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

Title	:	Reporting and Analysis Plan for a double blind (sponsor open) placebo-controlled, stratified, parallel group study to evaluate the efficacy and safety of repeat doses of GSK3772847 in participants with moderate to severe asthma with allergic fungal airway disease (AFAD).
Compound Number	:	GSK3772847
Effective Date	:	24-JAN-2020

Description:

- The purpose of this RAP is to describe the planned analyses and output to be included in the Clinical Study Report for Protocol 207972 (Document Number: 2017N331706_04)
- This RAP is intended to describe the Efficacy, Safety, PK, PD and Biomarker outputs required for the study.
- This RAP will be provided to the study team members to convey the content of the Statistical Analysis Complete (SAC) deliverable.

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1. INTRODUCTION

The purpose of this reporting and analysis plan (RAP) is to describe the analyses to be included in the Clinical Study Report for Protocol of study 207972 (GSK Document No.: 2017N331706_03).

Revision Chronology:		
2017N331706_00	01-SEP-2017	Original
2017N331706_01	05-FEB-2018	Clarified that participants with severe asthma for whom it is felt oral corticosteroids are warranted are not eligible for this study. Clarified the use of anti-fungal medication throughout the study. Clarified the run-in and randomisation criteria sections. Clarified the timing of contraceptive requirements for female participants. Provided a definition for former smokers. Removed the body temperature in the objectives and safety analyses and updated Section 9 to reflect that body temperature will be collected but only available in source documents. Corrected formatting and typographical errors.
2017N331706_02	26-JUL-2018	Russia specific: To allow Russian Federation Sites to conduct the screening assessments over 2 separate visits.
2017N331706_03	10-OCT-2018	To include participants with severe asthma with AFAD treated with low dose oral corticosteroid who still demonstrate a lack of complete control as demonstrated by ACQ-5, FeNO and blood eosinophil levels. Also, a few clarifications were included.
2017N331706_04	10-OCT-2018	Russia specific: To include participants with severe asthma with AFAD treated with low dose oral corticosteroid who still demonstrate a lack of complete control as demonstrated by ACQ-5, FeNO and blood eosinophil levels. Also, a few clarifications were included.

2. SUMMARY OF KEY PROTOCOL INFORMATION

2.1. Changes to the Protocol Defined Statistical Analysis Plan

Changes from the originally planned statistical analysis specified in the protocol are outlined in Table 1.

Table 1 Changes to Protocol Defined Analysis Plan

Protocol	**Reporting & Analysis Plan**	
Statistical Analysis Plan	**Statistical Analysis Plan**	**Rationale for Changes**
Primary and secondary endpoints to be analysed.	All endpoints to be summarised only.	Enrolment into the 207972 study was terminated early due to the

Protocol	Reporting & Analysis Plan	
Statistical Analysis Plan	**Statistical Analysis Plan**	**Rationale for Changes**
		feasibility of completing the study in a timely manner, resulting in insufficient subjects for analysis to be performed.
An internal Safety Review Committee (iSRC) was to review safety data after the 20th randomised subject received their first post-dose ECG/24hr Holter. A potential interim analysis, end of treatment analysis and final SAC analysis was due to be performed.	No iSRC analysis and only one final SAC analysis to be performed.	The study was unable to recruit the 20 randomised subjects required for the iSRC prior to termination. In addition, as recruitment was terminated early, and would not inform internal decision making, there was no requirement to report at multiple timepoints to align with portfolio decisions.
Primary, secondary and exploratory endpoints to be reported.	Primary and secondary endpoints only to be reported.	As there is insufficient data to draw any conclusions on exploratory endpoints, and they are not required for external disclosure, no outputs will be created.

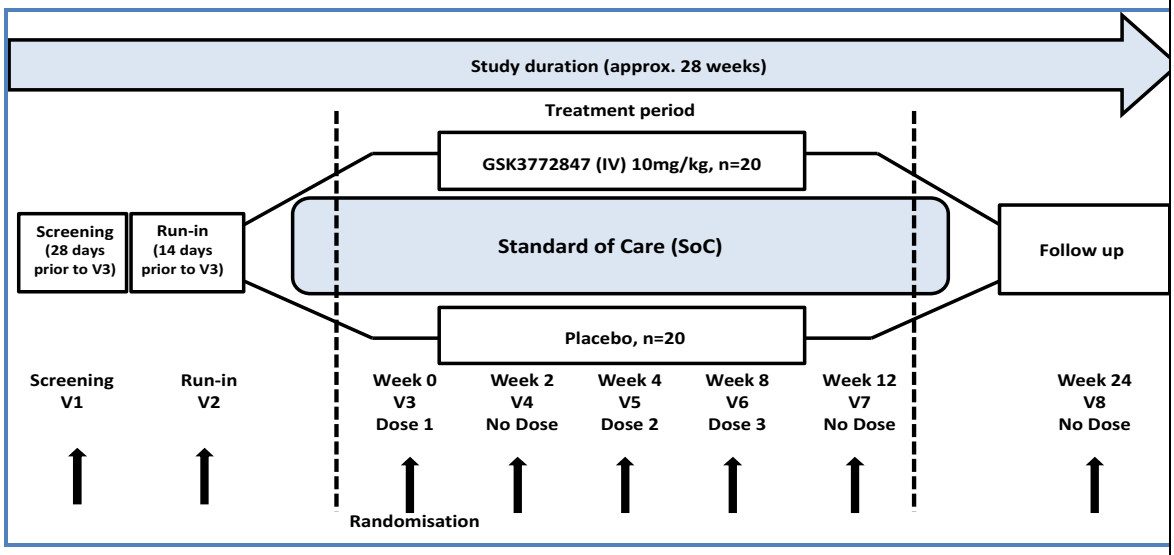
2.2. Study Objective(s) and Endpoint(s)

Objectives	Endpoints
Primary Objectives	**Primary Endpoints**
To evaluate the efficacy of 3 doses of GSK3772847 (administered every 4 weeks) compared with placebo in moderate to severe asthma participants with allergic fungal airway disease (AFAD) who are currently on Standard of Care (SoC)	• Change from baseline (Week 0) in blood eosinophils over time
	• Change from baseline (Week 0) in fractional exhaled nitric oxide (FeNO) over time
Secondary Objectives	**Secondary Endpoints**
To evaluate the serum pharmacokinetics (PK) of 3 doses of GSK3772847 (administered every 4 weeks) in moderate to severe asthma participants with AFAD	• Serum concentrations of GSK3772847
To evaluate the pharmacodynamics (PD) of GSK3772847 in moderate to severe asthma participants with AFAD	• Serum levels of free and total soluble suppressor of tumorigenicity 2 (sST2)
To evaluate the levels and specificity of any anti-drug antibodies formed following dosing with GSK3772847	• Incidence and titres of serum anti- GSK3772847 antibodies
To evaluate the health status of moderate to severe asthma participants with AFAD currently on SoC, and who are treated with GSK3772847 compared with placebo-treated participants	• Change from baseline (Week 0) in Asthma Control Questionnaire -5 (ACQ-5) absolute score at Weeks 2, 4, 8 and 12 • Change from baseline (Week 0) in Asthma Quality of Life Questionnaire (AQLQ) total and domain scores at Weeks 2, 4, 8 and 12 • Proportion of responders to ACQ-5. A responder to

Objectives	Endpoints
	ACQ-5 will be defined as a subject who has a decrease from baseline in ACQ-5 score of 0.5 or more at Weeks 2, 4, 8 and 12. • Proportion of responders to AQLQ. A responder to AQLQ will be defined as a subject who has an increase from baseline in AQLQ score of 0.5 or more at Weeks 2, 4, 8 and 12.
To evaluate the effect on lung function of moderate to severe asthma participants with AFAD currently on SoC, treated with GSK3772847 compared with placebo	• Change from baseline (Week 0) in spirometry parameters over time including but not limited to pre-bronchodilator Forced expiratory volume in 1 second (FEV1).
To evaluate the safety and tolerability of GSK3772847 compared with placebo in moderate to severe asthma participants with AFAD	Safety and tolerability parameters include: • Treatment emergent adverse events (AE) • Clinical Laboratory safety data • Vital signs (blood pressure, heart rate) • 12–Lead Electrocardiogram (ECG) monitoring • 24-hour Holter monitoring
Exploratory Objectives	**Exploratory Endpoints**
To evaluate changes in exploratory biomarkers in the blood of moderate to severe asthma participants with AFAD who have been treated with GSK3772847 compared with placebo	• Change over time in levels of serum total Immunoglobulin E (IgE), fungal-specific IgE
To evaluate changes in IL-33 related and disease biology biomarkers in the sputum of moderate to severe asthma participants with AFAD who have been treated with GSK3772847 compared with placebo	• Difference from placebo in levels of sputum biomarkers including but not limited to interleukin (IL)-33, IL-13, IL-4, IL-5 and TNF- α • Difference from placebo including but not limited to levels of sputum eosinophils

2.3. Study Design

Overview of Study Design and Key Features



Design Features	• The study is a double blind (sponsor open) placebo-controlled, stratified, parallel group study
Dosing	• Participants will remain on SoC treatments for the duration of the treatment period. • Following run-in, they will be randomised to receive three doses of either GSK3772847 or Placebo intravenously (Week 0, 4, 8) on top of their SoC treatment.
Treatment Assignment	• Participants will be randomised in a 1:1 ratio to receive three doses of either GSK3772847 10 mg/kg or Placebo administered intravenously every 4 weeks. • Randomisation will be stratified based on whether the participant is taking antifungal medication.
Final Analysis	• The Final Analysis will take place after all participants have completed the study. This will be the only analysis for the study.

2.4. Statistical Analyses

Due to the study being terminated early, there were insufficient subjects to enable the planned statistical analysis to be performed. As a result, all data will be summarised descriptively only.

3. PLANNED ANALYSES

3.1. Final Analyses

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

1. All participants have completed the study as defined in the protocol
2. All required database cleaning activities have been completed and database release has been declared by Data Management.
3. All criteria for unblinding the randomisation codes have been met.
4. Randomisation codes have been distributed according to RandAll NG procedures.
5. Database freeze (DBF) has been declared by Data Management.

4. ANALYSIS POPULATIONS

4.1. Analysis Populations

Population	Definition / Criteria	Analyses Evaluated
Enrolled	The All Subjects Enrolled (ASE) population will consist of all participants who sign the ICF.	• Study population • Subjects by country and site ID • Age ranges • Screening/run-in status and reason for screening/run-in failure.
Screened	The screened population will consist of all participants who sign the ICF, but who did not pass the screening/run-in criteria and therefore were not randomised.	• Reasons for screen/run-in failure
Randomised	The randomised population will consist of all participants who were randomised. A participant who is recorded as a screen or run-in failure and also randomised will be considered to be randomised in error provided they have not performed any study assessments.	• No formal analysis will be performed on this population
Modified Intent-to-Treat	• The modified Intent-to-Treat (mITT) will consist of all randomised participants who take at least 1 dose of study treatment. • Participants will be analysed according to the treatment they receive >=50% of the time. If the participant receives 50% of each treatment they will be analysed according to the randomised treatment.	• Study population • Inclusion, exclusion and randomisation criteria deviations • Participant disposition • Efficacy

Population	Definition / Criteria	Analyses Evaluated
Safety	This population will be the same as the Modified Intent-to-Treat population.	• Safety
Pharmacokinetic	The PK population will consist of all randomised participants who received at least one dose of study medication, and for whom at least one pharmacokinetic sample was obtained, analysed and was measurable.	• PK

Refer to Appendix 10: List of Data Displays which details the population used for each display.

4.2. Protocol Deviations

Important protocol deviations (including deviations related to study inclusion/exclusion criteria, conduct of the trial, patient management or patient assessment) will be summarised and listed.

Protocol deviations will be tracked by the study team throughout the conduct of the study in accordance with the Protocol Deviation Management Plan [Version 2 (19-JUN-2018) or higher].

- Data will be reviewed prior to unblinding and freezing the database, 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.

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 eCRF.

Note: Inclusion and exclusion criteria deviations are always reported as important.

5. CONSIDERATIONS FOR DATA ANALYSES AND DATA HANDLING CONVENTIONS

5.1. Study Treatment & Sub-group Display Descriptors

Treatment Group Descriptions			
RandAll NG		Data Displays for Reporting	
Code	Description	Description	Order [1]
G	GSK3772847 10 mg/kg	GSK3772847	2
P	Placebo	Placebo	1

NOTES:

[1] Order represents treatments being presented in TFL, as appropriate

Treatment comparisons will be displayed as follows using the descriptors as specified:

- GSK3772847 vs Placebo

5.2. Baseline Definitions

For all endpoints (except as noted in baseline definitions) the baseline value will be the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. If time is not collected, Day 1 assessments are assumed to be taken prior to first dose and used as baseline.

Parameter	Study Assessments Considered as Baseline			Baseline Used in Data Display
	Screening	Run-in	Day 1 (Pre-Dose)	
Primary Endpoints				
Fractional Exhaled Nitric Oxide (FeNO)	X		X	Day 1
Blood Eosinophils	X		X	Day 1
Other Patient Reported Outcomes				
AQLQ			X	Day 1
Asthma Control Questionnaire (ACQ-5) score	X		X	Day 1
Spirometry				
Forced Expiratory Volume (FEV1)	X		X	Day 1
Pharmacodynamics				
Free and total sST2 (serum)			X	Day 1

Parameter	Study Assessments Considered as Baseline			Baseline Used in Data Display
	Screening	Run-in	Day 1 (Pre-Dose)	
Safety				
Vital Signs	X	X	X	Day 1
12-lead Electrocardiogram (ECG) measurements	X		X	Day 1
24 hours Holter measurements		X	X	Day 1
Clinical laboratory tests (haematology and chemistry)	X		X	Day 1
Immunogenicity: Anti-GSK3772847 antibodies			X	Day 1
Biomarkers				
Induced sputum biomarkers		X	X	Run-in [1]
Exploratory serum markers (including IgE and Fungal-specific IgE)	X		X	Day 1

NOTES:

- Unless otherwise stated, the mean of replicate assessments taken on the same day will be used as the value for that day.

[1] Baseline is taken at run-in. If the sputum taken at run-in is not viable then a sample is taken at Day 1 (Pre-Dose) and is used as baseline.

5.3. Multicentre Studies

In this multicentre global study, enrolment will be presented by investigative site and country.

5.4. Examination of Covariates, Other Strata and Subgroups

No analysis will be performed on this data due to low subject numbers.

5.5. Multiple Comparisons and Multiplicity

No adjustment for multiplicity is required for this study, as no analysis will be performed.

5.6. Other Considerations for Data Analyses and Data Handling Conventions

Other considerations for data analyses and data handling conventions are outlined in the appendices:

Section	Component
12.3	Appendix 3: Assessment Windows
12.4	Appendix 4: Study Phases and Treatment Emergent Adverse Events
12.5	Appendix 5: Data Display Standards & Handling Conventions
12.6	Appendix 6: Derived and Transformed Data
12.7	Appendix 7: Reporting Standards for Missing Data
12.8	Appendix 8: Values of Potential Clinical Importance

6. STUDY POPULATION ANALYSES

6.1. Overview of Planned Study Population Analyses

The study population summaries will be based on the modified intent to treat population (mITT), unless specified to be on the All Subjects Enrolled (ASE) population.

Study population summaries including subject's disposition, protocol deviations, demographic and baseline characteristics, prior and concomitant medications, exposure and treatment compliance will be based on GSK Core Data Standards. Details of the planned displays are presented in Appendix 10: List of Data Displays.

6.2. Disposition

The study populations summary will use the All Subjects Enrolled (ASE) population and show the number of subjects overall who were enrolled, the number of screen failures and the number with each reason for screen failure. It will also show the number of subjects who were randomised and who were in the mITT, Safety and PK populations.

For the mITT population, two tables will be produced showing reasons for withdrawal from study and reasons for withdrawal from treatment. These summaries will show the number and percentage of subjects who completed the treatment/study, who withdrew prematurely and who reported each primary and sub-reason for withdrawal.

6.3. Medical Conditions

The number and percentage of subjects reporting each current medical condition will be presented. This table will include a subheading of 'Cardiovascular Risk Factors,' which will summarise the information taken from the cardiac disorders page in the eCRF. All medical conditions must be summarised on this table regardless of frequency. This will be repeated for past medical conditions.

6.4. Concomitant Medications

Non-Asthma medications will be summarised by Anatomical-Therapeutic-Chemical (ATC) level 1 and ingredient. Asthma medications will be summarised by the latest version of the Respiratory Medication Class (RMC), and will be derived for each asthma concomitant medication. Multi-ingredient medications will be presented according to their combination ATC classification rather than the classifications of the ingredients.

Asthma and non-asthma medications will be listed together. A listing of the relationship between ATC Level 1, ingredient and verbatim text will be produced for non-asthma medications only.

7. EFFICACY ANALYSES

Due to low subject numbers no statistical analysis will be performed.

7.1. Primary Efficacy Analyses

7.1.1. Endpoints and Summary Measures

Primary Endpoints	Summary Measure
Change from baseline (Week 0) in blood eosinophils over time	Summary statistics (raw and change from baseline)
Change from baseline (Week 0) in fractional exhaled nitric oxide over time	Summary statistics (raw and change from baseline)

Primary efficacy summaries will be based on the mITT population and no intercurrent events will be considered.

7.2. Secondary Efficacy Analyses

7.2.1. Endpoint and Summary Measure

Secondary Endpoints	Summary Measure
• Change from baseline (Week 0) in spirometry parameters over time including but not limited to pre-bronchodilator Forced expiratory volume in 1 second. • Change from baseline (Week 0) in Asthma Control Questionnaire -5 absolute score at Weeks 2, 4, 8 and 12 • Change from baseline (Week 0) in Asthma Quality of Life Questionnaire total and domain scores at Weeks 2, 4, 8 and 12	Summary statistics (raw and change from baseline)
• Proportion of responders to ACQ-5. A responder to ACQ-5 will be defined as a subject who has a decrease from baseline in ACQ-5 score of 0.5 or more at Weeks 2, 4, 8 and 12. • Proportion of responders to AQLQ. A responder to AQLQ will be defined as a subject who has an increase from baseline in AQLQ score of 0.5 or more at Weeks 2, 4, 8 and 12.	Number and percentage of responders

Secondary efficacy summaries will be based on the mITT population and no intercurrent events will be considered.

8. SAFETY ANALYSES

The safety analyses will be based on the Safety population, unless otherwise specified. The details of the planned displays are provided in Appendix 10: List of Data Displays.

8.1. Adverse Events Analyses

Adverse events analyses including the analysis of adverse events (AEs) and Serious (SAEs) will be based on GSK Core Data Standards.

8.2. Vital Signs, Electrocardiogram (ECG) and Holter

Summary statistics for vital signs at baseline, Weeks 0, 4, 8, 12, and 24 will be produced along with change from baseline summaries for each post baseline timepoint. In addition, the change between post-dose and pre-dose vital signs measurements will be summarised at weeks 0, 4 and 8.

A summary of ECG findings along with a table that shows the maximum increase in QTcF values post-baseline relative to baseline category will be produced.

In addition a summary of Holter interpretations will be produced for participants with at least 16 hours of data, however all data will be listed.

8.3. Clinical Chemistry, Haematology and Cardiac Markers

A summary of worst case clinical chemistry results relative to the normal range post-baseline, will be produced. Similar tables will be created for haematology and cardiac markers.

8.4. Antibodies

Summaries of the incidence of and titres of anti- GSK3772847 antibodies at weeks 0*, 2, 4*, 8*, 12 and 24.

* = Pre-dose only

8.5. Clinical Laboratory Analyses

Laboratory evaluations including the analyses of liver function tests will be based on GSK Core Data Standards.

9. PHARMACOKINETIC ANALYSES

Due to low subject numbers no statistical analysis will be performed.

9.1. Secondary Pharmacokinetic Analyses

Serum concentrations of GSK3772847 will be summarised by nominal time.

Pharmacokinetic summaries will be based on the Pharmacokinetic population, and no intercurrent events will be considered.

10. PHARMACODYNAMIC AND BIOMARKER ANALYSES

10.1. Secondary Pharmacodynamic Analyses

Summary statistics of raw and percentage change from baseline in free and total soluble ST2 levels (serum) will be produced.

Pharmacodynamics summaries will be based on the mITT population, and no intercurrent events will be considered.

11. REFERENCES

GlaxoSmithKline Document Number 2017N331706_04, Protocol Amendment 2: A double blind (sponsor open) placebo-controlled, stratified, parallel group study to evaluate the efficacy and safety of repeat doses of GSK3772847 in participants with moderate to severe asthma with allergic fungal airway disease (AFAD). [10/OCT/2018].

Charter for the Internal Safety Review Committee (iSRC): A double blind (sponsor open) placebo-controlled, stratified, parallel group study to evaluate the efficacy and safety of repeat doses of GSK3772847 in participants with moderate to severe asthma with allergic fungal airway disease (AFAD). [30/JAN/2018]

Protocol Deviation Management Plan Version 2 (19-JUN-2018) or higher.

Winthrop et al, 2015, Opportunistic infections and biologic therapies in immune-mediated inflammatory diseases: consensus recommendations for infection reporting during clinical trials and postmarketing surveillance, Annals of the Rheumatoid Arthritis Disease, doi: 10.1136/annrheumdis-2015-207841. Epub 2015 Sep 22

12. APPENDICES

12.1. Appendix 1: Protocol Deviation Management and Definitions for Per Protocol Population

The full list of protocol deviations collected on the eCRF is in the Protocol Deviation Management Plan (PDMP). Please refer to this document for current guidance.

There is no per protocol population in this study.

12.2. Appendix 2: Schedule of Activities

12.2.1. Protocol Defined Schedule of Events

Procedure	Screening (±5days)	Run-in (±5days)	Treatment Period (Visit window ±3days)				End of Treatment / EW (±3days)	FU (±3days)	Notes
Visit	V1	V2	V3	V4	V5	V6	V7	V8	
Week	-4	-2	0	2	4	8	12	24	
Day	-28	-14	1	15	29	57	85	169	
Informed consent	X								May be obtained prior to Screening.
Inclusion and exclusion criteria	X	X	X						Recheck clinical status before 1st dose of study medication.
Demography	X								
Full physical examination	X								To include height and weight
Medical/medication/ drug/alcohol/smoking history	X								Including smoking history, substance abuse, medical conditions and family history of premature cardiovascular disease; asthma disease duration and exacerbation history
Human immunodeficiency virus (HIV), Hepatitis B and C screening	X								If test otherwise performed within 3 months prior to first dose of study treatment, testing at screening is not required
Genetics									
Informed consent for Pharmacogenetic blood sample	X								

Procedure	Screening (±5days)	Run-in (±5days)	Treatment Period (Visit window ±3days)				End of Treatment / EW (±3days)	FU (±3days)	Notes
Visit	**V1**	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**	**V8**	
Week	**-4**	**-2**	**0**	**2**	**4**	**8**	**12**	**24**	
Pharmacogenetic (PGx) blood sample			X						PGx sample may be drawn any time from Visit 3 onwards, pre-dose. Informed consent must be obtained before collecting a sample.
Study Treatment and Questionnaires									
Randomisation			X						
Study treatment			X		X	X			
Dispense diary card		X							To be completed daily.
Diary card review			X	X	X	X	X		
Collect diary card							X		
Rescue medication dispensing		X	X[1]	X[1]	X[1]	X[1]			1. As needed
ACQ-5	X		X	X	X	X	X		Test to be performed before all other assessments
AQLQ			X	X	X	X	X		Test to be performed immediately after ACQ-5
Efficacy									
Haematology (including eosinophil count)	X		X[1]	X	X	X	X		1. Pre-dose
FeNO	X		X	X	X	X	X		Test to be performed pre-dose
Spirometry	X		X	X	X	X	X		Test to be performed pre-dose

Procedure	Screening (±5days)	Run-in (±5days)	Treatment Period (Visit window ±3days)				End of Treatment / EW (±3days)	FU (±3days)	Notes
Visit	**V1**	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**	**V8**	
Week	**-4**	**-2**	**0**	**2**	**4**	**8**	**12**	**24**	
Free and total sST2 (serum)			X[1]	X	X[2]	X[1]	X[3]	X[3]	1. Pre and Post Dose 2. Pre Dose 3. Anytime (± 5 days) Pre-dose samples: within 2 hours from the planned dosing time Post-dose samples as soon as possible after end of infusion but must be taken within 4 hours.
Total & fungal specific IgE	X[1]		X[2]	X	X	X	X		1. Fungal specific IgE only if no historical documented results available 2. Pre-dose

Procedure	Screening (±5days)	Run-in (±5days)	Treatment Period (Visit window ±3days)				End of Treatment / EW (±3days)	FU (±3days)	Notes
Visit	V1	V2	V3	V4	V5	V6	V7	V8	
Week	-4	-2	0	2	4	8	12	24	
Induced sputum sample for biomarkers		X	X[1,2]				X[3]		1. If no viable sample is produced at V2, induction should be repeated pre dose at V3 2. If a participant does not produce a viable baseline sputum sample at visit 2 or at visit 3, the participant will not need to undergo a sputum induction at the end of the treatment period. 3. If no viable sample is produced, induction should be repeated after a minimum of 72 hrs but no later than 7 days after scheduled visit.

Procedure	Screening (±5days)	Run-in (±5days)	Treatment Period (Visit window ±3days)				End of Treatment / EW (±3days)	FU (±3days)	Notes
Visit	V1	V2	V3	V4	V5	V6	V7	V8	
Week	-4	-2	0	2	4	8	12	24	
Pharmacokinetics									
Serum blood sample for PK			X[1]	X	X[2]	X[3]	X[4]	X[4]	1. Post Dose 2. Pre Dose 3. Pre and Post Dose 4. Anytime (± 5 days) Pre-dose samples: within 2 hours from the planned dosing time Post-dose samples as soon as possible after end of infusion but must be taken within 4 hours.
Safety									
Laboratory assessments	X[1,2]		X[1,3]	X[1]	X[1,3]	X[1]	X[1,3]	X[1]	1. Clinical chemistry (includes liver chemistry) 2. Routine urinalysis at screening (Visit 1) 3. Cardiac markers Note: haematology assessments in efficacy section
Serum blood sample for immunogenicity			X[1]	X	X[1]	X[1]	X	X	1. Pre Dose

Procedure	Screening (±5days)	Run-in (±5days)	Treatment Period (Visit window ±3days)				End of Treatment / EW (±3days)	FU (±3days)	Notes
Visit	**V1**	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**	**V8**	
Week	**-4**	**-2**	**0**	**2**	**4**	**8**	**12**	**24**	
Urine or serum pregnancy test (WOCBP only)	X[1]		X		X	X	X	X	To be performed pre-dose during the treatment period 1. Serum pregnancy test required
12-lead ECG	X		X[1]		X[1]	X[1]	X		1. Test to be performed pre-dose and post-dose within 30 mins after end of infusion.
24 hour Holter		X	X[1]						Holter monitor needs to be returned to the clinic at end of 24 hour recording (i.e. the next day). [1]Place the Holter 30-60mins prior to dosing
Vital signs	X	X	X[1]		X[1]	X[1]	X	X	1. Test to be performed prior to the 12-lead ECG (pre-dose and post dose)
AE review			←==========	==========	==========	==========→			
SAE review	X	X	←==========	==========	==========	==========→			At V1 and V2 collect only SAEs considered as related to study participation.
Concomitant medication review	X	X	←==========	==========	==========	==========→			

EW: Early Withdrawal. The list of assessments listed in this column should be completed for an early withdrawal visit.

12.3. Appendix 3: Assessment Windows

12.3.1. Definitions of Assessment Windows for Analyses

Nominal visits will be used and no windowing will be applied for analysis.

12.4. Appendix 4: Study Phases and Treatment Emergent Adverse Events

12.4.1. Study Phases

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

Study Phase	Definition
Pre-Treatment	Date ≤ Study Treatment Start Date
On-Treatment	Study Treatment Start Date < Date ≤ Study Treatment Stop Date + 28 days
Post-Treatment	Date > Study Treatment Stop Date + 28 days

Completion of study epochs will be defined as the following:

Study Phase	Definition of Completion
Run-in	Randomised into study and received first dose of study treatment
Treatment	Completed Week 12 visit
Follow up	Completed 12 week follow-up period

12.4.2. Study Phases for Concomitant Medication

Study Phase	Definition **Note: All programming should use start and end dates where available, CMSTRF and CMENRF are only to be used where dates are unavailable to help determine the correct study phase.**
Pre-Treatment	• Conmed Start Date < Study Treatment First Dose Date • Conmed End Date < Study Treatment First Dose Date • CMSTRF = ”BEFORE” • Randomisation date is missing i.e. subject was not randomised
On-Treatment	• Study Treatment First Dose Date <= Conmed Start Date <= Study Treatment Last Dose Date + 28 • Study Treatment First Dose Date <= Conmed End Date <= Study Treatment Last Dose Date + 28 • (Conmed Start Date <= Study Treatment Last Dose Date + 28) and (Conmed End Date >= Study Treatment First Dose Date) • (Conmed Start Date <= Study Treatment Last Dose Date + 28) and (CMENRF =”DURING/AFTER” or CMENRF =”AFTER” or CMSTRF = “DURING”) • (CMSTRF = ”BEFORE” or CMSTRF = ”DURING” or CMENRF =”DURING/AFTER”) and (Conmed End Date >= Study Treatment First Dose Date) • (CMSTRF = ”BEFORE” or CMSTRF =”DURING”) and (CMENRF =”DURING/AFTER” or CMENRF =”AFTER”) • CMSTRF = ”DURING” • CMENRF = ”DURING/AFTER”
Post-Treatment	• Conmed Start Date > Study Treatment Last Dose Date + 28

Study Phase	Definition **Note: All programming should use start and end dates where available, CMSTRF and CMENRF are only to be used where dates are unavailable to help determine the correct study phase.**
	• Conmed End Date > Study Treatment Last Dose Date + 28 • CMENRF = ”AFTER” • CMENRF = ”DURING/AFTER”
All phases	• Conmed start date is missing and CMSTRF is missing and conmed end date is missing and CMENRF is missing

NOTES:

- The duration of a single concomitant medication can extend over multiple study phases
- Please refer to Appendix 7: Reporting Standards for Missing Data for handling of missing and partial dates for concomitant medication. Use the rules in this table if concomitant medication date is completely missing.

12.4.3. Treatment Emergent Flag for Adverse Events

Flag	Definition
Treatment Emergent	If AE onset date is on or after treatment start date & on or before treatment stop date + 28 days. Study Treatment Start Date ≤ AE Start Date ≤ Study Treatment Stop Date + 28 days

NOTES:

- If the study treatment stop date is missing then the AE will be considered to be On-Treatment.

12.5. Appendix 5: Data Display Standards & Handling Conventions

12.5.1. Reporting Process

Software	
• The currently supported versions of SAS software will be used.	
Reporting Area	
HARP Server	: uk1salx00175
HARP Compound	: /arenv/arprod/gsk3772847/mid207972/
final_01:This is where the end of study analysis will take place.	
Analysis Datasets	
• Analysis datasets will be created according to CDISC standards	
Generation of RTF Files	
• RTF files will be generated for all reporting efforts	

12.5.2. Reporting Standards

General

• The current GSK Integrated Data Standards Library (IDSL) will be applied for reporting, unless otherwise stated (IDSL Standards Location: https://spope.gsk.com/sites/IDSLLibrary/SitePages/Home.aspx):
  • 4.03 to 4.23: General Principles
  • 5.01 to 5.08: Principles Related to Data Listings
  • 6.01 to 6.11: Principles Related to Summary Tables
  • 7.01 to 7.13: Principles Related to Graphics
• Do not include subject level listings in the main body of the GSK Clinical Study Report. All subject level listings should be located in the modular appendices as ICH or non-ICH listings

Formats
• GSK IDSL Statistical Principles (5.03 & 6.06.3) for decimal places (DP's) will be adopted for reporting of data based on the raw data collected, unless otherwise stated. • Numeric data will be reported at the precision collected on the eCRF. • The reported precision from non eCRF sources will follow the IDSL statistical principles but may be adjusted to a clinically interpretable number of DP's.
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.

Unscheduled Visits
• Unscheduled visits will only be included in summary tables as part of 'minimum/maximum post baseline'

and 'minimum/maximum change from baseline' summary. • Unscheduled visits will not be included in figures. • All unscheduled visits will be included in listings.	
Descriptive Summary Statistics	
Continuous Data	Refer to IDSL Statistical Principle 6.06.1
Categorical Data	N, n, frequency, %
Graphical Displays	
• Refer to IDSL Statistical Principals 7.01 to 7.13.	

12.6. Appendix 6: Derived and Transformed Data

12.6.1. General

Multiple Measurements at One Analysis Time Point
• Mean of the measurements will be calculated and used in any derivation of summary statistics but if listed, all data will be presented. • If there are two values within a time window (as per Section 12.3.1) the value closest to the target day for that window will be used. If values are the same distance from the target, then the mean will be taken. • Participants having both High and Low values for Normal Ranges at any post-baseline visit 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 Date:
  • Ref Date = Missing → Study Day = Missing
  • Ref Date < First Dose Date → Study Day = Ref Date – First Dose Date
  • Ref Data ≥ First Dose Date → Study Day = Ref Date – (First Dose Date) + 1

12.6.2. Study Population

Age
Date of birth will be set as 30-JUN-YYYY where YYYY is the year of birth taken from the CRF. For participants who attended a screening visit, age will be calculated at the screening visit date.
Body Mass Index (BMI)
BMI = Weight (kg) / Height(m)^2
Treatment Misallocations
To allocate treatment, the number of doses of GSK3772847 and Placebo that were given will be calculated, and the subject will be assigned to whichever treatment has the higher number. The only exception will be when both treatments were given equally, in which case the subject will be assigned their randomised treatment.
Extent of Exposure (Therapeutic Coverage)
• IP is administered approximately every 4 weeks and each dose viewed as providing therapeutic coverage for 4 weeks (28 days). • Number of days of exposure to study drug will be calculated based on the formula: **Duration of Exposure in Days = Study Treatment Last Dose Date – (Study Treatment First Dose Date) + 29** • The only exception to this will be when a participant dies in which case **Duration of Exposure in Days = Death Date – (Study Treatment First Dose Date) + 1**

12.6.3. Safety

Maximum/Minimum On-Treatment Definitions for Vital Signs Data
Maximum and Minimum on-treatment**:** Maximum and Minimum on-treatment value over all time-points (including scheduled and unscheduled assessments) will be presented.

Adverse Events
Adverse Events of Special Interest (AESI)
Systemic Allergic/Hypersensitivity and Non-allergic Reactions: • Hypersensitivity (SMQ) [narrow] • Anaphylactic reaction (SMQ) [narrow] • Angioedema (SMQ) [narrow] Alterations in immune response (infections) All infections and serious infections reported under the MedDRA system organ class of 'Infections and Infestations'. Specific events of interest are opportunistic infections with preferred terms matching identified/pre-determined terms based on a published list of pathogens and/or presentations of specific pathogens to be considered as opportunistic infections in the setting of biologic therapy [Winthrop et al, 2015]. Alterations in immune response (malignancies): All neoplasms reported under the MedDRA system organ class of 'Neoplasms, benign, malignant and unspecified (including cysts and polyps)'. Specific events of interest are malignancies which will be identified through matching of collected preferred terms with those from the following: Sub-SMQs under the Malignancies SMQ: • Malignant tumours sub-SMQ (narrow terms) • Tumours of unspecified malignancy sub-SMQ (narrow terms) Alterations in cardiovascular safety: Cardiac disorders and serious cardiac disorders reported under the MedDRA system organ class of 'Cardiac Disorders'. Serious cardiac, vascular and thromboembolic (CVT) events, identified as all serious events classified under the MedDRA system organ classes of 'Cardiac Disorders' and of 'Vascular Disorders', and thromboembolic events identified through matching of collected preferred terms with those from the following: Sub-SMQs under the Embolic and thrombotic events SMQ: • Embolic and thrombotic events, arterial sub-SMQ (narrow terms) • Embolic and thrombotic events, venous sub-SMQ (narrow terms) • Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous sub-SMQ (narrow terms) Sub-SMQs under the Ischaemic Heart Disease SMQ • Myocardial infarction sub-SMQ (narrow terms) • Other Ischaemic heart disease sub-SMQ (narrow terms) Sub-SMQs under the Central Nervous System Vascular Disorders SMQ • Ischaemic central nervous system vascular conditions sub-SMQ (narrow terms) • Central nervous system vascular disorders, not specified as haemorrhagic or ischaemic sub-SMQ (narrow terms) • Serious ischemic adverse events, a subset of the serious CVT events identified through matching of collected preferred terms with those from the following: Local Injection Site Reactions Local injection site reactions are identifying through preferred terms which had been selected by medical review of the MedDRA dictionary and are provided in a separate spreadsheet.

12.7. Appendix 7: Reporting Standards for Missing Data

12.7.1. Premature Withdrawals

Element	Reporting Detail
General	• Subject study completion (i.e. as specified in the protocol) was defined as completing the 12-week treatment period and three month safety follow up. • Withdrawn participants were not replaced in the study. • All available data from participants 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.

12.7.2. Handling of Missing Data

Element	Reporting Detail
General	• Missing data occurs when any requested data is not provided, leading to blank fields on the collection instrument: o 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 table. o Answers such as "Not applicable" and "Not evaluable" are not considered to be missing data and should be displayed as such.
Analysis	• All missing data will be handled according to estimand of interest as described within the main body of the RAP.
ACQ-5	• If one of the five items in the ACQ-5 is missing then the response from the four remaining items will be interpolated (pro-rata) to gain the overall response for the participant. • If more than one item is missing then the ACQ-5 will be considered missing.
AQLQ	• The AQLQ contains 32 items in four domains: activity limitation (11 items), symptoms (12 items), emotional function (five items), and environmental stimuli (four items). For the overall score, there must be no more than three missing responses (and never more than one per domain). The symptom and activity domain scores can have up to one missing value per domain, but for the emotional function and environmental stimuli domain scores must have no missing responses. • If there are missing values at a visit (for example visit 2) then data will be imputed using data from both this visit and the previous study visit (for example visit 1) as shown below: Visit 1 (completed data): Total score = A Visit 2 (incomplete data): Total score = B Visit 2 imputed score: B/A x 2

12.7.2.1. Handling of Missing and Partial Dates

Element	Reporting Detail
General	• Partial dates will be displayed as captured in subject listing displays.
Adverse	• The eCRF allows for the possibility of partial dates (i.e., only month and year) to be

Events	recorded for AE start and end dates; that is, the day of the month may be missing. In such a case, the following conventions will be applied for calculating the time to onset and the duration of the event: ○ Missing Start Day: First of the month will be used unless this is before the start date of study treatment; in this case the study treatment start date will be used and hence the event is considered On-treatment as per Appendix 4: Study Phases and Treatment Emergent Adverse Events. ○ Missing Stop Day: Last day of the month will be used, unless this is after the stop date of study treatment; in this case the study treatment stop date will be used. • 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.
Concomitant Medications/ Medical History	• Partial dates for any concomitant medications recorded in the CRF will be imputed using the following convention: ○ If the partial date is a start date, a '01' will be used for the day and 'Jan' will be used for the month ○ 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. • The recorded partial date will be displayed in listings.

12.8. Appendix 8: Values of Potential Clinical Importance

Values of potential clinical importance will not be used in this study, instead normal reference ranges of “Low”, “Normal” and “High” will be used.

12.9. Appendix 9: Abbreviations & Trade Marks

12.9.1. Abbreviations

Abbreviation	Description
ACQ-5	Asthma Control Questionnaire
ADaM	Analysis Data Model
AE	Adverse Event
AFAD	Allergic Fungal Airway Disease
AIC	Akaike's Information Criteria
AQLQ	Asthma Quality of Life Questionnaire
ASE	All Subjects Enrolled
A&R	Analysis and Reporting
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
CPMS	Clinical Pharmacology Modelling & Simulation
CRO	Contract Research Organisation
CS	Clinical Statistics
CSR	Clinical Study Report
CTR	Clinical Trial Register
CV_b / CV_w	Coefficient of Variation (Between) / Coefficient of Variation (Within)
DBF	Database Freeze
DBR	Database Release
DOB	Date of Birth
DP	Decimal Places
ECG	Electrocardiogram
eCRF	Electronic Case Record Form
EOS	Eosinophils
FeNO	Fractional Exhaled Oxide
FEV1	Forced expiratory volume in 1 second
HARP	Harmonisation of Analysis and Reporting Program
IA	Interim Analysis
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
IDMC	Independent Data Monitoring Committee
IDSL	Integrated Data Standards Library
IgE	Immunoglobulin E
IMMS	International Modules Management System
IP	Investigational Product
iSRC	Internal Safety Review Committee
ITT	Intent-To-Treat
GUI	Guidance
LOC	Last Observation Carries Forward
mITT	Modified Intent-To-Treat
MMRM	Mixed Model Repeated Measures
PCI	Potential Clinical Importance

Abbreviation	Description
PD	Pharmacodynamic
PDMP	Protocol Deviation Management Plan
PGx	Pharmacogenetic
PK	Pharmacokinetic
POC	Proof of Concept
PP	Per Protocol
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
RAMOS	Randomisation & Medication Ordering System
RTF	Rich Text Format
SAC	Statistical Analysis Complete
SAE	Serious Adverse Event
SDTM	Study Data Tabulation Model
SoC	Standard of Care
SOP	Standard Operation Procedure
ST2	Suppressor of Tumorigenicity 2
TA	Therapeutic Area
TFL	Tables, Figures & Listings
WOCBP	Woman of Child Bearing Potential
GSK	GlaxoSmithKline

12.9.2. Trademarks

Trademarks of the GlaxoSmithKline Group of Companies
None

Trademarks not owned by the GlaxoSmithKline Group of Companies
SAS

12.10. Appendix 10: List of Data Displays

All displays (Tables, Figures & Listings) will use the term 'Subjects' instead of "Participants".

12.10.1. Data Display Numbering

The following numbering will be applied for RAP generated displays:

Section	Tables	Figures
Study Population	1.1 to 1.n	1.1 to 1.n
Efficacy	2.1 to 2.n	2.1 to 2.n
Safety	3.1 to 3.n	3.1 to 3.n
Pharmacokinetic	4.1 to 4.n	4.1 to 4.n
Population Pharmacokinetic (PopPK)	5.1 to 5.n	5.1 to 5.n
Pharmacodynamic and / or Biomarker	6.1 to 6.n	6.1 to 6.n
Pharmacokinetic / Pharmacodynamic	7.1 to 7.n	7.1 to 7.n
Section	**Listings**	
ICH Listings	1 to x	
Other Listings	y to z	

12.10.2. Mock Example Shell Referencing

Non IDSL specifications will be referenced as indicated and if required example mock-up displays provided in Appendix 10: List of Data Displays: Example Mock Shells for Data Displays.

Section	Figure	Table	Listing
Study Population	POP_Fn	POP_Tn	POP_Ln
Efficacy	EFF_Fn	EFF_Tn	EFF_Ln
Safety	SAFE_Fn	SAFE_Tn	SAFE_Ln
Pharmacokinetic	PK_Fn	PK_Tn	PK_Ln
Population Pharmacokinetic (PopPK)	POPPK_Fn	POPPK_Tn	POPPK_Ln
Pharmacodynamic and / or Biomarker	PD_Fn	PD_Tn	PD_Ln
Pharmacokinetic / Pharmacodynamic	PKPD_Fn	PKPD_Tn	PK/PD_Ln

NOTES:

- Non-Standard displays are indicated in the 'IDSL / Example Shell' or 'Programming Notes' column as '[Non-Standard] + Reference.'

12.10.3. Deliverables

Delivery	Description
SAC	Final Statistical Analysis Complete

12.10.4. Study Population Tables

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.01.	mITT	ES8	Summary of Subject Status and Reason for Study Withdrawal	ICH E3, FDAAA, EudraCT	SAC
1.02.	mITT	SD4	Summary of Treatment Status and Reasons for Discontinuation of Study Treatment	ICH E3	SAC
1.03.	mITT	ES4	Summary of Subject Disposition at Each Study Epoch	ICH E3	SAC
1.04.	ASE	ES6	Summary of Screening/Run-in Status and Reasons for Screen/Run-in Failure	Journal Requirements	SAC
1.05.	ASE	NS1	Summary of Number of Subjects by Country and Site ID	EudraCT/Clinical Operations	SAC
1.06.	mITT	NS1	Summary of Number of Subjects by Country and Site ID	EudraCT/Clinical Operations	SAC
Protocol Deviation					
1.07.	mITT	DV1	Summary of Important Protocol Deviations	ICH E3	SAC
1.08.	mITT	IE1	Summary of Inclusion/ Exclusion Deviations	ICH E3	SAC
Population Analysed					
1.09.	Enrolled	SP1	Summary of Study Populations	IDSL. Footnote on population summary table that Safety and mITT populations are the same.	SAC
Demographic and Baseline Characteristics					
1.10.	mITT	DM1	Summary of Demographic Characteristics	ICH E3, FDAAA, EudraCT	SAC
1.11.	Enrolled	DM11	Summary of Age Ranges	EudraCT	SAC
1.12.	mITT	DM5	Summary of Race and Racial Combinations	ICH E3, FDA, FDAAA, EudraCT	SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Prior and Concomitant Medications					
1.13.	mITT		Summary of Anti-Fungal Medications at Screening		SAC
1.14.	mITT	MH4	Summary of Current Medical Conditions	ICH E3	SAC
1.15.	mITT	MH4	Summary of Past Medical Conditions	ICH E3	SAC
1.16.	mITT	POP_T01	Summary of Disease Duration and Exacerbation History		SAC
1.17.	mITT	CM1	Summary of On-treatment Concomitant Medications	ICH E3	SAC
1.18.	mITT	CM1	Summary of On-treatment Asthma Concomitant Medications	ICH E3	SAC

12.10.5. Efficacy Tables

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Primary Efficacy: Blood Eosinophils and FeNO					
2.01.	mITT	EX1	Summary of Exposure to Study Treatment	ICH E3	SAC
2.02.	mITT		Summary of Raw and Change from Baseline in Blood Eosinophils		SAC
2.03.	mITT		Summary of Raw and Change from Baseline in FeNO		SAC
Secondary Efficacy: Spirometry					
2.04.	mITT		Summary of Raw and Change from Baseline in FEV_1		SAC
Secondary Efficacy: Patient Reported Outcomes					
2.05.	mITT		Summary of Raw and Change from Baseline in ACQ-5 Total Score		SAC
2.06.	mITT		Summary of ACQ-5 Responders		SAC
2.07.	mITT		Summary of Raw and Change from Baseline in AQLQ Total Score		SAC
2.08.	mITT		Summary of AQLQ Responders		SAC

12.10.6. Safety Tables

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events (AEs)					
3.01.	SAFF	SAFE_T01	Overview of On-treatment Adverse Events During the Study		SAC
3.02.	SAFF	AE1	Summary of All On-treatment Adverse Events by System Organ Class and Preferred Term	ICH E3	SAC
3.03.	SAFF	AE1	Summary of All On-treatment Serious Adverse Events by System Organ Class and Preferred Term	ICH E3	SAC
3.04.	SAFF	AE3	Summary of All On-treatment Adverse Events by Overall Frequency	ICH E3, summarise by PT	SAC
Laboratory: Chemistry					
3.05.	SAFF	LB1	Summary of Worst Case Chemistry Results Relative to Normal Range Post-Baseline Relative to Baseline	ICH E3	SAC
Laboratory: Hematology and Cardiac Markers					
3.06.	SAFF	LB1	Summary of Worst Case Hematology and Cardiac Markers Results Relative to Normal Range Post-Baseline Relative to Baseline	ICH E3	SAC

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
ECG and Holter					
3.07.	SAFF	EG1	Summary of ECG Findings	IDSL	SAC
3.08.	SAFF	EG11	Summary of Maximum Increase in QTcF Values Post-Baseline Relative to Baseline by Category	IDSL	SAC
3.09.	SAFF	HM1	Summary of Holter Interpretations	IDSL	SAC
Vital Signs					
3.10.	SAFF	VS1	Summary of Vital Signs	ICH E3	SAC
3.11.	SAFF	VS1	Summary of Change from Baseline in Vital Signs	ICH E3	SAC
3.12.	SAFF	VS1	Summary of Change from Pre-dose to Post-dose in Vital Signs	ICH E3	SAC

12.10.7. Pharmacokinetic Tables

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Secondary: Pharmacokinetic					
4.01.	PK		Summary of GSK3772847 Serum Pharmacokinetic Concentration-Time Data (ug/ml)		SAC
4.02.	PK		Summaries of the Incidence of and Titres of Anti-GSK3772847 Antibodies		SAC

12.10.8. Pharmacodynamic and Biomarker Tables

Pharmacodynamic and Biomarker: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Secondary Pharmacodynamic: Free and Total SST2					
6.01.	mITT		Summary of Raw and Percentage Change from Baseline in Free Soluble ST2 concentration (ug/mL) (On-treatment)		SAC
6.02.	mITT		Summary of Raw and Percentage Change from Baseline in Total Soluble ST2 concentration (ng/mL) (On-treatment)		SAC

12.10.9. ICH Listings

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.	Screened	ES7	Listing of Reasons for Screen and Run-in Failure	Journal Guidelines	SAC
2.	mITT	ES2 / ES3	Listing of Reasons for Study Withdrawal	ICH E3	SAC
3.	mITT	SD2/SD3	Listing of Reasons for Study Treatment Discontinuation	ICH E3	SAC
4.	mITT	BL1 / BL2	Listing of Participants for Whom the Treatment Blind was Broken	ICH E3	SAC
5.	mITT	TA1 / CP_RD1x	Listing of Randomised and Actual Treatments	IDSL	SAC
Protocol Deviations					
6.	mITT	DV2	Listing of Important Protocol Deviations	ICH E3	SAC
7.	mITT	IE3	Listing of Subjects with Inclusion/Exclusion Criteria Deviations	ICH E3	SAC
Populations Analysed					
8.	mITT	SP3	Listing of Participants Excluded from Any Population	ICH E3.	SAC
Demographic and Baseline Characteristics					
9.	mITT	DM2	Listing of Demographic Characteristics	ICH E3	SAC
10.	mITT	DM9	Listing of Race	ICH E3	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Prior and Concomitant Medications					
11.	mITT	CP_CM3	Listing of Concomitant Medications	IDSL	SAC
Exposure and Treatment Compliance					
12.	mITT	EX3	Listing of Exposure Data	ICH E3	SAC
Adverse Events					
13.	SAFF	AE8	Listing of All Adverse Events	ICH E3	SAC
14.	SAFF	AE7	Listing of Subject Numbers for Individual Adverse Events	ICH E3	SAC
15.	SAFF	AE8	Listing of Adverse Events Leading to Withdrawal from Study / Permanent Discontinuation of Study Treatment	ICH E3	SAC
16.	SAFF	AE2	Listing of Relationship Between Adverse Event System Organ Classes, Preferred Terms, and Verbatim Text	IDSL	SAC
Serious and Other Significant Adverse Events					
17.	SAFF	AE8	Listing of Fatal Serious Adverse Events	ICH E3	SAC
18.	SAFF	AE8	Listing of Non-Fatal Serious Adverse Events	ICH E3	SAC
19.	SAFF	AE14	Listing of Reasons for Considering as a Serious Adverse Event	ICH E3	SAC
20.	SAFF	AE8	Listing of Serious Adverse Events Leading to Withdrawal from Study / Permanent Discontinuation of Study Treatment	ICH E3	SAC
21.	SAFF	AE8	Listing of Adverse Events of Special Interest	ICH E3	SAC
Hepatobiliary (Liver)					
22.	SAFF	MH2	Listing of Medical Conditions for Participants with Liver Stopping Events	IDSL	SAC
23.	SAFF	SU2	Listing of Substance Use for Participants with Liver Stopping Events	IDSL	SAC

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
All Laboratory					
24.	SAFF	LB5 / LB6	Listing of All Laboratory Data for Participants with Any Value Outside Normal Range	ICH E3	SAC
25.	SAFF	LB14	Listing of Laboratory Data with Character Results	ICH E3	SAC
ECG					
26.	SAFF	EG5	Listing of All ECG Findings for Participants with an Abnormal ECG Finding	IDSL	SAC
Holter					
27.	SAFF	MH6	Listing of Holter R-on-T Beat Data	IDSL	SAC
28.	SAFF	MH7	Listing of Holter {Supraventricular} {Ventricular} Event Data	IDSL, Update title as appropriate based on data	SAC
29.	SAFF	MH8	Listing of Holter {Sustained} {Non-sustained} {Supraventricular} {Ventricular} Run	IDSL, Update title as appropriate based on data	SAC
30.	SAFF	MH9	Listing of Holter Atrial {Fibrillation} {Flutter} Data	IDSL, Update title as appropriate based on data	SAC
31.	SAFF	MH10	Listing of Holter Abnormalities	IDSL	SAC
Vital Signs					
32.	SAFF	VS4	Listing of All Vital Signs Data	IDSL	SAC
Primary Endpoint Data: Blood Eosinophils and FeNO					
33.	mITT		Listing of Blood Eosinophils		SAC
34.	mITT		Listing of FeNO		SAC

12.10.10. Non-ICH Listings

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Liver Events: Note only produced if there is a Liver Event					
35.	SAFF	Patient Profile	Listing of Liver Events		SAC
36.	SAFF	Patient Profile	Listing of Liver Event Information for RUCAM Score		SAC
37.	SAFF	Patient Profile	Listing of Liver Biopsy		SAC
38.	SAFF	Patient Profile	Listing of Liver Imaging Details		SAC
Cardiovascular Events: Note only produced if there is a Cardiovascular Event					
39.	SAFF	Patient Profile	Listing of Myocardial infarction/unstable angina		SAC
40.	SAFF	Patient Profile	Listing of Congestive heart failure		SAC
41.	SAFF	Patient Profile	Listing of Arrhythmias		SAC
42.	SAFF	Patient Profile	Listing of Valvulopathy		SAC
43.	SAFF	Patient Profile	Listing of Pulmonary hypertension		SAC
44.	SAFF	Patient Profile	Listing of Cerebrovascular events/stroke and transient ischemic attack		SAC
45.	SAFF	Patient Profile	Listing of Peripheral arterial thromboembolism		SAC
46.	SAFF	Patient Profile	Listing of Deep venous thrombosis/pulmonary embolism		SAC
47.	SAFF	Patient Profile	Listing of Revascularisation		SAC
48.	SAFF	Patient Profile	Listing of Deaths		SAC