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

Title	:	Reporting and Analysis Plan for Study 202152: A multicentre, randomised, double-blind (sponsor-unblinded), placebo-controlled study with open label extension to investigate the safety and tolerability, pharmacokinetics, pharmacodynamics, and efficacy of GSK2982772 in subjects with active ulcerative colitis.
Compound Number	:	GSK2982772
Effective Date	:	18-Jul-2019

Description:

- The purpose of this RAP is to describe the planned analyses and output to be included in the Clinical Study Report (CSR) for Protocol 202152.
- This RAP is intended to describe the interim and final analyses 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.

RAP Author(s):

Author's Name and Functional Area:

PPD	15-JUL-2019
Principal Statistician (II Clinical Statistics)	
PPD	15-JUL-2019
Statistics Manager (II Clinical Statistics)	

RAP Team Review Confirmation:
(Email)

Reviewer	Date
PPD Principal Programmer/Analyst (Clinical Programming)	16-JUL-2019
PPD Operations and Science Lead (II Global Clinical & Data Operations)	16-JUL-2019
PPD Clinical Investigational Lead, Discovery Medicine	16-JUL-2019
PPD Director, CPMS	16-JUL-2019
PPD Project Physician Lead, iiTA	16-JUL-2019
PPD Senior Medical Director, GCSP SERM	16-JUL-2019
PPD Data Quality Lead (II Global Clinical & Data Operations)	15-JUL-2019

Clinical Statistics and Clinical Programming Line Approvals:
(PharmaTMF signoff)

Approver	Date
PPD Snr Statistical Director (II Clinical Statistics)	18-JUL-2019
PPD Programming Manager (II Clinical Programming)	18-JUL-2019

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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 CSR for Protocol 202152:

Revision Chronology:		
2015N251758_00	23-MAY-2016	Original
2015N251758_01	20-APR-2017	Protocol Amendment 1 - Change in dosing regimen from 60 mg BID to 60 mg TID, updates to Inclusion criteria 3 and 6 and Exclusion criteria 3, 9, 21 and 22, allowance for rescreening, and addition of suicidality stopping criteria plus some minor protocol clarifications and administrative changes.

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**
Two interim analyses (IA) were planned. The decision whether the first IA will be conducted was to be based on the recommendation of the DRC review to assess futility based on 6 weeks of treatment, or when an appropriate number have completed 6 weeks of treatment, whichever is earliest. The purpose of the first IA would be to assess whether to stop the study for futility and, if appropriate, to perform a sample size re-estimation. The second IA will occur when an appropriate number have completed 12 weeks of treatment. The purpose of the second IA would be to assess whether to stop the study for futility.	A formal IA at 6 weeks will no longer be conducted based recommendations of the DRC.	The DRC data review of the 6 week data concluded that there was insufficient evidence to stop for futility and recommended a single IA to be conducted when an appropriate number of subjects have completed 12 weeks of treatment. This DRC data review will be considered in replacement of the first IA.
Endpoints for the 3-domain partial Mayo, 3-domain Mayo clinical response and 3-domain Mayo clinical remission are not specified in the protocol.	Relevant definitions and required summaries was added to the RAP.	The landscape for UC has changed since the protocol was developed.
The total score for the Mayo is	The RAP uses the Total Mayo	To match terminology used in the

Protocol	Reporting & Analysis Plan	
Statistical Analysis Plan	**Statistical Analysis Plan**	**Rationale for Changes**
called the complete Mayo in the Protocol.	Score terminology.	FDA's Ulcerative Colitis: Clinical Trial Endpoints Guidance for Industry document.
The scoring algorithm for the Modified Riley Scale in Table 7 of the protocol has an error where reverse labelling was used for the Historical Characteristics for mild and moderate disease activity.	The RAP details the correct MRS scores as provided by Robarts (central reader).	To fix an error in the protocol. Further details can be found in the Protocol Note to File #4 dated 24 May 2018.
No endpoint and derivations for the Robarts Histology Index (RHI) was explicitly mentioned in the protocol. The protocol endpoints section states: Change from baseline on histologic severity including but not limited to MRS and Geboes. Robarts will also provide GSK with the RHI alongside the MRS and Geboes.	Relevant definitions for the RHI and required summaries were added to the RAP	To enable analysis of the RHI data.
GSK2982772 plasma concentrations will be summarised descriptively by day and nominal sampling time (Pre-dose on Day 43 and at 1, 2, 4, and 6 hours post dose on Days 1 and 43 and trough on Day 85 or Early Withdrawal).	The predicted trough concentration at 7am on Day 43 will be calculated using the observed pre-dose concentration at the time of the PK sample (see Section 9.1.1.1 for calculations) The predicted Day 43 trough concentration will be used in PK/PD assessments instead of the observed Day 43 Pre-Dose concentration	Since the half-life of GSK2982772 is short (2-3h), the duration of time between the Day 43 clinic visit and the usual dosing time (assumed to be 7am for all subjects) may result in the reported "pre-dose" concentration being lower than the true "trough concentration"

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

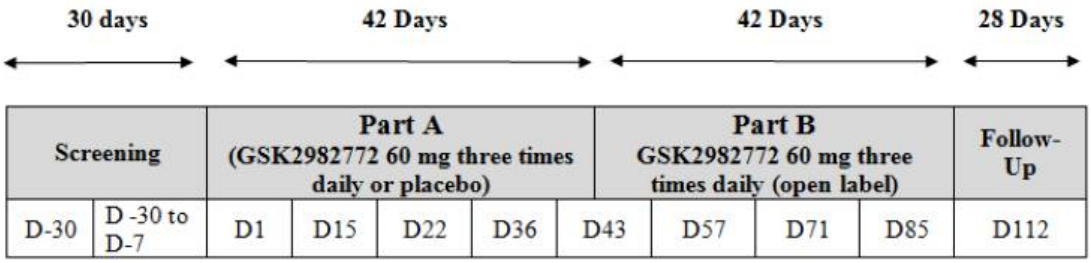
Objectives	Endpoints
Primary Objectives	**Primary Endpoints**
• To investigate the safety and tolerability of 60 mg three times daily doses of GSK2982772 in subjects with moderate to severe ulcerative colitis.	• Adverse events. • Clinical laboratory values (clinical chemistry, haematology and urinalysis). • Vital sign measurements (blood pressure, heart rate, respiratory rate, and body temperature). • 12-Lead ECG monitoring.
Secondary Objectives	**Secondary Endpoints**
• To investigate the preliminary efficacy of 60 mg three times daily doses of GSK2982772 in achieving mucosal healing after 6 and 12 weeks of treatment in subjects with active ulcerative colitis.	• The proportion of subjects who achieve an absolute Mayo endoscopy subscore of 0 or 1 at Days 43 (Week 6) and 85 (Week 12). • Change from baseline in mucosal appearance determined by Ulcerative Colitis Endoscopic Index of

Objectives	Endpoints
	Severity (UCEIS).
• To investigate the effect of 60 mg three times daily doses of GSK2982772 on biomarkers of disease activity in subjects with active ulcerative colitis.	• Change from baseline in markers which may include, but are not limited to, mean CRP and faecal calprotectin (FCP).
• To investigate the effect of 60 mg three times daily doses of GSK2982772 on histologic disease activity in subjects with active ulcerative colitis.	• Change from baseline in histologic severity, including but not limited to Modified Riley Score and Geboes Index.
• To investigate the effect of 60 mg three times daily doses of GSK2982772 in achieving clinical response and remission after 6 and 12 weeks of treatment in subjects with active ulcerative colitis.	• The proportion of subjects who achieve clinical response defined as reduction by ≥3 points or ≥30% improvement from baseline complete Mayo score, along with a decrease in the rectal bleeding score of ≥1 point, at Days 43 (Week 6) and 85 (Week 12). • The proportion of subjects who achieve clinical remission defined as a complete Mayo score of 2 points or lower, with no individual subscore exceeding 1 point, at Days 43 (Week 6) and 85 (Week 12).
• To investigate the preliminary efficacy of 60 mg three times daily doses of GSK2982772 in achieving symptomatic clinical remission after 6 and 12 weeks of treatment in subjects with active ulcerative colitis.	• Change from baseline in partial Mayo score.
• To investigate the plasma concentrations of GSK2982772 following 60 mg three times daily in subjects with active ulcerative colitis.	• Pre-dose plasma concentrations of GSK2982772 at Day 43 (Week 6). • Post-dose plasma concentrations of GSK2982772 on Days 1 and 43 (Week 6) at 1, 2, 4 and 6 hours. • Trough concentrations on Day 85 (Week 12).
Exploratory Objectives	**Exploratory Endpoints**
• To investigate the effect of 60 mg three times daily doses of GSK2982772 on expression of inflammatory biomarkers in mucosal tissue biopsies in subjects with active ulcerative colitis.	• Change from baseline in inflammatory markers which may include, but are not limited to IL-1, IL-6, IL-8, MMP3, TNFα, IFNγ.
• To investigate pathway and target engagement following 60 mg three times daily doses of GSK2982772 in blood and colon biopsy tissue.	• Pharmacology biomarker endpoints may include, but are not limited to the following, pre-dose at Days 1, 43 (Week 6) and trough on Day 85 (Week 12), as applicable and if evaluable samples and data permit: o Target Engagement Assay RiP1 (TEAR1) in blood and colon tissue. • Phosphorylated or total RIP1, MLKL, RIP3, cleaved and total caspase 3 and 8 signatures in colon biopsy tissue.
• To investigate the concentration of GSK2982772 and possible drug-related material, as well as specific distribution within tissue if feasible, in the colon tissue	• Pre-dose GSK2982772 and possible drug-related material concentrations, as well as specific distribution within tissue if feasible, in colon biopsies at Days 43 (Week 6) and 85 (Week 12), as evaluable samples

Objectives	Endpoints
after 60 mg three times daily doses of GSK2982772.	and data permit.
• To investigate the effect of 60 mg three times daily doses of GSK2982772 on quality of life in subjects with active ulcerative colitis.	• Change from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ).
• To investigate the effect of 60 mg three times daily doses of GSK2982772 on gene expression in the blood in subjects with active ulcerative colitis.	• Transcriptomic analysis of mRNA isolated from blood Days 1 and 43 (Week 6) and trough on Day 85 (Week 12).
• To investigate the effect of 60 mg three times daily doses of GSK2982772 on gene expression in colon tissue biopsies in subjects with active ulcerative colitis.	• Transcriptomic analysis of mRNA isolated from colon tissue biopsies at Screening, and Days 43 (Week 6) and trough on Day 85 (Week 12).

2.3. Study Design

Overview of Study Design and Key Features



Key assessments:
Safety assessments, PK samples, Mayo score, Modified Riley Scale, Geboes Index, IBDQ and PD samples

Design Features	• This is a multicentre, randomized, double-blind (sponsor-unblinded), placebo-controlled (Part A) study with an open label extension (Part B). • Investigate the safety and tolerability, PK, PD, and preliminary efficacy of GSK2982772 in subjects with active UC.
Study Duration and Dosing	• Each participant will participate in the study for approximately 20 weeks. This includes a screening period up to 30 days, an 84-day (12 week) treatment period, and a 28-day follow-up period after the last dose. • Within 30 days of the screening visit (defined as day of consent signing), eligible participants enter a 2-part treatment phase as follows with study treatment starting on study day 1: ○ Part A: Approximately 36 participants are randomly assigned to receive either GSK2982772 60 mg three times daily (TID) or placebo TID for 42 days (6 weeks) in a 2:1 ratio. ○ Part B: All participants who complete Part A move on to receive open label treatment of GSK2982772 60 mg TID for an additional 42 days (6 weeks). • Treatment duration is a total of 84 days (12 weeks) inclusive of Parts A and B. • Participants are followed-up for 28 days (4 weeks) after the last dose in Part B. • Prior to amendment 01 being effective in each country, participants were randomly assigned to receive either: • Part A: GSK2982772 60 mg two times daily (BID) or placebo BID for 42 days (6 weeks) in a 2:1 ratio. • Part B: Open label treatment for **all** participants who have completed Part A of GSK2982772 60 mg BID for an additional 42 days (6 weeks).
Time & Events	• Refer to Appendix 2: Schedule of Activities. • During the 84-day (12 week) treatment period, participants attend the clinical for visits on Days 1, 15, 29, 43, 57, 71 and 85. • At specific visits, participants must not take treatment prior to their scheduled treatment. • On Days 8, 22, 36, 50, 64 and 78 participants were to be contacted by telephone and asked about their general health. • Participants are given a diary card at every visit and asked to record daily study

Overview of Study Design and Key Features	
	medication, concomitant medication and adverse events.
Treatment Assignment	• At Screening a unique CRF number (Subject Number) is assigned. • Participants who meet screening eligibility criteria and complete pre-treatment assessments are randomised through an Interactive Response Technology System (IRTS). The IRTS confirms the participant's CRF number (Subject Number) and provides the randomisation number. • The randomisation number is generated by Clinical Statistics, prior to the start of the study, using validated internal software. Once assigned, this randomisation number must not be reassigned to any other participant in the study. • The randomisation is centrally controlled by the IRTS. • Approximately 36 participants were randomised in a 2:1 ratio to receive GSK2982772 60mg TID or Placebo TID in Part A. • Any participant that is re-screened outside of the allowed screening window at the approval of the GSK Medical Monitor, must be assigned a new unique Subject Number.

Interim Analysis	• An internal GSK Safety Review Team (SRT) reviews blinded safety data at appropriate intervals during the study and an internal GSK Data Review Committee (DRC) reviews unblinded safety, inflammatory biomarkers, clinical and mechanistic data at appropriate intervals during the study in accordance with the DRC Charter.
	• Two interim analyses were planned in the protocol to facilitate decision making regarding the subsequent clinical development of GSK2982772 for UC.
	• Interim Analysis #1:
	  • Was planned to occur either on the recommendation of the DRC, or when an appropriate number have completed 6 weeks of treatment, whichever is earliest.
	  • The purpose was to assess whether to stop the study for futility and, if appropriate, to perform a sample size re-estimation.
	• Interim Analysis #2:
	  • Was planned to occur when an appropriate number of participants have completed 12 weeks of treatment.
	  • The purpose was to assess whether to stop the study for futility.
	• A formal interim analysis at 6 weeks will no longer be conducted based on review of recruitment information and recommendation by the DRC. The DRC instead recommended a single interim analysis to be conducted when an appropriate number of participants have completed 12 weeks of treatment.
	• The DRC data review of the 6 week data concluded that there was insufficient evidence to stop for futility and recommended a single interim analysis to be conducted when an appropriate number of participants have completed 12 weeks of treatment.
	• This DRC data review will be considered in replacement of the first interim analysis.

2.4. Statistical Analyses

The primary objective of the study is to investigate the safety and tolerability of GSK2982772 60mg tid following 12 weeks of treatment. No formal statistical hypotheses will be conducted to assess this objective.

If appropriate, comparisons between the GSK2982772 arm and the placebo arm will be made to investigate the secondary pharmacodynamic, mechanistic and efficacy objectives. Trends over time will be investigated for both treatment arms along with associations between each of the parameters.

3. PLANNED ANALYSES

3.1. Interim Analyses

Two interim analyses were planned to be conducted during the study. Additionally, two review teams monitor data on an ongoing basis for routine pharmacovigilance and decision making regarding the subsequent clinical development of GSK2982772 for UC.

In line with routine pharmacovigilance, an internal GSK Safety Review Team (SRT) which includes members of the GSK2982772 project team, reviews blinded safety data, including clinical laboratory parameters and adverse events, at appropriate intervals during the period of study conduct.

Once an appropriate number of participants have completed Day 43 (Week 6), mucosal healing will be reviewed in an unblinded manner by the DRC consisting of the GSK study physician, the study statistician, the study pharmacokineticist, the PRR DPU Head, EDL and SRT Leader or designees on an ongoing basis. A physician external to the GSK2982772 project team may also be involved in the data review. Additional inflammatory biomarkers, clinical and mechanistic endpoints (e.g. target engagement) may be reviewed if available. No other member of the GSK core study team will be unblinded to this data. The primary purpose of these reviews is to monitor mucosal healing rates. On review of mucosal healing data, the review group may recommend an interim analysis of key clinical and mechanistic data is first conducted prior to any decision to terminate the study for futility. A data review charter identifies the specific GSK individuals involved; outline in detail the activities of this review and how the integrity of the study will be maintained.

The timing of Interim Analysis #1 in the protocol was either on the recommendation of the DRC to assess futility based on 6 weeks of treatment, or when an appropriate number have completed 6 weeks of treatment, whichever is earliest. The purpose of Interim Analysis #1 would be to assess whether to stop the study for futility and, if appropriate, to perform a sample size re-estimation. The timing of Interim Analysis #2 was to occur when an appropriate number have completed 12 weeks of treatment. The purpose of the Interim Analysis #2 was to assess whether to stop the study for futility.

A formal interim analysis at 6 weeks will no longer be conducted based on review of recruitment information and recommendation by the DRC. The DRC data review of the 6 week data concluded that there was insufficient evidence to stop for futility and recommended a single interim analysis be conducted when an appropriate number of participants have completed 12 weeks of treatment. This DRC data review will be considered in replacement of the first interim analysis.

3.2. Final Analyses

The final planned primary 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 final database release and database freeze has been declared by Data Management.
3. All criteria for unblinding the randomisation codes have been met.
4. Randomisation codes have been distributed per RandAll NG procedures.

4. ANALYSIS POPULATIONS

Population	Definition / Criteria	Analyses Evaluated
All Subjects	• Comprises of all participants who were screened for the study.	• Selected Study Population
Safety	• Comprise of all participants who receive at least one dose of study treatment.	• Study Population • Safety • Efficacy • PD • Biomarker
Pharmacokinetic	• Participants in the 'Safety' population who received an active dose and for whom a GSK2982772 pharmacokinetic sample was obtained and analysed.	• PK
Per Protocol (PP)	• All participants in the Safety population who comply with the protocol. • Protocol deviations that would exclude participants from the PP population are defined in Section 4.1 (Protocol Deviations) and Appendix 1: Protocol Deviation Management and Definitions for Per Protocol Population).	• Efficacy: Mayo only
PP + Completers	• All participants in the PP population who also complete the study (Parts A, B and Follow-up) [1]	• Efficacy: Mayo only

Refer to Appendix 10: List of Data Displays which details the population used for each display.
[1] Completion of the study as defined from the eCRF study conclusion page.
Note: All data displays (Tables, Figures & Listings) will use the term "Subject" which reflects CDISC and GSK Data Display Standards terminology

4.1. 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.

Important deviations which result in exclusion from the analysis population will also be summarised and listed. (Please refer to Appendix 1: Protocol Deviation Management and Definitions for Per Protocol Population).

Protocol deviations will be tracked by the study team throughout the conduct of the study in accordance with the Protocol Deviation Management Plan Version 3, dated 14th June

- Data will be reviewed instream 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.

5. CONSIDERATIONS FOR DATA ANALYSES AND DATA HANDLING CONVENTIONS

5.1. Study Treatment & Sub-group Display Descriptors

One subject was randomised to a BID regimen before the protocol was amended. Per instructions in the protocol, data will be summarised in tables and figures by treatment (GSK2982772 60mg or Placebo) irrespective of dosing regimen received (BID or TID). Data will be listed per treatment and dosing regimen received (BID or TID). Some key safety endpoints will be summarised by both randomised treatment and period treatment, details are provided in Appendix 9.

Should a participant receive the wrong medication at any point during the study in error, that participant will be treated as having received GSK2982772 60mg TID for the duration of the study.

Randomised Treatment Group Descriptions					
RandAll NG		Data Displays for Reporting			
Code	Description	Description in tables/non-PK figures	Order in TF	Description in Listings/PK figures	Order in Listing
A	GSK2982772 60mg BID (Double-blind)	GSK2982772 60mg	2	GSK2982772 60mg BID	3
C	GSK2982772 60mg TID (Double-blind)	GSK2982772 60mg	2	GSK2982772 60mg TID	4
P	Placebo BID (Double-blind)	Placebo	1	Placebo BID	1
Q	Placebo TID (Double-blind)	Placebo	1	Placebo TID	2

Period Treatment Group Descriptions					
RandAll NG		Data Displays for Reporting			
Code	Description	Description in tables	Order in TF	Description in Listings	Order in Listing
A	GSK2982772 60mg BID (Double-blind)	GSK2982772 60mg	2	GSK2982772 60mg DB BID	3
B	GSK2982772 60mg BID (Open-label)	GSK2982772 60mg	2	GSK2982772 60mg OL BID	5
C	GSK2982772 60mg TID (Double-blind)	GSK2982772 60mg	2	GSK2982772 60mg DB TID	4
D	GSK2982772 60mg TID (Open-label)	GSK2982772 60mg	2	GSK2982772 60mg OL TID	6
P	Placebo BID (Double-blind)	Placebo	1	Placebo DB BID	1
Q	Placebo TID (Double-blind)	Placebo	1	Placebo DB TID	2

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

- GSK2982772 60mg 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. Triplicate assessments at a timepoint will be averaged. An additional period baseline will be determined for vital signs, ECGs and clinical labs.

Unless otherwise stated, if baseline data is missing, no derivation will be performed and baseline will be set to missing.

For tables summarising from Day 43 (Part B), all data recorded on day 43 will be used as baseline and if this result is missing then there is no part B baseline.

Parameter	Study Assessments Considered as Baseline				Baseline Used in Data Display	Period Baseline Used in Data Display
	Screening (-30)	Screening (-7 to 30)	Day 1 (Pre-Dose)	Day 1		
Primary: Safety						
Vital Signs[1,2]	X		X		Day 1 (Pre-Dose)	Day 43
12-Lead ECG [2]	X[3]		X		Screening or Day 1 (Pre-Dose)	Day 43
Clinical Laboratory Values including CRP [2,4]	X		X		Day 1 (Pre-Dose)	Day 43

Parameter	Study Assessments Considered as Baseline				Baseline Used in Data Display	Period Baseline Used in Data Display
	Screening (-30)	Screening (-7 to 30)	Day 1 (Pre-Dose)	Day 1		
Columbia Suicide Severity Rating Scale (C-SSRS)	X		X		Day 1 (Pre-Dose)	
Secondary						
Mayo Score [5]	X				Screening	
UCEIS	X				Screening	
Modified Riley	X				Screening	
Geboes Index	X				Screening	
RHI	X				Screening	
FCP	X		X		Screening	
Exploratory						
Blood Sample: PK				X	Day 1	
Blood Sample: Exploratory Biomarkers, Target Engagement and mRNA Expression			X		Day 1 (Pre-Dose)	
Biopsy Tissue: PK, Inflammatory Biomarkers, mRNA Expression, Target Engagement and Pathway Marker	X				Screening	
IBDQ			X		Day 1 (Pre-Dose)	

NOTES:

- Unless otherwise stated, the mean of replicate assessments at any given time point will be used as the value for that time point.
  1: Vital sign measurements include Blood Pressure, Heart Rate, Respiratory Rate, and Body Temperature.
  2: Where both screening and pre-dose are available, the value closest to first dose will be used.
  3: ECG recordings will be performed in triplicate at screening. The mean of the triplicate measurements should be used.
  4: Clinical Laboratory measurements include Clinical Chemistry (which includes CRP), Haematology and Urinalysis.
  5: Includes Total Mayo, Partial Mayo and 3-domain Mayo Scores.

5.2.1. Derivations and Handling of Missing Baseline Data

Definition	Reporting Details
Change from Baseline	= Post-Dose Visit Value – Baseline
Log-Transformed Change from Baseline (Log_e Change)	= Log_e (Visit) – log_e (Baseline).

NOTES:

- Unless otherwise specified, the baseline definitions specified in Section 5.2. Baseline Definitions will be used for derivations for endpoints / parameters.
- Unless otherwise stated, if baseline data is missing no derivation will be performed and will be set to missing.
- The baseline definition will be footnoted on all the change from baseline displays.

5.3. Multicentre Studies

There are no planned adjustments for multiple centres or regions due to the size of the study. Enrolment will be presented by country. For all other analyses, all sites, countries and regions will be pooled.

5.4. Examination of Covariates, Other Strata and Subgroups

There are no planned subgroup analyses to be conducted on this study.

Category	Details
Strata	Not applicable for this study
Covariates	Baseline measure will be included as a covariate

5.5. Multiple Comparisons and Multiplicity

Overall, no adjustments will be made for multiple comparisons or multiplicity across different endpoints.

The process to reduce the false discovery rate for the transcriptomic analyses of mRNA expression is detailed in Section 10.1.3.1.

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
12.1	Appendix 1: Protocol Deviation Management and Definitions for Per Protocol Population
12.2	Appendix 2: Schedule of Activities
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

Section	Component
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
12.9	Appendix 9: Abbreviations & Trademarks
12.10	Appendix 10: List of Data Displays
12.11	Appendix 11: Example Mock Shells for Data Displays
12.12	Appendix 12: NONMEM datafile specification

6. STUDY POPULATION ANALYSES

6.1. Overview of Planned Study Population Analyses

Study population analyses including analyses of participant's disposition, protocol deviations, demographic and baseline characteristics, prior and concomitant medications, and exposure and treatment compliance will be based on GSK Core Data Standards. Details of the planned displays are presented in Table 2 below and Appendix 10: List of Data Displays.

The study population analyses will be based on the Safety population, unless otherwise specified.

6.1.1. Study Population Summary Measure

Population analyses will be presented (summarised in tables and listed) by randomised treatment group only.

Table 2 Overview of Planned Study Population Analyses

Endpoint / Parameter / Display Type	Data Displays Generated		
	Table	Figure	Listing
Subject Disposition			
Subject Disposition for the Subject Conclusion Record	Y		
Treatment Status and Reasons for Discontinuation of Study Treatment	Y		Y
Screen Status and Reason for Screen Failure	Y		Y
Subjects by Country and Site ID	Y		
Reasons for Subject Withdrawal			Y
Subjects for Whom the Treatment Blind was Broken			Y
Planned and Actual Treatments			Y
Protocol Deviations			
Important Protocol Deviations	Y		Y
Subjects with Inclusion/Exclusion Criteria Deviations			Y

Endpoint / Parameter / Display Type	Data Displays Generated		
	Table	Figure	Listing
Populations Analysed			
Study Populations	Y		
Exclusion from Any Population	Y		Y
Demographic and Baseline Characteristics			
Demographic Characteristics	Y		Y
Age Ranges	Y		
Race and Racial Combinations	Y		Y [1]
Ulcerative Colitis Baseline Characteristics [2]	Y		Y
Prior/Current Medical Conditions and Concomitant Medications [3]			
Medical Conditions	Y		Y
Concomitant Medications [4]	Y		Y
Cardiovascular Risk Factors	Y		Y
Exposure and Treatment Compliance			
Exposure to Study Treatment	Y		Y
Study Drug Accountability			Y

NOTES:

- Y = Yes display generated.

1: Listing of race.

2: Baseline characteristics including: Baseline Mucosal Appearance at Endoscopy Mayo Subscore, Baseline Total Mayo Score, Baseline Partial Mayo Score, Baseline 3-domain Mayo Score, Baseline UCEIS Total Score, Baseline Modified Riley Scale , Baseline FCP, Baseline FCP category, Baseline concomitant medications for UC (Glucocorticoids only, Immunosuppressants only, Glucocorticoids and immunosuppressants, No glucocorticoids or immunosuppressants), Baseline Prednisone dose, Family History of Premature Coronary Artery Disease and History of Tobacco Use.

3: Separate summaries for Current and Past Medical Conditions/Cardiovascular Risk Factors/Concomitant Medications.

4: The ingredients of concomitant medications will be reviewed by the clinical and medical team to determine baseline use of Glucocorticoids, Immunosuppressants and Prednisone.

7. SAFETY ANALYSES

The safety analyses will be based on the Safety population, unless otherwise specified.

7.1. Adverse Events Analyses

Adverse events analyses including the analysis of adverse events (AEs), Serious (SAEs) and other significant AEs will be based on GSK Core Data Standards. The details of the planned displays are provided in Table 3 below and Appendix 12: List of Data Displays.

7.1.1. Adverse Event Summary Measures

AE data will be summarised in tables and figures by the following:

- Part A by randomised treatment;
- Parts A, B and follow-up by randomised treatment;
- Parts A, B and follow-up by period treatment (i.e. treatment participant actually received).

AE data will be presented in data listings by the following:

- Parts A, B and follow-up by period treatment (i.e. treatment participant actually received).

Table 3 Overview of Planned Adverse Event Analyses

Endpoint / Parameter/ Display Type	Absolute		
	Summary		Individual
	T	F	L
Adverse Events (AEs)			
All AE by Maximum Intensity by SOC and PT	Y		
All Drug-Related AEs by Maximum Intensity by SOC and PT	Y		
Common (>=10%) AEs / Drug-Related AEs by Overall Frequency	Y	Y [1]	
Common (>=10%) Non-serious AEs by SOC and PT (Number of Subjects and Occurrences)	Y		
All AEs	Y		Y
Subject Numbers for Individual AEs			Y
Relationship Between AE SOCs, PT & Verbatim Text			Y
Serious and Other Significant AEs			
Serious AEs by SOC and PT (Number of Subjects and Occurrences)	Y		
Fatal Serious AEs			Y
Non-Fatal Serious AEs			Y
AEs Leading to Permanent Discontinuation of Study Treatment or Withdrawal from Study	Y		Y
Reasons for Considering as a Serious AE			Y
Possible Suicidality-Related AE (PSRAE)			Y

NOTES:

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

1: Plot of common AEs and relative risk will be generated.

7.2. Clinical Laboratory Analyses

Laboratory evaluations including the analyses of Chemistry laboratory tests, Hematology laboratory tests, Urinalysis, and liver function tests will be based on GSK Core Data Standards. Table 4 provides an overview of the planned analyses with further detail being presented in Appendix 10: List of Data Displays.

7.2.1. Clinical Laboratory Summary Measures

Clinical Laboratory data will be summarised in tables and figures by the following:

- Parts A, B and Follow-up by randomised treatment;
- Parts A, B and Follow-up by period treatment (i.e. treatment participant actually received).

Clinical Laboratory data will be presented in data listings by the following:

- Parts A and B and follow-up by period treatment (i.e. treatment participant actually received).

Table 4 Overview of Planned Clinical Laboratory Analyses

Endpoint / Parameter/ Display Type	Absolute			Change from BL		
	Summary		Individual	Summary		Individual
	T	F	L	T	F	L
Chemistry						
Chemistry Results				Y		
Chemistry Lipids Results [1]				Y [2]		
Worst Case Chemistry Results Relative to PCI Criteria Post-Baseline Relative to Baseline	Y					
Worst Case Lipids Results Relative to NR Criteria Post-Baseline Relative to Baseline [1]	Y					
Lipids Outside of the Normal Range [1]			Y			
Hematology						
Hematology Results				Y		
Worst Case Hematology Results Relative to PCI Criteria Post-Baseline Relative to Baseline	Y					

Endpoint / Parameter/ Display Type	Absolute			Change from BL		
	Summary		Individual	Summary		Individual
	T	F	L	T	F	L
Urinalysis						
Urine Concentration				Y		
Worst Case Urinalysis Results (Discrete or Character Values) Post-Baseline Relative to Baseline	Y					
Hepatobiliary (Liver)						
Liver Monitoring/Stopping Event Reporting	Y					
Hepatobiliary Laboratory Abnormalities	Y					
Medical Conditions for Subjects with Liver Stopping Events			Y			
Substance Use for Subjects with Liver Stopping Events			Y			
Scatter Plot of Maximum Versus Baseline for ALT		Y				
Scatter Plot of Maximum ALT Versus Maximum Total Bilirubin		Y				
All Laboratory [3]						
All Laboratory Data for Subjects with Any Value of PCI			Y			
Laboratory Data with Character Results			Y			

NOTES:

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

1: Lipids parameters = LDL Cholesterol, HDL Cholesterol, Total Cholesterol, Triglycerides and Cholesterol/HDL ratio

2: Percentage changes from baseline.

3: Chemistry, Hematology and Urinalysis will be considered.

7.3. Other Safety Analyses

The analyses of non-laboratory safety test results including ECGs and vital signs will be based on GSK Core Data Standards, unless otherwise specified. The details of the planned displays are presented in Table 5 below and Appendix 10: List of Data Displays.

7.3.1. Summary Measures

Non-laboratory safety results will be summarised in tables and figures by the following:

- Parts A, B and Follow-up by randomised treatment;
- Parts A, B and Follow-up by period treatment (i.e. treatment participant actually received).

Non-laboratory safety results will be presented in data listings by the following:

- Parts A and B and follow-up by period treatment (i.e. treatment participant actually received).

Table 5 Overview of Planned Other Safety Analyses

Endpoint / Parameter/ Display Type	Absolute			Change from BL		
	Summary		Individual	Summary		Individual
	T	F	L	T	F	L
ECG						
ECG Findings	Y					
ECG Values[1]				Y		
Maximum QTc Values Post-Baseline Relative to Baseline by Category[1]	Y					
Maximum Increase in QTc Values Post-Baseline Relative to Baseline by Category[1]	Y					
All ECG Values for Subjects with Any Value of PCI[1]			Y			
Vital Signs						
Vital Signs				Y		
Worst Case Vital Signs Results by PCI Criteria Post-Baseline Relative to Baseline	Y					
All Vital Signs for Subjects with Any Value of PCI			Y			
C-SSRS V4						
C-SSRS Suicidal Ideation and Behaviour Data			Y			

NOTES:

1. ECGs change from baseline are to be produced for change from screening (average triplicate) and change from baseline

- T = Table, F = Figures, L = Listings, Y = Yes display generated, PCI = Potential Clinical Importance
- 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 participant observed raw data.

7.4. Other Safety Analyses

If any of the following events are recorded in the eCRF as a CV event during the study, posthoc patient profile listings will be generated per IDSL and provided to the GCSP department:

- Arrhythmias, Congestive heart failure, Cerebrovascular events stroke (CVA) and Transient ischemic attack (TIA), Deep vein thrombosis (DVT)/Pulmonary embolism (PE), Myocardial Infarction/Unstable Angina, Peripheral arterial thromboembolism, Pulmonary Hypertension, Revascularisation, Valvopathy.

8. EFFICACY

8.1. Efficacy Endpoints

Table 6 below provides an overview of the planned efficacy analyses, with full details of data displays being available in Appendix 10: List of Data Displays.

Table 6 Overview of Planned Efficacy Analyses

Endpoint	Absolute							Change from Baseline						
	Stats Analysis			Summary		Individual		Stats Analysis			Summary		Individual	
	T	F	L[1]	T	F	F	L	T	F	L[1]	T	F	F	L
Mayo –Endoscopy Response														
Mucosal Appearance at Endoscopy Mayo Subscore				Y							Y			
Proportion Achieving Mayo Endoscopy Remission	C	C	C	Y	Y		Y							
Mayo – Clinical Response and Remission														
Proportion Achieving Mayo Clinical Response	C	C	C	Y	Y		Y							
Proportion Achieving Mayo Clinical Remission	C	C	C	Y	Y		Y							
Proportion Achieving 3-domain Mayo Clinical Response	C	C	C	Y	Y		Y							
Proportion Achieving 3-domain Mayo Clinical Remission	C	C	C	Y	Y		Y							
Mayo – Symptomatic Clinical Remission														
Total				Y	Y		Y	C	C	C	Y	Y		Y
Partial Mayo				Y	Y		Y	C	C	C	Y	Y		Y
3-domain Mayo				Y	Y		Y	C	C	C	Y	Y		Y
UCEIS – Mucosal Healing														
UCEIS Total Score				Y	Y		Y	C	C	C	Y	Y		Y
UCEIS – Remission														
Proportion Achieving UCEIS Remission	C	C	C	Y	Y		Y							
Biomarkers of Disease Activity														
CRP				Y	Y		Y	C	C	C	Y	Y		Y
FCP [2]				Y	Y		Y	C	C	C	Y	Y		Y
Histologic Disease Activity														
Modified Riley Scale				Y	Y		Y	C	C	C	Y	Y		Y
Geboes Index Total Score				Y	Y		Y	C	C	C	Y	Y		Y
RHI Total Score				Y	Y		Y	C	C	C	Y	Y		Y

Endpoint	Absolute							Change from Baseline						
	Stats Analysis			Summary		Individual		Stats Analysis			Summary		Individual	
	T	F	L[1]	T	F	F	L	T	F	L[1]	T	F	F	L
Quality of Life														
IBDQ Domains [3]				Y			Y				Y			Y
IBDQ Total Score				Y	Y		Y	C	C	C	Y	Y		Y
Subject Symptom Diary Cards														
Diary Card [4]				Y			Y							

NOTES:

T = Table, F = Figure, L = Listing, Y = Yes display generated, C = conditional
Stats Analysis = Represents TFL related to any formal statistical analyses (i.e. modelling) conducted.
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 participant observed raw data.

1. Listing of the RAW SAS output from the statistical modelling.
2. FCP will be log-transformed before determining change from baseline.
3. IBDQ domains: Bowel Symptoms, Systemic Systems, Emotional Function and Social Function.
4. Data from diary cards will be transcribed into the eCRF for the 5 days prior to the following visits: Screening, Day 15, Day 29, Day 43, Day 85 and EW.

8.1.1. Population of Interest

Analyses of the Mayo will be based on the Safety, PP and PP + Completers populations respectively.

All other efficacy analyses will be based on the Safety Population only.

8.1.2. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 10: List of Data Displays and will be based on GSK data standards and statistical principles.

All efficacy data will be summarised for Parts A, B and Follow-up (if applicable) by randomised treatment.

Unless otherwise specified, endpoints / variables defined will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

8.1.2.1. Statistical Methodology Specification

8.1.2.1.1 Continuous Endpoints

Secondary and Exploratory Endpoint(s)
• Change from baseline in Total and 3-domain Mayo Score at Day 43 pre-dose and Day 85.
• Change from baseline in Partial Mayo Score at Day 15, Day 29, Day 43 pre-dose and Day 85.
• Change from baseline in UCEIS Total Score at Day 43 pre-dose and Day 85.
• Change from baseline Modified Riley Scale at Day 43 pre-dose and Day 85.
• Change from baseline Geboes Index Total Score at Day 43 pre-dose and Day 85.
• Change from baseline RHI Score at Day 43 pre-dose and Day 85.
• Change from baseline in CRP at Day 43 pre-dose and Day 85.
• Change from baseline in Log-transformed FCP at Day 15, Day 29, Day 43, Day 57, Day 71 and Day 85.
• Change from baseline in IBDQ Total Score at Day 43 pre-dose and Day 85.

Model Specification

• Continuous endpoints will be statistically analyzed using a Mixed Models Repeated Measures (MMRM) approach.
• Terms fitted in the MMRM model will include:
  o Fixed Category : Treatment, Day, Treatment*Day
  o Fixed Continuous Covariates : Baseline Score, baseline*Day
  o Repeated Effect : Day
• The Kenward and Roger method for approximating the denominator degrees of freedom and correcting for bias in the estimated variance-covariance of the fixed effects will be used.
• An unstructured covariance structure for the R matrix will be used by specifying 'type=UN' on the REPEATED line with a subject=SUBJID option.
  o In the event that this model fails to converge, alternative correlation structures may be considered such as CS or AR(1).
  o Akaike's Information Criteria (AIC) will be used to assist with the selection of covariance structure.
• Other covariates maybe explored, if deemed appropriate for sensitivity analyses.

Model Checking & Diagnostics
• MMRM model assumptions will be applied, but appropriate adjustments may be made based on the data. • Distributional assumptions underlying the MMRM model will be examined by obtaining a normal probability plot of the residuals and a plot of the residuals versus the fitted values (i.e. checking the normality assumption and constant variance assumption of the model respectively) to gain confidence that the model assumptions are reasonable. • If there are any departures from the distributional assumptions, alternative models will be explored using appropriate transformed data.
Model Results Presentation - Untransformed
• Point estimates and corresponding 95% confidence intervals will be constructed for the treatment differences (GSK2982772 60mg tid- Placebo), using the residual error from the repeated measures model. • Plots of LS means and 95% confidence intervals from the model will be generated for each treatment group by time. • For log-transformed data the adjusted back-transformed geometric means and CV will be presented.
Model Results Presentation - Log transformed
• Adjusted geometric means, the mean difference between each dose (test) and the placebo (reference) at each timepoint and associated 95% confidence interval will be constructed using the residual variance • The treatment ratios and 95% CI will be calculated by back-transforming the difference between the least square means and associated 95% CI
Sensitivity and Supportive Statistical Analyses
• Non-parametric analyses may be conducted if the normality assumption does not hold. • Analyses using different covariance structures may be explored if the unstructured covariance matrix does not converge.

8.1.2.1.2 Binary Endpoints

Secondary and Exploratory Endpoint(s)
• Proportion of participants achieving a Mayo endoscopy remission at Day 43 pre-dose and Day 85. • Proportion of participants achieving Mayo clinical response and 3-domain Mayo clinical response at Day 43 pre-dose and Day 85.

• Proportion of participants achieving Mayo clinical remission and 3-domain Mayo clinical remission at Day 43 pre-dose and Day 85. • Proportion of participants achieving an UCEIS remission at Day 43 pre-dose and Day 85.
Model Specification
• Binary efficacy endpoints will be statistically analysed using a Generalised Estimating Equations (GEE) model. • GEE modelling will only be performed if at least 30% response rate at Day 85 for any one treatment group. • The model will be fitted using an unstructured covariance structure of the correlated responses. • Terms fitted in the GEE model will include: Fixed Categorical : Treatment group, Visit, Treatment group * Visit Interaction Repeated : Visit
Model Results Presentation
• Binary endpoints will be summarised using counts and proportions of participants achieving a response by treatment group. • Point estimates and corresponding 95% confidence intervals will be constructed using contrasts for the treatment group by visit interaction. • Plots of the point estimates and 95% confidence intervals from the model will be generated for each treatment group by time. • If a minimum 30% response rate at Day 85 for any one treatment group is not achieved, the display should be created with 'Insufficient data to produce GEE analysis' printed in the main body of the display.

8.2. Exploratory Efficacy Analyses

8.2.1. Responder Across Endpoints

For appraisal of trends across secondary efficacy endpoints, a nine-panel plot for each participant with a single panel for each of the following efficacy endpoints will be produced:

- Mayo Endoscopy Remission
- UCEIS Total Score,
- FCP,
- CRP,
- Modified Riley Scale Total Score
- Geboes Index Total Score,
- Total Mayo Score,
- Partial Mayo Score
- 3-domain Mayo Score.

8.2.2. Probabilities of Success

Probabilities of success may be determined, based on the data observed in the study, where the definition of success will be dependent on the endpoint. For example, what is the probability that we would observe a certain proportion of Mayo Endoscopic Remission (0 or 1) (i.e., comparatory rate), based on the data that we have observed in this study.

A Bayesian approach will be employed to determine a 95% credible confidence interval around the observed probability of success with a flat Beta (1, 1) prior. Any such analyses will be done by GSK II Clinical Statistics after unblinding of the interim data and thus will be deemed post-hoc.

8.3. Exploratory Pharmacodynamic / Efficacy Analyses

If deemed appropriate, the relationship between the biopsy biomarkers and efficacy endpoints will be explored further using multivariate statistical methods and/or Bayesian methodology as recommended by the GSK PCPS Experimental Medicine working group. The consistency in the changes over time between the endpoints will also be assessed. Any such analyses will be defined after unblinding of the interim data and thus will be deemed post-hoc.

9. PHARMACOKINETIC ANALYSES

9.1. Pharmacokinetic Analyses

9.1.1. Endpoint / Variables

9.1.1.1. Drug Concentration Measures

PK plasma and biopsy tissue Concentration data for GSK2982772 will be summarised and listed, no statistical analysis will be conducted. Summary statistics of GSK2982772 concentration by Day (1, 43, and 85) and nominal blood sampling time will be determined. PK blood samples are taken pre-dose on Day 43 and post-dose on Days 1 and Day 43 at the following time points: 1, 2, 4, and 6 hours and trough on Day 85 or Early Withdrawal.

PK data will be summarised for Parts A and B by randomised treatment.

Refer to Appendix 5: Data Display Standards & Handling Conventions (Section 12.5.3 Reporting Standards for Pharmacokinetic).

Table 7 Overview of Planned Pharmacokinetic Analyses

Endpoints	Untransformed				Log-transformed			
	Summary		Individual		Summary		Individual	
	T	F	F	L	T	F	F	L
Pharmacokinetic								
Plasma Drug concentration	Y	Y[1][2]	Y[1]	Y				
Biopsy Tissue Drug concentration	Y	Y[1][2]	Y[1]	Y				

NOTES:

- T = Table, F = Figure, L = Listings, Y = Display generated.
- Summary = represents TF related to any summaries (i.e. descriptive statistics) of the observed raw data.
- Individual = represents FL related to any displays of individual participant observed raw data.

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

Since the half-life of GSK2982772 is short (2-3h), the duration of time between the Day 43 clinic visit and the usual dosing time may result in the reported "pre-dose" concentration being lower than the true "pre-dose" or trough concentration (e.g. if the usual dose time was 7am and the clinic visit was 10am the "pre-dose" sample collected at 10 am would be approximately ½ that of the true "trough" concentration assuming a 3 hour half-life). Therefore, the predicted "trough" concentration will be calculated using the following equation-

$$Ctrough = Cpredose \div (e^{-(ke \times t)})$$

where

- Ctrough = predicted trough concentration prior to usual dosing time
- Cpredose = observed "pre-dose" concentration collected at the clinic
- t = time in hours between pre-dose blood sample collection and time of dosing (assumed to be 7am)
- ke = elimination rate constant (0.693/ t½), (t½ assumed to be 2.5h)

9.1.2. Population of Interest

The PK analyses will be based on the Pharmacokinetic population, unless otherwise specified.

9.2. Population PK Analyses

GSK2982772 plasma concentrations from this study may be included in a cross-study population pharmacokinetic (Pop PK) analysis. If deemed appropriate to conduct a Pop PK analysis, a NONMEM datafile will be generated. The details for the dataset specifications are provided in Appendix 12.

9.3. Pharmacokinetic/Pharmacodynamic Analyses

The relationship between GSK2982772 predicted trough concentration and the following variables will be explored graphically:

- Target engagement from the corresponding blood/biopsy tissue sample;
- Change from baseline in continuous efficacy endpoints (Total Mayo Score, Partial Mayo Score, 3-domain Mayo Score, UCEIS Total Score, Modified Riley Scale Score, Geboes Index Total Score, RHI Score, CRP and FCP.

Box plot of GSK2982772 concentrations in participants not achieving a Mayo Endoscopy Remission and participants achieving a Mayo Endoscopy Remission.

10. BIOMARKER ANALYSES

10.1. Biomarker/Target Engagement/Pathway Engagement/ Transcriptomics Analyses

10.1.1. Endpoint / Variables

Table 8 Overview of Planned Analyses

Endpoint	Absolute							Change from Baseline						
	Stats Analysis			Summary		Individual		Stats Analysis			Summary		Individual	
	T	F	L	T	F	F	L	T	F	L	T	F	F	L
Exploratory Biomarkers														
Inflammatory biomarkers in biopsy tissue[1]				Y		Y	Y	Y	Y	Y	Y			Y
Pathway and Target Engagement														
Pathway and target engagement in blood[2]	Y	Y	Y	Y		Y[3]	Y							
Pathway and target engagement in biopsy tissue[2]	Y	Y	Y	Y		Y	Y							
Transcriptomics														
mRNA expression from blood[3][4]				Y		Y	Y	Y	Y	Y				
mRNA expression from biopsy tissue[3][4]				Y		Y	Y	Y	Y	Y				

NOTES:

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

1: Markers including but not limited to: IL-1, IL-6, IL-8, MMP-3, TNFα and IFNγ
2: TEAR1, phosphorylated or total RIP1, MLKL, and RIP3, cleaved and total caspase 3 and caspase 8 signatures in blood and biopsy tissue if sample quantity and data allow.
3: mRNA expression of inflammatory gene transcripts including but not limited to: IL-4, IL-10, IL-17, IL-21, IL-22, IL-23, TNF and IFNγ.
4: Data to be analysed by the GSK II Statistics and Programming Team Post-SAC.

Scatter plots of Target Engagement and blood/biopsy tissue biomarkers for Day 43 and Day 85 will also be produced.

If deemed appropriate, the relationship between Target Engagement and the blood/biopsy tissue biomarkers will be explored further using multivariate statistical analyses. The consistency in the changes over time between the endpoints will also be assessed. Any such analyses will be defined after unblinding of the data and thus deemed post-hoc.

10.1.2. Population of Interest

The pharmacodynamic/biomarker analyses will be based on the Safety population, unless otherwise specified.

10.1.3. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 10: List of Data Displays and will be based on GSK Data Standards and statistical principles.

Unless otherwise specified, endpoints / variables defined in Section 10.1.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

Biomarker data will be summarised for Parts A and B combined by randomised treatment.

10.1.3.1. Statistical Methodology Specification

Exploratory Inflammatory Biomarkers
Endpoints
• Change from baseline on log transformed inflammatory biomarkers in biopsy tissue on Day 43 pre-dose and Day 85: Log_e Change = Log_e (Visit) – log_e (Baseline). Markers include but not limited to: IL-1, IL-6, IL-8, MMP-3, TNFα and IFNγ.
Model Specification

• Endpoints will be statistically analyzed using a mixed model repeated measures (MMRM) approach.
• Terms fitted in the MMRM model will include:
  ○ Fixed Category : Treatment, Day, Treatment*Day
  ○ Fixed Continuous Covariates : Baseline Score, baseline*Day
  ○ Repeated Effect : Day
 	
• The Kenward and Roger method for approximating the denominator degrees of freedom and correcting for bias in the estimated variance-covariance of the fixed effects will be used.
• An unstructured covariance structure for the R matrix will be used by specifying 'type=UN' on the REPEATED line with a subject=SUBJID option.

Model Checking & Diagnostics
• For the MMRM, model assumptions will be applied, but appropriate adjustments may be applied based on the data. • In the unlikely circumstance that there are convergence problems with the MMRM analysis, this will be explored. For example, the SCORING=4 option could be used in the MIXED statement, which makes SAS use Fisher scoring for the first 4 iterations. If the convergence problem cannot be resolved, the unstructured covariance matrix will be replaced by ANTE (1) covariance structure in combination with a

random participant effect.
    - If this model fails to converge, alternative correlation structures may be considered such as CS or AR (1).
    - Akaike's Information Criteria (AIC) will be used to assist with the selection of covariance structure.
- Distributional assumptions underlying the model used for analysis will be examined by obtaining a normal probability plot of the residuals and a plot of the residuals versus the fitted values (i.e. checking the normality assumption and constant variance assumption of the model respectively) to gain confidence that the model assumptions are reasonable.
- If there are any departures from the distributional assumptions, alternative models will be explored using appropriate transformed data.

Presentation of results

- Adjusted geometric means, the mean difference between each dose (test) and the placebo (reference) at each timepoint and associated 95% confidence interval will be constructed using the residual variance.
- The treatment ratios and 95% CI will be calculated by back-transforming the difference between the least square means and associated 95% CI.
- Percentage change from baseline at each timepoint will be calculated from the adjusted geometric means using the formula 100% x (exp (adj mean)- 1).

Pathway and Target Engagement

Endpoints

- Log Ratio = Log (free TEAR1) – log (total TEAR1).

Model Specification

- A mixed effect model will be fitted with randomised treatment, time (i.e. planned relative time) and randomised treatment * time as a fixed effect and participant as a random effect. Baseline log ratio will be fitted as a continuous covariate along with Baseline log ratio* time.
- The Kenward and Roger method for approximating the denominator degrees of freedom and correcting for bias in the estimated variance-covariance of the fixed effects will be used.
- An unstructured covariance structure for the R matrix will be used by specifying 'type=UN' on the REPEATED line with a subject=SUBJID option.

Model Checking

- For the MMRM, model assumptions will be applied, but appropriate adjustments may be applied based on the data.
- In the unlikely circumstance that there are convergence problems with the MMRM analysis, this will be explored. For example, the SCORING=4 option could be used in the MIXED statement, which makes SAS use Fisher scoring for the first 4 iterations. If the convergence problem cannot be resolved, the unstructured covariance matrix will be replaced by ANTE (1) covariance structure in combination with a random participant effect.
- If this model fails to converge, alternative correlation structures may be considered such as CSH or CS.
- Distributional assumptions underlying the model used for analysis will be examined by obtaining a normal probability plot of the residuals and a plot of the residuals versus the fitted values (i.e. checking the normality assumption and constant variance assumption of the model respectively) to gain confidence that the model assumptions are reasonable.
- If there are any departures from the distributional assumptions, alternative models will be explored using appropriate transformed data.

Pathway and Target Engagement
Presentation of Results
• Adjusted geometric means, the mean difference between each dose (test) and the placebo (reference) at each timepoint and associated 95% confidence interval will be constructed using the residual variance. • The treatment ratios and 95% CI will be calculated by back-transforming the difference between the least square means and associated 95% CI. • Percentage target engagement at each timepoint will be calculated from the adjusted geometric means using the formula: 100% x (exp (ln (v2 / v1) + 1) • percentage target engagement = (1 – engagement ratio) * 100.

Transcriptomics – Fold Change Analysis

• The log_2 normalised copy numbers (also referred to as log2(intensity)) received from the normalised process will be listed and summarised appropriately by randomised treatment.
 	
• As the data will be log_2 transformed prior to the analysis, the randomised treatment effects will be expressed as ratios after back transformation to the original scale. These ratios can be converted from randomised treatment ratios to fold change values as follows:
 	
  • If ratio ≥ 0 then fold change = ratio
  • If ratio <0 then fold change = -1/ratio

Endpoint(s)
• Log2(intensity) mRNA expression of inflammatory gene transcripts
Model Specification

• Endpoints will be statistically analyzed using a linear repeated measure mixed effects model.
• Terms fitted in the linear repeated measures mixed effects model will include:
  ○ Fixed Category : Treatment, Visit, Treatment * Visit
  ○ Random Effect : Participant

Model Checking & Diagnostics
• Model assumptions will be applied, but appropriate adjustments may be applied based on the data. • In the unlikely circumstance that there are convergence problems with the analysis, this will be explored. • If this model fails to converge, alternative correlation structures may be considered such as CSH or CS. • Distributional assumptions underlying the model used for analysis will be examined by obtaining a normal probability plot of the residuals and a plot of the residuals versus the fitted values (i.e. checking the normality assumption and constant variance assumption of the model respectively) to gain confidence that the model assumptions are reasonable. • If there are any departures from the distributional assumptions, alternative models will be explored using appropriate transformed data.
Presentation of Results
• For each probeset analysed adjusted means with corresponding 95% CI and fold changes with corresponding 95% CI's can be outputted. The fold change is derived from the ratio of the back-transformed estimate of the difference between adjusted means. • Plots of LS means and 95% confidence intervals from the model will be generated for each treatment by time. Additionally, plots of differences and 95% confidence intervals for the comparison between the treatment groups will be generated. • For each comparison subsets of probesets will be identified based on an appropriate fold-change, for example, fold changes >1.5 or <-1.5. The proportion of probesets with fold changes >1.5 or <-1.5 will

Transcriptomics – Fold Change Analysis

be summarised in a frequency table.

- Exploratory graphical reporting on the back-transformed scale can include:
  - Log_2 (intensity) plotted against time point separately for individual participants, grouped by randomised treatment group
  - Adjusted mean intensity and 95 CI% plotted by treatment group and time point.

Transcriptomics - MicroArray RNA Analysis

- MicroArray RNA will be extracted and hybridised using a balanced batch design by Epistem. An appropriate microarray platform will be determined at the time of hybridisation, to allow for improvements in technology. The quality of the data will be assessed and then normalised using appropriate methodologies and software.

- Microarray mRNA data will be normalised using gcRMA or RMA in Array Studio v5.0 or later. After normalisation, the data will be quality assessed and any samples deemed as QC fails will be excluded from any further analysis. This quality assessment will involve looking for outlying signals in both the normalised expression data and the MAS5 QC metrics generated from each sample. If any samples are excluded, the remaining data will be re-normalised. The output from the normalisation will be log_2 transformed mRNA intensity data (measured in arbitrary units).

- Microarray data consists of expression values (log_2-transformed) derived from individual probesets designed against coding regions of individual genes. More than one probeset can exist per gene. This analysis will be conducted at the probeset level.

- To identify the most robustly expressed probesets, the data can be filtered to remove low intensity probesets, low quality and control probe sets prior to analysis. This could be done simply by excluding all probesets where all observations are <6 (on the log_2 scale). Note it has been observed empirically that when you get below 100 (6.6 on the log_2 scale) you are into the noise of the assay. Other more stringent methods of filtering the data could be used. In total, there are 53,617 probesets that could be analysed.

- To compare the expression value for each probeset, the following linear repeated measures mixed effects model will be fitted to each probeset that passes any pre-filtering, with log_2 (intensity) as the response variable. Randomised Treatment by visit, randomised treatment and visit will be fitted as fixed effects and participant as a random effect. Example SAS code is given below:

```
proc mixed data=data;
ods output covparms=cov lsmeans=lse estimates=Compare;
class subjid treatment visit;
model lgintensity= treatment visit treatment*visit /ddfm=kr;
repeated visit / subject=subjid type=un;
lsmeans treatment*visit / diff cl alpha=0.05;
run;
```

- For each probeset analysed adjusted means with corresponding 95% CI and fold changes with corresponding 95% CI's can be outputted. The fold change is derived from the ratio of the back-transformed estimate of the difference between adjusted means.

Transcriptomics - MicroArray RNA Analysis

- Where appropriate, particularly with microarray data, multiple testing will be considered using the Benjamini-Hochberg correction *(Benjamini, Y; J Royal Stat Soc 1995;57:289-300)* to calculate FDR adjusted p-values. Proc Multtest incorporating the FDR adjusted p-value option is SAS is used to convert the raw p-values from the proc mixed code above into the FDR adjusted p-values based on the Benjamini-Hochberg correction. Example code to generate the FDR adjusted p-values is given below:

```
data pvalues (keep = probsid label probt rename=(probt=raw_p));
     set compare;
run;

proc multtest pdata=pvalues fdr out=FDRres noprint;
run;
```

- Where the FDRes dataset will include the following columns:

p-values		
Test	**Raw**	**False Discovery Rate**
1	0.2828	0.9243
2	0.9437	0.9437
3	0.0350	0.6305
etc.		

- Appropriate outputs will be created containing all the results for the relevant comparisons for all analysed probesets. A summary may be generated, including probeset ID, gene ID, time point, adjusted means with corresponding 95% CI for each randomised treatment group, Benjamini-Hochberg FDR adjusted p-value and fold changes corresponding 95% CI from each comparison. Note that probeset ID is required if there is more than one probeset per gene.

- For each comparison subsets of probesets will be identified based on an appropriate fold-change, for example, fold changes >1.5 or <-1.5. The proportion of probesets with fold changes >1.5 or <-1.5 will be summarised in a frequency table.

- The outputs should be reviewed by the study team and the pre-agreed subset of biologically relevant probesets will be reported within the CSR. If based on the fold-changes observed other probesets, which were not pre-specified in the RAP, are deemed relevant then these should be interpreted with caution.

- Exploratory graphical reporting on the back-transformed scale can include:

  - Log_2 (intensity) plotted against time point separately for individual participants, grouped by randomised treatment group

  - Adjusted mean intensity and 95 CI% plotted by randomised treatment group and time point.

Transcriptomics – Microarray Percentage Inhibition Analysis

- The log_2 normalised data is back transformed and the percentage inhibition is derived on a participant level on the back transformed data for each probeset. The percentage inhibition will be determined for each probeset per participant, where it is defined as the reduction from baseline. For example:

  Day X – baseline = -40% would be a 40% reduction (i.e. -40% change from baseline) which in turn is defined as a 40% inhibition. So, the percentage inhibition would be calculated as:

  [(Day x – Baseline) / Baseline] * -100 = % inhibition

- A subset of probesets may be identified and individual participant mRNA intensities and percentage inhibitions may be listed, summarised and plotted appropriately for each selected probeset. The selected probesets will be statistically analysed appropriately, and the output from the mixed effects model summarised. The probeset, gene or gene description will be included in the outputs.

- To compare the percentage inhibition for each selected probeset, the following linear repeated measures mixed effects model will be fitted to each selected probeset, with percentage inhibition as the response variable. Randomised Treatment by visit, randomised treatment and visit will be fitted as fixed effects and participant as a random effect. Example SAS code is given below:

```
proc mixed data=data;
class subjid treatment visit;
model perinhibit= treatment visit treatment*visit /ddfm=kr;
repeated visit / subject=subjid type=un;
lsmeans treatment*visit / diff cl alpha=0.05;
run;
```

11. REFERENCES

Guyatt, G, Mitchell A, Irvine E J, Singer J, Williams N, Goodacre R, and Tomkins C; A New Measure of Health Status for Clinical Trials in Inflammatory Bowel Disease. *Gastroenterology*. 1989; 96:804-10

12. APPENDICES

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

12.1.1. Exclusions from Per Protocol Population

A participant meeting any of the following criteria will be excluded from the Per Protocol population:

Number	Exclusion Description
01	Inclusion #9 – Informed Consent: Informed Consent not available at site or Patient did not sign or date
02	Inclusion #2 – Eligibility: Other medical conditions
03	Inclusion #3 – Eligibility: Confirmed diagnosis of UC
04	Inclusion #4 – Eligibility: Total Mayo score and endoscopy subscore
05	Inclusion #5 – Eligibility: Stable concurrent medication
06	Inclusion #6 – Eligibility: Prior treatment
07	Incorrect randomisation or study unblinding procedures

A participant meeting any of the following criteria will be reviewed for exclusion from the Per Protocol population:

Number	Exclusion Description
08	Exclusion #17 – Concomitant Medication

12.2. Appendix 2: Schedule of Activities

12.2.1. Protocol Defined Schedule of Events

Procedures	Screening (-30)	Screening (-7 to -30)	Treatment Period[18]													Early Withdrawal[19]	Follow Up (±3)[20]
			PART A							PART B							
			Day 1	Day 8 (±3)	Day 15 (±3)	Day 22 (±3)	Day 29 (±3)	Day 36 (±3)	Day 43 (±3) (week 6)	Day 50 (±3)	Day 57 (±3)	Day 64 (±3)	Day 71 (±3)	Day 78 (±3)	Day 85 (+2) (week 12)		
Site Visit	X	X	X		X		X		X		X		X		X	X	X
Phone call				X		X		X		X		X		X			
General/Safety Assessments and Procedures																	
Informed Consent	X																
Subject Demography	X																
Full medical history[1]	X																
Inclusion/Exclusion Criteria	X																
Full physical exam[2]	X														X	X	X
Brief physical exam			X[4]		X		X		X[4]		X		X				
Vital signs (BP, HR, RR, temperature)	X		X[4]		X		X		X[4]		X		X		X	X	X
12-lead ECG[3]	X		X[4]		X		X		X[4]		X		X		X	X	X
Concomitant medication review & AE reporting/SAEs[5]			X----------														
PROs/Questionnaires/Disease Assessments and Procedures																	
Columbia Suicide Severity Rating	X		X[4]						X[4]						X	X	

Procedures	Screening (-30)	Screening (-7 to -30)	Treatment Period[18]													Early Withdrawal[19]	Follow Up (±3)[20]
			PART A							PART B							
			Day 1	Day 8 (±3)	Day 15 (±3)	Day 22 (±3)	Day 29 (±3)	Day 36 (±3)	Day 43 (±3) (week 6)	Day 50 (±3)	Day 57 (±3)	Day 64 (±3)	Day 71 (±3)	Day 78 (±3)	Day 85 (+2) (week 12)		
Scale (C-SSRS)																	
IBDQ[6]			X[4]						X[4]						X	X	
UCEIS, Modified Riley, Geboes Index	X-------X[7]								X[4]						X	X	
Mayo Score (including sigmoidoscopy and biopsy)	X-----X[7]								X[4, 8]						X	X[9]	
Partial Mayo Score	X-----X[7]				X		X		X[4]						X	X	
Study Treatment																	
Randomisation			X														
Study medication (three times daily)[10]			X----------XX----------X[11]														
Dispensing of study medication			X		X				X								
Dispensing of diary cards			X		X		X		X		X		X				
Collection of diary cards					X		X		X		X		X		X		
Laboratory (Safety) Assessments and Procedures																	
TB, HIV, Hep B, Hep C Ab, C. Difficile toxin	X																
FSH & estradiol (if applicable)	X																
Serum pregnancy test (WCBP only)	X																

Procedures	Screening (-30)	Screening (-7 to -30)	Treatment Period[18]													Early Withdrawal[19]	Follow Up (±3)[20]
			PART A							PART B							
			Day 1	Day 8 (±3)	Day 15 (±3)	Day 22 (±3)	Day 29 (±3)	Day 36 (±3)	Day 43 (±3) (week 6)	Day 50 (±3)	Day 57 (±3)	Day 64 (±3)	Day 71 (±3)	Day 78 (±3)	Day 85 (+2) (week 12)		
Urine pregnancy test (WCBP only)[12]			X[4]		X		X		X[4]		X		X		X	X	X
Haematology, chemistry, urinalysis	X		X[4]		X		X[13]		X[4]		X[13]		X[13]		X	X	X
Faecal calprotectin[14]	X		X		X		X		X		X		X		X	X	
Blood sample for exploratory biomarkers and TE[15]			X[4]						X[4]						X	X	
PK blood samples GSK2982772[16]			X						X[4]						X	X	
Biopsies for PK, inflammatory biomarkers, mRNA, TE & pathway marker analysis	X-------X[7]								X[4]						X	X[8]	
Pharmacogenetic sample (PGx)[17]			X														

Footnotes:

1. Full medical history (includes past and current conditions, medication history, substance usage, and family history of premature CV disease).
2. Full physical exam (includes height/weight at screening, height not measured at later time points).
3. Triplicate ECG to be performed at screening only and if stopping criteria are met.
4. Pre-dose.
5. Any SAEs assessed as related to study participation (e.g., protocol-mandated procedures, invasive tests, or change in existing therapy) or related to a GSK product will be recorded from the time a participant consents to participate in the study up to and including any follow-up. AEs will be collected from the start of Study Treatment until the follow-up contact.
6. PRO assessments should be conducted before any tests, procedures or assessments to avoid influencing the participants' perception.

7. Sigmoidoscopy may be performed at any time during the screening window as an additional visit (if required) up to Day -7 in order for central reading confirmation of Mayo Score for inclusion. If a shorter window is required (e.g., within Day -3 to Day -7), this will be permitted as long as it has been confirmed with the sponsor and central reader that results of the Mayo endoscopy score will be available before end of screening window. Histological disease (e.g., UCEIS, MRS and Geboes Index) along with Mayo score assessments will also be completed.
8. Sigmoidoscopy may be performed on a separate day within the Day 43 visit window allowance (±3 days). A separate visit to perform sigmoidoscopy is only allowed to accommodate scheduling. This separate visit should be done before the full Day 43 visit where PK, clinical laboratory tests and all other required Day 43 procedures are performed. Participants must not take their study medication at home in the morning before the sigmoidoscopy procedure and also the morning before the full Day 43 visit, if being done on a separate day. Dispensing of study medication must be done at the 2nd visit (if separate visits are performed).
9. Biopsy only required at Early Withdrawal visit if after at least 14 days of treatment and prior to Day 43 or if after Day 57 and prior to Day 85.
10. Participants must take study medication three times a day approximately 8 hours apart. Exact time of dosing to be recorded in diary cards. On Day 43 and 85, participants must not take their study medication at home in the morning. Participant will complete specified pre-dose assessments and then will be administered their morning dose of medication at site on Day 43. On Day 85, participants are no longer receiving study medication.
11. In Part A, participants will be randomised 2:1 to GSK2982772 60 mg or placebo three times daily for 42 days. At the Day 43 visit, all participants who have completed Part A, will move in to Part B open label treatment with GSK2982772 60 mg three times daily for 42 days.
12. If urine pregnancy test is positive, a confirmatory serum pregnancy test must be performed.
13. Urinalysis not required on Days 29, 57 and 71.
14. Participants can provide a faecal sample at any time during the screening window and up to 48 hours prior to any visit where FCP is being collected. Please see laboratory manual for full details on sample handling and procedure.
15. Blood samples for exploratory biomarkers and Target engagement. See laboratory manual for full details on sample collection, handling and shipment.
16. PK blood samples for GSK2982772 will be taken pre-dose on Day 43. Post-dose serial PK samples will be taken on Days 1 and Day 43 at the following time points: 1, 2, 4, and 6 hours and trough on Day 85 or Early Withdrawal.
17. A PGx blood sample is collected at the baseline visit (Day 1), after the participant has been randomized and provided informed consent for genetic research. If the sample is not collected at the baseline visit, it can be collected at any time during the study after randomization.
18. Visit windows during the treatment period are relative to Day 1.
19. If a participant withdraws from the study, every effort will be made for the participant to complete an Early Withdrawal visit prior to the Follow Up visit.
20. Follow-up visit should be completed 28 days (±3 days) after the last dose of study medication.

12.3. Appendix 3: Assessment Windows

12.3.1. Definitions of Assessment Windows for Analyses

No Assessment Windows will be defined for Analysis, and summaries and analyses will be based on nominal visits.

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

12.4.1. Study Phases

Treatment phases will be defined for Part A and Part B of the study. Therefore, assessments and events will be classified according to the time of occurrence relative to study treatment start date and the Day 43 visit.

Study Phase	Definition
Pre-Treatment	Date ≤ Study Treatment Start Date
On-Treatment	Study Treatment Start Date < Date ≤ Study Treatment Stop Date
On-Treatment (Part A)	Study Treatment Start Date < Date ≤ Day 43 Visit Date
On-Treatment (Part B)	Day 43 Visit Date < Date ≤ Study Treatment Stop Date
Post-Treatment	Date > Study Treatment Stop Date

12.4.1.1. Study Phases for Concomitant Medication

Study Phase	Definition
Prior	If medication end date is not missing and is before 28 days prior to screening visit
Concomitant	Any medication that is not a prior
Post-Treatment	Any medication that is started >= Study Treatment Stop Date +1

NOTES:

- 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.

12.4.2. Treatment Emergent Flag for Adverse Events

Treatment State	Definition
AE = Pre-Treatment	If AE onset date is before treatment start date: **= AE Onset Date < Study Treatment Start Date**
AE = On-Treatment	If AE onset date is on or after treatment start date and on or before treatment stop date: **= Study Treatment Start Date ≤ AE Start Date ≤ Study Treatment Stop Date +1**
AE = Post-Treatment	If AE onset date is after the treatment stop date: **= AE Start Date > Study Treatment Stop Date +1**
AE Onset Time Since 1st Dose (Days)	If Treatment Start Date > AE Onset Date: **= AE Onset Date - Treatment Start Date** If Treatment Start Date ≤ AE Onset Date: **= AE Onset Date - Treatment Start Date +1** Missing otherwise.
AE Duration (Days)	**AE Resolution Date – AE Onset Date + 1**
AE = Drug-related	If relationship is marked 'YES' on Inform/CRF OR value is missing.

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 for Interim Analysis	
HARP Server	UK1SALX00175
HARP Area	arenv \ arprod \ gsk2982772 \ mid202152 \ interim1
QC Spreadsheet	arenv \ arwork \ gsk2982772 \ mid202152 \ interim1 \ documents
Reporting Area for Final Reporting	
HARP Server	UK1SALX00175
HARP Area	arenv \ arprod \ gsk2982772 \ mid202152 \ final
QC Spreadsheet	arenv \ arwork \ gsk2982772 \ mid202152 \ final \ documents
Analysis Datasets	
• Analysis datasets will be created per Integrated Data Standards Library (IDSL) GSK A&R dataset standards.	
Generation of RTF Files	
• RTF files will be generated for all tables at the time of the SAC.	

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
• Participant level listings will not be provided in the main body of the GSK Clinical Study Report. All participant level listings will 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 participant's listings.

Unscheduled Visits

• For all safety data:
  • Unscheduled visits will not be included in summary tables.
  • Unscheduled visits will not be included in figures.
  • All unscheduled visits will be included in listings.
• For efficacy data:
  • Early withdrawal visit will be included in all summary tables, figures and listings
  • Early withdrawal visit will be assigned to closest planned study assessment following withdrawal i.e. for data collected from biopsies at the Day 43 visit or Day 85 visit

Descriptive Summary Statistics
Continuous Data: N, n, mean, median, SD, SE, min, max
Categorical Data: N, n, frequency, %
Graphical Displays
• Refer to IDSL Statistical Principals 7.01 to 7.13. • Placebo in graphs to be shown in Black and GSK2982772 in Green

12.5.3. Reporting Standards for Pharmacokinetic

Pharmacokinetic Concentration Data	
Descriptive Summary Statistics, Graphical Displays and Listings	• Refer to IDSL PK Display Standards. • Refer to IDSL Statistical Principle 6.06.1. • Note: Concentration values will be imputed as per GUI_51487 for descriptive summary statistics/analysis and summarized graphical displays only.
NONMEM/PK/PD File	• PK/PD file (CSV format) for the PK/PD analysis by Clinical Pharmacology Modelling and Simulation function mayl be created according to the data specification detailed in Appendix 12: NONMEM datafile Specification.

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. • 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 (PCI) 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

Demographics
Date of Birth
• Only the year of birth will be captured, and therefore the date of birth is then derived as follows: Year of birth = YYYY → Date of birth = 30th June YYYY
Age
• Calculated as the integer part of (date of screening – date of birth) Age = integer part (date of study day 1 – 30th June YYYY) • Birth date will be presented in listings as 'YYYY'.
Body Mass Index (BMI)
• Calculated as Weight (kg) / [Height $(m)^2$]
Race category
• White: 'White: Arabic/North African Heritage' and 'White: White/Caucasian/European Heritage', or both of these, but no other category checked. • African descent: 'African American/African Heritage', and no other category checked. • Asian: 'Asian – Central/South Asian Heritage', 'Asian – East Asian Heritage', 'Asian – Japanese Heritage', and 'Asian – South East Asian Heritage', or any combination of these, but no other category checked. • Other: Any combination that has not been categorized above ('mixed race').
Treatment Compliance

• Participant compliance will be based on the number of expected tablets to be taken and the number actually taken and will depend on whether a participant was taking investigational product (two tablets) twice a day or three times a day.
• Treatment compliance will be calculated based on the formula:
  • **Treatment Compliance = (Total tablets taken/total tablets expected to be taken) *100**
  • Total tablets taken = (Total number of Tablets Dispensed-Total Tablets Returned)
  • Total Tablets expected to be taken is duration of exposure*4 (see derivation below) for BID participants and *6 for TID participants.

Demographics
• Note compliance will only be calculated for participants who took at least one dose (i.e. number of tablets taken is >=1).
Extent of Exposure

• Number of days of exposure to study drug will be calculated based on the formula:
  • **Duration of Exposure in Days = Treatment Stop Date – (Treatment Start Date) + 1**
• Participants who were randomized but did not report a treatment start date will be categorised as having zero days of exposure.
  • The cumulative dose will be based on the formula: **Cumulative Dose = Total Tablets taken*60**.

Concomitant Medications

• The following information will be added to the baseline characteristics table:
  • **Concomitant Medications for UC**: Participants will be categorized into one of 4 groups based on their ongoing prior concomitant medications:
  • Glucocorticoids only,
  • Immunosuppressants only,
  • Glucocorticoids and immunosuppressants and
  • No glucocorticoids or immunosuppressants.
  • **Prednisone dose (or equivalent):** Summary statistics will be presented.
• Glucocorticoids, Immunosuppressants and Prednisone will be identified by review of GSK drug terms by clinical and medical team.

12.6.3. Safety

ECG Parameters
RR Interval
• IF RR interval (msec) is not provided directly, then RR can be derived as: [1] If QTcB is machine read & QTcF is not provided, then: $$RR = \left[\left(\frac{QT}{QTcB}\right)^2\right] * 1000$$ [2] If QTcF is machine read and QTcB is not provided, then: $$RR = \left[\left(\frac{QT}{QTcF}\right)^3\right] * 1000$$ • If ECGs are manually read, the RR value preceding the measurement QT interval should be a collected value then do not derive.
Corrected QT Intervals
• When not entered directly in the eCRF, corrected QT intervals by Bazett's (QTcB) and Fridericia's (QTcF) formulas will be calculated, in msec, depending on the availability of other measurements. • IF RR interval (msec) is provided then missing QTcB and/or QTcF will be derived as: $$QTcB = \frac{QT}{\sqrt{\frac{RR}{1000}}} \qquad QTcF = \frac{QT}{\sqrt[3]{\frac{RR}{1000}}}$$

Laboratory Parameters
• If a laboratory value which is expected to have a numeric value for summary purposes, has a non-detectable level reported in the database, where the numeric value is missing, but typically a character value starting with '<x' or '>x' (or indicated as less than x or greater than x in the comment field) is present, the number of decimal places in the observed values will be used to determine how much to add or subtract in order to impute the corresponding numeric value. ○ Example 1: 2 Significant Digits = '< x 'becomes x – 0.01 ○ Example 2: 1 Significant Digit = '> x' becomes x + 0.1 ○ Example 3: 0 Significant Digits = '< x' becomes x – 1

12.6.4. Efficacy

Clinical Efficacy

Mayo

The Mayo is a 12-point scoring system used to assess UC disease activity based 4 subscores: CCI , CCI and CCI The following table describes how each subscore is composed:

Subscore	Score
CCI	
CCI - This section contained Clinical Outcome Assessment data collection questionnaires or indices, which are protected by third party copyright laws and therefore have been excluded.	

The following endpoints for the Mayo score are to be considered using the following algorithms:

- Mayo Endoscopy Remission: Participants with a score or C or C on the CCI CCI subscore.
- Total Mayo Score: the total score of all 4 domain subscores - CCI CCI and CCI
- Partial Mayo Score: the total score of the 3 domain subscores - CCI and CCI

Clinical Efficacy

- 3-domain Mayo Score: the total score of the 3 domain subscores: CCI and CCI

- Mayo Clinical Response: ≥3 points or ≥30% improvement from baseline in total Mayo score, along with a decrease in the CCI subscore of ≥1 point.

  - i.e., (C< change from baseline in total mayo score <= CC **OR** % change from baseline in total mayo score <= CCI) **AND** change from baseline in CCI subscore <=C.

- 3-domain Mayo Clinical Response: ≥2 points or ≥30% improvement from baseline in partial Mayo score, along with a decrease in the CCI subscore of ≥1 point or a CCI subscore of C or C.

  - i.e., (C< change from baseline in partial mayo score <=C **OR** % change from baseline in partial mayo score <= CCI) **AND** (change from baseline in CCI subscore <= C OR CCI subscore of C or C).

- Mayo Clinical Remission: Total Mayo score of 2 points or lower, with no individual subscore exceeding 1 point.

  - i.e., C<= total mayo score <=C **AND** CCI subscore = C or C **AND** CCI subscore = C or C **AND** CCI subscore = C or C **AND** CCI CCI subscore = C or C.

- 3-domain Mayo Clinical Remission: At least one point decrease in CCI subscore from Baseline to achieve a CCI subscore of C or C and CCI subscore = C and CCI subscore of C or C.

  - i.e. (CCI subscore C or C **AND** change from baseline in CCI subscore <= C) **AND** CCI subscore of C **AND** CCI subscore = C or C.

Clinical Efficacy

UCEIS

The UCEIS is used as an additional tool to assess disease activity based on endoscopic CCI, CCI and CCI. The following table describes how the UCEIS is scored:

Descriptor (score most severe lesions)	Likert scale anchor points	Definition
CCI - This section contained Clinical Outcome Assessment data collection questionnaires or indices, which are protected by third party copyright laws and therefore have been excluded.		

Clinical Efficacy

CCI - This section contained Clinical Outcome Assessment data collection questionnaires or indices, which are protected by third party copyright laws and therefore have been excluded.

The following endpoint for the UCEIS is to be considered at each visit:

- UCEIS Total Score: Sum of all likert scale anchor points scores.
- UCEIS Remission: Participants with a score or 0 or 1 on the UCEIS Total Score.

Geboes

The Geboes Index is divided in 6 grades: architectural changes [grade 0], chronic inflammatory infiltrate [grade 1], lamina propria neutrophils and eosinophils [grade 2], neutrophils in epithelium [grade 3], crypt destruction [grade 4] and erosions or ulcerations [grade 5], and each grade of the score is divided in 4 or 5 subcategories.

Grade		Subgrade	
0	Structural (architectural change)	0.0	No abnormality
		0.1	Mild abnormality
		0.2	Mild or moderate diffuse or multifocal abnormalities
		0.3	Severe diffuse or multifocal abnormalities
1	Chronic inflammatory infiltrate	1.0	No increase
		1.1	Mild but unequivocal increase
		1.2	Moderate increase
		1.3	Marked increase
2	Lamina propria eosinophils and neutrophils (to be graded separately)	2.0	No increase
		2.1	Mild but unequivocal increase
		2.2	Moderate increase
		2.3	Marked increase
3	Neutrophils in epithelium	3.0	None
		3.1	<5% crypts involved
		3.2	=<50% crypts involved
		3.3	>=50% crypts involved
4	Crypt destruction	4.0	None
		4.1	Probable – local excess of neutrophils in part of crypt

Clinical Efficacy

		4.2	Probable – marked attenuation
		4.3	Unequivocal crypt destruction
5	Erosion or ulcerative	5.0	No erosion, ulceration, or granulation tissue
		5.1	Recovering epithelium plus adjacent inflammation
		5.2	Probable erosion – focally stripped
		5.3	Unequivocal erosion
		5.4	Ulcer or granulation tissue

The following endpoint for the Geboes is to be considered at each relevant visit:

- Geboes Index Total Score: Sum of the all the subgrades (i.e. Structural (architectural change) = 0.2 is a score of 2, Chronic inflammatory infiltrate = 1.1 is scored as a 1 etc.).
-

Robarts Histology Index (RHI)

The RHI will be provided by Robarts as an additional tool to measure histologic disease activity.

The RHI Score is a continuous score, ranging from 0-33 with higher scores indicating more severe disease.

For the frequency table of RHI Score the following cut-points will be used:

- Remission: Score <=6,
- Low: Scores >6-<12,
- Moderate/Severe Score: > = 12

Modified Riley Scale

The Modified Riley Scale (MRS) is a 4-point scale (none, mild, moderate and severe) which scores histologic activity based on localization and quantification of neutrophils in the mucosa. A single modified riley scale score is collected at each relevant visit.

Activity	Histological Characteristics	
None	0	Normal biopsy or inactive colitis
Mild	1	Lamina propria neutrophils only = Scattered individual neutrophils
	2	Lamina propria neutrophils only = Patchy collections of neutrophils
	3	Lamina propria neutrophils only = Diffuse neutrophils infiltrate
Moderate	4	Cryptitis/crypt abscesses = <25% crypts involved
	5	Cryptitis/crypt abscesses = 25%- 74% crypts involved
	6	Cryptitis/crypt abscesses = >=75% crypts involved
Severe	7	Erosion or ulceration = Present

Clinical Efficacy

Faecal Calprotectin (FCP)

FCP, a protein biomarker, is measured from the faecal samples. The raw FCP data is highly variable and therefore data should be log-transformed before a change from baseline is calculated.

For the frequency table of FCP categories the following cut-points will be used:

- <250,
- >= 250 and
- >=1000.

C-Reactive Protein (CRP)

CRP will be provided as a clinical chemistry parameter in the Clinical Laboratory dataset.

Inflammatory Bowel Disease Questionnaire (IBDQ)

The IBDQ is a 32-item Inflammatory Bowel Disease-specific health related quality of life instrument evaluating general activities of daily living, intestinal function, social performance, personal interactions, and emotional status. Each item is presented on seven-point scale with higher representing better functioning.

The IBDQ items are grouped into four domains with a total score for each being calculated as follows:

- Bowel symptoms (10 items): Sum items 1, 5, 9, 13, 17, 20, 22, 24, 26, 29
- Systemic Symptoms (5 items): Sum items 2, 6, 10, 14, 18.
- Emotional Function (12 items): Sum items 3, 7, 11, 15, 19, 21, 23, 25, 27, 30, 31, 32
- Social Function (5 items): Sum items 4, 8, 12, 16 and 28

The IBDQ Total Score is calculated as follows:

- IBDQ Total Score: Sum of all 32-items.

Subject Symptom Diary Cards

Participants will be given a diary card at each visit. The number of stools, stool frequency score and rectal Bleeding Score will be transcribed into the eCRF for the 5 days prior to the following visits: Screening, Day 15, Day 29, Day 43, Day 85 and EW.

The stool frequency score is on a 4-point scale as follows:

- 0 = Normal
- 1 = 1-2 stools/day more than normal
- 2 = 3-4 stools/day more than normal
- 3 = >=4 stools/day more than normal

The rectal bleeding score is on a 4-point scale as follows:

- 0 = No blood seen
- 1 = Streaks of blood with stool less than half the time
- 2 = Obvious blood with stool most of the time

Clinical Efficacy
• 3 = Blood alone passed. The average score and maximum score be considered for both stool frequency and rectal bleeding over the 5 days prior to at each visit: • Average Score: [Sum of scores over 5 prior days] / [number of prior days with a score available] • Maximum Score: Maximum (i.e. highest) score collected over 5 prior days. The average score will be considered for number of stools over the 5 days prior to at each visit: • Average Score: [Sum of number of stools over 5 prior days] / [number of prior days with a stool data available]

12.6.5. Biomarker

TEAR
Target Engagement
• Ratio = free / total • Target Engagement = 100 – (ratio $_{post}$/ratio $_{baseline}$) * 100)) • BIOMARK dataset: BICAT = TRIPK1 (total) or FRIPK1 (free) and BITESTCD = CONC

12.7. Appendix 7: Reporting Standards for Missing Data

12.7.1. Premature Withdrawals

Element	Reporting Detail
General	• Participant study completion was defined as one who has completed all phases of the study including the follow-up visit. • Withdrawn participants may be replaced in the study at the discretion of the investigator. • 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:
	  • These data will be indicated by the use of a "blank" in participant listing displays. Unless all data for a specific visit are missing in which case the data is excluded from the table.
	  • Answers such as "Not applicable" and "Not evaluable" are not considered to be missing data and should be displayed as such.

Outliers	• Any participants excluded from the summaries and/or statistical analyses will be documented along with the reason for exclusion in the clinical study report.

12.7.2.1. Handling of Missing and Partial Dates

Element	Reporting Detail
General	• Partial dates will be displayed as captured in participant listing displays.

Adverse Events	• The eCRF allows for the possibility of partial dates (i.e., only month and year) to be 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/	• 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

12.8.1. Laboratory Values

Haematology				
Laboratory Parameter	**Units**	**Category**	**Clinical Concern Range**	
			Low Flag (< x)	**High Flag (>x)**
Hematocrit	Ratio of 1	Male		0.54
		Female		0.54
		Δ from BL	↓0.075	
Hemoglobin	g/L	Male		180
		Female		180
		Δ from BL	↓25	
Lymphocytes	$x10^9$/ L		0.8	
Neutrophil Count	$x10^9$/ L		1.5	
Platelet Count	$x10^9$/ L		100	550
While Blood Cell Count (WBC)	$x10^9$/ L		3	20
Clinical Chemistry				
Laboratory Parameter	**Units**	**Category**	**Clinical Concern Range**	
			Low Flag (< x)	**High Flag (>x)**
Albumin	g/L		30	
Calcium	mmol/L		2	2.75
Creatinine	µmol/L	Δ from BL		↑ 44.2
Glucose	mmol/L		3	9
Magnesium	mmol/L		0.5	1.23
Phosphorus	mmol/L		0.8	1.6
Potassium	mmol/L		3	5.5
Sodium	mmol/L		130	150
Total CO2	mmol/L		18	32
Liver Function				
Test Analyte	**Units**	**Category**	**Clinical Concern Range**	
ALT/SGPT	U/L	High	≥ 2x ULN	
AST/SGOT	U/L	High	≥ 2x ULN	
AlkPhos	U/L	High	≥ 2x ULN	
T Bilirubin	µmol/L	High	≥ 1.5xULN	
T. Bilirubin + ALT	µmol/L U/L	High	1.5xULN T. Bilirubin + ≥ 2x ULN ALT	

12.8.2. ECG

ECG Parameter	Units	Clinical Concern Range	
		Lower	Upper
Absolute			
Absolute QTc Interval	msec	> 450	≤ 479
		≥ 480	≤ 499
		≥ 500	
Absolute PR Interval	msec	< 110	> 220
Absolute QRS Interval	msec	< 75	> 110
Change from Baseline			
Increase from Baseline QTc	msec	> 30	<60
	msec	≥ 60	

12.8.3. Vital Signs

Vital Sign Parameter (Absolute)	Units	Clinical Concern Range	
		Lower	Upper
Systolic Blood Pressure	mmHg	< 85	> 160
Diastolic Blood Pressure	mmHg	< 45	> 100
Heart Rate	bpm	< 40	> 110

Vital Sign Parameter (Change from Baseline)	Units	Clinical Concern Range			
		Decrease		Increase	
		Lower	Upper	Lower	Upper
Systolic Blood Pressure	mmHg	≥ 20	≥ 40	≥ 20	≥ 40
Diastolic Blood Pressure	mmHg	≥ 10	≥ 20	≥ 10	≥ 20
Heart Rate	bpm	≥ 15	≥ 30	≥ 15	≥ 30

12.9. Appendix 9: Abbreviations & Trade Marks

12.9.1. Abbreviations

Abbreviation	Description
AE	Adverse Event
A&R	Analysis and Reporting
AIC	Akaike's Information Criteria
BID	Twice a day
CI	Confidence Interval
CRF	Case Report Form
CRP	C-Reactive Protein
CSR	Clinical Study Report
C-SSRS	Columbia Suicide Severity Rating Scale
CTR	Clinical Trial Register
CV_b / CV_w	Coefficient of Variation (Between) / Coefficient of Variation (Within)
DB	Double-Blind
DBF	Database Freeze
DBR	Database Release
DOB	Date of Birth
DP	Decimal Places
DRC	Data Review Committee
ECG	Electrocardiogram
eCRF	Electronic Case Record Form
EMA	European Medicines Agency
FCP	Faecal Calprotectin
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Clinical Results Disclosure Requirements
GEE	Generalised Estimating Equations
GSK	GlaxoSmithKline
IA	Interim Analysis
IBDQ	Inflammatory Bowel Disease Questionnaire
ICH	International Conference on Harmonization
IDSL	Integrated Data Standards Library
IMMS	International Modules Management System
IP	Investigational Product
IRTS	Interactive Response Technology System
ITT	Intent-To-Treat
Kg	Kilogram
mmol	Millimole
MMRM	Mixed Model Repeated Measures
MRS	Modified Riley Scale
NR	Normal Range
OL	Open-Label
PCI	Potential Clinical Importance
PD	Pharmacodynamic
PDMP	Protocol Deviation Management Plan
PK	Pharmacokinetic
PopPK	Population PK
PP	Per Protocol

Abbreviation	Description
PP	Per Protocol
PSRAE	Possible Suicidality-Related Adverse Event
PT	Preferred Term
QC	Quality Control
QTcB	Bazett's QT Interval Corrected for Heart Rate
QTcF	Frederica's QT Interval Corrected for Heart Rate
RAMOS	Randomization & Medication Ordering System
RAP	Reporting & Analysis Plan
RHI	Robarts Histology Index
SAC	Statistical Analysis Complete
SAE	Serious Adverse Event
SE	Standard Error
SOC	System Organ Class
SOP	Standard Operation Procedure
SRT	Safety Review Team
TA	Therapeutic Area
TEAR1	Target Engagement Assay RIP1
TFL	Tables, Figures & Listings
TID	Three times a day
UC	Ulcerative Colitis
UCEIS	Ulcerative Colitis Endoscopic Index of Severity
ULN	Upper Limit of Normal

12.9.2. Trademarks

Trademarks of the GlaxoSmithKline Group of Companies
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MedDRA
NONMEM
SAS

12.10. Appendix 10: List of Data Displays

12.10.1. Data Display Numbering

The following numbering will be applied for RAP generated displays:

Section	Tables	Figures
Study Population	1.1 to 1.16	NA
Efficacy	2.1 to 2.41	2.1 to 2.44
Safety	3.1 to 3.56	3.1 to 3.7
Pharmacokinetic	4.1	4.1 to 4.28
Pharmacodynamic and / or Biomarker	6.1 to 6.11	6.1 to 6.19
Section	**Listings**	
ICH Listings	1 to 42	
Other Listings	43 to 83	

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 11: 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
Pharmacodynamic and / or Biomarker	PD_Fn	PD_Tn	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 [Priority] [1]	Description
IA SAC [X]	Interim Analysis Statistical Analysis Complete
SAC [X]	Final Statistical Analysis Complete
SAC2 [X]	Post-Final Statistical Analysis Complete

NOTES:

1. Indicates priority (i.e. order) in which displays will be generated for the reporting effort

12.10.4. Study Population Tables

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.1.	Safety	ES1	Summary of Subject Disposition for the Subject Conclusion Record by Randomised Treatment	ICH E3, FDAAA, EudraCT Footnote: Add footnote : Note: "Subjects" is used to refer to "Participants" in all data displays to reflect GSK Display Standards	IA SAC[1], SAC [1]
1.2.	Safety	SD1	Summary of Treatment Status and Reasons for Discontinuation of Study Treatment by Randomised Treatment	ICH E3	IA SAC [1], SAC [1]
1.3.	All Subjects	ES6	Summary of Screening Status and Reasons for Screen Failure by Randomised Treatment	Journal Requirements	IA SAC [1], SAC [1]
1.4.	All Subjects	NS1	Summary of Number of Subjects by Country and Site ID by Randomised Treatment	EudraCT/Clinical Operations	IA SAC [1], SAC [1]
Protocol Deviation					
1.5.	Safety	DV1	Summary of Important Protocol Deviations by Randomised Treatment	ICH E3	IA SAC [1], SAC [1]
Population Analysed					
1.6.	Safety	SP1	Summary of Study Populations by Randomised Treatment	IDSL	IA SAC [1], SAC [1]
1.7.	Safety	SP2 / SP2A	Summary of Exclusions from the PP and PP + Completers Population	IDSL	IA SAC [1], SAC [1]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Demographic and Baseline Characteristics					
1.8.	Safety	DM1	Summary of Demographic Characteristics by Randomised Treatment	ICH E3, FDAAA, EudraCT If height and weight are collected only at baseline, then display in this demographic summary. Otherwise display height and weight with the vital signs data.	IA SAC [1], SAC [1]
1.9.	All Subjects	DM11	Summary of Age Ranges by Randomised Treatment	EudraCT	IA SAC [1], SAC [1]
1.10.	Safety	DM5	Summary of Race and Racial Combinations by Randomised Treatment	ICH E3, FDA, FDAAA, EudraCT	IA SAC [1], SAC [1]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.11.	Safety	DM1	Summary of Ulcerative Colitis Baseline Characteristics by Randomised Treatment	To include: Baseline Mucosal Appearance at Endoscopy Mayo Subscore, Baseline Total Mayo Score, Baseline Partial Mayo Score Baseline 3-domain Mayo Score, Baseline UCEIS Total Score, Baseline Modified Riley Scale Score, Baseline FCP, Baseline FCP category, Baseline Concomitant Medications for UC (Glucocorticoids only, Immunosuppressants only, Glucocorticoids and Immunosuppressants, No Glucocorticoids or Immunosuppressants, Baseline Prednisone dose, Family History of Premature Coronary Artery Disease and History of Tobacco Use. Include the footnote: Note: Glucocorticoids and Immunosuppressants were identified by review of all ingredients by clinical and medical team.	IA SAC[1], SAC [1]
Prior/Current Medical Conditions and Concomitant Medications					
1.12.	Safety	MH4	Summary of Current/Past Medical Conditions by Randomised Treatment	ICH E3 Separate summaries for Current & Past conditions, if collected.	IA SAC [1], SAC [1]

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.13.	Safety	MH1	Summary of Current/Past Cardiovascular Risk Factors by Randomised Treatment	ICH E3 Separate summaries for Current & Past, if collected	IA SAC [1], SAC [1]
1.14.	Safety	CM1	Summary of Prior Medications by Randomised Treatment	ICH E3	IA SAC [1], SAC [1]
1.15.	Safety	CM1	Summary of Concomitant Medications by Randomised Treatment	ICH E3	IA SAC [1], SAC [1]
Exposure and Treatment Compliance					
1.16.	Safety	EX1 / EX5	Summary of Exposure to Study Treatment by Randomised Treatment	ICH E3	IA SAC [1], SAC [1]

12.10.5. Safety Tables

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events (AEs)					
3.1.	Safety	AE5A	Summary of All Adverse Events by Maximum Intensity by System Organ Class and Preferred Term (Part A only) by Randomised Treatment	ICH E3 Include total column across all intensities	IA SAC [1], SAC [1]
3.2.	Safety	AE5A	Summary of All Adverse Events by Maximum Intensity by System Organ Class and Preferred Term (Parts A, B and Follow-up) by Randomised Treatment	ICH E3 Include total column across all intensities	IA SAC [1], SAC [1]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.3.	Safety	AE5A	Summary of All Adverse Events by Maximum Intensity by System Organ Class and Preferred Term (Parts A, B and Follow-up) by Period Treatment	ICH E3 Include total column across all intensities	IA SAC[1], SAC [1]
3.4.	Safety	AE1	Summary of All Adverse Events by System Organ Class and Preferred Term (Part A only) by Randomised Treatment		IA SAC[1], SAC [1]
3.5.	Safety	AE1	Summary of All Adverse Events by System Organ Class and Preferred Term (Parts A, B and Follow-up) by Randomised Treatment		IA SAC[1], SAC [1]
3.6.	Safety	AE1	Summary of All Adverse Events by System Organ Class and Preferred Term (Parts A, B and Follow-up) by Period Treatment		IA SAC[1], SAC [1]
3.7.	Safety	AE3	Summary of Common (>=10%) Adverse Events by Overall Frequency (Part A only) by Randomised Treatment	ICH E3 Common defined as >= 10% within either randomised treatment group	IA SAC [1], SAC [1]
3.8.	Safety	AE3	Summary of Common (>=10%) Adverse Events by Overall Frequency (Parts A, B and Follow-up) by Randomised Treatment	ICH E3 Common defined as >= 10% within either randomised treatment group	IA SAC[1], SAC [1]
3.9.	Safety	AE3	Summary of Common (>=10%) Adverse Events by Overall Frequency (Parts A, B and Follow-up) by Period Treatment	ICH E3 Common defined as >= 10% within either randomised treatment group	IA SAC[1], SAC [1]
3.10.	Safety	AE5A	Summary of All Drug-Related Adverse Events by Maximum Intensity and System Organ Class and Preferred Term (Part A only) by Randomised Treatment	ICH E3 Include total column across all intensities	IA SAC [1], SAC [1]
3.11.	Safety	AE5A	Summary of All Drug-Related Adverse Events by Maximum Intensity and System Organ Class and Preferred Term (Parts A, B and Follow-up) by Randomised Treatment	ICH E3 Include total column across all intensities	IA SAC [1], SAC [1]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.12.	Safety	AE5A	Summary of All Drug-Related Adverse Events by Maximum Intensity and System Organ Class and Preferred Term (Parts A, B and Follow-up) by Period Treatment	ICH E3 Include total column across all intensities	IA SAC [1], SAC [1]
3.13.	Safety	AE15	Summary of Common (>=10%) Non-serious Adverse Events by System Organ Class and Preferred Term (Number of Subjects and Occurrences) (Part A only) by Randomised Treatment	FDAAA, EudraCT	IA SAC [1], SAC [1]
3.14.	Safety	AE15	Summary of Common (>=10%) Non-serious Adverse Events by System Organ Class and Preferred Term (Number of Subjects and Occurrences) (Parts A, B and Follow-up) by Randomised Treatment	FDAAA, EudraCT	IA SAC [1], SAC [1]
3.15.	Safety	AE15	Summary of Common (>=10%) Non-serious Adverse Events by System Organ Class and Preferred Term (Number of Subjects and Occurrences) (Parts A, B and Follow-up) by Period Treatment	FDAAA, EudraCT	IA SAC [1], SAC [1]
3.16.	Safety	AE3	Summary of Common (>=10%) Drug-Related Adverse Events by Overall Frequency (Part A only) by Randomised Treatment	ICH E3	IA SAC [1], SAC [1]
3.17.	Safety	AE3	Summary of Common (>=10%) Drug-Related Adverse Events by Overall Frequency (Parts A, B and Follow-up) by Randomised Treatment	ICH E3	IA SAC [1], SAC [1]
3.18.	Safety	AE3	Summary of Common (>=10%) Drug-Related Adverse Events by Overall Frequency (Parts A, B and Follow-up) by Period Treatment	ICH E3	IA SAC [1], SAC [1]
Serious and Other Significant Adverse Events					
3.19.	Safety	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term (Number of Subjects and Occurrences) (Part A only) by Randomised Treatment	FDAAA, EudraCT	IA SAC [1], SAC [1]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.20.	Safety	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term (Number of Subjects and Occurrences) (Parts A, B and Follow-up) by Randomised Treatment	FDAAA, EudraCT	IA SAC [1], SAC [1]
3.21.	Safety	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term (Number of Subjects and Occurrences) (Parts A, B and Follow-up) by Period Treatment	FDAAA, EudraCT	IA SAC [1], SAC [1]
3.22.	Safety	AE1	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment or Withdrawal from Study (Part A only) by Randomised Treatment	IDSL	IA SAC [1], SAC [1]
3.23.	Safety	AE1	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment or Withdrawal from Study (Parts A, B and Follow-up) by Randomised Treatment	IDSL	IA SAC [1], SAC [1]
3.24.	Safety	AE1	Summary of Adverse Events Leading to Permanent Discontinuation of Study Treatment or Withdrawal from Study (Parts A, B and Follow-up) by Period Treatment	IDSL	IA SAC [1], SAC [1]
Laboratory: Chemistry					
3.25.	Safety	LB1	Summary of Chemistry Changes from Baseline (Parts A, B and Follow-up) by Randomised Treatment	ICH E3	IA SAC [1], SAC [1]
3.26.	Safety	LB1	Summary of Chemistry Changes from Period Baseline (Parts A, B and Follow-up) by Period Treatment	ICH E3	IA SAC [1], SAC [1]
3.27.	Safety	LB1	Summary of Lipids Percentage Changes from Baseline (Parts A, B and Follow-up) by Randomised Treatment	Lipids parameters = LDL Cholesterol, HDL Cholesterol, Total Cholesterol, Triglycerides and Cholesterol/HDL ratio	IA SAC [1], SAC [1]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.28.	Safety	LB1	Summary of Lipids Percentage Changes from Period Baseline (Parts A, B and Follow-up) by Period Treatment	Lipids parameters = LDL Cholesterol, HDL Cholesterol, Total Cholesterol Triglycerides and Cholesterol/HDL ratio	IA SAC[1], SAC [1]
3.29.	Safety	LB17	Summary of Worst Case Chemistry Results by PCI Criteria Post-Baseline Relative to Baseline (Parts A, B and Follow-up) by Randomised Treatment	ICH E3 (i.e. treatment emergent)	IA SAC [1], SAC [1]
3.30.	Safety	LB17	Summary of Worst Case Chemistry Results by PCI Criteria Post-Baseline Relative to Period Baseline (Parts A, B and Follow-up) by Period Treatment	ICH E3 (i.e. treatment emergent)	IA SAC [1], SAC [1]
3.31.	Safety	LB17	Summary of Worst Case Lipids Results by NR Criteria Post-Baseline Relative to Baseline (Parts A, B and Follow-up) by Randomised Treatment	Lipids parameters = LDL Cholesterol, HDL Cholesterol, Total CholesterolTriglycerides and Cholesterol/HDL ratio	IA SAC [1], SAC [1]
3.32.	Safety	LB17	Summary of Worst Case Lipids Results by NR Criteria Post-Baseline Relative to Period Baseline (Parts A, B and Follow-up) by Period Treatment	Lipids parameters = LDL Cholesterol, HDL Cholesterol, Total Cholesterol, Triglycerides and Cholesterol/HDL ratio	IA SAC [1], SAC [1]
Laboratory: Hematology					
3.33.	Safety	LB1	Summary of Hematology Changes from Baseline (Parts A, B and Follow-up) by Randomised Treatment	ICH E3	IA SAC [1], SAC [1]
3.34.	Safety	LB1	Summary of Hematology Changes from Period Baseline (Parts A, B and Follow-up) by Period Treatment	ICH E3	IA SAC [1], SAC [1]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.35.	Safety	LB17	Summary of Worst Case Hematology Results by PCI Criteria Post-Baseline Relative to Baseline (Parts A, B and Follow-up) by Randomised Treatment	ICH E3	IA SAC [1], SAC [1]
3.36.	Safety	LB17	Summary of Worst Case Hematology Results by PCI Criteria Post-Baseline Relative to Period Baseline (Parts A, B and Follow-up) by Period Treatment	ICH E3	IA SAC [1], SAC [1]
Laboratory: Urinalysis					
3.37.	Safety	LB1	Summary of Urine Concentration Changes from Baseline (Parts A, B and Follow-up) by Randomised Treatment	ICH E3	IA SAC [1], SAC [1]
3.38.	Safety	LB1	Summary of Urine Concentration Changes from Period Baseline (Parts A, B and Follow-up) by Period Treatment	ICH E3	IA SAC [1], SAC [1]
3.39.	Safety	UR1	Summary of Worst Case Urinalysis Results (Discrete or Character Values) Post-Baseline Relative to Baseline (Parts A, B and Follow-up) by Randomised Treatment	ICH E3	IA SAC [1], SAC [1]
3.40.	Safety	UR1	Summary of Worst Case Urinalysis Results (Discrete or Character Values) Post-Baseline Relative to Period Baseline (Parts A, B and Follow-up) by Period Treatment	ICH E3	IA SAC [1], SAC [1]
Laboratory: Hepatobiliary (Liver)					
3.41.	Safety	LIVER1	Summary of Liver Monitoring/Stopping Event Reporting (Parts A, B and Follow-up) by Randomised Treatment	IDSL	IA SAC [1], SAC [1]
3.42.	Safety	LIVER1	Summary of Liver Monitoring/Stopping Event Reporting (Parts A, B and Follow-up) by Period Treatment	IDSL	IA SAC [1], SAC [1]
3.43.	Safety	LIVER10	Summary of Hepatobiliary Laboratory Abnormalities (Parts A, B and Follow-up) by Randomised Treatment	IDSL	IASAC [1], SAC [1]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.44.	Safety	LIVER10	Summary of Hepatobiliary Laboratory Abnormalities (Parts A, B and Follow-up) by Period Treatment	IDSL	IA SAC [1], SAC [1]
ECGs					
3.45.	Safety	EG1	Summary of ECG Findings (Parts A, B and Follow-up) by Randomised Treatment	IDSL	IA SAC [1], SAC [1]
3.46.	Safety	EG1	Summary of ECG Findings (Parts A, B and Follow-up) by Period Treatment	IDSL	IA SAC [1], SAC [1]
3.47.	Safety	EG10	Summary of Maximum QTc Values Post-Baseline Relative to Baseline by Category (Parts A, B and Follow-up) by Randomised Treatment	IDSL	IA SAC [1], SAC [1]
3.48.	Safety	EG10	Summary of Maximum QTc Values Post-Baseline Relative to Screening by Category (Parts A, B and Follow-up) by Randomised Treatment	Change relative to average of screening triplicates	SAC[1]
3.49.	Safety	EG10	Summary of Maximum QTc Values Post-Baseline Relative to Period Baseline by Category (Parts A, B and Follow-up) by Period Treatment	IDSL	IA SAC [1], SAC [1]
3.50.	Safety	EG2	Summary of Change from Baseline in ECG Values (Parts A, B and Follow-up) by Randomised Treatment	IDSL	IA SAC [1], SAC [1]
3.51.	Safety	EG2	Summary of Change from Screening in ECG Values (Parts A, B and Follow-up) by Randomised Treatment	Change relative to average of screening triplicates	SAC [1]
3.52.	Safety	EG2	Summary of Change from Period Baseline in ECG Values (Parts A, B and Follow-up) by Period Treatment	IDSL	IA SAC [1], SAC [1]
3.53.	Safety	EG11	Summary of Maximum Increase in QTc Values Post-Baseline Relative to Baseline by Category (Parts A, B and Follow-up) by Randomised Treatment	IDSL	IA SAC [1], SAC [1]

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.54.	Safety	EG11	Summary of Maximum Increase in QTc Values Post-Baseline Relative to Screening by Category (Parts A, B and Follow-up) by Randomised Treatment	Change relative to average of screening triplicates	SAC [1]
3.55.	Safety	EG11	Summary of Maximum Increase in QTc Values Post-Baseline Relative to Period Baseline by Category (Parts A, B and Follow-up) by Period Treatment	IDSL	IA SAC [1], SAC [1]
Vital Signs					
3.56.	Safety	VS1	Summary of Change from Baseline in Vital Signs (Parts A, B and Follow-up) by Randomised Treatment	ICH E3	IA SAC [1], SAC [1]
3.57.	Safety	VS1	Summary of Change from Period Baseline in Vital Signs (Parts A, B and Follow-up) by Period Treatment	ICH E3	IA SAC [1], SAC [1]
3.58.	Safety	VS7	Summary of Worst Case Vital Signs Results by PCI Criteria Post-Baseline Relative to Baseline (Parts A, B and Follow-up) by Randomised Treatment	IDSL	IA SAC [1], SAC [1]
3.59.	Safety	VS7	Summary of Worst Case Vital Signs Results by PCI Criteria Post-Baseline Relative to Period Baseline (Parts A, B and Follow-up) by Period Treatment	IDSL	IA SAC [1], SAC [1]

12.10.6. Safety Figures

Safety: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events					
3.1.	Safety	AE10	Plot of Common (>=10%) Adverse Events and Relative Risk (Part A only) by Randomised Treatment	IDSL	IA SAC [1], SAC [1]
3.2.	Safety	AE10	Plot of Common (>=10%) Adverse Events and Relative Risk (Parts A, B and Follow-up) by Randomised Treatment	IDSL	IA SAC [1], SAC [1]
3.3.	Safety	AE10	Plot of Common (>=10%) Adverse Events and Relative Risk (Parts A, B and Follow-up) by Period Treatment	IDSL	IA SAC [1], SAC [1]
Laboratory					
3.4.	Safety	LIVER14	Scatter Plot of Maximum Versus Baseline for ALT (Parts A, B and Follow-up) by Randomised Treatment	IDSL	IA SAC [1], SAC [1]
3.5.	Safety	LIVER14	Scatter Plot of Maximum Versus Period Baseline for ALT (Parts A, B and Follow-up) by Period Treatment	IDSL	IA SAC [1], SAC [1]
3.6.	Safety	LIVER9	Scatter Plot of Maximum ALT Versus Maximum Total Bilirubin ALT (Parts A, B and Follow-up) by Randomised Treatment	IDSL	IA SAC [1], SAC [1]
3.7.	Safety	LIVER9	Scatter Plot of Maximum ALT Versus Maximum Total Bilirubin (Parts A, B and Follow-up) by Period Treatment	IDSL	IA SAC [1], SAC [1]

12.10.7. Efficacy Tables

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Mayo – Endoscopy Response					
2.1.	Safety	EFF_T1	Summary Statistics for Actual and Change from Baseline in Mucosal Appearance at Endoscopy Mayo Subscore (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.2.	Safety	EFF_T2b	Frequency Table of Mucosal Appearance at Endoscopy Mayo Subscore (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.3.	Safety	EFF_T3	GEE Point Estimate and 95% CI for Subjects Achieving Mayo Endoscopy Remission (Parts A and B) by Randomised Treatment	GEE modelling will only be performed if at least 30% response rate at Day 85 for any one treatment group.	IA SAC [1], SAC [1]
2.4.	PP	EFF_T1	Summary Statistics for Actual and Change from Baseline in Mucosal Appearance at Endoscopy Mayo Subscore (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.5.	PP	EFF_T2b	Frequency Table of Mucosal Appearance at Endoscopy Mayo Subscore (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.6.	PP	EFF_T3	GEE Point Estimate and 95% CI for Subjects Achieving Mayo Endoscopy Remission (Parts A and B) by Randomised Treatment	GEE modelling will only be performed if at least 30% response rate at Day 85 for any one treatment group.	IA SAC [1], SAC [1]
2.7.	PP + Completers	EFF_T1	Summary Statistics for Actual and Change from Baseline in Mucosal Appearance at Endoscopy Mayo Subscore (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.8.	PP + Completers	EFF_T2b	Frequency Table of Mucosal Appearance at Endoscopy Mayo Subscore (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.9.	PP + Completers	EFF_T3	GEE Point Estimate and 95% CI for Subjects Achieving Mayo Endoscopy Remission (Parts A and B) by Randomised Treatment	GEE modelling will only be performed if at least 30% response rate at Day 85 for any one treatment group.	IA SAC [1], SAC [1]
Mayo – Clinical Response and Remission					
2.10.	Safety	EFF_T2a	Frequency Table of Subjects Achieving Mayo Clinical Response, 3-domain Clinical Response, Mayo Clinical Remission and 3-Domain Mayo Clinical Remission (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.11.	Safety	EFF_T3	GEE Point Estimate and 95% CI for Subjects Achieving Mayo Clinical Response, 3-domain Mayo Clinical Response, Mayo Clinical Remission and 3-domain Mayo Clinical Remission (Parts A and B) by Randomised Treatment	GEE modelling will only be performed if at least 30% response rate at Day 85 for any one treatment group.	IA SAC [1], SAC [1]
2.12.	PP	EFF_T2a	Frequency Table of Subjects Achieving Mayo Clinical Response, 3-domain Clinical Response, Mayo Clinical Remission and 3-Domain Mayo Clinical Remission (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.13.	PP	EFF_T3	GEE Point Estimate and 95% CI for Subjects Achieving Mayo Clinical Response, 3-domain Mayo Clinical Response, Mayo Clinical Remission and 3-domain Mayo Clinical Remission (Parts A and B) by Randomised Treatment	GEE modelling will only be performed if at least 30% response rate at Day 85 for any one treatment group.	IA SAC [1], SAC [1]
2.14.	PP + Completers	EFF_T2a	Frequency Table of Subjects Achieving Mayo Clinical Response, 3-domain Clinical Response, Mayo Clinical Remission and 3-Domain Mayo Clinical Remission (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.15.	PP + Completers	EFF_T3	GEE Point Estimate and 95% CI for Subjects Achieving Mayo Clinical Response, 3-domain Mayo Clinical Response, Mayo Clinical Remission and 3-domain Mayo Clinical Remission (Parts A and B) by Randomised Treatment	GEE modelling will only be performed if at least 30% response rate at Day 85 for any one treatment group.	IA SAC [1], SAC [1]
Mayo – Symptomatic Clinical Remission					
2.16.	Safety	EFF_T1	Summary Statistics for Actual and Change from Baseline in Total, Partial and 3-domain Mayo Scores (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.17.	Safety	EFF_T4	Adjusted Mean (95% CI) of the Change from Baseline in Total, Partial and 3-domain Mayo Scores (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.18.	PP	EFF_T1	Summary Statistics for Actual and Change from Baseline in Total, Partial and 3-domain Mayo Scores (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.19.	PP	EFF_T4	Adjusted Mean (95% CI) of the Change from Baseline in Total, Partial and 3-domain Mayo Scores (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.20.	PP + Completers	EFF_T1	Summary Statistics for Actual and Change from Baseline in Total, Partial and 3-domain Mayo Scores (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.21.	PP + Completers	EFF_T4	Adjusted Mean (95% CI) of the Change from Baseline in Total, Partial and 3-domain Mayo Scores (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
UCEIS – Mucosal Healing					
2.22.	Safety	EFF_T1	Summary Statistics for Actual and Change from Baseline in UCEIS Total Score (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.23.	Safety	EFF_T4	Adjusted Mean (95% CI) of the Change from Baseline in UCEIS Total Score (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
UCEIS – Remission					
2.24.	Safety	EFF_T2a	Frequency Table of Subjects Achieving UCEIS Remission (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.25.	Safety	EFF_T3	GEE Point Estimate and 95% CI for Subjects Achieving UCEIS Remission (Parts A and B) by Randomised Treatment	GEE modelling will only be performed if at least 30% response rate at Day 85 for any one treatment group.	IA SAC [1], SAC [1]
Biomarkers of Disease Activity					
2.26.	Safety	EFF_T1	Summary Statistics for Actual and Change from Baseline in CRP (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.27.	Safety	EFF_T4	Adjusted Mean (95% CI) of the Change from Baseline in CRP (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.28.	Safety	EFF_T2b	Frequency Table of FCP Categories (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.29.	Safety	EFF_T1	Summary Statistics for Actual and Log-Transformed Change from Baseline in FCP (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.30.	Safety	EFF_T4	Adjusted Mean (95% CI) of the Log-transformed Change from Baseline in FCP (Parts A and B) by Randomised Treatment	Include related estimated adjusted geometric means and treatment differences	IA SAC [1], SAC [1]
Histologic Disease Activity					
2.31.	Safety	EFF_T2b	Frequency Table of Modified Riley Scale Categories (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.32.	Safety	EFF_T1	Summary Statistics for Actual and Change from Baseline in Modified Riley Scale Score (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.33.	Safety	EFF_T4	Adjusted Mean (95% CI) of the Change from Baseline in Modified Riley Scale Score (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.34.	Safety	EFF_T2b	Frequency Table of RHI Categories (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.35.	Safety	EFF_T1	Summary Statistics for Actual and Change from Baseline in RHI Score (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.36.	Safety	EFF_T4	Adjusted Mean (95% CI) of the Change from Baseline in RHI Score (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.37.	Safety	EFF_T1	Summary Statistics for Actual and Change from Baseline in Geboes Index Total Score (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.38.	Safety	EFF_T4	Adjusted Mean (95% CI) of the Change from Baseline in Geboes Index Total Score (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
Quality of Life					
2.39.	Safety	EFF_T1	Summary Statistics for Actual and Change from Baseline in IBDQ Domain Scores and Total Score (Parts A and B) by Randomised Treatment		SAC [1]
2.40.	Safety	EFF_T4	Adjusted Mean (95% CI) of the Change from Baseline in IBDQ Total Score (Parts A and B) by Randomised Treatment		SAC [1]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Symptom Diary Cards					
2.41.	Safety	EFF_T1	Summary Statistics of Average and Maximum Stool Frequency Score over 5 days from Subject Symptom Diary (Parts A and B) by Randomised Treatment	Include Average and Maximum Stool Frequency Score, Average and Maximum Rectal Bleeding Score and Average Number of Stools.	SAC [1]

12.10.8. Efficacy Figures

Efficacy: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Mayo					
2	Safety	EFF_F1	Individual Subject Profiles for Subjects Achieving Mayo Endoscopy Remission, Total Mayo Score, Partial Mayo Score, 3-domain Mayo Score, Mayo Clinical Response, 3-domain Mayo Clinical Response, Mayo Clinical Remission and 3-domain Clinical Remission over Time (Parts A and B) by Randomised Treatment	Separate pages for each endpoint.	IA SAC [1], SAC [1]
2	Safety	EFF_F4	Proportion of Subjects Achieving Mayo Endoscopy Remission and over Time (Parts A and B) by Randomised Treatment	Line graph with randomised treatment on the same plot	IA SAC [1], SAC [1]
2.3.	Safety	EFF_F3	Odds Ratio and 95% CI for Proportion of Subjects Achieving Mayo Endoscopy Remission (Parts A and B) by Randomised Treatment	GEE modelling will only be performed if at least 30% response rate at Day 85 for any one treatment group.	IA SAC [1], SAC [1]

Efficacy: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.4.	Safety	EFF_F4	Proportion of Subjects Mayo Clinical Response, 3-domain Mayo Clinical Response, Mayo Clinical Remission and 3-domain Clinical Remission over Time (Parts A and B) by Randomised Treatment	Separate pages for each endpoint. Line graph with randomised treatment on the same plot.	IA SAC [1], SAC [1]
2.5.	Safety	EFF_F3	Odds Ratio and 95% CI for Achieving Mayo Clinical Response, 3-domain Mayo Clinical Response, Mayo Clinical Remission and 3-domain Clinical Remission over Time (Parts A and B) by Randomised Treatment	Separate pages for each endpoint. GEE modelling will only be performed if at least 30% response rate at Day 85 for any one treatment group.	IA SAC [1], SAC [1]
2.6.	Safety	EFF_F2	Mean (±SE) Total, Partial and 3-domain Mayo Scores over Time (Parts A and B) by Randomised Treatment	Separate pages for each endpoint.	IA SAC [1], SAC [1]
2.7.	Safety	EFF_F3	Point Estimates and 95% CI of Change from Baseline in Total, Partial and 3-domain Mayo Scores over Time (Parts A and B) by Randomised Treatment	Separate pages for each endpoint. Grey dashed line at y=0.	IA SAC [1], SAC [1]
2.8.	PP	EFF_F1	Individual Subject Profiles for Subjects Achieving Mayo Endoscopy Remission, Total Mayo Score, Partial Mayo Score, 3-domain Mayo Score, Mayo Clinical Response, 3-domain Mayo Clinical Response, Mayo Clinical Remission and 3-domain Clinical Remission over Time (Parts A and B) by Randomised Treatment	Separate pages for each endpoint.	IA SAC [1], SAC [1]
2.9.	PP	EFF_F4	Proportion of Subjects Achieving Mayo Endoscopy Remission and over Time (Parts A and B) by Randomised Treatment	Line graph with randomised treatment on the same plot	IA SAC [1], SAC [1]
2.10.	PP	EFF_F3	Odds Ratio and 95% CI for Proportion of Subjects Achieving Mayo Endoscopy Remission (Parts A and B) by Randomised Treatment	GEE modelling will only be performed if at least 30% response rate at Day 85 for any one treatment group.	IA SAC [1], SAC [1]
2.11.	PP	EFF_F4	Proportion of Subjects Mayo Clinical Response, 3-domain Mayo	Separate pages for each endpoint.	IA SAC [1],

Efficacy: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
			Clinical Response, Mayo Clinical Remission and 3-domain Clinical Remission over Time (Parts A and B) by Randomised Treatment	Line graph with randomised treatment on the same plot.	SAC [1]
2.12.	PP	EFF_F3	Odds Ratio and 95% CI for Achieving Mayo Clinical Response, 3-domain Mayo Clinical Response, Mayo Clinical Remission and 3-domain Clinical Remission over Time (Parts A and B) by Randomised Treatment	Separate pages for each endpoint. GEE modelling will only be performed if at least 30% response rate at Day 85 for any one treatment group.	IA SAC [1], SAC [1]
2.13.	PP	EFF_F2	Mean (±SE) Total, Partial and 3-domain Mayo Scores over Time (Parts A and B) by Randomised Treatment	Separate pages for each endpoint.	IA SAC [1], SAC [1]
2.14.	PP	EFF_F3	Point Estimates and 95% CI of Change from Baseline in Total, Partial and 3-domain Mayo Scores over Time (Parts A and B) by Randomised Treatment	Separate pages for each endpoint. Grey dashed line at y=0.	IA SAC [1], SAC [1]
2.15.	PP + Completers	EFF_F1	Individual Subject Profiles for Subjects Achieving Mayo Endoscopy Remission, Total Mayo Score, Partial Mayo Score, 3-domain Mayo Score, Mayo Clinical Response, Mayo Clinical Remission and 3-domain Clinical Remission over Time (Parts A and B) by Randomised Treatment	Separate pages for each endpoint.	IA SAC [1], SAC [1]
2.16.	PP + Completers	EFF_F4	Proportion of Subjects Achieving Mayo Endoscopy Remission and over Time (Parts A and B) by Randomised Treatment	Line graph with randomised treatment on the same plot	IA SAC [1], SAC [1]
2.17.	PP + Completers	EFF_F3	Odds Ratio and 95% CI for Proportion of Subjects Achieving Mayo Endoscopy Remission (Parts A and B) by Randomised Treatment	GEE modelling will only be performed if at least 30% response rate at Day 85 for any one treatment group.	IA SAC [1], SAC [1]
2.18.	PP + Completers	EFF_F4	Proportion of Subjects Mayo Clinical Response, 3-domain Mayo Clinical Response, Mayo Clinical Remission and 3-domain Clinical Remission over Time (Parts A and B) by Randomised	Separate pages for each endpoint. Line graph with randomised treatment on the same plot.	IA SAC [1], SAC [1]

Efficacy: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
			Treatment		
2.19.	PP + Completers	EFF_F3	Odds Ratio and 95% CI for Achieving Mayo Clinical Response, 3-domain Mayo Clinical Response, Mayo Clinical Remission and 3-domain Clinical Remission over Time (Parts A and B) by Randomised Treatment	Separate pages for each endpoint. GEE modelling will only be performed if at least 30% response rate at Day 85 for any one treatment group.	IA SAC [1], SAC [1]
2.20.	PP + Completers	EFF_F2	Mean (±SE) Total, Partial and 3-domain Mayo Scores over Time (Parts A and B) by Randomised Treatment	Separate pages for each endpoint.	IA SAC [1], SAC [1]
2.21.	PP + Completers	EFF_F3	Point Estimates and 95% CI of Change from Baseline in Total, Partial and 3-domain Mayo Scores over Time (Parts A and B) by Randomised Treatment	Separate pages for each endpoint. Grey dashed line at y=0.	IA SAC [1], SAC [1]
UCEIS					
2.22.	Safety	EFF_F1	Individual Subject Profiles for UCEIS Total Score over Time (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.23.	Safety	EFF_F2	Mean (± SE) UCEIS Total Score over Time (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.24.	Safety	EFF_F3	Point Estimates and 95% CI of Change from Baseline in UCEIS Total Score over Time (Parts A and B) by Randomised Treatment	Grey dashed line at y=0.	IA SAC [1], SAC [1]
2.25.	Safety	EFF_F4	Proportion of Subjects Achieving UCEIS Clinical Remission over Time (Parts A and B) by Randomised Treatment	Line graph with randomised treatment on the same plot.	IA SAC [1], SAC [1]
2.26.	Safety	EFF_F3	Odds Ratio and 95% CI for Achieving UCEIS Clinical Remission over Time (Parts A and B) by Randomised Treatment	GEE modelling will only be performed if at least 30% response rate at Day 85 for any one treatment group.	IA SAC [1], SAC [1]

Efficacy: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Biomarkers of Disease Activity					
2.27.	Safety	EFF_F1	Individual Subject Profiles for CRP and FCP over Time (Parts A and B) by Randomised Treatment	Separate pages for each endpoint.	IA SAC [1], SAC [1]
2.28.	Safety	EFF_F2	Mean (±SE) CRP over Time (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.29.	Safety	EFF_F3	Point Estimates and 95% CI of Change from Baseline in CRP over Time (Parts A and B) by Randomised Treatment	Grey dashed line at y=0.	IA SAC [1], SAC [1]
2.30.	Safety	EFF_F2	Mean (±SE) FCP over Time (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.31.	Safety	EFF_F3	Point Estimates and 95% CI of Change from Baseline in log-transformed FCP over Time (Parts A and B) by Randomised Treatment	Grey dashed line at y=0.	IA SAC [1], SAC [1]
Histologic Disease Activity					
2.32.	Safety	EFF_F1	Individual Subject Profiles for Modified Riley Scale Score over Time (Parts A and B) by Randomised Treatment	Separate pages for each endpoint.	IA SAC [1], SAC [1]
2.33.	Safety	EFF_F2	Mean (±SE) Modified Riley Scale Score over Time (Parts A and B) by Randomised Treatment	Separate pages for each endpoint.	IA SAC [1], SAC [1]
2.34.	Safety	EFF_F3	Point Estimates and 95% CI of Change from Baseline in Modified Riley Scale Score over Time (Parts A and B) by Randomised Treatment	Separate pages for each endpoint. Grey dashed line at y=0.	IA SAC [1], SAC [1]
2.35.	Safety	EFF_F1	Individual Subject Profiles for RHI Total Score over Time (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.36.	Safety	EFF_F2	Mean (±SE) RHI Total Score over Time (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]

Efficacy: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.37.	Safety	EFF_F3	Point Estimates and 95% CI of Change from Baseline in RHI Total Score over Time (Parts A and B) by Randomised Treatment	Grey dashed line at y=0.	IA SAC [1], SAC [1]
2.38.	Safety	EFF_F1	Individual Subject Profiles for Geboes Index Total Score over Time (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.39.	Safety	EFF_F2	Mean (±SE) Geboes Index Total Score over Time (Parts A and B) by Randomised Treatment		IA SAC [1], SAC [1]
2.40.	Safety	EFF_F3	Point Estimates and 95% CI of Change from Baseline in Geboes Index Total Score over Time (Parts A and B) by Randomised Treatment	Grey dashed line at y=0.	IA SAC [1], SAC [1]
Quality of Life					
2.41.	Safety	EFF_F1	Individual Subject Profiles for IBDQ Total Score over Time (Parts A and B) by Randomised Treatment	Separate pages for each endpoint.	SAC [1]
2.42.	Safety	EFF_F2	Mean (±SE) IBDQ Total Score over Time (Parts A and B) by Randomised Treatment		SAC [1]
2.43.	Safety	EFF_F3	Point Estimates and 95% CI of Change from Baseline in IBDQ Total Score over Time (Parts A and B) by Randomised Treatment	Grey dashed line at y=0.	SAC [1]
Responder Across Efficacy Endpoints					
2.44.	Safety	EFF_F4	Individual Subject Profile Plot of Efficacy Endpoints over Time (Parts A and B) by Randomised Treatment	Separate pages for each Subject 9 panel plot with a panel for: (order change following IA) Top Row: Total Mayo Score, Partial Mayo Score, 3-domain Mayo Score	IA SAC [1] SAC [1]

Efficacy: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Middle Row: Mayo Endoscopy Remission, Mayo Rectal Bleed, UCEIS Total Score, Bottom Row: Geboes Index Total Score, FCP, CRP	

12.10.9. Pharmacokinetic Tables

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
PK concentration data					
4.1.	PK	PK01	Summary of GSK2982772 Concentration-Time Data (ng/mL)	Separate summaries for blood and biopsy tissue samples. Pre-dose: Day 43, Post-dose: Day 1 and 43 at 1, 2, 4 and 6 hours.	IA SAC [1] SAC [1]
			Summary of GSK2982772 Predicted Trough Concentrations (ng/mL)	Predicted trough Day 43	

12.10.10. Pharmacokinetic Figures

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Individual PK Concentration					
4.1.					
Mean/Median Concentration					
4.2.	PK	PKCF2	Mean (±SE) Plot: GSK2982772 Concentrations versus Time (Linear) on Day 1 and Day 43 (60 mg TID only)		IA SAC [1] SAC [1]
4.3.					
Trough Concentration					
4.4.	PK		GSK2982772 Observed pre-dose Concentration Data vs Day (60 TID only)	Separate pages for plasma Spaghetti Plot of individual trough concentrations vs day.	IA SAC [1] SAC [1]
4.5.	PK		GSK2982772 Observed Pre-Dose Concentration Data vs Day	Plot of individual trough concentrations vs day overlaid with box and whisker plot.	IA SAC [1] SAC [1]
4.6.	PK	PD_F1	Scatter Plot GSK2982772 Observed Pre-Dose Plasma Concentration Versus Biopsy Pre-Dose Tissue Concentration	X axis – Plasma Y axis – Biopsy	IA SAC [1] SAC [1]
PK/PD					
4.7.	PK	PD_F1	Scatter Plot of Individual GSK2982772 Pre-Dose Concentrations Versus Individual Pre-Dose % Target Engagement	Separate pages sample type (Plasma/Biopsy) X axis – PK concentration, Y axis – TE	IA SAC [1] SAC [1]

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
4.8.	PK	PD_F1	Box Plots of GSK2982772 Day 43 Predicted Trough Concentration for participants not achieving Mayo Endoscopy Remission and for participants achieving Mayo Endoscopy Remission	Separate pages sample type (predicted trough /Biopsy) X axis – Non Mayo Endoscopy Remission / Mayo Endoscopy Remission Y axis – PK Conc	IA SAC [1] SAC [1]
4.9.	PK	PD_F1	Scatter Plot of Individual GSK2982772 Predicted Trough Concentration Versus Change from Baseline in Total Mayo Score	Separate pages sample type (Blood/Biopsy) X axis – PK concentration, Y axis – Efficacy Parameter	IA SAC [1] SAC [1]
4.10.	PK	PD_F1	Scatter Plot of Individual GSK2982772 Predicted Trough Concentration Versus Change from Baseline in Partial Mayo Score	Separate pages sample type (Blood/Biopsy) X axis – PK concentration, Y axis – Efficacy Parameter	IA SAC [1] SAC [1]
4.11.	PK	PD_F1	Scatter Plot of Individual GSK2982772 Predicted Trough Concentration Versus Change from Baseline in 3-domain Mayo Score	Separate pages sample type (Blood/Biopsy) X axis – PK concentration, Y axis – Efficacy Parameter	IA SAC [1] SAC [1]
4.12.	PK	PD_F1	Scatter Plot of Individual GSK2982772 Predicted Trough Concentration Versus Change from Baseline in UCEIS Total Score	Separate pages sample type (Blood/Biopsy) X axis – PK concentration, Y axis – Efficacy Parameter	IA SAC [1] SAC [1]
4.13.	PK	PD_F1	Scatter Plot of Individual GSK2982772 Predicted Trough Concentration Versus Change from Baseline in Modified Riley Scale Score	Separate pages sample type (Blood/Biopsy) X axis – PK concentration, Y axis – Efficacy Parameter	IA SAC [1] SAC [1]

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
4.14.	PK	PD_F1	Scatter Plot of Individual GSK2982772 Predicted Trough Concentration Versus Change from Baseline in RHI	Separate pages sample type (Blood/Biopsy) X axis – PK concentration, Y axis – Efficacy Parameter	IA SAC [1] SAC [1]
4.15.	PK	PD_F1	Scatter Plot of Individual GSK2982772 Predicted Trough Concentration Versus Change from Baseline in Geboes Index Total Score	Separate pages sample type (Blood/Biopsy) X axis – PK concentration, Y axis – Efficacy Parameter	IA SAC [1] SAC [1]
4.16.	PK	PD_F1	Scatter Plot of Individual GSK2982772 Predicted Trough Concentration Versus Change from Baseline in CRP	Separate pages sample type (Blood/Biopsy) X axis – PK concentration, Y axis – Efficacy Parameter	IA SAC [1] SAC [1]
4.17.	PK	PD_F1	Scatter Plot of Individual GSK2982772 Predicted Trough Concentration Versus Change from Baseline in FCP	Separate pages sample type (Blood/Biopsy) X axis – PK concentration, Y axis – Efficacy Parameter	IA SAC [1] SAC [1]
4.18.	PK	PD_F1	Scatter Plot of GSK2982772 Pre-Dose Concentration Versus Pre-Dose TEAR 1 % Target Engagement	Separate pages sample type (Blood/Biopsy) X axis – PK Trough concentration, Y axis – TE	SAC [1]

12.10.11. Pharmacodynamic and/or Biomarker Tables

Pharmacodynamic and Biomarker: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Exploratory Biomarkers					
6.1.	Safety	PD_T1	Summary Statistics for Actual and Percentage Change from Baseline in Biopsy Tissue Inflammatory Biomarkers (Parts A and B)	One page for each cell type/measure by visit/time and treatment	SAC [1]
6.2.	Safety	PD_T2	Adjusted Mean (95% CI) of Percentage Change from Baseline in Biopsy Tissue Inflammatory Biomarkers (Parts A and B)	One page for each cell type/measure by visit/time and treatment/dosing regimen	SAC [1]
Pathway and Target Engagement					
6.3.	Safety	EFF_T1	Summary Statistics for Observed TEAR1 % Target Engagement (Parts A and B)	Separate summaries for sample type (Blood/Biopsy) % Target Engagement by visit/time	SAC [1]
6.4.			Summary Statistics for Predicted TEAR1 % Target Engagement based on predicted GSK2982772 trough concentrations (Parts A and B)		
6.5.	Safety	PD_T3	Adjusted Mean (95% CI) of TEAR1 % Target Engagement in Blood (Parts A and B) by Randomised Treatment		SAC [1]
6.6.	Safety	PD_T3	Adjusted Mean (95% CI) of TEAR1 % Target Engagement in Biopsy Tissue (Parts A and B) by Randomised Treatment		SAC [1]
6.7.	Safety	EFF_T1	Summary Statistics of Pathway Engagement (Parts A and B) by Randomised Treatment	Separate summaries for sample type (Blood/Biopsy)	SAC [1]
6.8.	Safety	PD_T3	Adjusted Mean (95% CI) of Pathway Engagement in Blood (Parts A and B) by Randomised Treatment		SAC [1]
6.9.	Safety	PD_T3	Adjusted Mean (95% CI) of Pathway Engagement in Biopsy Tissue (Parts A and B) by Randomised Treatment		SAC [1]

Pharmacodynamic and Biomarker: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
mRNA Expression					
6.10.	Safety	PD_T4	Summary of mRNA Expression of Inflammatory Gene Transcripts (Parts A and B) by Randomised Treatment	Separate summaries for sample type (Blood/Biopsy) qPCR – micarray dataset	SAC2 [1]
6.11.	Safety	PD_T5	Frequency Table Summarising the Number of Probe Sets with Various Fold Change (Parts A and B) by Randomised Treatment	Separate summaries for sample type (Blood/Biopsy). Use cut-offs 1.5 and -1.5 initially. Change to -1.25 and 1.5 if no one achieves the initial cut-offs	SAC2 [1]
6.12.	Safety	PD_T6	Summary of Adjusted Mean Fold Changes in mRNA Expression of Inflammatory Gene Transcripts (Parts A and B) by Randomised Treatment	Separate summaries for sample type (Blood/Biopsy). If Adj Mean FC lies between -1 and 1 then do not include on table	SAC2 [1]
6.13.	Safety		Summary of Analysis for Microaray mRNA Intensity Data in Blood	GSK to produce Only to be produced for significant probsets based on adjusted p-values. If Adj Mean FC lies between -1 and 1 then do not include on table	SAC2 [1]
6.14.	Safety		Summary of mRNA Percentage Inhibition of Inflammatory Gene Transcripts in Blood	GSK to produce Only to be produced for significant probsets based on adjusted p-values.	SAC2 [1]

Pharmacodynamic and Biomarker: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
6.15.	Safety		Summary of Analysis for Microaray mRNA Percentage Inhibition Data in Blood	GSK to produce Only to be produced for significant probsets based on adjusted p-values. If Adj Mean FC lies between -1 and 1 then do not include on table	SAC2 [1]

12.10.12. Pharmacodynamic and/or Biomarker Figures

Pharmacodynamic and or Biomarker: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Exploratory Biomarkers					
6.1.	Safety	EFF_F1	Individual Subject Profiles for Biopsy Tissue Inflammatory Biomarkers over Time (Parts A and B) by Randomised Treatment	Separate pages for each endpoint.	SAC [1]
6.2.	Safety	EFF_F3	Point Estimates and 95% CI for Percentage Change from Baseline in Biopsy Tissue Inflammatory Biomarkers over Time (Parts A and B) by Randomised Treatment		SAC [1]
Pathway and Target Engagement					
6.3.	Safety	EFF_F1	Individual Subject Profiles for TEAR1 % Target Engagement (Parts A and B) by Randomised Treatment	Separate pages sample type (Blood/Biopsy) Panel plot, line colours by treatment group, subjid as cell header	SAC [1]
6.4.	Safety	EFF_F3	Point Estimates and (95% CI) TEAR1 % Target Engagement in Blood (Parts A and B) by Randomised Treatment		SAC [1]
6.5.	Safety	EFF_F3	Point Estimates and (95% CI) TEAR1 % Target Engagement in Biopsy Tissue (Parts A and B) by Randomised Treatment		SAC [1]
6.6.	Safety	PD_F1	Scatter Plot of TEAR 1 % Target Engagement in Blood Versus TEAR1 % Target Engagement in Biopsy Tissue by Randomised Treatment		SAC [1]

Pharmacodynamic and or Biomarker: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
6.7.	PK	PD_F1	Scatter Plot of TEAR 1 % Target Engagement Versus Proportion Achieving Mayo Endoscopy Remission Randomised Treatment	Separate pages sample type (Blood/Biopsy) X axis – PK concentration, Y axis – Efficacy Parameter	SAC2 [1]
6.8.	Safety	PD_F1	Scatter Plot of TEAR1 % Target Engagement Versus Change from Baseline in Total Mayo Score by Randomised Treatment	Separate pages for each biomarker parameter and sample type (blood/ Biopsy) X axis – Target Engagement, Y axis – Efficacy Parameter Different markers for each randomised treatment group	SAC2 [1]
6.9.	Safety	PD_F1	Scatter Plot of TEAR1 % Target Engagement Versus Change from Baseline in Partial Mayo Score by Randomised Treatment	Separate pages for each biomarker parameter and sample type (blood/ Biopsy) X axis – Target Engagement, Y axis – Efficacy Parameter Different markers for each randomised treatment group	SAC2 [1]
6.10.	Safety	PD_F1	Scatter Plot of TEAR1 % Target Engagement Versus Change from Baseline in 3-domain Mayo Score by Randomised Treatment	Separate pages for each biomarker parameter and sample type (blood/ Biopsy) X axis – Target Engagement, Y axis – Efficacy Parameter Different markers for each randomised treatment group	SAC2 [1]

Pharmacodynamic and or Biomarker: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
6.11.	Safety	PD_F1	Scatter Plot of TEAR1 % Target Engagement Versus Change from Baseline in UCEIS Total Score by Randomised Treatment	Separate pages for each biomarker parameter and sample type (blood/ Biopsy) X axis – Target Engagement, Y axis – Efficacy Parameter Different markers for each randomised treatment group	SAC2 [1]
6.12.	Safety	PD_F1	Scatter Plot of TEAR1 % Target Engagement Versus Change from Baseline in Modified Riley Scale Score by Randomised Treatment	Separate pages for each biomarker parameter and sample type (blood/ Biopsy) X axis – Target Engagement, Y axis – Efficacy Parameter Different markers for each randomised treatment group	SAC2 [1]
6.13.	Safety	PD_F1	Scatter Plot of TEAR1 % Target Engagement Versus Change from Baseline in RHI by Randomised Treatment	Separate pages for each biomarker parameter and sample type (blood/Biopsy) X axis – Target Engagement, Y axis – Efficacy Parameter Different markers for each randomised treatment group	SAC2 [1]

Pharmacodynamic and or Biomarker: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
6.14.	Safety	PD_F1	Scatter Plot of TEAR1 % Target Engagement Versus Change from Baseline in Geboes Index Total Score by Randomised Treatment	Separate pages for each biomarker parameter and sample type (blood/Biopsy) X axis – Target Engagement, Y axis – Efficacy Parameter Different markers for each randomised treatment group	SAC2 [1]
6.15.	Safety	PD_F1	Scatter Plot of TEAR1 % Target Engagement Versus Change from Baseline in CRP by Randomised Treatment	Separate pages for each biomarker parameter and sample type (blood/Biopsy) X axis – Target Engagement, Y axis – Efficacy Parameter Different markers for each randomised treatment group	SAC2 [1]
6.16.	Safety	PD_F1	Scatter Plot of TEAR1 % Target Engagement Versus Change from Baseline in FCP by Randomised Treatment	Separate pages for each biomarker parameter and sample type (blood/Biopsy) X axis – Target Engagement, Y axis – Efficacy Parameter Different markers for each randomised treatment group	SAC2 [1]
mRNA Expression					
6.17.	Safety	EFF_F1	Individual Subject Profiles for mRNA Expression of Inflammatory Gene Transcripts (Parts A and B) by Randomised Treatment	Separate pages for each gene and sample type (blood/Biopsy).	SAC2 [1]

Pharmacodynamic and or Biomarker: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
6.18.	Safety	PD_F2	Adjusted Mean Intensities for mRNA Expression of Inflammatory Gene Transcripts (Parts A and B) by Randomised Treatment	Separate pages for each gene and sample type (blood/biopsy). .	SAC2 [1]
6.19.	Safety	PD_F3	Adjusted Mean (95% CI) Fold Change in mRNA Expression of Inflammatory Gene Transcripts (Parts A and B) by Randomised Treatment	Separate pages for each gene and sample type (blood/biopsy). Include band from FC -1 to 1, transparency 0.5	SAC2 [1]

12.10.13. ICH Listings

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.	All Subjects	ES7	Listing of Reasons for Screen Failure by Randomised Treatment	Journal Guidelines	IA SAC [1] SAC [1]
2.	Safety	ES2	Listing of Reasons for Study Withdrawal by Randomised Treatment	ICH E3	IA SAC [1] SAC [1]
3.	Safety	SD2	Listing of Reasons for Study Treatment Discontinuation by Randomised Treatment	ICH E3	IA SAC [1] SAC [1]1]
4.	Safety	BL1	Listing of Subjects for Whom the Treatment Blind was Broken During the Study by Randomised Treatment	ICH E3	IA SAC [1] SAC [1]
5.	Safety	TA1	Listing of Planned and Actual Treatments	IDSL	IA SAC [1] SAC [1] [1]
Protocol Deviations					
6.	Safety	DV2	Listing of Important Protocol Deviations by Randomised Treatment	ICH E3	IA SAC [1] SAC [1]
7.	Safety	IE3	Listing of Subjects with Inclusion/Exclusion Criteria Deviations by Randomised Treatment	ICH E3	IA SAC [1] SAC [1]1]
Populations Analysed					
8.	Safety	SP3	Listing of Subjects Excluded from Any Population by Randomised Treatment	ICH E3	IA SAC [1] SAC [1]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Demographic and Baseline Characteristics					
9.	Safety	DM2 / DM4	Listing of Demographic Characteristics by Randomised Treatment	ICH E3	IA SAC [1] SAC [1]
10.	Safety	DM9 / DM10	Listing of Race by Randomised Treatment	ICH E3	IA SAC [1] SAC [1]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
11.	Safety	DM2	Listing of Ulcerative Colitis Baseline Characteristics by Randomised Treatment	To include: Baseline Mucosal Appearance at Endoscopy Mayo Subscore, Baseline Total Mayo Score, Baseline Partial Mayo Score Baseline 3-domain Mayo Score, Baseline UCEIS Total Score, Baseline Modified Riley Scale Score Baseline FCP, Baseline FCP category, Baseline Concomitant Medications for UC (Glucocorticoids only, Immunosuppressants only, Glucocorticoids and Immunosuppressants, No Glucocorticoids or Immunosuppressants, Baseline Prednisone dose, Family History of Premature Coronary Artery Disease and History of Tobacco Use. Include the footnote: Note: Glucocorticoids and Immunosuppressants were identified by review of all ingredients by clinical and medical team.	IA SAC [1] SAC [1]
Prior, Current and Concomitant Medications					
12.	Safety	MH2	Listing of Medical Conditions by Randomised Treatment		IA SAC [1] SAC [1]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
13.	Safety	CP_CM3	Listing of Concomitant Medications by Randomised Treatment	IDSL	IA SAC [1] SAC [1]
Exposure and Treatment Compliance					
14.	Safety	EX3 / EX4	Listing of Exposure Data by Randomised Treatment	ICH E3	IA SAC [1] SAC [1]
15.	Safety	COMP3A/ COMP3B	Listing of Drug Accountability Data by Randomised Treatment		IA SAC [1] SAC [1]
Adverse Events					
16.	Safety	AE9CP	Listing of All Adverse Events by Period Treatment	ICH E3	IA SAC [1] SAC [1]
17.	Safety	AE7	Listing of Subject Numbers for Individual Adverse Events by Period Treatment	ICH E3	IA SAC [1] SAC [1]1]
18.	Safety	AE2	Listing of Relationship Between Adverse Event System Organ Classes, Preferred Terms, and Verbatim Text	IDSL	IA SAC [1] SAC [1]]
Serious and Other Significant Adverse Events					
19.	Safety	AE9CPa	Listing of Fatal Serious Adverse Events by Period Treatment	ICH E3	IA SAC [1] SAC [1]
20.	Safety	AE9CPa	Listing of Non-Fatal Serious Adverse Events by Period Treatment	ICH E3	IA SAC [1] SAC [1]
21.	Safety	AE14	Listing of Reasons for Considering as a Serious Adverse Event by Period Treatment	ICH E3	IA SAC [1] SAC [1]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
22.	Safety	AE9CP	Listing of Adverse Events Leading to Withdrawal from Study / Permanent Discontinuation of Study Treatment by Period Treatment	ICH E3	IA SAC [1] SAC [1]
23.	Safety	AE9CP	Listing of Other Significant Adverse Events by Period Treatment	ICH E3	IA SAC [1] SAC [1] [1]
24.	Safety	PSRAE1	Listing of Possible Suicidality-Related Adverse Event Data: Event and Description (Section 1- Section 2) by Period Treatment	IDSL	IA SAC [1] SAC [1]
25.	Safety	PSRAE2	Listing of Possible Suicidality-Related Adverse Event Data: Event and Description (Sections 1- Section 2) by Period Treatment	IDSL	IA SAC [1] SAC [1]1]
26.	Safety	PSRAE3	Listing of Possible Suicidality-Related Adverse Event Data: Possible Cause(s) (Section 3) by Period Treatment	IDSL	IA SAC [1] SAC [1]
27.	Safety	PSRAE4	Listing of Possible Suicidality-Related Adverse Event Data (Section 4) by Period Treatment	IDSL	IA SAC [1] SAC [1]1]
Hepatobiliary (Liver)					
28.	Safety	MH2	Listing of Medical Conditions for Subjects with Liver Stopping Events by Period Treatment	IDSL	IA SAC [1] SAC [1]]
29.	Safety	SU2	Listing of Substance Use for Subjects with Liver Stopping Events by Period Treatment	IDSL	IA SAC [1] SAC [1] [1]
All Laboratory					
30.	Safety	LB5	Listing of All Laboratory Data for Subjects with Any Value of Potential Clinical Importance by Period Treatment	ICH E3	IA SAC [1] SAC [1]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
31.	Safety	LB5	Listing of Laboratory Values of Potential Clinical Importance by Period Treatment		IA SAC [1] SAC [1] [1]
32.	Safety	LB14	Listing of Laboratory Data with Character Results by Period Treatment	ICH E3	IA SAC [1] SAC [1]]
33.	Safety	UR2A	Listing of Urinalysis Data for Subjects with Any Value of Potential Clinical Importance by Period Treatment	ICH E3	IA SAC [1] SAC [1]
34.	Safety	LB5	Listing of Lipids Outside of the Normal Range by Period Treatment	Lipids parameters = LDL Cholesterol, HDL Cholesterol, Total Cholesterol Triglycerides and Cholesterol/HDL ratio Include fasted status	IA SAC [1] SAC [1]
ECG					
35.	Safety	EG3*	Listing of All ECG Values for Subjects with Any Value of Potential Clinical Importance by Period Treatment (including manually corrected values)	IDSL EG3 plus extra columns for Manually Calculated QTcB and QTcF. Highlighted provided QTc value See 203168 Listing 89 for shell Include absolute PCI subjects. Footnote: H=High absolute, L= Low absolute. * Provided QTc	IA SAC [1] SAC [1]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
36.	Safety	EG3*	Listing of All ECG Changes for Subjects with a Value of Potential Clinical Importance by Period Treatment (including manually corrected values)	Include change from baseline or change from screening PCI subjects. IDSL EG3 plus extra columns for Manually Calculated QTcB and QTcF. Highlighted provided QTc value Footnote: H=High change from baseline value, L= Low change from baseline value * Provided QTc	IA SAC [1] SAC [1]
37.	Safety	EG3	Listing of ECG Values of Potential Clinical Importance by Period Treatment (including manually corrected values)	"Include absolute PCIs. IDSL EG3 plus extra columns for Manually Calculated QTcB and QTcF. Highlighted provided QTc value Footnote: H=High absolute, L= Low absolute." * Provided QTc	IA SAC [1] SAC [1]]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
38.	Safety	EG3	Listing of ECG Changes of Potential Clinical Importance by Period Treatment (including manually corrected values)	"Include change from baseline PCIs. IDSL EG3 plus extra columns for Manually Calculated QTcB and QTcF. Highlighted provided QTc value Footnote: H=High change, L= Low change."	IA SAC [1] SAC [1]
39.	Safety	EG5	Listing of All ECG Findings for Subjects with an Abnormal ECG Finding by Period Treatment	IDSL	IA SAC [1] SAC [1]
40.	Safety	EG5	Listing of Abnormal ECG Findings by Period Treatment	IDSL	IA SAC [1] SAC [1]
Vital Signs					
41.	Safety	VS4 / VS5	Listing of All Vital Signs Data for Subjects with Any Value of Potential Clinical Importance by Period Treatment	IDSL	IA SAC [1] SAC [1]
42.	Safety	VS4 / VS5	Listing of Vital Signs of Potential Clinical Importance by Period Treatment	IDSL	IA SAC [1] SAC [1]

12.10.14. Non-ICH Listings

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
CSSRS					
43.	Safety	ECSSRS4	Listing of C-SSRS Suicidal Ideation and Behaviour Data by Period Treatment		IA SAC [1] SAC [1]
44.	Safety	ECSSRS5	Listing of C-SSRS Suicidal Behaviour Details by Period Treatment		IA SAC [1] SAC [1]
PK					
45.	PK	PK07	Listing of GSK2982772 Pharmacokinetic Concentration-Time Data	Separate listings for Blood and Biopsy data	IA SAC [1] SAC [1]
Efficacy					
46.	Safety	LS2	Listing of Individual Mayo Subscores by Randomised Treatment		IA SAC [1] SAC [1]

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
47.	Safety	LS2	Listing of Mayo Data by Randomised Treatment	Actual and Change from Baseline in Total Mayo, Partial Mayo and 3-domain Mayo Scores. Proportion of Subjects Achieving Endoscopy Remission, Mayo Clinical Response, 3-domain Mayo Clinical Response, Mayo Clinical Remission and 3-domain Mayo Clinical Remission. Add variables which determine if the subjects are in the PP and /or PP + Completers Population.	IA SAC [1] SAC [1]
48.	Safety	LS2	Listing of Individual UCEIS Scores by Randomised Treatment		IA SAC [1] SAC [1]
49.	Safety	LS2	Listing of UCEIS Data by Randomised Treatment	Actual and Change from Baseline in UCEIS Total Score Proportion of Subjects Achieving UCEIS Remission	IA SAC [1] SAC [1]
50.	Safety	LS2	Listing of Actual and Change from Baseline in CRP by Randomised Treatment		IA SAC [1] SAC [1]
51.	Safety	LS2	Listing of Actual and Log-transformed Change from Baseline in FCP by Randomised Treatment		IA SAC [1] SAC [1]

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
52.	Safety	LS2	Listing of Actual and Change from Baseline in Modified Riley Scale Score by Randomised Treatment		IA SAC [1] SAC [1]
53.	Safety	LS2	Listing of Actual and Change from Baseline in RHI Score by Randomised Treatment		IA SAC [1] SAC [1]
54.	Safety	LS2	Listing of Actual and Change from Baseline in Geboes Index Total Score by Randomised Treatment		IA SAC [1] SAC [1]
55.	Safety	LS2	Listing of Actual and Change from Baseline in IBDQ Domains and Total Score by Randomised Treatment		SAC [1]
56.	Safety	EFF_L1	Listing of Subject Symptom Diary Card Data by Randomised Treatment	Use the decodes specified in RAP Section 12.6.4 and not codelist defined in FCEORS.	SAC [1]
57.	Safety	n/a	Raw SAS output of Statistical Analysis Results for GEE Analysis for Subjects Achieving Mayo Endoscopic Remission (Parts A and B) by Randomised Treatment	GEE modelling will only be performed if at least 30% response rate at Day 85 for any one treatment group.	IA SAC [1] SAC [1]
58.	PP	n/a	Raw SAS output of Statistical Analysis Results for GEE Analysis for Subjects Achieving Mayo Endoscopic Remission (Parts A and B) by Randomised Treatment	GEE modelling will only be performed if at least 30% response rate at Day 85 for any one treatment group.	IA SAC [1] SAC [1]
59.	PP + Completers	n/a	Raw SAS output of Statistical Analysis Results for GEE Analysis for Subjects Achieving Mayo Endoscopic Remission (Parts A and B) by Randomised Treatment	GEE modelling will only be performed if at least 30% response rate at Day 85 for any one treatment group.	IA SAC [1] SAC [1]

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
60.	Safety	n/a	Raw SAS Output of Statistical Analysis Results for GEE Analysis for Subjects Achieving Mayo Clinical Response. 3-domain Mayo Clinical Response, Mayo Clinical Remission and 3-domain Mayo Clinical Remission (Parts A and B) by Randomised Treatment	GEE modelling will only be performed if at least 30% response rate at Day 85 for any one treatment group.	IA SAC [1] SAC [1]
61.	PP	n/a	Raw SAS Output of Statistical Analysis Results for GEE Analysis for Subjects Achieving Mayo Clinical Response. 3-domain Mayo Clinical Response, Mayo Clinical Remission and 3-domain Mayo Clinical Remission (Parts A and B) by Randomised Treatment	GEE modelling will only be performed if at least 30% response rate at Day 85 for any one treatment group.	IA SAC [1] SAC [1]
62.	PP + Completers	n/a	Raw SAS Output of Statistical Analysis Results for GEE Analysis for Subjects Achieving Mayo Clinical Response. 3-domain Mayo Clinical Response, Mayo Clinical Remission and 3-domain Mayo Clinical Remission (Parts A and B) by Randomised Treatment	GEE modelling will only be performed if at least 30% response rate at Day 85 for any one treatment group.	IA SAC [1] SAC [1]
63.	Safety	n/a	Raw SAS Output of Statistical Analysis Results for MMRM Analysis of the Change from Baseline in Total, Partial and 3-domain Mayo Scores (Parts A and B) by Randomised Treatment		IA SAC [1] SAC [1]
64.	PP	n/a	Raw SAS Output of Statistical Analysis Results for MMRM Analysis of the Change from Baseline in Total, Partial and 3-domain Mayo Scores (Parts A and B) by Randomised Treatment		IA SAC [1] SAC [1]
65.	PP + Completers	n/a	Raw SAS Output of Statistical Analysis Results for MMRM Analysis of the Change from Baseline in Total, Partial and 3-domain Mayo Scores (Parts A and B) by Randomised Treatment		IA SAC [1] SAC [1]

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
66.	Safety	n/a	Raw SAS Output of Statistical Analysis Results for MMRM Analysis of the Change from Baseline in UCEIS Total Score (Parts A and B) by Randomised Treatment		IA SAC [1] SAC [1]
67.	Safety	n/a	Raw SAS Output of Statistical Analysis Results for GEE Analysis for Subjects Achieving UCEIS Remission (Parts A and B) by Randomised Treatment	GEE modelling will only be performed if at least 30% response rate at Day 85 for any one treatment group.	IA SAC [1] SAC [1]]
68.	Safety	n/a	Raw SAS Output of Statistical Analysis Results for MMRM Analysis of the Change from Baseline in CRP (Parts A and B) by Randomised Treatment		IA SAC [1] SAC [1]
69.	Safety	n/a	Raw SAS Output of Statistical Analysis Results for MMRM Analysis of the Change from Baseline in Log-Transformed FCP (Parts A and B) by Randomised Treatment		IA SAC [1] SAC [1]
70.	Safety	n/a	Raw SAS Output of Statistical Analysis Results for MMRM Analysis of the Change from Baseline in Modified Riley Scale Score (Parts A and B) by Randomised Treatment		IA SAC [1] SAC [1]
71.	Safety	n/a	Raw SAS Output of Statistical Analysis Results for MMRM Analysis of the Change from Baseline in RHI Score (Parts A and B) by Randomised Treatment		IA SAC [1] SAC [1]
72.	Safety	n/a	Raw SAS Output of Statistical Analysis Results for MMRM Analysis of the Change from Baseline in Geboes Index Total Score (Parts A and B) by Randomised Treatment		IA SAC [1] SAC [1]]
73.	Safety	n/a	Raw SAS Output of Statistical Analysis Results for MMRM Analysis of the Change from Baseline in IBDQ Total Score (Parts A and B) by Randomised Treatment		SAC [1]

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Biomarker					
74.	Safety	PD_L1	Listing of Inflammatory Biomarkers in Biopsy Tissue by Randomised Treatment		SAC [1]
75.	Safety	PD_L2	Listing of TEAR1 Concentrations % Target Engagement and Pathway Engagement by Randomised Treatment	Separate listings for Blood and Biopsy Tissue	SAC [1]
76.	Safety	PD_L3	Listing of mRNA Expression of Inflammatory Gene Transcripts by Randomised Treatment	Separate listings for Blood and Biopsy Tissue	SAC [1]
77.	Safety	n/a	Raw SAS Output of Statistical Analysis of Biopsy Tissue Inflammatory Biomarkers (Parts A and B) by Randomised Treatment		SAC [1]
78.	Safety	n/a	Raw SAS Output of Statistical Analysis of TEAR1 % Target Engagement in Blood (Parts A and B) by Randomised Treatment		SAC [1]
79.	Safety	n/a	Raw SAS Output of Statistical Analysis of TEAR1 % Target Engagement in Biopsy Tissue (Parts A and B) by Randomised Treatment		SAC [1]
80.	Safety	n/a	Raw SAS Output of Statistical Analysis of Pathway Engagement in Blood (Parts A and B) by Randomised Treatment		SAC [1]
81.	Safety	n/a	Raw SAS Output of Statistical Analysis of Pathway Engagement in Biopsy Tissue (Parts A and B) by Randomised Treatment		SAC [1]
82.	Safety	n/a	Raw SAS Output of Statistical Analysis of mRNA Expression in Blood (Parts A and B) by Randomised Treatment		SAC2 [1]
83.	Safety	n/a	Raw SAS Output of Statistical Analysis of mRNA Expression in Biopsy Tissue (Parts A and B) by Randomised Treatment		SAC2 [1]

12.11. Appendix 11: Example Mock Shells for Data Displays

Data Display Specification will be made available on Request

12.12. Appendix 12: NONMEM datafile specification

GSK to produce based on 203176 dataspec file