Division	:	Worldwide Development
Information Type	:	Reporting and Analysis Plan (RAP)

Title	:	Reporting and Analysis Plan for Study 205667: An open-label, single arm, repeat dose, multi-centre study to evaluate the use of a safety syringe for the subcutaneous administration of mepolizumab in subjects with severe eosinophilic asthma.
Compound Number	:	SB-240563
Effective Date	:	03-AUG-2017

Description :

- The purpose of this RAP is to describe the planned analyses and associated data displays to be included in the Clinical Study Report for Protocol 205667.
- This RAP defined the content of the final Statistical Analysis Complete (SAC) deliverable

Author's Name and Functional Area:

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1. REPORTING & ANALYSIS PLAN SYNOPSIS

Overview	Key Elements of the Reporting and Analysis Plan (RAP)
Purpose	• This RAP defines the content of the final Statistical Analysis Complete (SAC) deliverable.
Protocol	• This RAP is based on protocol amendment 1 dated 06-OCT-2016 [GlaxoSmithKline Document Number: 2016N275349_02].
Primary Objective / Endpoint	• To assess the use of the combination product, mepolizumab liquid drug product in safety syringe, for the subcutaneous self-administration of mepolizumab by subjects with severe eosinophilic asthma. o Proportion of subjects successfully able to self-administer their observed third dose at Week 8.
Study Design	• 12-week treatment period, open-label, single arm, repeat-dose, multi-centre study in subjects with severe eosinophilic asthma. • Subjects (or their caregiver, if appropriate) will be trained to administer mepolizumab liquid drug product in safety syringe prior to the first dose (Visit 2). • Mepolizumab will be self-administered (by subject or caregiver, if appropriate) under observation in the clinic for first dose (Visit 2) and third dose (Visit 4). The second dose of mepolizumab will be self-administered (by subject or caregiver, if appropriate) at home without observation following Visit 3. • All injections will be assessed by the investigator for success
Analysis Population	• Primary: All Subjects (Safety) Population. Comprise all enrolled subjects attempting at least one self-administration of mepolizumab.
Hypothesis	• No formal hypothesis will be tested. The study is designed to descriptively evaluate the successful use of the mepolizumab liquid drug product in safety syringe for self-administration by subjects with severe eosinophilic asthma.
Primary Analyses	• The number and percentage of subjects successfully able to self-administer their observed mepolizumab dose at Week 8 (Visit 4) will be summarized together with 95% confidence intervals (CI). No formal statistical analysis will be conducted.
Secondary Analyses	• The number and percentage of subjects successfully able to self-administer their unobserved mepolizumab dose at Week 4 (Visit 3) will be summarized together with 95% CI.
Other Analyses	• The number and percentage of subjects successfully able to self-administer their observed mepolizumab dose at Week 0 (Visit 2) will be summarized together with 95% CI. • The number and percentage of subjects successfully able to self-administer their mepolizumab dose at Week 4 and 8 will be summarized together with 95% CI. • The number and percentage of subjects successfully able to self-administer their mepolizumab dose at Week 0, 4 and 8 will be summarized together with 95% CI. • Mepolizumab plasma concentration-time data will be summarised by visit. • Ratio to baseline blood eosinophils will be summarised by visit.

	• Safety data will be presented in tabular and/or graphical format and summarised descriptively according to GSK's Integrated Data Standards Library (IDSL) standards.

2. SUMMARY OF KEY PROTOCOL INFORMATION

2.1. Changes to the Protocol Defined Statistical Analysis Plan

An additional analysis population was defined for reporting screen failures and inclusion exclusion criteria deviations. This population is described in Section 4.

There are no other changes to the protocol defined statistical analysis plan.

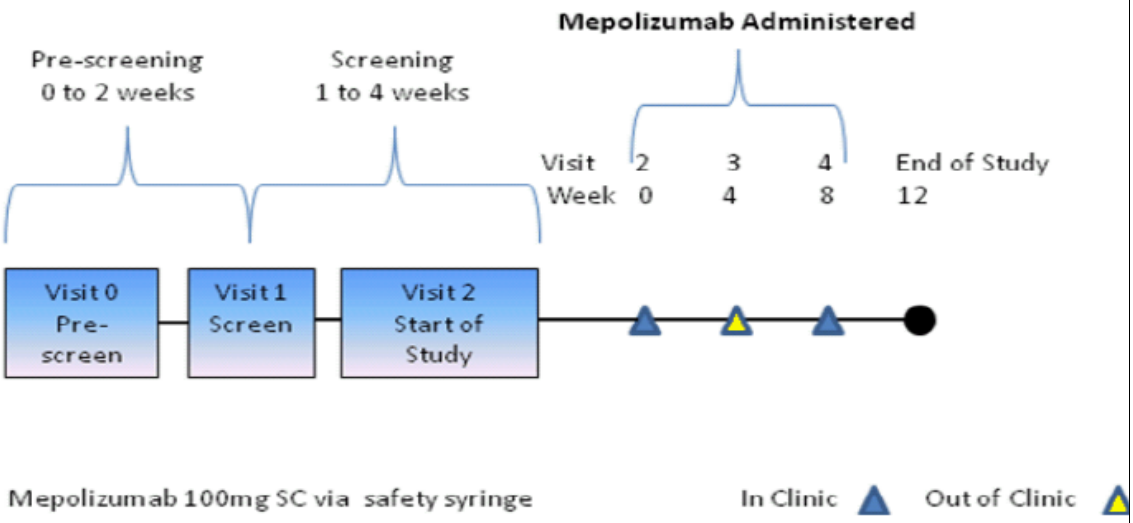
2.2. Study Objective(s) and Endpoint(s)

Objectives	Endpoints
Primary Objectives	**Primary Endpoint**
• To assess the use of the combination product, mepolizumab liquid drug product in safety syringe, for the subcutaneous self-administration of mepolizumab by subjects with severe eosinophilic asthma.	• Proportion of subjects successfully able to self-administer their observed third dose at Week 8.
Secondary Objectives	**Secondary Endpoints**
• To assess the use of mepolizumab liquid drug product in safety syringe outside the clinic setting.	• Proportion of subjects successfully able to self-administer their unobserved second dose outside the clinic setting at Week 4
Other Objectives	**Other Endpoints**
• To assess the use of mepolizumab liquid drug product in safety syringe both inside and outside of the clinic setting.	• Proportion of subjects successfully able to self-administer their observed first dose at Week 0 • Proportion of subjects successfully able to self-administer both their unobserved second dose and observed third observed dose at Weeks 4 and 8 • Proportion of subjects successfully able to self-administer all three doses at Weeks 0, 4 and 8
• To evaluate safety syringe use & functionality.	• Device usability/functionality questionnaire completed at the End of Study/Early Withdrawal Visit
• To evaluate any safety syringe injection errors/failures related to use or device performance.	• Investigator evaluation of user/device errors • Root cause analysis of each unsuccessful injection
• To characterise the subject experience of using the mepolizumab liquid drug product in safety syringe.	• Subject Exit Interviews completed over the telephone after the End of Study/Early Withdrawal Visit

Objectives	Endpoints
• To assess mepolizumab plasma trough concentrations (Ctrough) following the SC administration of mepolizumab liquid drug product in safety syringe.	• Mepolizumab plasma Ctrough at Weeks 4, 8 and 12
• To assess the pharmacodynamic (PD) effect following the SC administration of mepolizumab liquid drug product in safety syringe.	• Ratio to baseline of blood eosinophils at Weeks 4, 8 and 12
• To assess the frequency of asthma exacerbations[1]	• Incidence of asthma exacerbations, expressed as the number of subjects with at least one exacerbation
Safety Objectives	**Safety Endpoints**
• To evaluate the safety and tolerability of mepolizumab liquid drug product in safety syringe.	• Incidence and frequency of Adverse Events (AEs) / Serious Adverse Events (SAEs) including systemic reactions and injection site reactions • Clinically significant change in haematological and/or clinical chemistry parameters • Vital signs • 12-lead electrocardiogram (ECG) • Incidence of immunogenicity • Level of self-reported pain immediately following,1- and 24-hours following each injection (patient diary)

[1] Frequency of asthma exacerbations is listed as a safety endpoint in the protocol.

2.3. Study Design

Overview of Study Design and Key Features	
	

Design Features	• 12-week treatment period, open-label, single arm, repeat-dose, multi-centre study in subjects with severe eosinophilic asthma.
	• Subjects (or their caregiver, if applicable) will be trained to administer mepolizumab liquid drug product in safety syringe prior to the first dose (Visit 2).
	• Mepolizumab will be self-administered (by subject or caregiver, if appropriate) under observation in the clinic for first dose (Visit 2) and third dose (Visit 4). The second dose of mepolizumab will be self-administered (by subject or caregiver, if appropriate) at home without observation following Visit 3.
	• All injections will be assessed by the investigator for success based on
	  ○ Direct observation of the self-administration if the dose was administered in the clinic, and inspection of the safety syringe.
	  ○ Subject/caregiver completed checklist if the dose was administered outside the clinic, and inspection of the returned safety syringe.

Main Subject Entry Criteria	• Subjects aged 12 or older with physician diagnosis of asthma for ≥2 years. *Either* • Subjects receiving 100mg SC mepolizumab for the treatment of severe eosinophilic asthma every 4 weeks for at least 12 weeks prior to the study. *or*

Overview of Study Design and Key Features	
	• Subjects not receiving mepolizumab treatment at Visit 1 meeting additional criteria of asthma of eosinophilic phenotype requiring regular treatment with high dose inhaled corticosteroids (ICS) in the 12 months prior to Visit 1, current treatment with an additional controller medication besides ICS for at least 3 months, and with one or more exacerbations in the 12 months prior to Visit 1.
Dosing	• 100 mg mepolizumab SC every 4 weeks (3 administrations) in thigh, abdomen or upper arm (care giver only).
Treatment Assignment	• All subjects will receive the same treatment.
Interim Analysis	• No interim analysis is planned.
Time and events	• See Appendix 1: Time & Events.

2.4. Statistical Hypotheses

The study is designed to descriptively evaluate the successful use of the mepolizumab liquid drug product in safety syringe for self-administration by subjects with severe eosinophilic asthma.

No formal statistical hypothesis testing is planned. The number and percentage of subjects successfully able to self-administer each mepolizumab dose will be summarized together with 95% CI.

3. PLANNED ANALYSES

3.1. Interim Analyses

No interim analysis is planned.

3.2. Final Analyses

The final planned analyses will be performed after the completion of the following steps:

1. All subjects have completed the study as defined in the protocol.
2. All required database cleaning activities have been completed and final database release and database freeze (DBF) has been declared by Data Management.

4. ANALYSIS POPULATIONS

Population	Definition / Criteria	Analyses Evaluated
All Subjects Enrolled (ASE)	• All subjects for whom a record exists in the data base.	• Pre-screen and screen failures
All Subjects (Safety)	• All enrolled subjects attempting at least one self-administration of mepolizumab.	• Endpoints relating to safety syringe use and functionality, including primary endpoint • Study Population • Safety
Pharmacokinetic (PK)	• All enrolled subjects attempting at least one self-administration of mepolizumab for whom a PK sample was obtained and analysed.	• PK
Pharmacodynamic (PD)	• All enrolled subjects attempting at least one self-administration of mepolizumab who had a baseline PD measurement and at least one post-treatment PD measurement.	• PD

NOTES :

- Please refer to Appendix 8: List of Data Displays which details the population to be used for each displays being generated.

4.1. Protocol Deviations

- Protocol deviations will be tracked by the study team throughout the conduct of the study in accordance with the Protocol Deviation Management Plan.
    - Data will be reviewed prior to DBF to ensure all important deviations are captured and categorised on the protocol deviations dataset.
    - This dataset will be the basis for the summaries and listings of protocol deviations.
- Important protocol deviations (including deviations related to study inclusion/exclusion criteria, conduct of the trial, subject management or subject assessment) will be summarised and listed.
- A separate summary and listing of all inclusion/exclusion criteria deviations will also be provided. This summary will be based on data as recorded on the inclusion/exclusion page of the electronic case report form (eCRF).

5. CONSIDERATIONS FOR DATA ANALYSES AND DATA HANDLING CONVENTIONS

5.1. Methods for Handling Centres

In this multi-centre global study, enrolment will be presented by investigative site within country. No adjustment for centre or country will be made when presenting the study endpoints.

5.2. Multiple Comparisons and Multiplicity

No formal hypothesis will be tested in the study. Each endpoint will be considered separately and no adjustment for multiplicity will be made.

5.3. Handling of Missing Data

In general, analysis will be performed on all available data and no imputation will be performed for missing data. However, if there are withdrawals from study treatment due to issues pertaining to the use of the safety syringe, sensitivity analysis of the primary endpoint will be performed, as described in Section 7.1.

5.4. Data Display Standards

5.4.1. Study Treatment Descriptors

RandAll NG		Data Displays for Reporting	
Code	**Description**	**Description**	**Order**
Not applicable		Liquid Safety Syringe	1

5.4.2. Sub-group Display Descriptors

Data Displays for Reporting		
Subgroup Descriptor	**Category**	**Order**
Baseline Mepolizumab Use	No	1
	Yes	2
Injection Site	Abdomen	1
	Upper Arm	2
	Thigh	3

5.5. Other Considerations for Data Analysis and Data Handling Conventions

Table 1 provides an overview of the appendices within the RAP for outlining other general considerations for data analyses and data handling conventions.

Table 1 Overview of Appendices

Section	Component
Section 14.1	Appendix 1: Time & Events
Section 14.2	Appendix 2: Treatment States and Phases • Treatment Phases for Adverse Events • Treatment Phases for Exacerbations
Section 14.3	Appendix 3: Data Handling Conventions • Baseline Definition & Derivations • Reporting Process & Standards
Section 14.4	Appendix 4: Derived and Transformed Data • General, Study Population & Safety
Section 14.5	Appendix 5: Premature Withdrawals & Handling of Missing Data • Premature Withdrawals • Handling of Missing Data • Handling of Missing and Partial Dates
Section 14.6	Appendix 6: Values of Potential Clinical Importance

6. STUDY POPULATION ANALYSES

The study population analyses will be based on the "All Subjects (Safety)" population.

6.1. Overview of Planned Analyses

Table 2 provides an overview of the planned study population analyses. Full details of the data displays to be presented are given in Appendix 8: List of Data Displays.

Table 2 Overview of Planned Study Population Analyses

Display Type	Data Displays Generated		
	Table	Figure	Listing
Study Populations	Y		Y
Screen Failures	Y		Y
Treatment Discontinuation	Y		Y
Subject Disposition	Y		Y
Important Protocol Deviations	Y		Y
Exposure to Study Treatment	Y		Y
Inclusion/Exclusion Deviations			Y
Demographics	Y		Y
Disease Duration	Y		
Baseline Mepolizumab Use	Y		Y
Prior Experience with Self-Injection	Y		
Past and Current Medical Conditions	Y		Y
Family History of Cardiovascular Risk Factors	Y		Y
Other Family History			Y
Smoking History	Y		
Concomitant Medications			Y

NOTES :

- Y = Yes display generated.

7. ANALYSES TO EVALUATE SAFETY SYRINGE

All analyses will be based on the "All Subjects (Safety)" population.

7.1. Overview of Planned Primary Analyses

The primary endpoint is the proportion of subjects successfully able to self-administer their observed third dose at Week 8.

- The number and percentage of subjects successfully able to self-administer their observed third dose at Week 8 will be summarized together with 95% CI.
- The denominator for the percentage calculation will be the number of subjects attempting an injection at Week 8.
- CI for the percentages will be generated using the Exact (Clopper-Pearson) method for binomial proportions.
- No formal statistical analysis will be conducted.
- If there are withdrawals from study treatment due to issues pertaining to the use of the safety syringe, a sensitivity analysis of the primary endpoint will be performed. Missing injection success assessments following withdrawal from study treatment due to issues with the safety syringe will be included in the analysis as injection failures i.e. unsuccessful attempts to self-administer mepolizumab. Injection success assessments classed as "not attempted" on the eCRF following withdrawal from study treatment due to issues with the safety syringe will also be included in this analysis as injection failures.

Table 3 provides an overview of the planned analysis of the primary endpoint, with full details of data displays being presented in Appendix 8: List of Data Displays.

7.2. Other Analyses to Evaluate Safety Syringe

The following endpoints will be summarised in the same way as the primary endpoint (Section 7.1).

- The number and percentage of subjects successfully able to self-administer their unobserved second dose at Week 4. The denominator for the percentage calculation will be the number of subjects attempting an injection at Week 4.
- The number and percentage of subjects successfully able to self-administer their observed first dose at Week 0. The denominator for the percentage calculation will be the number of subjects attempting an injection at Week 0.
- The number and percentage of subjects successfully able to self-administer both their unobserved second dose at Week 4 and their observed third dose at Week 8. The denominator for the percentage calculation will be the number of subjects attempting an injection at both Week 4 and Week 8.

- The number and percentage of subjects successfully able to self-administer all three doses at Week 0, 4 and 8. The denominator for the percentage calculation will be the number of subjects attempting all three doses at Week 0, 4 and 8.

Table 3 provides an overview of the analyses to evaluate the safety syringe, with full details of data displays being presented in Appendix 8: List of Data Displays.

Table 3 Overview of Analyses to Evaluate Safety Syringe

	Summary		Individual	
	T	F	F	L
Primary Endpoint				
Proportion of subjects successfully able to self-administer their observed third dose at Week 8.	Y			Y
Secondary Endpoint				
Proportion of subjects successfully able to self-administer their unobserved second dose at Week 4.	Y			Y
Other Endpoint				
Proportion of subjects successfully able to self-administer their observed first dose at Week 0.	Y			Y
Proportion of subjects successfully able to self-administer their unobserved second dose at Week 4 and their observed third dose at Week 8.	Y			Y
Proportion of subjects successfully able to self-administer all three doses at Week 0, 4 and 8.	Y			Y
Investigator assessment of user/device errors by visit	Y			Y
Observer checklist for in-clinic injections	Y			Y[1]
Subject completed checklist for home injection	Y			Y[1]
Device usability/functionality subject completed questionnaire	Y			

NOTES :

- T = Table, F = Figure, L = Listing, Y = Yes display generated.
- Summary = Represents TFL related to any summaries (i.e. descriptive statistics) of the observed raw data.
- Individual = Represents FL related to any displays of individual subject observed raw data.
- [1] Listings will include person administering injection and time from removal of syringe from storage to injection only. Injection site will be included on the exposure listing (see Table 2).

8. PHARMACOKINETIC ANALYSES

The PK analyses will be based on the "Pharmacokinetic" population.

8.1. Overview of Planned Pharmacokinetic Analyses

- Linear and semi-logarithmic individual plasma concentration-time profiles will be produced for each subject. Time will be relative to the first dose of study treatment. Individual plasma concentration-time profile plots grouped by baseline mepolizumab use and by baseline mepolizumab use and injection site (performed only for the subset of subjects using the same injection site throughout the study) will also be produced.

- Plasma concentrations will be listed and summarised by nominal time and by nominal time and baseline mepolizumab use. Mean (±SD) and median profiles by nominal time and baseline mepolizumab use will be plotted.

- Summaries of plasma concentration-time data will also be produced by baseline mepolizumab use and injection site, and mean (±SD) and median concentration-time profiles by baseline mepolizumab use and injection site will be plotted. These summaries will be performed only for the subset of subjects using the same injection site throughout the study.

- Refer to Appendix 3: Data Handling Conventions, Section 14.3.2 Reporting Process & Standards.

Table 4 provides an overview of the planned pharmacokinetic data displays. Full details of the data displays to be presented are given in Appendix 8: List of Data Displays.

Table 4 Overview of Planned Pharmacokinetic Analyses

Endpoints	Stats Analysis			Summary		Individual	
	F	T	L	F	T	F	L
PK Plasma Concentrations				Y [1] [2]	Y	Y [1]	Y

NOTES :

- T = Table, F = Figures, L = Listings, Y = Yes display generated.
- Stats Analysis = Represents TFL related to any formal statistical analyses (i.e. modelling) conducted.
- Summary = Represents TFL related to any summaries (descriptive statistics) of the observed raw data.
- Individual = Represents FL related to any displays of individual subject observed raw data.

1. Linear and Semi-Log plots will be created on the same display.
2. Separate Mean (± SD) and Median plots will be generated.

9. BLOOD EOSINOPHILS

Blood eosinophil analyses will be based on the "Pharmacodynamic" population.

9.1. Overview of Planned Analyses for Blood Eosinophils

- Blood eosinophil values will be $\log_e$-transformed prior to summarising. Non-detectable values of 0 GI/L, will be replaced by half of the lowest observed detectable (non-zero) value in the study data set, prior to log transformation.

- Blood eosinophil values will be summarised by visit, and by visit and baseline mepolizumab use.

- Blood eosinophil values will also be summarised by visit, baseline mepolizumab use and injection site. These summaries will be performed only for the subset of subjects using the same injection site throughout the study.

Table 5 provides an overview of the planned analyses for blood eosinophils. Full details of data displays to be presented are given in Appendix 8: List of Data Displays.

Table 5 Overview of Planned Analyses for Blood Eosinophils

Endpoint	Untransformed							Log-Transformed						
	Stats Analysis			Summary		Individual		Stats Analysis			Summary		Individual	
	F	T	L	F	T	F	L	F	T	L	F	T	F	L
Absolute Blood Eosinophils					Y						Y	Y		
Ratio to Baseline Blood Eosinophils					Y						Y	Y		

NOTES :
- T = Table, F = Figures, L = Listings, Y = Yes display generated.
- Stats Analysis = Represents TFL related to any formal statistical analyses (i.e. modelling) conducted.
- Summary = Represents TFL related to any summaries (descriptive statistics) of the observed raw data.
- Individual = Represents FL related to any displays of individual subject observed raw data.

10. EXACERBATIONS

Analyses of exacerbations will be based on the "All Subjects (Safety)" population. The number and percentage of subjects with at least one on-treatment exacerbation will be summarised. On-treatment exacerbations are defined in Section 14.2.1.2. All exacerbation data will be listed.

11. SAFETY ANALYSES

The safety displays to be created as part of this RAP include all the required and relevant displays identified as per the IDSL Core Safety Statistical Displays.

Analysis of safety data will be based on the 'All Subjects (Safety)" population.

11.1. Overview of Planned Adverse Event Analyses

Table 6 provides an overview of the planned analyses of AE data. Full details of the data displays to be presented are given in Appendix 8: List of Data Displays.

Table 6 Overview of Planned Adverse Event Analyses

Endpoint / Parameter/ Display Type	Absolute		
	Summary		Individual
	T	F	L
Adverse Events (AEs)			
All AEs by SOC	Y		Y
Common AEs by Overall Frequency[1]	Y		
No. of Subjects & No. of Occurrences of Common AEs by SOC and PT[1]	Y		
All AEs by SOC and Maximum Intensity	Y		
All Drug-Related AEs by SOC	Y		
All Drug-Related AEs by SOC and Maximum Intensity	Y		
AEs by Week 12/Early Withdrawal Binding Antibody Result (see Section 12)	Y		
AEs Leading to Permanent Discontinuation of Study Treatment or Withdrawal from Study by Overall Frequency	Y		Y
AEs reported on the Day of Dosing[2]	Y		Y
Subject Numbers for Individual AEs			Y
Relationship Between AE SOCs, PT & Verbatim Text			Y
Serious AEs (SAEs) and Other Significant AEs			
Fatal SAEs by Overall Frequency	Y		Y
All SAEs by SOC	Y		
Non-Fatal SAEs			Y
Reasons for Considering as a SAE			Y
Drug-Related Fatal SAEs by Overall Frequency	Y		
Drug-Related SAEs by SOC	Y		
No. of Subjects & No. of Occurrences of All SAEs	Y		
Adverse Events of Special Interest (AESI)			
Anaphylaxis	Y		Y
Systemic Reactions – Allergic (Type I Hypersensitivity) and Other Systemic	Y		Y
Systemic Reactions – Allergic (Type I Hypersensitivity)	Y		Y
Systemic Reactions – Other Systemic	Y		Y
Local Injection Site Reactions	Y		Y
Opportunistic Infections	Y		Y
Malignancies	Y		Y
Serious Cardiac, Vascular and Thromboembolic Events	Y		Y
Serious Ischemic Events	Y		Y

NOTES :

- T = Table, F = Figure, L = Listing, Y = Yes display generated, SOC = System Organ Class, PT = Preferred Term.
- Summary = Represents TFL related to any summaries (i.e. descriptive statistics) of the observed raw data.
- Individual = Represents FL related to any displays of individual subject observed raw data.

[1] Common AEs will be defined as AEs with frequency ≥3% (prior to rounding to nearest percent) in either the Total Liquid or Lyophilised Vial treatment groups.

[2] AEs reported on the day of dosing will be defined as adverse events with a start date equal to the date of dosing.

11.1.1. Adverse Events of Special Interest

Adverse events of special interest (AESIs) are adverse events associated with the identified and potential risks of mepolizumab. AESIs reported by the investigator as anaphylaxis reactions, systemic reactions (further categorised by the investigator as either allergic (type I hypersensitivity) or other systemic reactions) and local injection site reactions are collected via targeted eCRF within the study.

AESIs of opportunistic infections, malignancies, serious cardiac vascular and thromboembolic (CVT) events and serious ischemic events will be identified from a list of relevant preferred terms maintained within a project level reference dataset created based on the MedDRA dictionary available at the time of database freeze for this study. Further details of how relevant preferred terms are identified are given in the Program Safety Analysis Plan (PSAP).

Separate summary tables showing the number and percent of subjects with each type of AESI, broken down by preferred term will be created.

For each type of AESI a profile summary table will be produced containing information including, but not be limited to, the number of occurrences of the event, event characteristics, time to onset, intensity, outcome and action taken.

Separate listings of AESIs identified by the investigator as anaphylaxis, allergic (type I hypersensitivity), other systemic reactions and local injection site reactions will be produced, as well as listings of opportunistic infections, malignancies, serious CVT events and serious ischemic events.

11.2. Overview of Other Safety Analyses

Table 7 provides an overview of the planned analyses for laboratory data, immunogenicity, ECG and vital signs. Full details of the data displays to be presented are given in Appendix 8: List of Data Displays.

Table 7 Overview of Other Safety Analyses

Endpoint / Parameter/ Display Type	Absolute			Change from BL		
	Summary		Individual	Summary		Individual
	T	F	L	T	F	L
Haematology						
Haematology Changes from Baseline				Y		
Haematology Shifts from Baseline Relative to Normal Range				Y		
Haematology Shifts from Baseline Relative to PCI Range				Y		
Haematology Data for Subjects with Any Value of Potential Clinical Concern			Y			
Chemistry						
Chemistry Changes from Baseline				Y		
Chemistry Shifts from Baseline Relative to Normal Range				Y		
Chemistry Shifts from Baseline Relative to PCI Range				Y		
Chemistry Data for Subjects with Any Value of Potential Clinical Concern			Y			
ECG						
ECG Findings	Y					
Vital Signs						
Vital Signs Change from Baseline				Y		
Injection Pain Assessment						
Injection Pain VAS Scores	Y		Y			
Injection Pain Categorical Pain Assessment	Y		Y			

NOTES:

- T = Table, F = Figures, L = Listings, Y = Yes display generated. PCI = Potential Clinical Importance – see Section 14.6.
- Summary = Represents TFL related to any summaries (i.e. descriptive statistics) of the observed raw data.
- Individual = Represents FL related to any displays of individual subject observed raw data.

11.2.1. Injection Pain Assessment

Injection pain assessed immediately after the injection and at 1 and 24 hours post-injection, will be summarised by visit and time point. Summary statistics of the Visual Analogue Scale (VAS) score for injection pain will be presented. Categorical summaries of pain description (sharp/stinging, dull/aching, burning, other), pain relative to expectation (greater than expected, less than expected, as expected) and acceptability of pain will also be summarised. All injection pain data will be listed.

12. IMMUNOGENICITY ANALYSES

12.1. Overview of Immunogenicity Analyses

For the immunogenicity assessment, two types of anti-drug antibody (ADA) assays will be performed, a binding antibody assay and a neutralizing antibody assay.

For the binding assay, there will be a three tiered analysis: screening, confirmation and titration. The screening assay produces a result of positive or negative relative to a screening cut point. Positive samples continue with the confirmation assay, which also produces a result of positive or negative relative to a confirmation cut point. For positive confirmation samples, a titre value will also be obtained to quantify the degree of binding in a titration assay and the sample will be tested with the neutralizing assay, which also reports results as positive or negative.

The binding ADA results at Week 0 and Week 12/Early withdrawal will be summarised by visit. Summary statistics for the titre result at Week 12/Early Withdrawal will also be presented. Summaries will also be produced by visit and baseline mepolizumab use.

A summary of adverse events by Week 12/Early Withdrawal binding ADA result will be produced.

A summary of liquid treatment emergent positive confirmatory binding ADA assays in the subset of subjects who did not have a positive confirmatory binding ADA assay prior to the first dose of liquid study treatment at Week 0 will also be presented.

Neutralizing antibody assay results will be summarised by visit, and by visit and baseline mepolizumab use.

Immunogenicity data will be listed for subjects with at least one positive screening binding assay.

13. REFERENCES

GlaxoSmithKline Document Number 2016N275349_02 Study ID 205667. Protocol for Study 205667: An open-label, single arm, repeat dose, multi-centre study to evaluate the use of a safety syringe for the subcutaneous administration of mepolizumab in subjects with severe eosinophilic asthma. Report Date 06-OCT-2016.

14. APPENDICES

Section	Appendix
RAP Section 5 : General Considerations for Data Analyses & Data Handling Conventions	
Section 14.1	Appendix 1: Time & Events
Section 14.2	Appendix 2: Treatment States and Phases • Treatment Phases for Adverse Events • Treatment Phases for Exacerbations
Section 14.3	Appendix 3: Data Handling Conventions • Baseline Definition & Derivations • Reporting Process & Standards
Section 14.4	Appendix 4: Derived and Transformed Data • General, Study Population & Safety
Section 14.5	Appendix 5: Premature Withdrawals & Handling of Missing Data • Premature Withdrawals • Handling of Missing Data • Handling of Missing and Partial Dates
Section 14.6	Appendix 6: Values of Potential Clinical Importance
Other RAP Appendices	
Section 14.7	Appendix 7: Abbreviations & Trade Marks
Section 14.8	Appendix 8: List of Data Displays
Section 14.9	Appendix 9: Example Mock Shells for Data Displays

14.1. Appendix 1: Time & Events

14.1.1. Protocol Defined Time & Events

	Pre-screening Week -6 to Week -5[a]	Screening Week -4 to Week -1	Week 0 (Day 1)	Week 4 (±7 days)	Week 8 (±7 days)	Week 12 (±7 days) End of Study/ Early Withdrawal[b]
Procedures Visit number	**V0**	**V1**	**V2**	**V3**	**V4**	**V5**
Informed consent	X					
Demography/child bearing status assessment	X					
Medical history		X				
Asthma and Exacerbation history	X					
Asthma Therapy history	X					
Smoking history		X				
Parasitic screening[c]		X				
Prior needle use / self-administration assessment		X				
Inclusion/Exclusion criteria		X				
Training session			X[d]			
Safety syringe self-administration in clinic			X		X	
Safety syringe self-administration outside of clinic				X[e, f]		
Laboratory:						
Urine pregnancy test		X	X[d]	X[d]	X[d]	X
Hematology (including eosinophils)[g] / Clinical Chemistry		X	X[d]	X[d]	X[d]	X[d]
Urinalysis		X				
Immunogenicity			X[d]			X[d]
PK			X[d]	X[d]	X[d]	X[d]
Pharmacogenetics[h]			X			
Physical/Clinical:						
Vital signs[i]		X	X[d]	X[d]	X[d]	X
12-lead ECG		X				X
Physical examination		X				X

	Pre-screening Week -6 to Week -5[a]	Screening Week -4 to Week -1	Week 0 (Day 1)	Week 4 (±7 days)	Week 8 (±7 days)	Week 12 (±7 days) End of Study/ Early Withdrawal[b]
Procedures Visit number	**V0**	**V1**	**V2**	**V3**	**V4**	**V5**
Weight		X				
Concomitant Medication	X	X	X	X	X	X
Serious Adverse Events[j,k,l]	X	X	X	X	X	X
Adverse Events[j,k,l]			X	X	X	X
Dispense patient diary			X[m]	X	X	
Return/review patient diary				X	X	X[n]
Dispense safety syringe for self-administration outside of clinic				X		
Return/ inspect safety syringe following self-administration outside of clinic					X	X[n,o]
Subject completed pain assessment diary (0, 1- and 24hours post dose)			X	X[f]	X	
Safety syringe observer assessment checklist			X		X	
Subject/caregiver completed safety syringe checklist				X[f]		
Assessment of injection success			X		X[p]	
Device usability/functionality questionnaire						X
Exit Interview[q]						(X)

a. Pre-screening Visit can occur on the same day as the Screening Visit but must be completed prior to initiating any Visit 1 procedures; The Pre-screening Visit can be conducted up to a maximum of 2 weeks prior to the Screening Visit.

b. The Early Withdrawal Visit will occur 4 weeks (±7 days) after last dose of mepolizumab for any subject who withdraws prior to Week 12

c. Parasitic screening is only required in countries with high-risk or for subjects who have visited high-risk countries in the past 6 months. Sites should use local laboratories.

d. Perform prior to mepolizumab administration during the study and prior to restarting pre-study mepolizumab treatment on study completion/early withdrawal.

e. Subjects will be instructed to contact clinical study staff at any time if they have concerns or questions regarding self-administration. They will have the option of returning to the clinical site for further training or assistance with self-administration. Requirement for additional training or assistance will be documented.

f. Self-administration of mepolizumab using the safety syringe should occur within 24 hours following the clinic visit.

g. Includes measurement of eosinophil levels for pharmacodynamic analysis at Visits 2, 3, 4 and 5

h. Pharmacogenetic sample may be drawn any time after the respective informed consent form is signed and the subject is enrolled.

i. Vital signs include temperature, sitting blood pressure, respiratory rate and pulse.

j. Any SAEs assessed as related to study participation (e.g., study treatment, protocol-mandated procedures, invasive tests, or change in existing therapy) or related to a GSK concomitant medication, will be recorded from the time a subject consents to participate in the study up to and including any follow up contact. All other AEs/SAEs are recorded from the start of study treatment until the End of Study / Early Withdrawal visit.
k. Injection site reactions (e.g., induration, erythema, edema, rash, pruritus, pain) are to be recorded on both AE and SAE CRF forms.
l. Information on systemic reactions and events that meet the anaphylaxis criteria is collected on both AE and SAE CRF forms.
m. Patient diary should be dispensed prior to administration of injection
n. For any subject who withdraws prior to Week 12, patient diary and study drug for self-administration outside of clinic will be returned at the Early Withdrawal visit (if applicable).
o. Assessment to be completed at the Early Withdrawal visit only if the dose of mepolizumab immediately prior to withdrawal was administered outside of the clinic.
p. Includes both the injection outside the clinic from Week 4 and the injection in clinic at Week 8
q. In a subset of subjects only. Completed over the telephone after the End of Study/Early Withdrawal Visit

14.2. Appendix 2: Treatment States and Phases

14.2.1. Treatment Phases

Assessments and events will be classified according to the time of occurrence relative to the first dose of study treatment.

14.2.1.1. Treatment Phases for Adverse Events

Treatment State	Definition
Pre-Treatment	• AE start date < First dose of study treatment
On-Treatment	• First dose of study treatment ≤ AE start date ≤ First dose of study treatment + 28 days • Any adverse event with missing start date will be assumed to be "On-Treatment". • Any adverse event with partial start date will be assumed to be "On-Treatment" unless there is evidence to the contrary (e.g. month/year of onset is present and is earlier than the month/year of the first dose of study treatment).
Post-Treatment	• AE start date > First dose of study treatment + 28 days

14.2.1.2. Treatment Phases for Exacerbations

Treatment State	Definition
Pre-Treatment	• Exacerbation onset date < First dose of study treatment
On-Treatment	• First dose of study treatment ≤ exacerbation onset date ≤ First dose of study treatment + 28 days • Any exacerbation with missing onset date will be assumed to be "On-Treatment". • Any exacerbation with partial onset date will be assumed to be "On-Treatment" unless there is evidence to the contrary (e.g. month/year of onset is present and is earlier than the month/year of the first dose of study treatment).
Post-Treatment	• Exacerbation onset date > First dose of study treatment + 28 days

14.3. Appendix 3: Data Handling Conventions

14.3.1. Baseline Definition & Derivations

14.3.1.1. Baseline Definitions

- Baseline will be defined for all subjects in the 'All Subjects (Safety)' population.
- The baseline values for each assessment will be the latest available assessment prior to administration of mepolizumab at Visit 2.

14.3.1.2. Derivations and Handling of Missing Baseline Data

Definition	Reporting Details
Change from Baseline	= Post-Dose Visit Value – Baseline
% Change from Baseline	= 100 x [(Post-Dose Visit Value – Baseline) / Baseline]
Ratio to Baseline	= Visit Value / Baseline

NOTES :

- Unless otherwise specified, the baseline definitions specified in Section 14.3.1.1 Baseline Definitions will be used for derivations for endpoints / parameters and indicated on summaries and listings.
- Unless otherwise stated, if baseline data is missing no derivation will be performed and will be set to missing.

14.3.2. Reporting Process & Standards

Reporting Process	
Software	
• The currently supported versions of SAS software will be used.	
Reporting Area	
HARP Server	: uk1salx00175
HARP Area	: sb240563/mid205667
Analysis Datasets	
• Analysis datasets will be created according to CDISC standards. • For creation of ADaM datasets (ADCM/ADAE), the same version of dictionary datasets will be implemented for conversion from SI to SDTM.	
Generation of RTF Files	
• RTF files (rich text format) will be generated for the final reporting effort.	

Reporting Standards
General
• The current GSK Integrated Data Standards Library (IDSL) will be applied for reporting, unless otherwise stated: o 4.03 to 4.23: General Principles o 5.01 to 5.08: Principles Related to Data Listings o 6.01 to 6.11: Principles Related to Summary Tables o 7.01 to 7.13: Principles Related to Graphics

Reporting Standards	
○ Safety and study population displays will be based on the core IDSL templates for these data types.	
Formats	
• The reported precision (decimal places) will follow the IDSL statistical principles but may be adjusted to a clinically interpretable number of decimal places (DPs).	
Planned and Actual Time	

• Reporting for tables, figures and formal statistical analyses:
  • Planned time relative to dosing will be used in figures, summaries, statistical analyses and calculation of any derived parameters, unless otherwise stated.
  • The impact of any major deviation from the planned assessment times and/or scheduled visit days on the analyses and interpretation of the results will be assessed as appropriate.
• Reporting for Data Listings:
  • Planned and actual time relative to study drug dosing will be shown in listings (Refer to IDSL Statistical Principle 5.05.1).
  • Unscheduled or unplanned readings will be presented within the subject's listings.
  • Visits outside the protocol defined time-windows (i.e. recorded as protocol deviations) will be included in listings.	

Unscheduled Visits	
• Data recorded at an unscheduled visit will be re-assigned to the closest nominal visit at which collection of data was scheduled, unless information already exists at that visit. Unscheduled data re-assigned to a scheduled visit will be reported in summary tables and figures. Unscheduled data that is not re-assigned to a scheduled visit will not be included in summary tables or figures. • Data from all unscheduled visits will be included in listings and individual subject figures.	
Descriptive Summary Statistics	
Continuous Data	Refer to IDSL Statistical Principle 6.06.1
Categorical Data	N, n, frequency, %
Reporting of Pharmacokinetic Concentration Data	
Descriptive Summary Statistics	Refer to IDSL Statistical Principle 6.06.1 Assign zero to non-quantifiable (NQ) values (Refer to GUI_51487 for further details)
Graphical Displays	
• Refer to IDSL Statistical Principals 7.01 to 7.13.	

14.4. Appendix 4: Derived and Transformed Data

14.4.1. General

Multiple Measurements at One Time Point
• May arise when unscheduled visits are re-assigned to a nominal visit (see Section 14.3.2). If there is data at the nominal visit, the nominal visit data will be used in the summary tables and figures. All assessments will be listed. • Subjects having both High and Low values for Normal Ranges at any post-baseline visits for safety parameters will be counted in both the High and Low categories of "Any visit post-baseline" row of related summary tables. This will also be applicable to relevant Potential Clinical Importance summary tables.
Study Day

• Calculated as the number of days from first dose of mepolizumab at Visit 2:
  • Ref Date = Missing → Study Day = Missing
  • Ref Date < Visit 2 Date → Study Day = Ref Date – Visit 2 Date
  • Ref Data ≥ Visit 2 Date → Study Day = Ref Date – (Visit 2 Date) + 1

14.4.2. Study Population

Demographics
Age
• GSK standard IDSL algorithms will be used for calculating age where birth day and month will be imputed '30th June'. • Birth date will be presented in listings as 'YYYY'. • Age will be calculated relative to the date of the screening visit (Visit 1).
Body Mass Index (BMI)
• Calculated as **Weight (kg) / [Height (m)^2]**
Disease Duration
• Calculated in years as **Number of Years + (Number of Months)/12**
Extent of Exposure
• Number of months of exposure to liquid mepolizumab during this study will be calculated based on the formula: **Duration of Exposure (Months) = (Date of Last Dose of Study Treatment – Date of First Dose of Study Treatment + 29) * 12/365.25**

14.4.3. Evaluation of Safety Syringe

Time from removal of safety syringe from storage to injection
• Calculated in minutes as **Time of Injection – Time Syringe Removed from Storage**

14.4.4. Safety

Adverse Events
Drug Related AEs
AEs with relationship marked 'YES' or relationship missing.
AEs Leading to Permanent Discontinuation from Study Treatment or Withdrawal from the Study
AEs with action marked "Study treatment withdrawn" or withdrawn from study status marked "YES", or a response to either of these questions is missing.
AE Time Since First Dose (Days)
• If AE start date < Date of first dose of study treatment then Time since first dose = Date of first dose of study treatment – AE start date • If AE start date ≥ Date of first dose of study treatment then Time since first dose = AE start date – Date of first dose of study treatment +1 • Missing if AE start date or date of first dose of study treatment is missing.
AE Duration (Days)
• AE end date – AE start date + 1 • Missing if AE start date or end date is missing.
AEs of Special Interest
• See Section 11.1.1

14.5. Appendix 5: Premature Withdrawals & Handling of Missing Data

14.5.1. Premature Withdrawals

Element	Reporting Detail
General	• Subject study completion is defined as completion of the End of Study (Week 12) visit. • Withdrawn subjects will not be replaced in the study. • All available data from subjects who were withdrawn from the study will be listed and all available planned data will be included in summary tables and figures, unless otherwise specified.
Pre-Screen and Screen Failures	• A subject will be assigned a subject number at the time when the informed consent form (ICF) is signed. • A subject who is assigned a subject number but does not have any screening procedures at Visit 1 will be considered a pre-screen failure. • A subject who completes at least one Visit 1 procedure but does not attempt to self-administer a dose of mepolizumab will be considered a screen failure.

14.5.2. Handling of Missing Data

Element	Reporting Detail
General	• In general, analysis will be performed on all available data and no imputation will be performed for missing data. However, if there are withdrawals from the study due to issues pertaining to the use of the safety syringe, a sensitivity analysis of the primary analysis will be performed. Missing or "not attempted" injection success assessments following these withdrawals will be imputed as injection failures i.e. unsuccessful attempts to self-administer mepolizumab in this sensitivity analysis. • Missing data occurs when any requested data is not provided, leading to blank fields on the collection instrument. These data will be indicated by the use of a "blank" in subject listing displays, unless all data for a specific visit are missing in which case the data is excluded from the listing. • Data below the limit of quantification (BLQ) is not missing data and must be displayed as such and included in all listings and summaries.
Outliers	• Any subjects excluded from the summaries and/or statistical analyses because their values are considered outliers will be documented along with the reason for exclusion in the clinical study report.

14.5.3. Handling of Missing and Partial Dates

Element	Reporting Detail
General	• **Partial dates will be displayed as captured in subject listing displays.**
Adverse Events	• Any partial dates for AEs will be raised to data management. If the full date cannot be ascertained, the following assumptions will be made: o If the partial date is a start date, a '01' will be used for the day and 'Jan' will be used for the month. o However, if this imputation results in a date prior to the first dose of mepolizumab and the event could possibly have occurred during treatment from the partial information, then the date of the first dose of mepolizumab will be assumed to be the start date. o The event will then be considered to start on-treatment (worst case). o If the partial date is a stop date, a '28/29/30/31' will be used for the day (dependent on the month and year) and 'Dec' will be used for the month. • Completely missing start or end dates will remain missing, with no imputation applied. Consequently, time to onset and duration of such events will be missing. AEs with completely missing start dates will be considered to start on-treatment (worst case). • The recorded partial date will be displayed in listings.

14.6. Appendix 6: Values of Potential Clinical Importance

14.6.1. Laboratory Values of Potential Clinical Concern

Haematology				
Laboratory Parameter	**Units**	**Age Category**	**Clinical Concern Range**	
			Low Flag (< x)	**High Flag (>x)**
Hematocrit	Ratio of 1	12+	0.201	0.599
Haemoglobin	G/L	12+	71	199
Platelet Count	GI/L	1+	31	1499
While Blood Cell Count (WBC)	GI/L	12+	1.1	

Clinical Chemistry				
Laboratory Parameter	**Units**	**Age Category**	**Clinical Concern Range**	
			Low Flag (< x)	**High Flag (>x)**
ALT	U/L	3-12		>143 (and Total Bilirubin >43)
	U/L	13+		>239 (and Total Bilirubin >43)
Calcium	mmol/L	3+	1.50	3.24
Glucose	mmol/L	1+	2.2	27.8
Phosphorus, Inorg	mmol/L	3+	0.32	
Potassium	mmol/L	3+	2.8	6.5
Sodium	mmol/L	0+	120	160

Possible Hy's Law Cases			
Laboratory Parameter	**Units**	**Category**	**Clinical Concern Range**
ALT, Bilirubin			ALT ≥ 3xULN and Bilirubin ≥ 2xULN (>35% direct)
ALT, INR			ALT ≥ 3xULN and INR > 1.5

NOTES:

- ULN = Upper Limit of Normal.

14.7. Appendix 7: Abbreviations & Trade Marks

14.7.1. Abbreviations

Abbreviation	Description
ADA	Anti-drug Antibody
ADaM	Analysis Data Model
AE	Adverse Event
A&R	Analysis and Reporting
BLQ	Below the Limit of Quantification
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
CPMS	Clinical Pharmacology Modelling & Simulation
CS	Clinical Statistics
CSR	Clinical Study Report
CTR	Clinical Trial Register
Ctrough	Concentration at the end of the dosing interval
DOB	Date of Birth
DP	Decimal Places
eCRF	Electronic Case Record Form
IA	Interim Analysis
ICH	International Conference on Harmonisation
IDMC	Independent Data Monitoring Committee
IDSL	Integrated Data Standards Library
IMMS	International Modules Management System
IP	Investigational Product
GUI	Guidance
GSK	GlaxoSmithKline
PCI	Potential Clinical Importance
PD	Pharmacodynamic
PDMP	Protocol Deviation Management Plan
PK	Pharmacokinetic
QC	Quality Control
QTcF	Frederica's QT Interval Corrected for Heart Rate
QTcB	Bazett's QT Interval Corrected for Heart Rate
RAP	Reporting & Analysis Plan
SAC	Statistical Analysis Complete
SDTM	Study Data Tabulation Model
SOP	Standard Operation Procedure
TA	Therapeutic Area
TFL	Tables, Figures & Listings
ULN	Upper Limit of Normal
VAS	Visual Analogue Scale

14.7.2. Trademarks

Trademarks of the GlaxoSmithKline Group of Companies
NONE

Trademarks not owned by the GlaxoSmithKline Group of Companies
SAS

14.8. Appendix 8: List of Data Displays

14.8.1. Study Population Tables

Study Population - Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
6.1	ASE	*TAB_POP1*	Summary of Study Populations		SAC
6.2	ASE	ES6	Summary of Screen Failures	Include footnote "Note: Inclusion/exclusion criteria include protocol defined continuation criteria."	SAC
6.3	ASE	NS1	Summary of Number of Subjects by Country and Site	"Not Treated" column should be added to include subjects who did not receive treatment.	SAC
6.4	All Subjects	SD1	Summary of IP Discontinuation		SAC
6.5	All Subjects	ES1	Summary of Subject Disposition		SAC
6.6	All Subjects	DV1	Summary of Important Protocol Deviations		SAC
6.7	All Subjects	EX1	Summary of Exposure to Study Treatment (months)	Categories 1, 2, 3 months Summary statistics for duration of exposure (months)	SAC
6.8	All Subjects	TAB_EX1	Summary of Injection Site by Visit		SAC
6.9	All Subjects	DM1	Summary of Demographic Characteristics		SAC
6.10	All Subjects	DM5	Summary of Race and Racial Combinations		SAC
6.11	ASE	DM11	Summary of Age Ranges	"Not Treated" column should be added to include subjects who did not receive treatment.	SAC
6.12	All Subjects	*TAB_POP2*	Summary of Disease Duration		SAC
6.13	All Subjects	*TAB_POP3*	Summary of Prior Experience with Self-Injection of Medication		SAC
6.14	All Subjects	*TAB_POP4*	Summary of Baseline Mepolizumab Use		SAC
6.15	All Subjects	MH1	Summary of Past Medical Conditions		SAC
6.16	All Subjects	MH1	Summary of Current Medical Conditions		SAC
6.17	All Subjects	FH1	Summary of Family History of Cardiovascular Risk Factors		SAC

Study Population - Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
6.18	All Subjects	SU1	Summary of Smoking History	Smoking status (current/former/never) only	SAC

14.8.2. Evaluation of Safety Syringe

No.	Population	IDSL / TST ID / Example Shell	Title	Programming Notes	Deliverable [Priority]
Evaluation of Safety Syringe - Tables					
7.1	All Subjects	*TAB_INJ1*	Summary of the Proportion of Subjects Successfully Able to Self-Administer Injection by Visit		SAC
7.2	All Subjects	*TAB_INJ2*	Summary of Investigator Evaluation of User/Device Errors by Visit		SAC
7.3	All Subjects	*TAB_INJ3*	Summary of Observer Checklist for In-Clinic Injections		SAC
7.4	All Subjects	*TAB_INJ4*	Summary of Subject Completed Checklist for At-Home Injection at Week 4		SAC
7.5	All Subjects	*TAB_INJ5*	Summary of Device Usability/Functionality Questionnaire		SAC

14.8.3. Pharmacokinetic Analyses

No.	Population	IDSL / TST ID / Example Shell	Title	Programming Notes	Deliverable [Priority]
PK Concentration: Figures					
8.1	PK	PK16a	Individual Plasma Mepolizumab Concentration-Time Plots (Linear and Semi-Log) by Subject	Subject number and baseline mepolizumab use as by-line. Indicate the injection site used for each dose using different plotting characters.	SAC
8.2	PK	PK26	Individual Plasma Mepolizumab Concentration-Time Plots (Linear and Semi-Log) by Baseline Mepolizumab Use	Baseline mepolizumab use as a by-line. All subjects in the same baseline mepolizumab group on the same graph ("spaghetti" plot).	SAC
8.3	PK	PK26	Individual Plasma Mepolizumab Concentration-Time Plots (Linear and Semi-Log) by Baseline Mepolizumab Use and Injection Site – Subjects Using the Same Injection Site Throughout the Study	Baseline mepolizumab use and injection site as a by-line. All subjects in the same baseline mepolizumab group and injection site on the same graph ("spaghetti" plot). Include only the subset of subjects using the same injection site for all doses of study treatment.	SAC
8.4	PK	PK17	Mean Plasma Mepolizumab Concentration-Time Plots by Baseline Mepolizumab Use (Linear and Semi-Log)		SAC
8.5	PK	PK18	Median Plasma Mepolizumab Concentration-Time Plots by Baseline Mepolizumab Use (Linear and Semi-Log)		SAC
8.6	PK	PK17	Mean Plasma Mepolizumab Concentration-Time Plots by Baseline Mepolizumab Use and Injection Site (Linear and Semi-Log) – Subjects Using the Same Injection Site Throughout the Study	Include only the subset of subjects using the same injection site for all doses of study treatment.	SAC

No.	Population	IDSL / TST ID / Example Shell	Title	Programming Notes	Deliverable [Priority]
8.7	PK	PK18	Median Plasma Mepolizumab Concentration-Time Plots by Baseline Mepolizumab Use and Injection Site (Linear and Semi-Log) – Subjects Using the Same Injection Site Throughout the Study	Include only the subset of subjects using the same injection site for all doses of study treatment.	SAC
Pharmacokinetic – Tables					
8.1	PK	PK01	Summary of Plasma Mepolizumab Concentration-Time Data		SAC
8.2	PK	PK01	Summary of Plasma Mepolizumab Concentration-Time Data by Baseline Mepolizumab Use		SAC
8.3	PK	PK01	Summary of Plasma Mepolizumab Concentration-Time Data by Baseline Mepolizumab Use and Injection Site – Subjects Using the Same Injection Site Throughout the Study	Include only the subset of subjects using the same injection site for all doses of study treatment.	SAC

14.8.4. Pharmacodynamic Analyses

No.	Population	IDSL / TST ID / Example Shell	Title	Programming Notes	Deliverable [Priority]
Pharmacodynamic – Figures					
9.1	PD	*FIG_PD1*	Geometric Mean (95% CI) Absolute Blood Eosinophils by Visit and Baseline Mepolizumab Use		SAC
9.2	PD	*FIG_PD1*	Geometric Mean (95% CI) Absolute Blood Eosinophils by Visit, Baseline Mepolizumab Use and Injection Site – Subjects Using the Same Injection Site Throughout the Study	Baseline mepolizumab use as by-line. Separate lines on graph corresponding to injection sites. Include only the subset of subjects using the same injection site for all doses of study treatment.	SAC
9.3	PD	*FIG_PD1*	Geometric Mean (95% CI) Ratio to Baseline Blood Eosinophils by Visit and Baseline Mepolizumab Use		SAC
9.4	PD	*FIG_PD1*	Geometric Mean (95% CI) Ratio to Baseline Blood Eosinophils by Visit, Baseline Mepolizumab Use and Injection Site – Subjects Using the Same Injection Site Throughout the Study	Baseline mepolizumab use as by-line. Separate lines on graph corresponding to injection sites. Include only the subset of subjects using the same injection site for all doses of study treatment.	SAC
Pharmacodynamic – Tables					
9.1	PD	*TAB_PD1*	Summary of Blood Eosinophils (GI/L) by Visit		SAC
9.2	PD	*TAB_PD2*	Summary of Ratio to Baseline Blood Eosinophils by Visit		SAC
9.3	PD	*TAB_PD3*	Summary of Blood Eosinophils by Visit and Baseline Mepolizumab Use		SAC
9.4	PD	*TAB_PD4*	Summary of Ratio to Baseline Blood Eosinophils by Visit and Baseline Mepolizumab Use		SAC

No.	Population	IDSL / TST ID / Example Shell	Title	Programming Notes	Deliverable [Priority]
9.5	PD	*TAB_PD3*	Summary of Blood Eosinophils by Visit, Baseline Mepolizumab Use and Injection Site– Subjects Using the Same Injection Site Throughout the Study	Add baseline mepolizumab use to by line, and include injection site in first column. Include only the subset of subjects using the same injection site for all doses of study treatment.	SAC
9.6	PD	*TAB_PD4*	Summary of Ratio to Baseline Blood Eosinophils by Visit, Baseline Mepolizumab Use and Injection Site– Subjects Using the Same Injection Site Throughout the Study	Add baseline mepolizumab use to by line, and include injection site in first column. Include only the subset of subjects using the same injection site for all doses of study treatment.	SAC

14.8.5. Exacerbations

No.	Population	IDSL / TST ID / Example Shell	Title	Programming Notes	Deliverable [Priority]
Exacerbations : Tables					
10.1	All Subjects	*TAB_EX1*	Summary of Number of Subjects with at Least One On-Treatment Exacerbation		SAC

14.8.6. Safety Analyses

No.	Population	IDSL / TST ID / Example Shell	Title	Programming Notes	Deliverable [Priority]
Safety : Tables					
Adverse Events					
11.1	All Subjects	AE1	Summary of All On-Treatment Adverse Events by System Organ Class and Preferred Term		SAC
11.2	All Subjects	AE1	Summary of All Post-Treatment Adverse Events by System Organ Class and Preferred Term		SAC
11.3	All Subjects	AE3	Summary of Common (>=3% Incidence) On-Treatment Adverse Events by Overall Frequency		SAC
11.4	All Subjects	AE15	Summary of Common (>=3% Incidence) On-Treatment Adverse Events by Preferred Term (Number of Subjects and Occurrences)		SAC
11.5	All Subjects	AE5A	Summary of All On-Treatment Adverse Events by Maximum Intensity by System Organ Class and Preferred Term		SAC
11.6	All Subjects	AE1	Summary of All Drug-Related Adverse Events by System Organ Class and Preferred Term		SAC
11.7	All Subjects	AE5A	Summary of All Drug-Related Adverse Events by Maximum Intensity by System Organ Class and Preferred Term		SAC
11.8	All Subjects	AE1	Summary of On-Treatment Adverse Events by Week 12 Binding Antibody Result	Add in row with n in each binding antibody result category. See Section 12.	SAC
11.9	All Subjects	AE3	Summary of All Adverse Events Leading to Permanent Discontinuation from Study Treatment and/orWithdrawal from the Study by Overall Frequency		SAC

No.	Population	IDSL / TST ID / Example Shell	Title	Programming Notes	Deliverable [Priority]
Safety : Tables					
11.10	All Subjects	AE1	Summary of Adverse Events Reported on the Day of Dosing by System Organ Class and Preferred Term		SAC
11.11	All Subjects	AE7	Listing of Subject Numbers for Individual On-Treatment Adverse Events		SAC
11.12	All Subjects	AE2	Listing of Relationship of Adverse Event, System Organ Classes, Preferred Terms and Verbatim Text		SAC
Serious Adverse Events					
11.13	All Subjects	AE3	Summary of Fatal Serious Adverse Events by Overall Frequency		SAC
11.14	All Subjects	AE3	Summary of Drug-Related Fatal Serious Adverse Events by Overall Frequency		SAC
11.15	All Subjects	AE1	Summary of All On-Treatment Serious Adverse Events by System Organ Class and Preferred Term		SAC
11.16	All Subjects	AE16	Summary of All On-Treatment Serious Adverse Events by System Organ Class and Preferred Term (Number of Subjects and Occurrences)		SAC
11.17	All Subjects	AE1	Summary of All Post-Treatment Serious Adverse Events by System Organ Class and Preferred Term		SAC
11.18	All Subjects	AE1	Summary of All Pre-Treatment Serious Adverse Events by System Organ Class and Preferred Term		SAC
11.19	All Subjects	AE1	Summary of All Drug-Related Serious Adverse Events by System Organ Class and Preferred Term		SAC

No.	Population	IDSL / TST ID / Example Shell	Title	Programming Notes	Deliverable [Priority]
Safety : Tables					
Adverse Events of Special Interest					
11.20	All Subjects	AE1	Summary of On-Treatment Adverse Events Reported by the Investigator as Meeting the Criteria for Anaphylaxis		SAC
11.21	All Subjects	*TAB_S1*	Summary Profile of On-Treatment Adverse Events Reported by the Investigator as Meeting the Criteria for Anaphylaxis		SAC
11.22	All Subjects	AE1	Summary of On-Treatment Adverse Events Defined by the Investigator as Systemic Reactions - Allergic (Type I Hypersensitivity) and Other Systemic		SAC
11.23	All Subjects	*TAB_S1*	Summary Profile of On-Treatment Adverse Events Defined by the Investigator as Systemic Reactions - Allergic (Type I Hypersensitivity) and Other Systemic		SAC
11.24	All Subjects	AE1	Summary of On-Treatment Adverse Events Defined by the Investigator as Systemic Reactions - Allergic (Type I Hypersensitivity)		SAC
11.25	All Subjects	*TAB_S1*	Summary Profile of On-Treatment Adverse Events Defined by the Investigator as Systemic Reactions - Allergic (Type I Hypersensitivity)		SAC
11.26	All Subjects	AE1	Summary of On-Treatment Adverse Events Defined by the Investigator as Systemic Reactions – Other Systemic		SAC
11.27	All Subjects	*TAB_S1*	Summary Profile of On-Treatment Adverse Events Defined by the Investigator as Systemic Reactions - Other Systemic		SAC
11.28	All Subjects	AE1	Summary of On-Treatment Adverse Events Defined by the Investigator as Local Injection Site Reactions		SAC

No.	Population	IDSL / TST ID / Example Shell	Title	Programming Notes	Deliverable [Priority]
Safety : Tables					
11.29	All Subjects	*TAB_S1*	Summary Profile of On-Treatment Adverse Events Defined by the Investigator as Local Injection Site Reactions		SAC
11.30	All Subjects	AE1	Summary of On-Treatment Adverse Events Categorised as Serious Cardiac, Vascular and Thromboembolic Events		SAC
11.31	All Subjects	*TAB_S1*	Summary Profile of On-Treatment Adverse Events Categorised as Serious Cardiac, Vascular and Thromboembolic Events		SAC
11.32	All Subjects	AE1	Summary of On-Treatment Adverse Events Categorised as Serious Ischemic Events		SAC
11.33	All Subjects	*TAB_S1*	Summary Profile of On-Treatment Adverse Events Categorised as Serious Ischemic Events		SAC
11.34	All Subjects	AE1	Summary of On-Treatment Adverse Events Categorised as Malignancies		SAC
11.35	All Subjects	*TAB_S1*	Summary Profile of On-Treatment Adverse Events Categorised as Malignancies		SAC
11.36	All Subjects	AE1	Summary of On-Treatment Adverse Events Categorised as Opportunistic Infections		SAC
11.37	All Subjects	*TAB_S1*	Summary Profile of On-Treatment Adverse Events Categorised as Opportunistic Infections		SAC
Laboratory - Haematology					
11.38	All Subjects	LB1	Summary of Haematology Changes from Baseline by Visit	Include baseline values	SAC
11.39	All Subjects	LB3	Summary of Haematology Shifts from Baseline Relative to Normal Range by Visit		SAC

No.	Population	IDSL / TST ID / Example Shell	Title	Programming Notes	Deliverable [Priority]
Safety : Tables					
11.40	All Subjects	LB3	Summary of Haematology Shifts from Baseline Relative to PCI Criteria by Visit		SAC
Laboratory – Clinical Chemistry					
11.41	All Subjects	LB1	Summary of Clinical Chemistry Changes from Baseline by Visit	Include baseline values	SAC
11.42	All Subjects	LB3	Summary of Clinical Chemistry Shifts from Baseline Relative to Normal Range by Visit		SAC
11.43	All Subjects	LB3	Summary of Clinical Chemistry Shifts from Baseline Relative to PCI Criteria by Visit		SAC
ECG					
11.43	All Subjects	EG1	Summary of ECG Findings by Visit		SAC
11.45	All Subjects	EG2	Summary of ECG Values by Visit		SAC
11.46	All Subjects	EG2	Summary of Change from Baseline in ECG Values by Visit	Include baseline values	SAC
Vital Signs					
11.47	All Subjects	VS1	Summary of Vital Signs by Visit		SAC
11.48	All Subjects	VS1	Summary of Change from Baseline in Vital Signs by Visit	Include baseline values	SAC
Injection Pain Assessments					
11.49	All Subjects	*TAB_S3*	Summary of Injection Pain – VAS Scores (mm)	By Visit and time point post-injection (injection, 1 hr post, 24 hrs post)	SAC
11.50	All Subjects	*TAB_S4*	Summary of Injection Pain – Categorical Pain Assessment	By Visit and time point post-injection (injection, 1 hr post, 24 hrs post)	SAC

14.8.7. Immunogenicity

No.	Population	IDSL / TST ID / Example Shell	Title	Programming Notes	Deliverable [Priority]
Immunogenicity : Tables					
12.1	All Subjects	*TAB_S2*	Summary of Binding Antibody by Visit	Positive/Negative at Week 0 and Week 12/Early Withdrawal. For Week 12/Early Withdrawal, include min, median, max values for titre.	SAC
12.2	All Subjects	*TAB_S2*	Summary of Binding Antibody by Visit and Baseline Mepolizumab Use	Positive/Negative at Week 0 and Week 12/Early Withdrawal. For Week 12/Early Withdrawal, include min, median, max values for titre.	SAC
12.3	All Subjects	*TAB_S2*	Summary of Binding Antibody – Subjects Without Positive Result at Week 0	Positive/Negative at Week 12/Early Withdrawal, include min, median, max values for titre.	SAC
12.4	All Subjects	*TAB_S2*	Summary of Neutralising Antibody by Visit	No titre values available for Neutralising antibody.	SAC
12.5	All Subjects	*TAB_S2*	Summary of Neutralising Antibody by Visit and Baseline Mepolizumab Use	No titre values available for Neutralising antibody.	SAC

14.8.8. ICH and Other Listings

ICH and Other Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Study Population					
1	ASE	ES7	Listing of Reasons for Screen Failure	Include footnote "Note: Inclusion/exclusion criteria include protocol defined continuation criteria."	SAC
2	All Subjects	SP3	Listing of Subjects Excluded from Any Population		SAC
3	All Subjects	SD2	Listing of Reasons for Study Treatment Discontinuation		
4	All Subjects	ES2	Listing of Reasons for Study Withdrawal		SAC
5	All Subjects	DV2	Listing of Important Protocol Deviations		SAC
6	All Subjects	IE3	Listing of Subjects with Inclusion/Exclusion Criteria Deviations	Include any deviations in protocol defined continuation criteria.	SAC
7	All Subjects	EX3	Listing of Exposure Data	Include injection site.	SAC
8	All Subjects	*LIST_INJ2*	Listing of Person Administering Injection[1] and Time From Removal of Syringe from Storage to Injection	Include data for all 3 doses. Footnote: "[1] For the at-home injection (week 4), the person administering the injection is documented by the eDiary as the user (caregiver/patient) who logged in to complete the at-home injection checklist."	SAC
9	All Subjects	DM2	Listing of Demographic Characteristics		SAC
10	All Subjects	DM9	Listing of Race		SAC
11	All Subjects	*LIST_POP1*	Listing of Baseline Mepolizumab Use		SAC
12	All Subjects	MH2	Listing of Medical Conditions		SAC
13	All Subjects	FH5	Listing of Family History		SAC

ICH and Other Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
14	All Subjects	CM3	Listing of Concomitant Medications	Include all data collected on the CRF, plus study day for start date	
Evaluation of Safety Syringe					
15	All Subjects	*LIST_INJ1*	Listing of Investigator Assessment of Injection Success		SAC
PK Concentration					
16	PK	PK07	Listing of Plasma Concentration-Time Data		SAC
Exacerbations					
17	All Subjects	*LIST_EX1*	Listing of Exacerbations		SAC
Adverse Events					
18	All Subjects	AE8	Listing of All Adverse Events	Add phase: Pre-treatment, on-treatment, post-treatment (see Section 14.2.1.1).	SAC
19	All Subjects	AE8	Listing of Adverse Events Leading to Withdrawal From Study	Add phase: Pre-treatment, on-treatment, post-treatment (see Section 14.2.1.1).	SAC
20	All Subjects	AE8	Listing of Adverse Events Reported on the Day of Dosing	Add phase: Pre-treatment, on-treatment, post-treatment (see Section 14.2.1.1).	SAC

ICH and Other Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Serious Adverse Events					
21	All Subjects	AE8	Listing of Fatal Serious Adverse Events	Add phase: Pre-treatment, on-treatment, post-treatment (see Section 14.2.1.1).	SAC
22	All Subjects	AE8	Listing of Non-Fatal Serious Adverse Events	Add phase: Pre-treatment, on-treatment, post-treatment (see Section 14.2.1.1).	SAC
23	All Subjects	AE14	Listing of Reasons for Considering as a Serious Adverse Event		SAC
Adverse Events of Special Interest					
24	All Subjects	AE8	Listing of Adverse Events Reported by the Investigator as Meeting the Criteria for Anaphylaxis	Add phase: Pre-treatment, on-treatment, post-treatment (see Section 14.2.1.1). Add injection reaction symptoms and number of doses prior to event.	SAC
25	All Subjects	AE8	Listing of Adverse Events Defined by the Investigator as Systemic Reactions - Allergic (Type I Hypersensitivity)	Add phase: Pre-treatment, on-treatment, post-treatment (see Section 14.2.1.1). Add injection reaction symptoms and number of doses prior to event.	SAC
26	All Subjects	AE8	Listing of Adverse Events Defined by the Investigator as Systemic Reactions – Other Systemic	Add phase: Pre-treatment, on-treatment, post-treatment (see Section 14.2.1.1). Add injection reaction symptoms and number of doses prior to event.	SAC

ICH and Other Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
27	All Subjects	AE8	Listing of Adverse Events Defined by the Investigator as Local Injection Site Reactions	Add phase: Pre-treatment, on-treatment, post-treatment (see Section 14.2.1.1). Add injection reaction symptoms and number of doses prior to event.	SAC
28	All Subjects	AE8	Listing of Adverse Events Categorised as Serious Cardiac, Vascular and Thromboembolic Events	Add phase: Pre-treatment, on-treatment, post-treatment (see Section 14.2.1.1).	SAC
29	All Subjects	AE8	Listing of Adverse Events Categorised as Serious Ischemic Events	Add phase: Pre-treatment, on-treatment, post-treatment (see Section 14.2.1.1).	SAC
30	All Subjects	AE8	Listing of Adverse Events Categorised as Malignancies	Add phase: Pre-treatment, on-treatment, post-treatment (see Section 14.2.1.1).	SAC
31	All Subjects	AE8	Listing of Adverse Events Categorised as Opportunistic Infections	Add phase: Pre-treatment, on-treatment, post-treatment (see Section 14.2.1.1).	SAC
Laboratory					
32	All Subjects	LB5	Listing of Haematology Data for Subjects with Abnormalities of Potential Clinical Concern		SAC
33	All Subjects	LB5	Listing of Chemistry Data for Subjects with Abnormalities of Potential Clinical Concern		SAC

ICH and Other Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Injection Pain					
34	All Subjects	LIST_S1	Listing of Injection Pain Assessment		SAC

ICH and Other Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Immunogenicity					
35	All Subjects	IMM2	Listing of Immunogenicity Data for Subjects with at Least One Positive Screening Binding Assay	Include columns for Screening Binding Assay, Confirmation Binding Assay, Confirmation Binding Assay Titre, Transient/Persistent, Neutralizing Antibody Assay	SAC

14.9. Appendix 9: Example Mock Shells for Data Displays

Example TAB_POP1
Protocol: MID205667
Population: All Subjects Enrolled

Table X
Summary of Study Populations

Population	Liquid Safety Syringe (N=XX)
All Subjects Enrolled	XX
All Subjects (Safety)	XX (XX%)
Pharmacokinetic	XX (XX%)
Pharmacodynamic	XX (XX%)

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example TAB_POP2
Protocol: MID205667
Population: All Subjects (Safety)

Table X
Summary of Disease Duration

		Liquid Safety Syringe (N=XX)
Duration of Disease (years)	n	XX
	>=1 to <5	XX (XX%)
	>=5 to <10	XX (XX%)
	etc.	XX (XX%)
	Mean	XX.X
	SD	XX.XX
	Median	XX.X
	Minimum	XX
	Maximum	XX

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example TAB_EX1
Protocol: MID205667
Population: All Subjects (Safety)

Table X
Summary of Injection Site

Visit	Injection Site	Liquid Safety Syringe (N=XX)
WEEK 0	n	XX
	Abdomen	XX (XX%)
	Upper arm	XX (XX%)
	Thigh	XX (XX%)
	Other, or intervention required	XX (XX%)
WEEK 4	n	XX
	Abdomen	XX (XX%)
	Upper arm	XX (XX%)
	Thigh	XX (XX%)
	Other	XX (XX%)
WEEK 8	n	XX
	Abdomen	XX (XX%)
	Upper arm	XX (XX%)
	Thigh	XX (XX%)
	Other, or intervention required	XX (XX%)

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example TAB_POP3
Protocol: MID205667
Population: All Subjects (Safety)

Table X
Summary of Prior Experience with Self-Injection of Medication

Visit		Liquid Safety Syringe (N=XX)
Does the subject have any prior experience with self-injection of medication?	n	XX
	No	XX (XX%)
	Yes	XX (XX%)
	Autoinjector (Pen)	XX (XX%)
	Prefilled syringe	XX (XX%)
	Vial and syringe	XX (XX%)
	Other method	XX (XX%)

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example TAB_POP4
Protocol: MID205667
Population: All Subjects (Safety)

Table X
Summary of Baseline Mepolizumab Use

		Liquid Safety Syringe (N=XX)
Is the subject currently receiving treatment with mepolizumab?	n	XX
	No	XX (XX%)
	Yes	XX (XX%)
Blood eosinophil count criteria met [1][2]?	n	
	No	XX (XX%)
	Yes	XX (XX%)
Most recent blood eosinophil count prior to starting mepolizumab (cells/uL) [2]	n	XX
	Median	XX.X
	Minimum	XX
	Maximum	XX

[1] Blood eosinophil count immediately before starting mepolizumab that was >= 150 cells/uL or a blood eosinophil count that was >= 300 cells/uL in the 12 months prior to starting mepolizumab.
[2] Subjects currently receiving treatment with mepolizumab only.

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example TAB_INJ1
Protocol: MID205667
Population: All Subjects (Safety)

Table X
Summary of Proportion of Subjects Successfully Able to Self-Administer Injection by Visit

	Liquid Safety Syringe (N = XX)		
	Attempted Injections	Successful Injections [1]	
Visit	n (%)	n (%)	95% CI
WEEK 0	XX (XX%)	XX (XX%)	(XX%, XX%)
WEEK 4	XX (XX%)	XX (XX%)	(XX%, XX%)
WEEK 8	XX (XX%)	XX (XX%)	(XX%, XX%)
WEEK 4 and 8	XX (XX%)	XX (XX%)	(XX%, XX%)
WEEK 0, 4 and 8	XX (XX%)	XX (XX%)	(XX%, XX%)

[1] The denominator for the percentage of successful injections is the number of attempted injections.

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example TAB_INJ2
Protocol: MID205667
Population: All Subjects (Safety)

Table X.X
Summary of Investigator Evaluation of User/Device Errors by Visit

Visit	n			Liquid Safety Syringe (N=XX)
WEEK 0	XX	Was the drug successfully injected?	Yes	XX (XX%)
			No	XX (XX%)
			Not attempted	XX (XX%)
		User Error	Any User Error	XX (XX%)
			Ring cap not removed from autoinjector	XX (XX%)
			Autoinjector not properly activated on injection site (e.g., gold needle guard not flush with skin)	XX (XX%)
			Autoinjector used upside down	XX (XX%)
			Autoinjector pulled away before end of injection (i.e., before purple indicator stopped moving)	XX (XX%)
			Other	XX (XX%)
		Device Error	Any Device Error	XX (XX%)
			Autoinjector leaking	XX (XX%)
			Components missing / broken / cracked	XX (XX%)
			Inspection window not clear	XX (XX%)
			Cannot remove ring cap	XX (XX%)
			Bent needle	XX (XX%)
			Cannot push the gold needle guard down to activate (i.e., force too high)	XX (XX%)
			Autoinjector does not activate (after pressing gold needle guard down)	XX (XX%)

Programming Note: Continue for Week 4 and 8

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example TAB_INJ3
Protocol: MID205667
Population: All Subjects (Safety)

Table X.X
Summary of Observer Checklist for In-Clinic Injections

Visit: WEEK 0

		Liquid Safety Syringe (N=XX)
Time from removal of syringe from storage to injection (mins)	n	XX
	Mean	XX.X
	SD	XX.XX
	Median	XX.X
	Minimum	XX
	Maximum	XX
Confirm who will be administering the injection	n	XX
	Patient	XX (XX%)
	Caregiver	XX (XX%)
Subject/caregiver completed all the training required	n	XX
	Yes	XX (XX%)
	No	XX (XX%)
Subject/caregiver had instructions for use (IFU) available for review during injection (as recommended)	n	XX
	Yes	XX (XX%)
	No	XX (XX%)

[1] Subject / caregiver completed task easily without repeated reference to the IFU.
[2] Subject / caregiver completed task but with some difficulty or repeated reference to the IFU for assistance.
[3] Subject / caregiver was not able to (or did not) complete task after multiple attempts and reference to the IFU, or intervention was required.

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example TAB_INJ3 (cont.)
Protocol: MID205667
Population: All Subjects (Safety)

Table X.X
Summary of Observer Checklist for In-Clinic Injections

Visit: WEEK 0

		Liquid Safety Syringe (N=XX)
Check that the subject / caregiver looks at the label to check the expiration date on the syringe prior to use.	n	XX
	Easily [1]	XX (XX%)
	With some difficulty [2]	XX (XX%)
	Did not complete [3]	XX (XX%)
Check that the subject / caregiver looks in the inspection window to check the liquid prior to use.	n	XX
	Easily [1]	XX (XX%)
	With some difficulty [2]	XX (XX%)
	Did not complete [3]	XX (XX%)

[1] Subject / caregiver completed task easily without repeated reference to the IFU.
[2] Subject / caregiver completed task but with some difficulty or repeated reference to the IFU for assistance.
[3] Subject / caregiver was not able to (or did not) complete task after multiple attempts and reference to the IFU, or intervention was required.

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example TAB_INJ3 (cont.)
Protocol: MID205667
Population: All Subjects (Safety)

Table X.X
Summary of Observer Checklist for In-Clinic Injections

Visit: WEEK 0

		Liquid Safety Syringe (N=XX)
Check that the subject / caregiver removes the clear needle cap from the safety syringe prior to use.	n	XX
	Easily [1]	XX (XX%)
	With some difficulty [2]	XX (XX%)
	Did not complete [3]	XX (XX%)
Check that the subject / caregiver injects within 5 minutes of removing the needle cap.	n	XX
	Easily [1]	XX (XX%)
	With some difficulty [2]	XX (XX%)
	Did not complete [3]	XX (XX%)
Check that the subject / caregiver pinches the skin around the injection site. Inserts the entire needle into the pinched area at an angle.	n	XX
	Easily [1]	XX (XX%)
	With some difficulty [2]	XX (XX%)
	Did not complete [3]	XX (XX%)

[1] Subject / caregiver completed task easily without repeated reference to the IFU.
[2] Subject / caregiver completed task but with some difficulty or repeated reference to the IFU for assistance.
[3] Subject / caregiver was not able to (or did not) complete task after multiple attempts and reference to the IFU, or intervention was required.

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example TAB_INJ3 (cont.)
Protocol: MID205667
Population: All Subjects (Safety)

Table X.X
Summary of Observer Checklist for In-Clinic Injections

Visit: WEEK 0

		Liquid Safety Syringe (N=XX)
Check that the subject / caregiver begins to push the plunger slowly down.	n	XX
	Easily [1]	XX (XX%)
	With some difficulty [2]	XX (XX%)
	Did not complete [3]	XX (XX%)
Check that the subject / caregiver continues to push the plunger all the way down until the stopper reaches the bottom of the syringe and all of the solution is injected.	n	XX
	Easily [1]	XX (XX%)
	With some difficulty [2]	XX (XX%)
	Did not complete [3]	XX (XX%)
Check that the subject / caregiver moves thumb up, allowing the plunger to rise to activate the needle guard.	n	XX
	Easily [1]	XX (XX%)
	With some difficulty [2]	XX (XX%)
	Did not complete [3]	XX (XX%)

[1] Subject / caregiver completed task easily without repeated reference to the IFU.
[2] Subject / caregiver completed task but with some difficulty or repeated reference to the IFU for assistance.
[3] Subject / caregiver was not able to (or did not) complete task after multiple attempts and reference to the IFU, or intervention was required.

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Programming Note: Continue for Week 8.

Example TAB_INJ4
Protocol: MID205667
Population: All Subjects (Safety)

Table X.X
Summary of Subject Completed Checklist for At-Home Injection at Week 4

		Liquid Safety Syringe (N=XX)
User who logged in to complete the at-home injection checklist."	n	XX
	Patient	XX (XX%)
	Caregiver	XX (XX%)
Time from removal of syringe from storage to injection (mins)	n	XX
	Mean	XX.X
	SD	XX.XX
	Median	XX.X
	Minimum	XX
	Maximum	XX
Did you need to contact the investigator / site prior to the injection for additional training?	n	XX
	Yes – Telephone	XX (XX%)
	Yes – Clinic Visit	XX (XX%)
	No	XX (XX%)
Was the safety syringe stored in the fridge at 2-8 degrees C before preparing for use?	n	XX
	Yes	XX (XX%)
	No	XX (XX%)

[1] I was able to complete the task easily without repeated reference to the IFU.
[2] I was able to complete the task but with some difficulty or repeated reference to the IFU for assistance.
[3] I was not able to (or did not) complete task after multiple attempts and reference to the IFU.

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example TAB_INJ4 (cont.)
Protocol: MID205667
Population: All Subjects (Safety)

Table X.X
Summary of Subject Completed Checklist for At-Home Injection at Week 4

		Liquid Safety Syringe (N=XX)
Check expiration date on the safety syringe has not passed.	n	XX
	Easily [1]	XX (XX%)
	With some difficulty [2]	XX (XX%)
	Did not complete [3]	XX (XX%)
Look in the inspection window to check that the liquid is clear (free from cloudiness or particles) and colorless to slightly yellow in color.	n	XX
	Easily [1]	XX (XX%)
	With some difficulty [2]	XX (XX%)
	Did not complete [3]	XX (XX%)

[1] I was able to complete the task easily without repeated reference to the IFU.
[2] I was able to complete the task but with some difficulty or repeated reference to the IFU for assistance.
[3] I was not able to (or did not) complete task after multiple attempts and reference to the IFU.

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example TAB_INJ4 (cont.)
Protocol: MID205667
Population: All Subjects (Safety)

Table X.X
Summary of Subject Completed Checklist for At-Home Injection at Week 4

		Liquid Safety Syringe (N=XX)
Remove the clear needle cap from the safety syringe by pulling it straight off.	n	XX
	Easily [1]	XX (XX%)
	With some difficulty [2]	XX (XX%)
	Did not complete [3]	XX (XX%)
Inject within 5 minutes of removing the needle cap.	n	XX
	Easily [1]	XX (XX%)
	With some difficulty [2]	XX (XX%)
	Did not complete [3]	XX (XX%)
Use your free hand to gently pinch the skin around the injection site. Insert the entire needle into the pinched area at an angle as shown.	n	XX
	Easily [1]	XX (XX%)
	With some difficulty [2]	XX (XX%)
	Did not complete [3]	XX (XX%)

[1] I was able to complete the task easily without repeated reference to the IFU.
[2] I was able to complete the task but with some difficulty or repeated reference to the IFU for assistance.
[3] I was not able to (or did not) complete task after multiple attempts and reference to the IFU.

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example TAB_INJ4 (cont.)
Protocol: MID205667
Population: All Subjects (Safety)

Table X.X
Summary of Subject Completed Checklist for At-Home Injection at Week 4

		Liquid Safety Syringe (N=XX)
Begin to push the plunger slowly down.	n	XX
	Easily [1]	XX (XX%)
	With some difficulty [2]	XX (XX%)
	Did not complete [3]	XX (XX%)
Continue to push the plunger all the way down until the stopper reaches the bottom of the syringe and all of the solution is injected.	n	XX
	Easily [1]	XX (XX%)
	With some difficulty [2]	XX (XX%)
	Did not complete [3]	XX (XX%)
Move thumb up, allowing the plunger to rise.	n	XX
	Easily [1]	XX (XX%)
	With some difficulty [2]	XX (XX%)
	Did not complete [3]	XX (XX%)

[1] I was able to complete the task easily without repeated reference to the IFU.
[2] I was able to complete the task but with some difficulty or repeated reference to the IFU for assistance.
[3] I was not able to (or did not) complete task after multiple attempts and reference to the IFU.

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example TAB_INJ5
Protocol: MID205667
Population: All Subjects (Safety)

Table X.X
Summary of Device Usability/Functionality Questionnaire

Question	Category	Liquid Safety Syringe (N=XX)
How comfortable did you feel with the training you received on how to use the safety syringe to administer your Nucala (mepolizumab)?	n	XX
	Not at all comfortable	XX (XX%)
	A little comfortable	XX (XX%)
	Moderately comfortable	XX (XX%)
	Very comfortable	XX (XX%)
	Extremely comfortable	XX (XX%)
At the end of the study, how confident were you about your ability to use the safety syringe in the correct way on your own when you were not in the doctor's office?	n	XX
	Not at all confident	XX (XX%)
	A little confident	XX (XX%)
	Moderately confident	XX (XX%)
	Very confident	XX (XX%)
	Extremely confident	XX (XX%)

Programming Note: Continue for all remaining questions on the questionnaire.

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example TAB_PD1
Protocol: MID205667
Population: Pharmacodynamic

Table X
Summary of Blood Eosinophils (GI/L) by Visit

Treatment: Liquid Safety Syringe (N=XX)

Visit	n	Geom. Mean	95% CI (Lower,Upper)	SD (logs)	Min.	Median	Max.
SCREENING	XX	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.x	xxxx.xx	xx.x
WEEK 0	XX	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.x	xxxx.xx	xx.x
WEEK 4	XX	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.x	xxxx.xx	xx.x
WEEK 8	XX	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.x	xxxx.xx	xx.x
WEEK 12	XX	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.x	xxxx.xx	xx.x

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example TAB_PD2
Protocol: MID205667
Population: Pharmacodynamic

Table X
Summary of Ratio to Baseline Blood Eosinophils by Visit

Treatment: Liquid Safety Syringe (N=XX)

Visit	n	Geom. Mean	95% CI (Lower,Upper)	SD (logs)	Min.	Median	Max.
WEEK 4	XX	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.x	xxxx.xx	xx.x
WEEK 8	XX	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.x	xxxx.xx	xx.x
WEEK 12	XX	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.x	xxxx.xx	xx.x

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example TAB_PD3
Protocol: MID205667
Population: Pharmacodynamic

Table X
Summary of Blood Eosinophils (GI/L) by Visit and Baseline Mepolizumab Use

Treatment: Liquid Safety Syringe (N=XX)

Baseline Mepolizumab Use	N	Visit	n	Geom. Mean	95% CI (Lower,Upper)	SD (logs)	Min.	Median	Max.
Yes	XX	SCREENING	XX	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.x	xxxx.xx	xx.x
		WEEK 0	XX	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.x	xxxx.xx	xx.x
		WEEK 4	XX	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.x	xxxx.xx	xx.x
		WEEK 8	XX	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.x	xxxx.xx	xx.x
		WEEK 12	XX	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.x	xxxx.xx	xx.x
No	XX	SCREENING	XX	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.x	xxxx.xx	xx.x
		WEEK 0	XX	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.x	xxxx.xx	xx.x
		WEEK 4	XX	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.x	xxxx.xx	xx.x
		WEEK 8	XX	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.x	xxxx.xx	xx.x
		WEEK 12	XX	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.x	xxxx.xx	xx.x

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example TAB_PD4
Protocol: MID205667
Population: Pharmacodynamic

Table X
Summary of Ratio to Baseline Blood Eosinophils by Visit and Baseline Mepolizumab Use

Treatment: Liquid Safety Syringe (N=XX)

Baseline Mepolizumab Use	N	Visit	n	Geom. Mean	95% CI (Lower,Upper)	SD (logs)	Min.	Median	Max.
Yes	XX	WEEK 4	XX	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.x	xxxx.xx	xx.x
		WEEK 8	XX	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.x	xxxx.xx	xx.x
		WEEK 12	XX	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.x	xxxx.xx	xx.x
No	XX	WEEK 4	XX	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.x	xxxx.xx	xx.x
		WEEK 8	XX	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.x	xxxx.xx	xx.x
		WEEK 12	XX	xxxx.xx	(xxxx.xx,xxxx.xx)	xx.xxx	xx.x	xxxx.xx	xx.x

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example TAB_S1
Protocol: MID205667
Population: All Subjects (Safety)

Table X.X
Summary Profile of On-Treatment Adverse Events Defined by the Investigator as Allergic (Type I Hypersensitivity) Reactions

		Liquid Safety Syringe (N=XX)
1	All Events	
	>= 1 event [1]	xx/xx (x%)
	1 event	xx (x%)
	2 events	xx (x%)
	3 events	xx (x%)
	>=4 events	xx (x%)
2	Serious Events	xx/xx (x%)
	>= 1 event [1]	
3	Events considered related to investigational product	xx/xx (x%)
	>= 1 event [1]	
4	Intensity [1]	
	Mild	xx/xx (x%)
	Moderate	xx/xx (x%)
	Severe	xx/xx (x%)
5	Outcome [1]	
	Recovered/Resolving	xx/xx (x%)
	Recovering/Resolving	xx/xx (x%)
	Not recovered/Not Resolved	xx/xx (x%)
	Recovered/Resolved with sequelae	xx/xx (x%)
	Fatal	xx/xx (x%)

[1] Information presented as number of events / number (%) subjects with at least one event. Subjects may be counted in more than one row.
[2] Cardiac History=Yes includes all subjects with any past medical condition under Cardiac Disorders.
[3] Unable to categorise time since last dose as event time not reported.

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example TAB_S1 (Cont.)
Protocol: MID205667
Population: All Subjects (Safety)

Table X.X
Summary Profile of On-Treatment Adverse Events Defined by the Investigator as Allergic (Type I Hypersensitivity) Reactions

		Liquid Safety Syringe (N=XX)
6	Action Taken [1]	
	Study treatment withdrawn	xx/xx (x%)
	Dose reduced	xx/xx (x%)
	Dose increased	xx/xx (x%)
	Dose not changed	xx/xx (x%)
	Dose interrupted/delayed	xx/xx (x%)
	Not applicable	xx/xx (x%)
7	Cardiac History [1][2]	
	Yes	xx/xx (x%)
	No	xx/xx (x%)
8	Anaphylaxis Criteria Met	
	Anaphylactic Criterion 1	xx/xx (x%)
	Anaphylactic Criterion 2	xx/xx (x%)
	Anaphylactic Criterion 3	xx/xx (x%)
9	No. doses prior to event [1]	
	1	xx/xx (x%)
	2	xx/xx (x%)
	3	xx/xx (x%)
	etc.	
10	No. doses prior to first event	
	1	xx (x%)
	2	xx (x%)
	3	xx (x%)
	etc.	

[1] Information presented as number of events / number (%) subjects with at least one event. Subjects may be counted in more than one row.
[2] Cardiac History=Yes includes all subjects with any past medical condition under Cardiac Disorders.
[3] Unable to categorise time since last dose as event time not reported.

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example TAB_S1 (Cont.)
Protocol: MID205667
Population: All Subjects (Safety)

Table X.X
Summary Profile of On-Treatment Adverse Events Defined by the Investigator as Allergic (Type I Hypersensitivity) Reactions

		Liquid Safety Syringe (N=XX)
11	Time since last dose to event onset [1]	
	<=1 hr	xx/xx (x%)
	1-<6 hrs	xx/xx (x%)
	6-<24 hrs	xx/xx (x%)
	>=24 hrs	xx/xx (x%)
	Missing [3]	xx/xx (x%)
12	Time since last dose to first event onset	
	<=1 hr	xx (x%)
	1-<6 hrs	xx (x%)
	6-<24 hrs	xx (x%)
	>=24 hrs	xx (x%)
	Missing [3]	xx (x%)
13	No. symptoms associated with event [1]	
	0 symptoms	xx/xx (x%)
	1 symptom	xx/xx (x%)
	2-5 symptoms	xx/xx (x%)
	>5 symptoms	xx/xx (x%)
14	Symptoms [1]	
	ABDOMINAL	xx/xx (x%)
	ANGIOEDEMA	xx/xx (x%)
	ARTHRALGIA	xx/xx (x%)
	Etc.	

[1] Information presented as number of events / number (%) subjects with at least one event. Subjects may be counted in more than one row.
[2] Cardiac History=Yes includes all subjects with any past medical condition under Cardiac Disorders.
[3] Unable to categorise time since last dose as event time not reported.

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Programming Notes:-

Remove footnotes that are not relevant for the table.

Sections 1 – 6, 9, 10: Create for all adverse events of special interest

Sections 9 and 10: For studies longer than 1 year can consider the following categories: 1, 2, 3, 4, 5, 6, 7–12, 13–18, 19–24, >24

Section 7: Only for the following adverse events of special interest
Serious Cardiac, Vascular and Thromboembolic Events
Serious Ischemic Events

Section 8: Only for the following adverse events of special interest
Anaphylaxis
Systemic – Allergic (Type I Hypersensitivity)

Sections 11 – 14: Only for the following adverse events of special interest
Anaphylaxis
Systemic – Allergic (Type I Hypersensitivity) and Other Systemic
Systemic – Allergic (Type I Hypersensitivity)
Systemic – Other Systemic
Local Injection Site Reactions

Example TAB_S2
Protocol: MID205667
Population: All Subjects (Safety)

Table X
Summary of Binding Antibody Results by Visit

Visit	Assay Result		Liquid Safety Syringe (N=XX)
WEEK 0	n		X
	NEGATIVE		X (XX%)
	POSITIVE		X (XX%)
WEEK 12/EARLY WITHDRAWAL	n		X
	NEGATIVE		X (XX%)
	POSITIVE		X (XX%)
	Titre value	Min.	X
		Median	X.X
		Max.	X

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example TAB_S3
Protocol: MID205667
Population: All Subjects (Safety)

Table X
Summary of Injection Pain – VAS Scores (mm)

Treatment: Liquid Safety Syringe (N=XX)

Visit	N	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
WEEK 0	XX	INJECTION	XX	X.X	X.XX	X.X	XX	XX
		1 HR POST INJECTION	XX	X.X	X.XX	X.X	XX	XX
		24 HRS POST INJECTION	XX	X.X	X.XX	X.X	XX	XX
WEEK 4	XX	INJECTION	XX	X.X	X.XX	X.X	XX	XX
		1 HR POST INJECTION	XX	X.X	X.XX	X.X	XX	XX
		24 HRS POST INJECTION	XX	X.X	X.XX	X.X	XX	XX
WEEK 8	XX	INJECTION	XX	X.X	X.XX	X.X	XX	XX
		1 HR POST INJECTION	XX	X.X	X.XX	X.X	XX	XX
		24 HRS POST INJECTION	XX	X.X	X.XX	X.X	XX	XX

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example TAB_S4
Protocol: MID205667
Population: All Subjects (Safety)

Table X
Summary of Injection Pain – Categorical Pain Assessment

Visit	N	Planned Relative Time	Pain Assessment	Category	Liquid Safety Syringe (N=XX)
WEEK 0	XX	INJECTION	VAS Score (mm)	n	XX
				0	XX (XX%)
				>0	XX (XX%)
			Description of Pain [1]	n	XX
				Sharp/Stinging	XX (XX%)
				Dull/aching	XX (XX%)
				Burning	XX (XX%)
				Other	XX (XX%)
			Pain Relative to Expectation	n	XX
				Greater than expected	XX (XX%)
				Less than expected	XX (XX%)
				As expected	XX (XX%)
			Pain acceptable?	n	XX
				Yes	XX (XX%)
				No	XX (XX%)

[1] More than one description may be ticked.

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Programming Note: continue for planned relative time = 1 HR POST INJECTION, 24 HRS POST INJECTION and Week 4 and 8.

Example TAB_EX1
Protocol: MID205667
Population: All Subjects Enrolled

Table X
Summary of Number of Subjects With at Least One On-Treatment Exacerbation

Population	Liquid Safety Syringe (N=XX)
Number of Subjects With at Least One Exacerbation	XX (XX%)

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example LIST_POP1
Protocol: MID205667
Population: All Subjects (Safety)

Table X.X
Listing of Baseline Mepolizumab Use

Treatment: Liquid Safety Syringe

Site Id./ Unique Subject Id.	Subject Currently Receiving Treatment with Mepolizumab?	Blood Eosinophil Count Criteria Met [1]?	Most Recent Blood Eosinophil Count Prior to Starting Mepolizumab (cells/uL)
XXXXXX/ MID205667.XXXXXX	Yes	Yes	300

[1] Blood eosinophil count immediately before starting mepolizumab that was >= 150 cells/uL or a blood eosinophil count that was >= 300 cells/uL in the 12 months prior to starting mepolizumab.

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example LIST_INJ1
Protocol: MID205667
Population: All Subjects (Safety)

Table X.X
Listing of Investigator Assessment of Injection Success

Treatment: Liquid Safety Syringe

Site Id./ Unique Subject Id.	Visit	Was Self-Administration of the Injection Successful?	User Error	Device Error
XXXXXX/ MID205667.XXXXXX	WEEK 0	Yes		
	WEEK 4	Yes		
	WEEK 8	Yes		
XXXXXX/ MID205667.XXXXXX	WEEK 0	No	Incorrect injection site selected - arm	
	WEEK 4	Yes		
	WEEK 8	Yes		
XXXXXX/ MID205667.XXXXXX	WEEK 0	No		Syringe leaking Components broken / cracked

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example LIST_INJ2
Protocol: MID205667
Population: All Subjects (Safety)

Table X.X
Listing of Person Administering Injection [1] and Time From Removal of Syringe from Storage to Injection

Treatment: Liquid Safety Syringe

Site Id./ Unique Subject Id.	Visit	Confirm who will be administering the injection [1]	Time from removal of safety syringe from storage to injection (mins)
XXXXXX/ MID205667.XXXXXX	WEEK 0	Patient	Yes
	WEEK 4	Patient	Yes
	WEEK 8	Patient	Yes
XXXXXX/ MID205667.XXXXXX	WEEK 0	Patient	Yes

[1] For the at-home injection (week 4), the person administering the injection is documented by the eDiary as the user (caregiver/patient) who logged in to complete the at-home injection checklist.

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example LIST_EX1
Protocol: MID205667
Population: All Subjects (Safety)

Table X.X
Listing of Exacerbations

Treatment: Liquid Safety Syringe

Site Id.	Unique Subject Id.	Date of Onset	Treatment Phase	Withdrawn	Outcome/ End Date	CS Taken [1]	Hospitalised?/ ER Visit?	Intubated?
PPD	MID205667.XXXXXX	DDMMYYYY	On-Treatment	No	RESOLVED/ DDMMYYYY	Y	N/ N	N

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

[1] CS = Systemic/oral corticosteroids

Example LIST_S1
Protocol: MID205667
Population: All Subjects (Safety)

Table X.X
Listing of Injection Pain Assessment

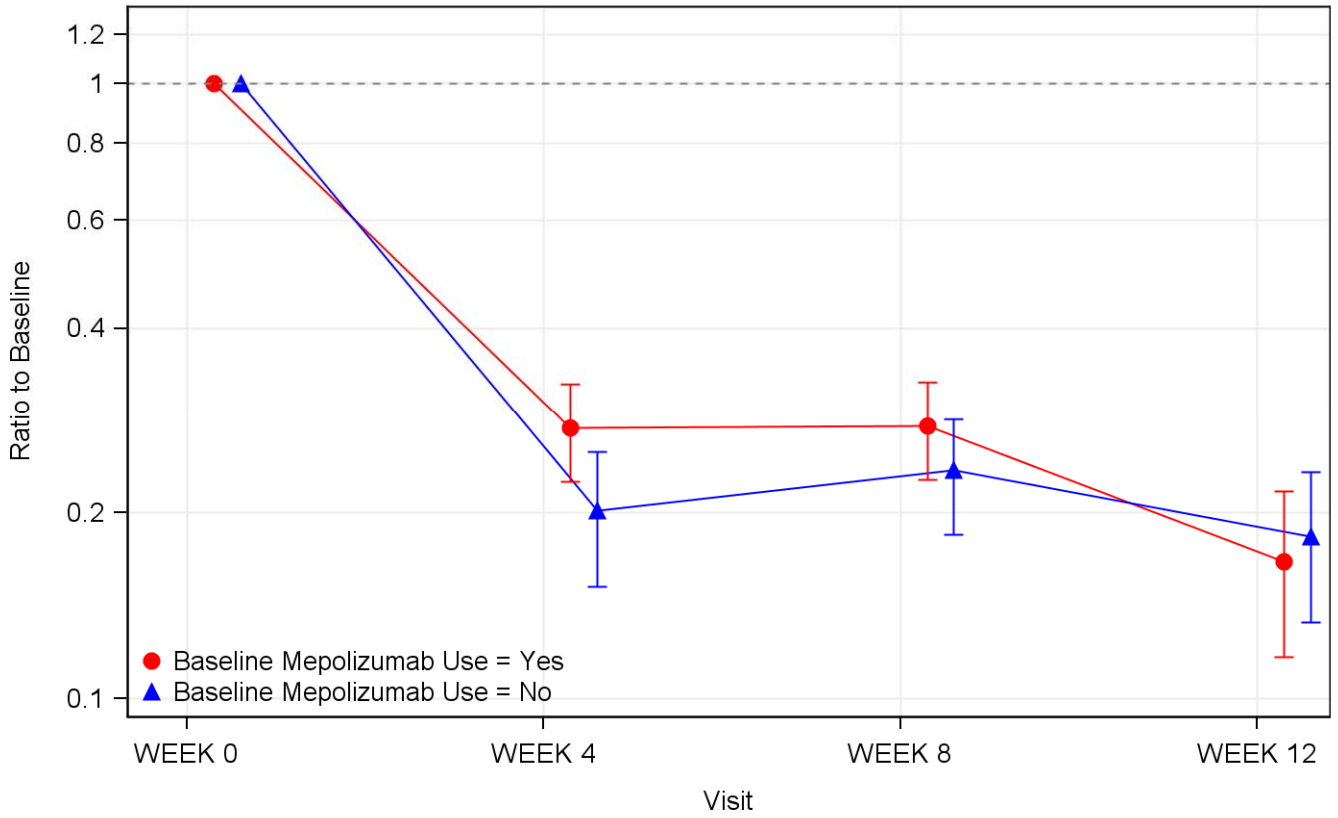
Treatment: Liquid Safety Syringe

Site Id./ Unique Subject Id.	Visit/ Planned Relative Time	Date/Time of Assessment	Study Day	VAS Score (mm)	Description of pain	Pain Relative to Expectation	Was the Pain Acceptable?
XXXXXX/ MID205667.XXXXXX	WEEK 0/ INJECTION	DDMMYYYY/ HH:MM	1	XX	Sharp/stinging	Greater	Yes

userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM

Example FIG_PD1
Protocol: MID205667
Population: Pharmacodynamic

Figure X.X
Geometric Mean Ratio to Baseline Blood Eosinophils by Visit and Baseline Mepolizumab Use



userid: /arenv/arprod/compound/study/final/drivers/drivername.sas DDMMMYYYY HH:MM