number and Percentage of Participants of each Solicited Administration Site Events Reported within 7 days (Days 1-7) after each vaccine dose and overall by Severity
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Grade 3	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
At least one solicited administration site event leading to medical attention	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
Injection site pain	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 2	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 3	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Redness at injection site	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 2	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 3	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Swelling at injection site	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 2	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 3	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. CI = Confidence Interval.
N is the number of participants in the Exposed Set for each period except Overall dose, where N is the total number of doses in the Exposed Set.

Table 14.3.2.4
Number and Percentage of Participants of each Solicited Administration Site Events Reported within 7 days (Days 1-7) after each vaccine dose and overall by Severity
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)

n is the number of participants with an event in the Exposed Set for each period except Overall dose, where n is the total number of doses in the Exposed Set where an event occurs.
e is the number of events.
Percentages are calculated as 100 * n/N.

95% CI are based on Clopper-Pearson

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.3.2.5: Number and Percentage of Participants of Solicited Systemic Events Reported within 7 days (Days 1-7) after each vaccine dose and overall by Severity (Exposed Set)

Table 14.3.2.5
Number and Percentage of Participants of Solicited Systemic Events Reported within 7 days (Days 1-7) after each vaccine dose and overall by Severity
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
At least one solicited systemic event	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
Fever	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 2	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 3	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Headache	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 2	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 3	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Myalgia	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 2	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)

Table 14.3.2.5
Number and Percentage of Participants of Solicited Systemic Events Reported within 7 days (Days 1-7) after each vaccine dose and overall by Severity
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 3	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Arthralgia	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 2	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 3	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Fatigue	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 2	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 3	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
At least one solicited systemic event leading to medical attention	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
Fever	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 2	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 3	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Headache	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]

Table 14.3.2.5
Number and Percentage of Participants of Solicited Systemic Events Reported within 7 days (Days 1-7) after each vaccine dose and overall by Severity
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Grade 2	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 3	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Myalgia	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 2	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 3	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Arthralgia	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 2	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 3	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Fatigue	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 2	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Grade 3	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. CI = Confidence Interval.
N is the number of participants in the Exposed Set for each period except Overall dose, where N is the total number of doses in the Exposed Set.
n is the number of participants with an event in the Exposed Set for each period except Overall dose, where n is the total number of doses in the Exposed Set where an event occurs.

Table 14.3.2.5
Number and Percentage of Participants of Solicited Systemic Events Reported within 7 days (Days 1-7) after each vaccine dose and overall by Severity
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)

e is the number of events.
Percentages are calculated as 100 * n/N.

95% CI are based on Clopper-Pearson

Output ID: SE0002
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.3.2.6.1: Solicited Events, Completeness Analysis, by Administration Site and Systemic Category by Intervention Group and overall (Exposed Set)

Study 213749 - DELIVERY DESIGNATION

Table 14.3.2.6.1
Solicited Events, Completeness Analysis, by Administration Site and Systemic Category by Intervention Group and overall
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Any solicited administration site event	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
Injection site pain	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Redness at injection site	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Swelling at injection site	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Any solicited systemic event	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
Fever	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Headache	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Myalgia	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Arthralgia	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]
Fatigue	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]

Table 14.3.2.6.1
Solicited Events, Completeness Analysis, by Administration Site and Systemic Category by Intervention Group and overall
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. CI = Confidence Interval.
N is the number of participants in the Exposed Set for each period except Overall dose, where N is the total number of doses in the Exposed
Set.
n is the number of participants with documented absence or presence of the event on at least one day.
Percentages are calculated as 100 * n/N.
95% CI are based on Clopper-Pearson

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.3.2.6.2: eDiary Collection, Compliance and Completeness in Solicited Events by Intervention Group and overall (Exposed Set)

Table 14.3.2.6.2
eDiary Collection, Compliance and Completeness in Solicited Events by Intervention Group and overall
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

		HPV9 High		HPV9 Medium		HPV9 Low		Gardasil 9		Total	
		N		N		N		N		N	
Solicited administration site event											
Injection site pain											
Day 1	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 2	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 3	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 4	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
…											
Redness at injection site	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 1	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 2	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 3	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 4	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
…											
Swelling at injection site	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 1	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 2	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 3	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 4	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
…											
Solicited systemic event											
Fever											
Day 1	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 2	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)

Table 14.3.2.6.2
eDiary Collection, Compliance and Completeness in Solicited Events by Intervention Group and overall
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

		HPV9 High		HPV9 Medium		HPV9 Low		Gardasil 9		Total	
		N		N		N		N		N	
Day 3	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 4	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
…											
Headache	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 1	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 2	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 3	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 4	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
…											
Myalgia	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 1	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 2	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 3	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 4	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
…											
Arthralgia	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 1	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 2	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 3	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 4	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
…											
Fatigue	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 1	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 2	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 3	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
Day 4	N* n (%)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)	xxx	x x (x.x)
…											

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus.
N is the number of participants in the Exposed Set for each period except Overall dose, where N is the total number of doses in the Exposed Set.

Table 14.3.2.6.2
eDiary Collection, Compliance and Completeness in Solicited Events by Intervention Group and overall
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

	HPV9 High	HPV9 Medium	HPV9 Low	Gardasil 9	Total
	N	N	N	N	N

N* is the number of participants with documented absence or presence of the event on that day.
n is the number of participants with documented presence of the event in the Exposed Set for each period except Overall dose, where n is the total number of doses in the Exposed Set where there is documented presence of the event.
Percentages are calculated as 100 * n/N*

Programming Notes
All events will go up to day 7.

Output ID: SE0005
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.3.2.7.1: Summary of Participants with any Unsolicited Adverse Events and Potential Immune-Mediated Disease (Exposed Set)

Table 14.3.2.7.1
Summary of Participants with any Unsolicited Adverse Events and Potential Immune-Mediated Disease
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
At least one Unsolicited Adverse Event	n (%) [95% CI] e	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x
At least one causally related Unsolicited Adverse Event	n (%) [95% CI] e	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x
At least one Unsolicited Adverse Event Leading to Medical Attention	n (%) [95% CI] e	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x
At least one Potential Immune-Mediated Disease	n (%) [95% CI] e	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x
At least one causally related Potential Immune-Mediated Disease	n (%) [95% CI] e	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x	x (x.x) [xx.x, xx.x] x

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. CI = Confidence Interval.
N is the number of participants in the Exposed Set.
n is the number of participants included in each category.
Percentages are calculated as 100 * n/N.
e is the number of events.

Table 14.3.2.7.1
Summary of Participants with any Unsolicited Adverse Events and Potential Immune-Mediated Disease
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)

The unsolicited adverse event summaries include events that are reported within 28 days (Day 1 – 28) after each vaccine dose. The Potential Immune-Mediated Disease summaries include events that are reported upto Study End.

95% CI are based on Clopper-Pearson
Causally related events are those that are related to HPV vaccine according to the investigator.
MedDRA version xx.x.

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.3.2.7.2: Number and Percentage of Participants of Unsolicited Adverse Events Reported within 28 days (Days 1-28) after each vaccine dose and overall by System Organ Class and Preferred Term (Exposed Set)

Table 14.3.2.7.2
Number and Percentage of Participants of Unsolicited Adverse Events Reported within 28 days (Days 1-28) after each vaccine dose and overall by System Organ Class and Preferred Term
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
At least one unsolicited adverse event	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<System organ class 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x]x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 2>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<System organ class 2>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 2>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. CI = Confidence Interval. MedDRA = Medical dictionary for regulatory activities
N is the number of participants in the Exposed Set for each period except Overall dose, where N is the total number of doses in the Exposed Set.

Table 14.3.2.7.2
Number and Percentage of Participants of Unsolicited Adverse Events Reported within 28 days (Days 1-28) after each vaccine dose and overall by System Organ Class and Preferred Term
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)

n is the number of participants with an event in the Exposed Set for each period except Overall dose, where n is the total number of doses in the Exposed Set where an event occurs.
Percentages are calculated as 100 * n/N.
Participants with multiple events in the same preferred term are counted only once in that preferred term.
e is the number of events; participants with events in more than one preferred term are counted once in each of those preferred terms.
Unsolicited AEs include serious AEs.
MedDRA version xx.x.
95% CI are based on Clopper-Pearson

Table 14.3.2.7.3: Number and Percentage of Participants of causally related Unsolicited Adverse Events Reported within 28 days (Days 1-28) after each vaccine dose and overall by System Organ Class and Preferred Term (Exposed Set)

Table 14.3.2.7.3
Number and Percentage of Participants of causally related Unsolicited Adverse Events Reported within 28 days (Days 1-28) after each vaccine dose and overall by System Organ Class and Preferred Term
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
At least one causally related unsolicited adverse event	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<System organ class 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x]x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 2>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<System organ class 2>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 2>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. CI = Confidence Interval. MedDRA = Medical dictionary for regulatory activities
N is the number of participants in the Exposed Set for each period except Overall dose, where N is the total number of doses in the Exposed Set.

Table 14.3.2.7.3
Number and Percentage of Participants of causally related Unsolicited Adverse Events Reported within 28 days (Days 1-28) after each vaccine dose and overall by System Organ Class and Preferred Term
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)

n is the number of participants with an event in the Exposed Set for each period except Overall dose, where n is the total number of doses in the Exposed Set where an event occurs.
Percentages are calculated as 100 * n/N.
Participants with multiple events in the same preferred term are counted only once in that preferred term.
e is the number of events; participants with events in more than one preferred term are counted once in each of those preferred terms.
Unsolicited AEs include serious AEs.
MedDRA version xx.x.
95% CI are based on Clopper-Pearson

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYY

Table 14.3.2.7.4: Number and Percentage of Participants with Unsolicited Adverse Events Leading to Medical Attention Reported within 28 days (Days 1-28) after each vaccine dose and overall by System Organ Class and Preferred Term (Exposed Set)

Table 14.3.2.7.4
Number and Percentage of Participants with Unsolicited Adverse Events Leading to Medical Attention Reported within 28 days (Days 1-28) after each vaccine dose and overall by System Organ Class and Preferred Term
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
At least one unsolicited adverse event	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<System organ class 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x]x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 2>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<System organ class 2>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 2>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. CI = Confidence Interval. MedDRA = Medical dictionary for regulatory activities
N is the number of participants in the Exposed Set for each period except Overall dose, where N is the total number of doses in the Exposed Set.

Table 14.3.2.7.4
Number and Percentage of Participants with Unsolicited Adverse Events Leading to Medical Attention Reported within 28 days (Days 1-28) after each vaccine dose and overall by System Organ Class and Preferred Term
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)

n is the number of participants with an event in the Exposed Set for each period except Overall dose, where n is the total number of doses in the Exposed Set where an event occurs.
Percentages are calculated as 100 * n/N.
Participants with multiple events in the same preferred term are counted only once in that preferred term.
e is the number of events; participants with events in more than one preferred term are counted once in each of those preferred terms.
Unsolicited AEs include serious AEs.
MedDRA version xx.x.
95% CI are based on Clopper-Pearson

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYY

Table 14.3.2.7.5: Number and Percentage of Participants with Unsolicited Adverse Events Reported within 28 days (Days 1-28) after each vaccine dose and overall by System Organ Class, Preferred Term and Severity (Exposed Set)

Table 14.3.2.7.5
Number and Percentage of Participants with Unsolicited Adverse Events Reported within 28 days (Days 1-28) after each vaccine dose and overall by System Organ Class, Preferred Term and Severity
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
At least one unsolicited adverse event	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
Grade 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
Grade 2	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
Grade 3	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<System organ class 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
Grade 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
Grade 2	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
Grade 3	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x]x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
Grade 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
Grade 2	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
Grade 3	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)

Table 14.3.2.7.5
Number and Percentage of Participants with Unsolicited Adverse Events Reported within 28 days (Days 1-28) after each vaccine dose and overall by System Organ Class, Preferred Term and Severity
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
<<Preferred term 2>>	[95% CI] e n (%)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)
Mild	[95% CI] e n (%)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)
Moderate	[95% CI] e n (%)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)
Severe	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<System organ class 2>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Mild	[95% CI] e n (%)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)
Moderate	[95% CI] e n (%)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)
Severe	[95% CI] e n (%)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)
<<Preferred term 1>>	[95% CI] e n (%)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)
Mild	[95% CI] e n (%)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)
Moderate	[95% CI] e n (%)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)
Severe	[95% CI] e n (%)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)
<<Preferred term 2>>	[95% CI] e n (%)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)
Mild	[95% CI] e n (%)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)
Moderate	[95% CI] e n (%)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)	[xx.x, xx.x] x x (x.x)
Severe	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x

Source: Listing xx.x.x.x

Table 14.3.2.7.5
Number and Percentage of Participants with Unsolicited Adverse Events Reported within 28 days (Days 1-28) after each vaccine dose and overall by System Organ Class, Preferred Term and Severity
Exposed Set

Period: After first vaccine dose / After second vaccine dose / After third vaccine dose / Overall (dose) / Overall (participant)

	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)

Abbreviations: HPV = Human Papillomavirus. CI = Confidence Interval. MedDRA = Medical dictionary for regulatory activities
N is the number of participants in the Exposed Set for each period except Overall dose, where N is the total number of doses in the Exposed Set.
n is the number of participants with an event in the Exposed Set for each period except Overall dose, where n is the total number of doses in the Exposed Set where an event occurs.
Percentages are calculated as 100 * n/N.
Participants with multiple events in the same preferred term are counted only once in that preferred term.
e is the number of events; participants with events in more than one preferred term are counted once in each of those preferred terms.
Unsolicited AEs include serious AEs.
MedDRA version xx.x.
95% CI are based on Clopper-Pearson

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYY

Table 14.3.2.8.1: Number and Percentage of Participants of Potential Immune-Mediated Disease Reported up to Study End by System Organ Class and Preferred Term (Exposed Set)

Table 14.3.2.8.1
Number and Percentage of Participants of Potential Immune-Mediated Disease Reported up to Study End by System Organ Class and Preferred Term
Exposed Set

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
At least one potential immune-mediated disease	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<System organ class 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 2>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<System organ class 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. CI = Confidence Interval. MedDRA = Medical dictionary for regulatory activities
N is the number of participants in the Exposed Set.
n is the number of participants included in each category.
Percentages are calculated as 100 * n/N.
Participants with multiple events in the same preferred term are counted only once in that preferred term.
e is the number of events; participants with events in more than one preferred term are counted once in each of those preferred terms.
Includes AEs with an onset date on or after the date of first vaccine up to Study End.
95% CI are based on Clopper-Pearson

Table 14.3.2.8.1
Number and Percentage of Participants of Potential Immune-Mediated Disease Reported up to Study End by System Organ Class and Preferred Term
Exposed Set

	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)

MedDRA version xx.x.

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.3.2.8.2: Number and Percentage of Participants with causally related Potential Immune-Mediated Disease Reported up to Study End by System Organ Class and Preferred Term (Exposed Set)

Table 14.3.2.8.2
Number and Percentage of Participants with causally related Potential Immune-Mediated Disease Reported up to Study End by System Organ Class and Preferred Term
Exposed Set

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
At least one potential immune-mediated disease	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<System organ class 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 2>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<System organ class 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x
<<Preferred term 1>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
	[95% CI] e	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x	[xx.x, xx.x] x

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus. CI = Confidence Interval. MedDRA = Medical dictionary for regulatory activities
N is the number of participants in the Exposed Set.
n is the number of participants included in each category.
Percentages are calculated as 100 * n/N.
Participants with multiple events in the same preferred term are counted only once in that preferred term.
e is the number of events; participants with events in more than one preferred term are counted once in each of those preferred terms.
Includes AEs with an onset date on or after the date of first vaccine up to Study End.

Table 14.3.2.8.2
Number and Percentage of Participants with causally related Potential Immune-Mediated Disease Reported up to Study End by System Organ Class and Preferred Term
Exposed Set

	HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)

95% CI are based on Clopper-Pearson
MedDRA version xx.x.

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.3.2.9.1: Number and Percentage of Participants of Pregnancies Reported up to Study End (Exposed Set)

Table 14.3.2.9.1
Number and Percentage of Participants of Pregnancies Reported up to Study End
Exposed Set

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
At least one pregnancy reported during the study	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus.
N is the number of participants in the Exposed Set.
n is the number of participants included in each category.
Percentages are calculated as 100 * n/N.

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.3.2.9.2: Number and Percentage of Participants of Pregnancies Reported around each Vaccination (Exposed Set)

Study 213749 - DELIVERY DESIGNATION

Table 14.3.2.9.2
Number and Percentage of Participants of Pregnancies Reported around each Vaccination
Exposed Set

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
At least one pregnancy reported around first vaccination	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
At least one pregnancy reported around second vaccination	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
At least one pregnancy reported around third vaccination	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus.
Percentages are calculated as 100 * n/N.
Around each vaccination is defined as any pregnancy reported within 30 days before and 45 days after each vaccination.

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.3.2.9.3: Number and Percentage of Participants of Pregnancies Outcomes Reported up to Study End (Exposed Set)

Table 14.3.2.9.3
Number and Percentage of Participants of Pregnancies Outcomes Reported up to Study End
Exposed Set

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Number of pregnancies reported	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
At least one pregnancy reported around first vaccination	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Outcome:						
Live infant, no apparent congenital anomaly	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Live infant congenital anomaly	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Elective termination, no apparent congenital anomaly	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Elective termination congenital anomaly	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Spontaneous abortion, no apparent congenital anomaly	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Spontaneous abortion congenital anomaly	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Stillbirth, no apparent congenital anomaly	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Stillbirth congenital anomaly	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Ectopic pregnancy	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Molar pregnancy	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Lost to follow-up	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Pregnancy ongoing	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
At least one pregnancy reported around second vaccination	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Live infant, no apparent congenital anomaly	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
…						

Table 14.3.2.9.3
Number and Percentage of Participants of Pregnancies Outcomes Reported up to Study End
Exposed Set

		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
At least one pregnancy reported around third vaccination	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Live infant, no apparent congenital anomaly	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
…						
At least one pregnancy reported around all vaccinations	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Live infant, no apparent congenital anomaly	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
…						

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus.
Percentages are calculated as 100 * n/N.
Around each vaccination is defined as any pregnancy reported within 30 days before and 45 days after each vaccination.

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Table 14.3.3.1: Summary of Laboratory Parameters Grades: Hematology by study group and overall (Exposed Set)

Study 213749 - DELIVERY DESIGNATION

Table 14.3.3.1
Summary of Laboratory Parameters Grades: Hematology by study group and overall
Exposed Set

Lab parameter / Visit / Grade		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Hemoglobin						
Visit 1						
Grade 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Grade 2	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Grade 3	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Grade 4	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Visit 2						
Grade 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Grade 2	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Grade 3	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Grade 4	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus.
Percentages are calculated as 100 * n/N.
Baseline is the result at Visit 1.

See table 13 in the protocol for definition of the grades for each lab parameter

Programming note:

Include hemoglobin, hemoglobin change from baseline, white blood cells increase, white blood cell decrease, lymphocyte decrease, neutrophils decrease, eosinophils and platelet decrease

```
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749
(HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM
```

Table 14.3.3.2: Summary of Laboratory Parameters Grades: Chemistry by study group and overall (Exposed Set)

Study 213749 - DELIVERY DESIGNATION

Table 14.3.3.2
Summary of Laboratory Parameters Grades: Chemistry by study group and overall
Exposed Set

Lab parameter / Visit / Grade		HPV9 High (N=XXX)	HPV9 Medium (N=XXX)	HPV9 Low (N=XXX)	Gardasil 9 (N=XXX)	Total (N=XXX)
Blood Urea Nitrogen						
Visit 1						
Grade 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Grade 2	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Grade 3	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Grade 4	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Visit 2						
Grade 1	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Grade 2	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Grade 3	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Grade 4	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)

Source: Listing xx.x.x.x
Abbreviations: HPV = Human Papillomavirus.
Percentages are calculated as 100 *n/N.
See table 13 in the protocol for definition of the grades for each lab parameter

Programming note:

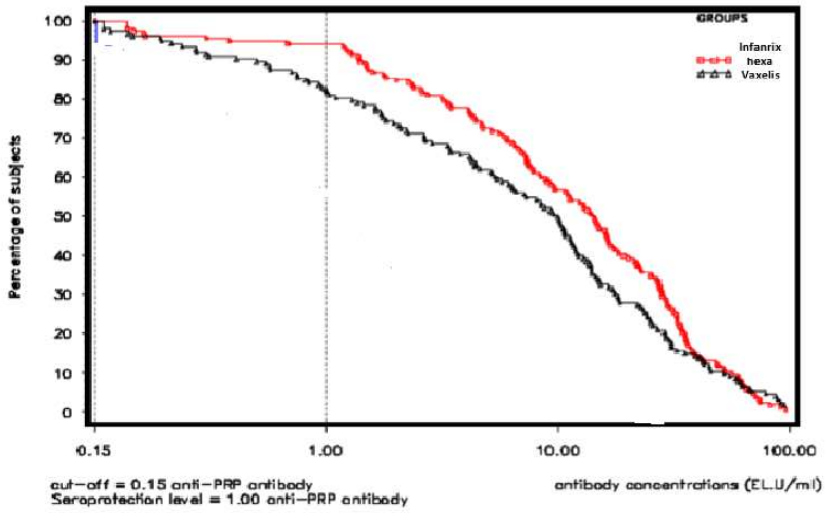
Include blood urea nitrogen, AST and ALT

[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Figure 16.1.2.1: Reverse Cumulative Curve (RCC) for anti-HPV IgG Antibody Concentration for each antigen at Day 1, Month 2, Month 3, Month 7 and Month 12 (Per Protocol Set)

Figure 16.1.2.1
Reverse Cumulative Curve (RCC) for anti-HPV IgG Antibody Concentration for each antigen at Day 1, Month 2, Month 3, Month 7 and Month 12
Per Protocol Set

Antigen: xx (LLOQ=xx; ULOQ=xx; Unit=xx) Timepoint: Day 1/Month 2/Month 3/Month 7/Month 12



Programming Notes
The above graph is for reference and following programming notes should be followed

1. Represent number of participants in percentage on y-axis and log of the concentration value on x-axis
2. Present separate curve for each treatment group. Present separate plots for each timepoint and antigen

Output ID: IM0011
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Figure 16.1.2.2: Reverse Cumulative Curve (RCC) for anti-HPV Neutralizing Antibody Titers for each antigen at Day 1, Month 2, Month 3 and Month 7 (Per Protocol Set)

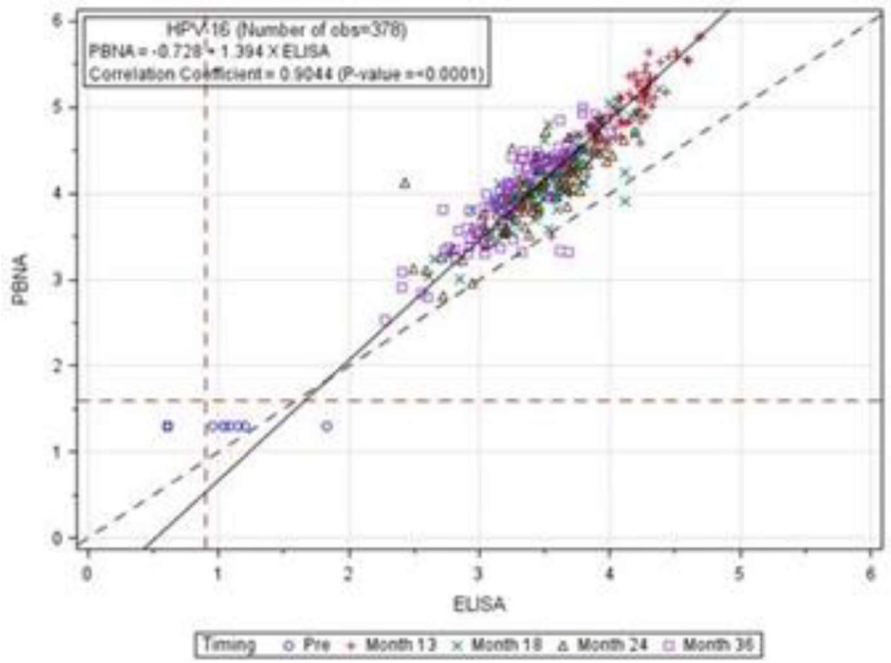
Figure 16.1.2.2
Reverse Cumulative Curve (RCC) for anti-HPV Neutralizing Antibody Titers at Day 1, Month 2, Month 3 and Month 7
Exposed Set

IM0012: This output uses shell IM0011 [Figure 16.1.2.1]

Programming Notes
• Replace footnotes in original shell with those listed above

Figure 16.1.2.3: Scatterplot for Deming's regression of the Anti-HPV Neutralizing titers and Anti-HPV IgG antibody concentrations for each antigen (Per Protocol Set)

Figure 16.1.2.3
Scatterplot for Deming's regression of the Anti-HPV Neutralizing titers and Anti-HPV IgG antibody concentrations for each antigen
Per Protocol Set



Source: Listing xx.x.x.x

Abbreviations: HPV = Human Papillomavirus. ECL = Electrochemiluminescence assay. PBNA = Pseudovirion-Based Neutralization Assay.

Deming regression model is fitted to the Anti-HPV IgG antibody concentration (ECL) with Anti-HPV Neutralizing titers (PBMA) as a covariate.

Deming's regression is computed by the log10-transformation of the antibody concentration and neutralizing titer. Samples testing below the LLOQ or above ULOQ in either assay were excluded from the analysis.

The dotted red line is the LLOQ value of xx.x for PBNA and xx.x for ECL.

The dashed red line is the ULOQ value of xx.x for PBNA and xx.x for ECL.

The solid line is based on the estimates obtained from Deming regression

Programming Notes

Timepoints will be Day 1 (blue circle), Month 2(red plus), Month 3 (green cross) and Month 7 (black triangle).
Create each antigen and treatment group in separate plots
The dashed line is a reference plotted at 45 degrees
The x-axis is the PBNA value (Anti-HPV Neutralizing titers) while the Y axis will be the ECL value (Anti-HPV IgG antibody concentration.

Output ID: IM0009
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Listing 16.2.1.1: Participants Disposition (Enrolled Set)

Study 213749 - DELIVERY DESIGNATION

Listing 16.2.1.1
Participants Disposition
Enrolled Set

Participant Identifier	Site ID	Vaccine Group	Date of Vaccine Dose	Completed / Discontinued the Study	Date of Completion / Discontinuation	Reason for Early Discontinuation	Was Treatment Unblinded by Site?
xxxxxxxx	xx	HPV9 High HPV9 Medium HPV9 Low Gardasil 9	ddmmmyyyy	Completed Discontinued	ddmmmyyyy	AE requiring expedited reporting; AE no: xx Pregnancy Unsolicited AE; AE no: xx Withdrawal by participant; Specify: xxxxxxxx Migrated/moved from study area Lost to follow-up Study termination Subject discontinued due to COVID-19 pandemic Other; Specify: xxxxx	Yes: xxxxxxx No

Abbreviations: HPV = Human Papillomavirus. COVID-19 = Coronavirus disease 2019.

Programming Notes

```
Output ID: LS0001
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749
(HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM
```

Listing 16.2.1.2: Participants with Early Withdrawal or Discontinuation due to COVID-19 (Enrolled Set)

Study 213749 - DELIVERY DESIGNATION

Listing 16.2.1.2
Participants with Early Withdrawal or Discontinuation due to COVID-19
Enrolled Set

Vaccine Group: HPV9 High / HPV9 Medium / HPV9 Low / Gardasil 9

Participant Identifier	Site ID	Discontinue Treatment due to COVID-19	Discontinue Study due to COVID-19
xxxxxxxx	xx	Yes	Yes
		No	No

Abbreviations: HPV = Human Papillomavirus. COVID-19 = Coronavirus disease 2019.

Programming Notes

Output ID: LS0002
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Listing 16.2.1.3: Participant Analysis Set (Enrolled Set)

Study 213749 - DELIVERY DESIGNATION

Listing 16.2.1.3
Participant Analysis Set
Enrolled Set

Vaccine Group: HPV9 High / HPV9 Medium / HPV9 Low / Gardasil 9

Participant Identifier	Site ID	Date; Time of Informed Consent	Enrolled Set (ENR); If no, reason for exclusion	Exposed Set (ES); If no, reason for exclusion	Per Protocol Set (PPS); If no, reason for exclusion
xxxxxxxx	xx	ddmmmyyyy; hh:mm	Yes	Yes	Yes
			No; xxxxxx	No; xxxxxx	No; xxxxxx

Abbreviations: HPV = Human Papillomavirus.

Programming Notes

Output ID: LS0003
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Listing 16.2.1.4: Inclusion and Exclusion Criteria at Enrolment (Enrolled Set)

Study 213749 - DELIVERY DESIGNATION

Listing 16.2.1.4
Inclusion and Exclusion Criteria at Enrolment
Enrolled Set

Vaccine Group: HPV9 High / HPV9 Medium / HPV9 Low / Gardasil 9

Participant Identifier	Site ID	Inclusion/ Exclusion Category Failed	Criteria Failed
xxxxxxxx	xx	Inclusion	xxxxxxxxxxxxxxxxx
		Exclusion	

Abbreviations: HPV = Human Papillomavirus.

Programming Notes

Output ID: LS0004
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Listing 16.2.2.1: All Protocol Deviations (Enrolled Set)

Study 213749 - DELIVERY DESIGNATION

Listing 16.2.2.1
All Protocol Deviations
Enrolled Set

Vaccine Group: HPV9 High / HPV9 Medium / HPV9 Low / Gardasil 9

Participant Identifier	Site ID	Classification	Date of Deviation	Deviation Category	Description	Exclusion from Per Protocol Set?
xxxxxxxx	xx	Important	ddmmmyyyy	Inclusion: xxxxxxxxxxxxx	Xxxxxxxxxxxxx	Yes
		Not important	ddmmmyyyy	Exclusion: xxxxxxxxxxxxx	xxxxxxxxxxxxx	No

Abbreviations: HPV = Human Papillomavirus.

Programming Notes

Output ID: LS0005
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Listing 16.2.4.1: Demographics and Other Baseline Characteristics (Enrolled Set)

Study 213749 - DELIVERY DESIGNATION

Listing 16.2.4.1
Demographics and Other Baseline Characteristics
Enrolled Set

Vaccine Group: HPV9 High / HPV9 Medium / HPV9 Low / Gardasil 9

Participant Identifier	Site ID	Age (years)	Year of Birth	Sex	Race	Ethnicity
xxxxxxxx	xx	xx	yyyy	Female	Black or African American	Hispanic or Latino
		xx	yyyy		American Indian or Alaska Native	Not Hispanic or Latino
		xx	yyyy		Asian	
					Native Hawaiian or other Pacific Islander	
					White	
					Other	

Abbreviations: HPV = Human Papillomavirus.

Programming Notes

Output ID: LS0006
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Listing 16.2.4.2: General Medical and Vaccination History (Enrolled Set)

Study 213749 - DELIVERY DESIGNATION

Listing 16.2.4.2
General Medical and Vaccination History
Enrolled Set

Vaccine Group: HPV9 High / HPV9 Medium / HPV9 Low / Gardasil 9

Participant Identifier	Site ID	Diagnosis	Start / End Date	System Organ Class; Preferred Term; Description	Taking Medication Related to this Condition?
xxxxxxxx	xx	xxxxxxxxxxx	ddmmmyyyy/ ddmmmyyyy	xxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxx	Yes
			ddmmmyyyy/ Ongoing	xxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxx	No

Abbreviations: HPV = Human Papillomavirus. MedDRA = Medical dictionary for regulatory activities.
MedDRA version xx.x.

Programming Notes

Output ID: LS0007
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Listing 16.2.4.3: Prior and Concomitant Vaccinations (Enrolled Set)

Listing 16.2.4.3
Prior and Concomitant Vaccinations
Enrolled Set

Vaccine Group: HPV9 High / HPV9 Medium / HPV9 Low / Gardasil 9

Participant Identifier	Site ID	ATC Classification; Preferred Term; Drug name (No.)	Indication	Prophy-laxis	Dose	Unit	Frequency; Route	Start (Onset Day)/ End Date (End Day)	Prior/ Concomitant?
xxxxxxxx	xx	xxxxxxxxxxxxxx; xxxxxxxxxxxx; xxxxxx (xx)	xxxxxxxx	xxxxxxx	xxxx	xxx	QID; Oral	Ddmmmyyyy (xx)/ ddmmmyyyy (xx)	Concomitant
		xxxxxxxxxxxxxx; xxxxxxxxxxxx; xxxxx (xx)	xxxxxxxxxx	xxxxxxx	xxxx	xxx	BID; Topical	Ddmmmyyyy (xx)/ Ongoing	Prior
		xxxxxxxxxxxxxx; xxxxxxxxxxxx; xxxxxx (xx)					TID; xxx		Concomitant
							QD; xxx		

Abbreviations: HPV = Human Papillomavirus. VV = Comparator vaccine. ATC = Anatomical therapeutic chemical.
Prior vaccinations are vaccinations which started prior to the dose of study vaccination.
Concomitant vaccinations are vaccinations which started on or after the day of the administration of study vaccination.

Programming Notes

Output ID: LS0008
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Listing 16.2.4.4: Concomitant Medications (Enrolled Set)

Listing 16.2.4.4
Prior and Concomitant Medications
Enrolled Set

Vaccine Group: HPV9 High / HPV9 Medium / HPV9 Low / Gardasil 9

Participant Identifier	Site ID	ATC Classification; Preferred Term; Drug name (No.)	Indication	Prophy-laxis	Dose	Unit	Frequency; Route	Start (Onset Day)/ End Date (End Day)	Prior/ Concomitant?
xxxxxxxx	xx	xxxxxxxxxxxxxx; xxxxxxxxxxxx; xxxxxx (xx)	xxxxxxxx	xxxxxxx	xxxx	xxx	QID; Oral	Ddmmmyyyy (xx)/ ddmmmyyyy (xx)	Concomitant
		xxxxxxxxxxxxxx; xxxxxxxxxxxx; xxxxx (xx) +^	xxxxxxxxxx	xxxxxxx	xxxx	xxx	BID; Topical	Ddmmmyyyy (xx)/ Ongoing	Prior
		xxxxxxxxxxxxxx; xxxxxxxxxxxx; xxxxxx (xx) *					TID; xxx		Concomitant
							QD; xxx		

Abbreviations: HPV = Human Papillomavirus. VV = Comparator vaccine. ATC = Anatomical therapeutic chemical.
* = Anti-pyretic medication, + = Antibiotic medications. ^ = Prophylactic medications.
Prior medications are medications which started prior to the dose of study vaccination.
Concomitant medications are medications which started on or after the day of the administration of study vaccination.

Programming Notes

Output ID: LS0009
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Listing 16.2.5: Vaccine Administration (Enrolled Set)

Study 213749 - DELIVERY DESIGNATION

Listing 16.2.5
Vaccine Administration
Enrolled Set

Vaccine Group: HPV9 High / HPV9 Medium / HPV9 Low / Gardasil 9

Participant Identifier	Site ID	Vaccine Administered? If no, reason	Date of Administration (Study Day)	Route; Location	Kit Number	Remain under observation?
xxxxxxxx	xx	Yes	ddmmmyyyy (xx)	Intramuscular; Arm Upper Left	xxxxxx	Yes
		No; Adverse Event (xx)		Intramuscular; Arm Upper Right		No
		No; not willing to be vaccinated				
		No; Other: *specify*				

Abbreviations: HPV = Human Papillomavirus.

Programming Notes

Output ID: LS0010
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Listing 16.2.6.1: Listing of anti-HPV IgG Antibody Concentration for each Participant (Enrolled Set)

Study 213749 - DELIVERY DESIGNATION

Listing 16.2.6.1
Listing of anti-HPV IgG Antibody Concentration for each Participant
Enrolled Set

Vaccine Group: HPV9 High / HPV9 Medium / HPV9 Low / Gardasil 9

Participant Identifier	Site ID	Visit	anti-HPV Antibody Concentration (mIU/mL)	Seropositive	Seroconversion
xxxxxxxx	xx	Day 1	xx	Yes	
		Month 1		No	No
		Month 2			Yes
		Month 3			
		Month 6			
		Month 7			
		Month 12			

Abbreviations: HPV = Human Papillomavirus.
Seropositive is defined as the appearance of antibodies (i.e, concentrations greater than or equal to xx mIU/mL) in the serum of participants.
Seroconversion is defined as the appearance of antibodies (i.e, concentrations greater than or equal to xx mIU/mL) in the serum of participants seronegative before vaccination.

Programming Notes

Output ID: LS0011
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Listing 16.2.6.2: Listing of anti-HPV IgG Neutralizing Antibody Titers for each Participant (Enrolled Set)

Study 213749 - DELIVERY DESIGNATION

Listing 16.2.6.2
Listing of anti-HPV IgG Neutralizing Antibody Titers for each Participant
Enrolled Set

Vaccine Group: HPV9 High / HPV9 Medium / HPV9 Low / Gardasil 9

Participant Identifier	Site ID	Visit	anti-HPV Antibody Titers (mIU/mL)	Seropositive	Seroconversion
xxxxxxxx	xx	Day 1	xx	Yes	
		Month 1		No	No
		Month 2			Yes
		Month 3			
		Month 6			
		Month 7			
		Month 12			

Abbreviations: HPV = Human Papillomavirus.
Seropositive is defined as the appearance of antibodies (i.e, titer greater than or equal to xx mIU/mL) in the serum of participants.
Seroconversion is defined as the appearance of antibodies (i.e, titer greater than or equal to xx mIU/mL) in the serum of participants seronegative before vaccination.

Programming Notes

Output ID: LS0012
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Listing 16.2.7.1: Solicited Administration Site Events (Enrolled Set)

Study 213749 - DELIVERY DESIGNATION

Listing 16.2.7.1
Solicited Administration Site Events
Enrolled Set

Vaccine Group: HPV9 High / HPV9 Medium / HPV9 Low / Gardasil 9

Participant Identifier	Site ID	Date of Assessment (Study Day)	Vaccine dose	Injection Site Pain? If Yes, severity	Injection Site Pain leading to Medical Attention	Redness at Injection Site? If Yes, size (mm), Grade	Redness leading to Medical Attention	Swelling at Injection Site? If Yes, size (mm), Grade	Swelling leading to Medical Attention
xxxxxxxx	xx	ddmmmyyyy (Day x)	1/2/3	Yes; Mild/ Moderate/ Severe	None	Yes; xx, Gx	None	Yes; xx, Gx	None
				No	Hospitalization ER Visit Other	No	Hospitalization ER Visit Other	No	Hospitalization ER Visit Other

Abbreviations: HPV = Human Papillomavirus. G1 = Mild, G2 = Moderate, G3 = Severe.

Programming Notes

Output ID: LS0013
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Listing 16.2.7.2: Solicited Systemic Events (Enrolled Set)

Study 213749 - DELIVERY DESIGNATION

Listing 16.2.7.2
Solicited Systemic Events
Enrolled Set

Vaccine Group: HPV9 High / HPV9 Medium / HPV9 Low / Gardasil 9

Participant Identifier	Site ID	Date of Assessment (Study Day)	Vaccine dose	Highest Daily Temper-ature, Grade	Headache? If Yes, intensity	Myalgia? If Yes, Intensity	Arthralgia? If Yes, Intensity	Fatigue? If Yes, severity	Experience other serious symptoms?	Additional medications?; Additional vaccinations?	Day; Additi-onal Vaccin-ation; Date
xxxxxxxx	xx	ddmmmyyyy (Day x)	1/2/3	xx, Gx	Yes; Mild / Moderate/ Severe	Yes; Mild / Moderate / Severe	Yes; Mild/ Moderate/ Severe	Yes; Mild/ Moderate / Severe	Yes	Yes; Yes	Xx; Xxxx Xxxxx
					No	No	No	No	No	No; No	

Abbreviations: HPV = Human Papillomavirus.

Programming Notes

Output ID: LS0014
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Listing 16.2.7.3: Unsolicited Adverse Events (Enrolled Set)

Study 213749 - DELIVERY DESIGNATION

Listing 16.2.7.3
Unsolicited Adverse Events
Enrolled Set

Vaccine Group: HPV9 High / HPV9 Medium / HPV9 Low / Gardasil 9

Participant Identifier	Site ID	System Organ Class; Preferred Term; AE term (Vaccine Dose)	Start Date (Onset Day); End Date (Study Day)	Duration (Days)	Severity; Relationship to Study Treatment	Action Taken to Study Drug; Outcome	Potential Immune-Mediated Disease (pIMD) event?	Serious; If yes, Criteria	Medical Attention	COVID19?	Treatment Given? If Yes, Treatment
xxxxxxxx	xx	xxxxxxxxxx; xxxxxxxxxx; xxxxxx (x)	ddmmmyyyy (x); ddmmmyyyy (x)	xx	Mild / Moderate/ Severe; Related / Not Related	xxxxxx; xxxxxxxx	Yes	Yes; xxxx No	Yes No	Yes No	No Yes; xxxx

Abbreviations: HPV = Human Papillomavirus. COVID19 = Coronavirus disease 2019. MedDRA = Medical dictionary for regulatory activities.
MedDRA version xx.x.
Unsolicited AEs include serious AEs.

Programming Notes

Output ID: LS0015
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Listing 16.2.7.4: Unsolicited Adverse Events Leading to Withdrawal or Discontinuation from Study (Enrolled Set)

Listing 16.2.7.4
Unsolicited Adverse Events Leading to Withdrawal or Discontinuation from Study
Enrolled Set

Vaccine Group: HPV9 High / HPV9 Medium / HPV9 Low / Gardasil 9

Participant Identifier	Site ID	System Organ Class; Preferred Term; AE term (Vaccine Dose)	Start Date (Onset Day); End Date (Study Day)	Duration (Days)	Severity; Relationship to Study Treatment	Action Taken to Study Drug; Outcome	Potential Immune-Mediated Disease (pIMD) event?	Serious; If yes, Criteria	Medical Attention	COVID19?	Treatment Given? If Yes, Treatment
xxxxxxxx	xx	xxxxxxxxxx; xxxxxxxxxx; xxxxxx (x)	ddmmmyyyy (x); ddmmmyyyy (x)	xx	Mild / Moderate/ Severe; Related / Not Related	xxxxxx; xxxxxxxx	Yes	Yes; xxxx	Yes	Yes	No
								No	No	No	Yes; xxxx

Abbreviations: HPV = Human Papillomavirus. COVID19 = Coronavirus disease 2019. MedDRA = Medical dictionary for regulatory activities.
MedDRA version xx.x.
Unsolicited AEs include serious AEs.

Programming Notes

Output ID: LS0016
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Listing 16.2.7.5: Serious Adverse Events (Enrolled Set)

Listing 16.2.7.5
Serious Adverse Events
Enrolled Set

Vaccine Group: HPV9 High / HPV9 Medium / HPV9 Low / Gardasil 9

Participant Identifier	Site ID	System Organ Class; Preferred Term; AE Term (Vaccine Dose)	Country
xxxxxxxx	xx	xxxxxxxxxxxxxxxxxx; xxxxxxxxxxxxxxxx; xxxxxxxxxxxxxxx (x)	xxxxxxxxxx

Abbreviations: HPV = Human Papillomavirus.
Serious AEs are expedited adverse events.

Programming Notes

Output ID: LS0017
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Listing 16.2.7.6: All Serious Adverse Events Leading to Withdrawal or Discontinuation from Study (Enrolled Set)

Study 213749 - DELIVERY DESIGNATION

Listing 16.2.7.6
All Serious Adverse Events Leading to Withdrawal or Discontinuation from Study
Enrolled Set

Vaccine Group: HPV9 High / HPV9 Medium / HPV9 Low / Gardasil 9

Participant Identifier	Site ID	System Organ Class; Preferred Term; AE Term (Vaccine Dose)	Country
xxxxxxxx	xx	xxxxxxxxxxxxxxxxx; xxxxxxxxxxxxxxx; xxxxxxxxxxxxxxx (x)	xxxxxxxxxx

Abbreviations: HPV = Human Papillomavirus.
Serious AEs are expedited adverse events.

Programming Notes

Output ID: LS0018
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Listing 16.2.7.7: Potential Immune-Mediated Disease Events (Enrolled Set)

Study 213749 - DELIVERY DESIGNATION

Listing 16.2.7.7
Potential Immune-Mediated Disease Events
Enrolled Set

Vaccine Group: HPV9 High / HPV9 Medium / HPV9 Low / Gardasil 9

Participant Identifier	Site ID	System Organ Class; Preferred Term; AE Term (Vaccine Dose)	Country
xxxxxxxx	xx	xxxxxxxxxxxxxxxxx; xxxxxxxxxxxxxxx; xxxxxxxxxxxxxxx (x)	xxxxxxxxxx

Abbreviations: HPV = Human Papillomavirus.

Programming Notes

Output ID: LS0019
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Listing 16.2.8.1: Laboratory Results (Enrolled Set)

Listing 16.2.8.1
Laboratory Results
Enrolled Set

Vaccine Group: HPV9 High / HPV9 Medium / HPV9 Low / Gardasil 9

Participant Identifier	Site ID	Visit	Collection date	Lab test	Result	Unit	Reference Range	Investigator assessment	Grade
xxxxxxxx	xx	Visit 1 Visit 2	ddmmmyyyy	Leukocytes Erythrocyte Hemoglobin Platelets Neutrophils Lymphocytes Monocytes Eosinophils Basophils BUN AST ALT	xx	xx	Xx - xx No	Normal Abnormal, not clinically significant Abnormal, clinically significant	Grade 1 Grade 2 Grade 3 Grade 4

Abbreviations: HPV = Human Papillomavirus.

Programming Notes

Output ID: LS0020
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Listing 16.2.8.2: Pregnancies – Follow up Report (Enrolled Set)

Listing 16.2.8.2
Pregnancies – Follow up Report
Enrolled Set

Vaccine Group: HPV9 High / HPV9 Medium / HPV9 Low / Gardasil 9

Participant Identifier	Site ID	Pregnancy outcome	Date of outcome	Method used for delivery	Number of neonates	Gestational weeks at birth / miscarriage / termination
xxxxxxxx	xx	Live infant, no apparent congenital anomaly Live infant congenital anomaly Elective termination, no apparent congenital anomaly Elective termination congenital anomaly Spontaneous abortion, no apparent congenital anomaly Spontaneous abortion congenital anomaly Stillbirth, no apparent congenital anomaly Stillbirth congenital anomaly Ectopic pregnancy Molar pregnancy Lost to follow-up Pregnancy ongoing	ddmmmyyyy	Normal vaginal Caesarean section Forceps delivery Vacuum delivery	xx	xx

Abbreviations: HPV = Human Papillomavirus.

Programming Notes

```
Output ID: LS0021
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749
(HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM
```

Listing 16.2.8.3: Vital Signs (Enrolled Set)

Listing 16.2.8.3
Vital Signs
Enrolled Set

Vaccine Group: HPV9 High / HPV9 Medium / HPV9 Low / Gardasil 9

Participant Identifier	Site ID	Visit	Assessment date	Parameter (unit)	Result
xxxxxxxx	xx	Day 1	ddmmmyyyy	Systolic Blood Pressure (mmHg)	xx
		Month 1		Diastolic Blood Pressure (mmHg)	
		Month 2		Heart rate (bpm)	
		Month 3		Respiratory rate (breathes/min)	
		Month 6			
		Month 7			
		Month 12			

Abbreviations: HPV = Human Papillomavirus.

Programming Notes

Output ID: LS0022
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

Listing 16.2.8.4: Body Temperature (Enrolled Set)

GSK Vaccines

Study 213749 - DELIVERY DESIGNATION

Listing 16.2.8.4
Body Temperature
Enrolled Set

Vaccine Group: HPV9 High / HPV9 Medium / HPV9 Low / Gardasil 9

Participant Identifier	Site ID	Visit	Assessment date	Temperature (unit)	Route
xxxxxxxx	xx	Day 1	ddmmmyyyy	Xx C	Axilla
		Month 2		Xx F	Oral cavity
		Month 6			Tympanic membrane
					Temporal artery

Abbreviations: HPV = Human Papillomavirus.

Programming Notes

Output ID: LS0023
[Source: \\quintiles.net\Enterprise\Apps\sasdata\SASb\SAS\GlaxoSmithKline\HPV\213749 (HPV9)\Biostatistics\Filename.sas] IQVIA DDMMMYYYY HH:MM

DocuSign

Certificate Of Completion

Envelope Id: PPD
Status: Completed
Subject: Complete with DocuSign: GSK_213749(HPV9-AS04-001)_WZA97329_SAP_Final_v3.0_02FEB2024.docx, GSK_2...
Project Code (Enter 0 for non-billable projects): WZA97329
IQVIA ID (Login ID): PPD
Business Unit:
Global Business Operations
Source Envelope:
Document Pages: 207
Signatures: 6
Envelope Originator:
Certificate Pages: 5
Initials: 0
PPD
AutoNav: Enabled
EnvelopeId Stamping: Disabled
Time Zone: (UTC-08:00) Pacific Time (US & Canada)

Record Tracking

Status: Original
2/5/2024 7:30:11 AM
Holder: PPD
Location: DocuSign

Signer Events	Signature	Timestamp
PPD Security Level: Email, Account Authentication (Required)	PPD Signature Adoption: Pre-selected Style Signature ID: PPD Using IP Address: PPD With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document I approve this document	Sent: 2/5/2024 7:34:34 AM Viewed: 2/8/2024 11:19:23 AM Signed: 2/8/2024 11:20:58 AM
Electronic Record and Signature Disclosure: Not Offered via DocuSign		
PPD Security Level: Email, Account Authentication (Required)	PPD Signature Adoption: PPD Signature ID: PPD Using IP Address: PPD With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document I approve this document	Sent: 2/5/2024 7:34:34 AM Viewed: 2/5/2024 7:41:43 AM Signed: 2/5/2024 7:42:41 AM
Electronic Record and Signature Disclosure: Accepted: 11/13/2020 12:14:20 AM ID: PPD		

Signer Events	Signature	Timestamp
PPD Security Level: Email, Account Authentication (Required)	PPD Signature Adoption: Pre-selected Style Signature ID: PPD Using IP Address: PPD With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document I approve this document	Sent: 2/5/2024 7:34:35 AM Viewed: 2/5/2024 11:24:02 AM Signed: 2/5/2024 11:26:38 AM
Electronic Record and Signature Disclosure: Accepted: 7/24/2023 3:40:35 AM ID: PPD		

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	2/5/2024 7:34:35 AM
Certified Delivered	Security Checked	2/5/2024 11:24:02 AM
Signing Complete	Security Checked	2/5/2024 11:26:38 AM
Completed	Security Checked	2/8/2024 11:20:58 AM

Payment Events	Status	Timestamps

Electronic Record and Signature Disclosure

CONSENT TO ELECTRONIC DELIVERY AND EXECUTION OF DOCUMENTS

From time to time, IQVIA (“we” or “us”) may provide you certain written contracts, notices, disclosures, authorizations, acknowledgements or other documents (collectively, the "Documents") electronically. Please read this consent form carefully. It explains the terms and conditions under which such Documents are provided by us and executed by you electronically through your DocuSign, Inc. (“DocuSign”) user account. If you consent to the delivery and execution of such Documents electronically, please click the "I Agree" button.

Documents will be sent to you electronically

If you consent to electronic delivery, Documents will be sent to your DocuSign user account. You may request a paper copy of documents previously made available through your DocuSign user account, but an additional charge may be incurred. Alternatively, you can download and print documents sent to your DocuSign user account. Unless otherwise noted, you can access a Document up to 30 days from the date we first sent the Document to you.

Withhold Consent or Withdrawing Consent to Electronic Delivery

If you withhold consent to electronic delivery or execution, or withdraw your consent at a later date, all Documents will be sent to your mailing address following our receipt of notice of such action. The following sections explain the consequences of withholding or withdrawing your consent to electronic delivery and execution of Documents, and also the procedures you must follow in order to effectuate delivery to your mailing address.

Consequences of Withdrawing Consent

By electing to only receive and execute Documents sent to your mailing address, we will not be able to carry out transactions or services as efficiently. For instance, some transactions or services require your express consent. We can perform these transaction or services only if we first receive an acknowledgement that indicates you received and consent to the Document related to the proposed transaction or service.

To withhold consent now or withdraw consent at a later date, please sign DocuSign's "Withdraw Consent" form on the signing page of your DocuSign user account. This will indicate that you have withdrawn your consent to receive Documents electronically. Once you sign the "Withdraw Consent" form, you will no longer be able to use your DocuSign user account to execute Documents electronically and we will send Documents to your mailing address. Withdrawal of consent does not affect the validity of any Documents previously executed electronically prior to such withdrawal of Consent. In addition, should you execute any Documents electronically, your execution of such Documents shall indicate your continued consent to execute such Documents electronically.

How to contact IQVIA:

If you would like us to send the Documents to a different e-mail address, request paper copies of Documents you have previously received electronically, or withdraw your consent to receive electronic documents, please follow the instructions below. If you have any other questions, please contact: DocuSignSupport@IQVIA.com

1. To advise IQVIA of your new e-mail address

If you would like your Documents sent to a different e-mail address, you must send an e-mail message to DocuSignSupport@IQVIA.com . In the body of the e-mail please state the following: (i) your previous e-mail address, and (ii) your new e-mail address. No other information is required.

In addition, you must notify DocuSign of your new e-mail address. Please log into your DocuSign user account, and follow the instructions to update your e-mail address.

2. To request paper copies from IQVIA

To request paper copies of Documents you have received previously through your DocuSign user account, send an e-mail to DocuSignSupport@IQVIA.com

In the body of the e-mail please state the following: (i) your e-mail address, (ii) full name, (iii) U.S. Postal address, and (iv) telephone number. Additional charges may apply for such paper copies.

3. To withdraw your consent with IQVIA

To withdraw your consent to receiving and executing Documents in an electronic format, you may do one of the following:

i. decline to sign a document from within your DocuSign user account, and on the subsequent page, select the check-box indicating you wish to withdraw your consent; or
ii. send us an e-mail to DocuSignSupport@IQVIA.com and in the body of such request you must state your e-mail, full name, US Postal Address, telephone number, and account number. No additional information is necessary.

Required hardware and software

Operating Systems:	Windows® 2000, Windows® XP, Windows Vista®; Mac OS® X
Browsers:	• Internet Explorer (Windows Only) 8.0 or above – compatibility mode is supported only for 9.0 and above. • Windows Edge Current Version • Mozilla Firefox Current Version • Safari (Mac OS only) 6.2 or above • Google Chrome Current Version
PDF Reader:	Acrobat® or similar software may be required to view and print PDF files
Screen Resolution:	1024 x 768 Recommended
Enabled Security Settings:	Allow per session cookies
Mobile Signing:	• Apple iOS 7.0 or above • Android 4.0 or above

** These minimum requirements are subject to change. If these requirements change, we will provide you with an e-mail message at the e-mail address we have on file for you at the time the hardware and software requirements are revised.

Pre-release (e.g. beta) versions of operating systems and browsers are not supported.

Acknowledging your access and consent to receive materials electronically

To confirm you can access this information electronically and that you consent to receiving and executing Documents electronically on the terms and conditions described above, please let us know by clicking the "I Agree" button.

By clicking the "I Agree" button, you confirm that

- You can access and read this Consent To Electronic Delivery and Execution of Documents; and
- You can print on paper the disclosure or save or send the disclosure to a place where you can print it, for future reference and access; and
- Until or unless you notify IQVIA as described above, you consent to the delivery and execution of Documents electronically.