Division	:	Worldwide Development
Information Type	:	Reporting and Analysis Plan (RAP)
Title	:	Reporting and Analysis Plan for a phase I/II, open-label, 2 arm study to investigate the safety, clinical activity, pharmacokinetics and pharmacodynamics of GSK2879552 administered alone or in combination with Azacitidine, in adult subjects with IPSS-R high and very high risk myelodysplastic syndromes (MDS) previously treated with hypomethylating agents (HMA)
Compound Number	:	GSK2879552
Effective Date	:	21-Jun-2018

Description:

- The purpose of this RAP is to describe the planned reporting and outputs to be included in the synoptic Clinical Study Report for Protocol 205744 and/or regulatory disclosure.
- This RAP is intended to describe details for reporting the safety, clinical activity, pharmacokinetic and pharmacodynamics analyses for the study.
- The study was terminated early, therefore a streamlined reporting will be taken as described in this document.

RAP Author(s):

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1. INTRODUCTION

The purpose of this reporting and analysis plan (RAP) is to describe the streamlined analyses to be included in the synoptic Clinical Study Report and/or regulatory disclosure for Protocol GSK205744:

Revision Chronology:		
Version 01	15-Jul-2016	Original
Amendment 1	08-MAY-2017	Addition of language to include a stopping rule that halts enrollment upon the occurrence of any encephalopathy, unless clearly attributable to central nervous system disease involvement or inter-current illness. Minor clarifications, correction of typographical errors, reformatting of tables, administrative and grammatical changes to text and Time and Events tables/footnotes.

Given the premature termination of the study, the study objectives and the statistical analyses planned (or described) in the protocol are no longer appropriate. Consequently, the reporting and analysis plan will be abbreviated to the tables and listings described in this document.

A streamlined final reporting will be conducted after all required database cleaning activities have been completed and final database release and database freeze has been declared by Data Management.

This is an open label study so there will be no special criteria for unblinding.

2. SUMMARY OF KEY PROTOCOL INFORMATION - STUDY OBJECTIVE(S) AND ENDPOINT(S)

2.1.1. Part 1: Dose Confirmation and Escalation

Objectives	**Endpoints**
Primary Objectives	**Primary Endpoints**
• To determine the recommended phase 2 dose (RP2D) of GSK2879552 administered alone and in combination with Azacitidine in adult subjects with HR MDS previously treated with HMA.	• AEs, SAEs, dose limiting toxicities, dose reductions or delays, withdrawals due to toxicities and changes in safety parameters (e.g., laboratory values, vital signs, electrocardiograms [ECGs], physical examinations).
Secondary Objectives	**Secondary Endpoints**
• To evaluate clinical activity after treatment with GSK2879552, alone or in combination with	• Clinical benefit rate (CBR) defined as % of subjects achieving CR, mCR, PR, HI or SD. Objective response rate (ORR)

Objectives	Endpoints
Azacitidine, in adult subjects with HR MDS previously treated with HMA.	defined as % of subjects achieving CR, mCR, PR, or HI [as per 2006 IWG criteria]).
• To measure the exposure to GSK2879552 alone and to GSK2879552 and Azacitidine in combination, in patients with HR MDS previously treated with HMA.	• GSK2879552 and Azacitidine concentrations pre-dose and post-dose.
• To evaluate duration of response, duration of clinical benefit, progression-free survival and overall survival.	• Duration of response (DOR) defined as the time from first documented response to disease progression. Progression-free survival (PFS) defined as the time from first dosing day to disease progression or death from any cause. Overall survival (OS) defined as the time from first dosing day until death from and cause.
• To evaluate frequency and time to progression to AML (per 2006 IWG criteria).	• Proportion of subjects with disease progression to AML. Time to AML progression.
• To evaluate platelet and RBC transfusion dependence.	• Number of documented platelet and RBC transfusions per month prior to study entry and on study.
Exploratory Objectives	**Exploratory Endpoints**
• To investigate the mechanism of action and indicators of sensitivity and resistance to GSK2879552 alone and in combination with Azacitidine.	• Gene and/or protein expression studies of peripheral blood and/or bone marrow aspirates; correlation of baseline epigenetic and genomic profiles with response.

2.1.2. Part 2: Expansion Cohorts (This part of the study was not initiated)

Objectives	Endpoints
Primary Objectives	**Primary Endpoints**
• To evaluate clinical activity after treatment with GSK2879552, alone or in combination with Azacitidine, in adult subjects with HR MDS previously treated with HMA.	• Clinical benefit rate (CBR) defined as % of subjects achieving CR, mCR, PR, HI or SD. Objective response rate (ORR) defined as % of subjects achieving CR, mCR, PR, or HI [as per 2006 IWG criteria]).
Secondary Objectives	**Secondary Endpoints**
• To further evaluate the safety and tolerability of GSK2879552	• Changes in safety parameters: e.g. AEs and SAEs, changes in laboratory values,

Objectives	Endpoints
administered alone or in combination with Azacitidine.	vital signs, electrocardiograms [ECGs], and physical examinations.
• To characterize the population PK of GSK2879552, alone or in combination with Azacitidine in patients with HR MDS previously treated with HMA.	• Population PK parameters for GSK2879552 such as clearance (CL/F).
• To evaluate duration of response, duration of clinical benefit, progression-free survival, and overall survival.	• Duration of response (DOR) defined as the time from first documented response to disease progression. Progression free survival (PFS) defined as the time from first dosing day to disease progression or death from any cause. Overall survival (OS) defined as the time from first dosing day until death from any cause.
• To evaluate frequency and time to progression to AML (per 2006 IWG criteria)	• Proportion of subjects with disease progression to AML. Time to AML progression.
• To evaluate platelet and RBC transfusion dependence.	• Number of documented platelet and RBC transfusions per month within 3 months prior to study entry and while on study.
Exploratory Objectives	**Exploratory Endpoints**
• To investigate the mechanism of action and indicators of sensitivity and resistance to GSK2879552 administered alone or in combination with Azacitidine to patients with HR MDS previously treated with HMA.	• Gene and/or protein expression studies of peripheral blood and/or bone marrow aspirates; correlation of baseline epigenetic and genomic profiles with response.
• To evaluate the relationship of exposure of GSK2879552, administered alone or in combination with Azacitidine, and safety/efficacy parameters, based on Part 1 and 2 data combined.	• Relationship between GSK2879552 exposure markers (e.g. dose, concentration, Cmax or AUC (0-tau)) and safety/clinical activity.
• To investigate the relationship between genetic variants in host DNA and the safety, tolerability, and efficacy of GSK2879552 alone or in combination with azacitidine based on Part 1 and 2 data combined.	• Pharmacogenomic (PGx) analysis using saliva samples.

3. PLANNED REPORTING

Only Part 1 of the study was initiated so the scope of the planned reporting will be limited to Part 1. Summaries for primary and secondary endpoints for Part 1 will be reported. Other relevant Part 1 data will be listed. There are no data to report for Part 2.

4. ANALYSIS POPULATIONS

Population	Definition / Criteria	Analyses Evaluated
All Treated Subjects Population	• This will consist of all subjects who received at least one dose of study treatment. Safety and clinical activity data will be evaluated based on this population.	• Study Population • Safety • Clinical Activity
Pharmacokinetic Population	• This population will consist of all subjects in the All Treated Subject Population for whom a blood sample for pharmacokinetics is obtained and analysed.	• Pharmacokinetic analysis

5. CONSIDERATIONS FOR REPORTING

The reporting will be based on the All Treated Subjects population, unless otherwise specified. All summaries will be presented by treatment group initially treated and overall unless otherwise specified. All subjects in the study belong to one treatment group so all summaries will display only one group.

5.1. Study Population Reporting

Patient disposition, demographic characteristics and race will be summarized using IDSL standard reporting shells as indicated in Section 5.7.1.

5.2. Efficacy Reporting

Secondary efficacy (clinical activity) endpoints will be summarized using IDSL standard reporting shells as indicated in Section 5.7.2. The following are considerations for handling and/or reporting secondary efficacy endpoints:

Clinical benefit rate and objective response rate in monotherapy group will be displayed using the All Treated Subjects Population and based on the disease assessment data up to crossover and prior to new anti-cancer therapy.

For the time to event efficacy endpoints (including DOR, PFS and Time to AML), crossover will be considered as censor situation (if no progressions before crossover) using the All Treated Subjects Population. The number of subjects with progression to AML will apply the same AML definition as the one used in time to event endpoint.

OS is defined as the time from first treatment dose until death due to any reason regardless of crossover using the All Treated Subjects Population.

Platelet and RBC transfusions will apply the same rule as CBR and ORR to present summaries by treatment group using the All Treated Subjects Population.

Objective response rate and Clinical benefit rate

This study employs response criteria from IWG criteria [Cheson, 2006] for response definition. The Clinical Benefit Rate (CBR) is defined as the percentage of subjects achieving a confirmed Complete Remission (CR) or Partial Remission (PR) or Marrow Complete Remission (mCR) or confirmed Hematologic Improvement (HI) or Stable Disease (SD) prior to new anti-cancer therapy and crossover on the All Treated Subjects Population.

Objective response rate is defined as the percentage of subjects who achieved CR or PR or mCR or HI prior to new anti-cancer therapy on the All Treated Subjects Population.

Subjects with Not Evaluable or missing response will be treated as non-responders; i.e. they will be included in the denominator when calculating the percentage.

The CBR and ORR will be reported for combined treatment group in Part 1 with the same drug and the same dose. Confirmed and unconfirmed response summaries will be provided. The number and types of responses, as outlined in IWG criteria [Cheson, 2006, also presented in the table below], will be produced, along with two-sided 95% exact confidence interval (CI).

The CBR and ORR differences between the two cohorts will be provided along with corresponding two-sided 95% exact confidence interval (CI). A chi-square test will be used to test for differences between arms if the data warrant. Otherwise, a fisher's exact test will be employed if sample sizes are small at the beginning of trial.

IWG CRITERIA FOR RESPONSE

Category	Response Criteria
Complete Remission	Bone marrow: ≤ 5% myeloblasts with normal maturation of all cell linesa Persistent dysplasia will be noteda,b Peripheral blood (Response must be maintained for at least 4 weeks) Hgb ≥ 11 g/dL Platelets ≥ 100 Gi/L Neutrophils ≥ 1.0 Gi/Lb Blasts 0%
Partial Remission	All CR criteria if abnormal before treatment except: Bone marrow blasts decreased by ≥ 50% over pre-treatment but still >

	5% Cellularity and morphology not relevant
Marrow CRb	Bone marrow: ≤ 5% myeloblasts and decrease by ≥ 50% over pretreatmentb Peripheral blood: if HI responses, they will be noted in addition to marrow CRb
HI	Erythroid (HI-E): hgb increase of > 1.5 g/dL decrease of > RBC transfusions/8weeks versus pretreatment requirement in previous 8 weeks; only RBC transfusions given for a pretreatment Hgb of < 9.0 g/dL count Platelet (HI-P): increase of > 30,000/mL (starting with > 20,000/mL) increase from < 20,000/mL to >20,000/mL by > 100% Neutrophil (HI-N): increase of > 100% and > 500/uL
Stable Disease	Failure to achieve at least PR, but no evidence of progression > 8 wks
Disease Progression	For subjects with: □ Less than 5% BM blasts: ≥ 50% increase in blasts to > 5% blasts □ 5%-<10% BM blasts: ≥ 50% increase to > 10% blasts □ 10%-<20% BM blasts: ≥ 50% increase to > 20% blasts □ 20%-30% BM blasts: ≥ 50% increase to > 30% blasts Any of the following: □ At least 50% decrement from maximum remission/response in granulocytes or platelets □ Reduction in Hgb by □ 2 g/dL □ Transfusion dependence
Non-evaluable	Subject does not meet any of the above criteria

BM = bone marrow ; CR = complete remission; Hgb = hemoglobin;; PR = partial remission

a. Dysplastic changes should consider the normal range of dysplastic changes (modification).

b. Modification to IWG response criteria [Cheson, 2006].

Progression-free Survival

Progression-free survival (PFS) is defined as the time from first treatment dose until the first documented sign of disease progression or death. For the analysis of Progression-free survival (PFS), if the subject received subsequent anti-cancer therapy or crossed over from monotherapy to combination therapy prior to the date of documented events, PFS will be censored at the last adequate assessment prior to the initiation of anti-cancer therapy and crossover. If the subject missed more than one visit prior to the date of documented events, PFS will be censored at the last adequate assessment prior to missing. Otherwise, if the subject does not have a documented date of events, PFS will be

censored at the date of the last adequate assessment. The description of PFS could be summarized as Table 1 using the All Treated Subjects Population.

Table 1 Progression-free Survival

Situation	Date of Progression or Censoring	Outcome
No baseline disease assessments	Date of first dose	Censored
No post-baseline disease assessments	Date of first dose	Censored
Crossover before progression	Date of disease assessment prior to crossover	Censored
Progression documented between scheduled visits	Date of disease assessment	Progressed
No progression	Last date of disease assessment	Censored
New anticancer treatment started	Date of disease assessment prior to initiation of anti-cancer therapy	Censored
Death before first PD assessment	Date of death	Progressed
Death between adequate assessment visits	Date of death	Progressed
Death or progression after more than one missed visit	Date of disease assessment prior to missed visits	Censored

Duration of Response

Duration of response is defined as the subset of subjects (responders) who show a response (CR, mCR, PR, or HI), the time from first documented evidence of response until the first documented sign of disease progression or death. If no disease progression or death, the DOR will be censored at last disease assessment. The same censoring and event rules for PFS will be applied for DOR using the All Treated Subjects Population.

Overall Survival

Overall survival (OS) is defined as the time from first treatment dose until death due to any reason. For the analysis of overall survival (OS), the last date of known contact will be used for those subjects who have not died at the time of analysis; such subjects will be considered censored.

AML Progression

The proportion of subjects with disease progression to Acute Myeloblastic Leukemia (AML) is defined as the percentage of patients experiencing AML on the All Treated Subjects Population. The number of patients experiencing progression due to AML will be summarized using the All Treated Subjects Population as well. Time to AML progression is defined as the time from first treatment dose until AML progression or crossover if using the All Treated Subjects Population. For the analysis of time to AML,

if the subject did not experience AML, time to AML will be censored at the last treatment prior to the initiation of anti-cancer therapy or crossover.

Documented Platelet and RBC Transfusions

The number and percentage of documented platelet and RBC transfusions per month prior to study entry and during the treatment period will be produced on the All Treated Subjects Population. The number of transfusions will be summarized on the data up to crossover for monotherapy treatment on the All Treated Subjects Population.

5.3. Safety Reporting

Safety parameters specified as primary and secondary endpoints will be summarized using IDSL standard reporting shells as indicated in Section 5.7.3.

5.4. Pharmacokinetic Reporting

GSK GSK2879552 concentrations pre-dose and post-dose will be summarized using IDSL standard reporting shell as indicated in Section 5.7.4.

5.5. Data Display Numbering

The following numbering will be applied for RAP generated displays:

Section	Tables	Figures
Study Population	1.1 to 1.5	
Efficacy	2.1 to 2.8	
Safety	3.1 to 4.10	
Section	**Listings**	
ICH Listings	1 to 32	

5.6. Mock Example Shell Referencing

Non IDSL specifications will be referenced as indicated.

Section	Figure	Table	Listing
Study Population			POP_Ln
Safety		SAFE_Tn	SAFE_Ln
Efficacy	EFF_Fn	EFF_Tn	EFF_Ln
Pharmacokinetic		PK_Tn	PK_Ln

NOTES:

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

5.7. Deliverables

Delivery [Priority] [1]	Description
SAC [X]	Final Statistical Analysis Complete

NOTES:

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

5.7.1. Study Population Tables

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.1.	All treated	ES1	Summary of Participant Disposition for the Participant Conclusion Record	ICH E3, FDAAA, EudraCT	SAC [1]
1.2.	All treated	NS1	Summary of Number of Participant by Country and Site ID	EudraCT/Clinical Operations	SAC [1]
Demographic and Baseline Characteristics					
1.3.	All treated	DM1	Summary of Demographic Characteristics	ICH E3, FDAAA, EudraCT	SAC [1]
1.4.	All treated	DM11	Summary of Age Ranges	EudraCT	SAC [1]
1.5.	All treated	DM5	Summary of Race and Racial Combinations	ICH E3, FDA, FDAAA, EudraCT	SAC [1]

5.7.2. Efficacy Tables: Clinical Activity

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Efficacy Tables: Clinical Activity					
2.1.	All treated	RE1a	Summary of Investigator-Assessed Best Response (Without Confirmation) (IMWG 2016)	FDAAA, EudraCT Notes: Summarize by arm; Do not include Total. Best Response: Complete response (CR), molecular Complete Remission (mCR), Partial Response (PR), Cytogenetic Response, Hematologic Improvement (HI), or Stable Disease (SD), Not Evaluable (NE). Add a category of 'Missing' if summarize for Unconfirmed response. Objective Response Rate (ORR): % of subjects achieving CR, mCR, PR, Cytogenic Response, or HI. Clinical Benefit Rate (CBR): % subjects achieving CR, mCR, PR, Cytogenic Response, HI, or SD. Include: ORR and CBR (No p-value) in one table.	SAC [1]

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.2.	All treated	RE1a	Summary of Investigator-Assessed Best Response (With Confirmation) (IMWG 2016)	FDAAA, EudraCT Note: See comments above for table 2.1.	SAC [1]
2.3.	All treated	TTE1	Summary of Progression-free Survival	FDAAA, EudraCT	SAC [1]
2.4.	All treated	TTE1a	Summary of Duration of Response	FDAAA, EudraCT	SAC [1]
2.5.	All treated	TTE1	Summary of Overall Survival	FDAAA, EudraCT	SAC [1]
2.6.	All treated	TTE1a	Summary of Time to AML	FDAAA, EudraCT	SAC [1]
2.7.	All treated	BPA1	Summary of Documented Platelet Transfusions	FDAAA, EudraCT	SAC [1]
2.8.	All treated	BPA1	Summary of Documented RBC Transfusions	FDAAA, EudraCT	SAC [1]

5.7.3. Safety Tables

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events (AEs)					
3.1.	All treated	AE15	Summary of Common (>=X%) Non-serious Adverse Events by System Organ Class and Preferred Term (Number of Participant and Occurrences)	FDAAA, EudraCT X% will be set to 0% so table will include all Non-serious AEs	SAC [1]
3.2.	All treated	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term (Number of Participants and Occurrences)	FDAAA, EudraCT	SAC [1]
3.3.	All treated	DL1	Summary of Dose-Limiting Toxicities during the Determinative Period	FDAAA, EudraCT	SAC [1]
Laboratory Parameters					

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.4.	All treated	LB1	Summary of Chemistry Changes from Baseline	FDAAA, EudraCT	SAC [1]
3.5.	All treated	LB1	Summary of Haematology Changes from Baseline	FDAAA, EudraCT	SAC [1]
3.6.	All treated	LB1	Summary of Coagulation Changes from Baseline	FDAAA, EudraCT	SAC [1]
3.7.	All treated	LB1	Summary of Urinalysis Changes from Baseline	FDAAA, EudraCT	SAC [1]
3.8.	All treated	LIVER1	Summary of Liver Monitoring/Stopping Event Reporting	FDAAA, EudraCT	SAC [1]
Vital Signs					
3.9.	All treated	Vs1	Summary of Change from Baseline in Vital Signs	FDAAA, EudraCT	SAC [1]
ECG					
3.10.	All treated	EG2	Summary of Change from Baseline in ECG Values by Visit	FDAAA, EudraCT	SAC [1]

5.7.4. Pharmacokinetic Table

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
4.1.	PK	PK01	Summary of GSK2879552 Plasma Pharmacokinetic Concentration-Time Data (Part 1)		SAC [1]

5.7.5. ICH Listings

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.	All treated	ES2	Listing of Reasons for Study Withdrawal	ICH E3	SAC [1]
2.	All treated	SD2	Listing of Reasons for Study Treatment Discontinuation	ICH E3	SAC [1]
Protocol Deviations					
3.	All treated	DV2	Listing of Important Protocol Deviations	ICH E3	SAC [1]
4.	All treated	IE3	Listing of Participants with Inclusion/Exclusion Criteria Deviations	ICH E3	SAC [1]
Populations Analysed					
5.	All treated	SP3	Listing of Participants Excluded from Any Population	ICH E3	SAC [1]
Demographic and Baseline Characteristics					
6.	All treated	DM2	Listing of Demographic Characteristics	ICH E3	SAC [1]
7.	All treated	DM9	Listing of Race	ICH E3	SAC [1]
Exposure and Treatment Compliance					
8.	All treated	EX3	Listing of Exposure Data	ICH E3	SAC [1]
Prior and Concomitant Medications					
9.	All treated	AC6	Listing of Prior Anti-Cancer Therapy	ICH E3	SAC [1]
10.	All treated	AC7	Listing of Prior Anti-Cancer Radiotherapy	ICH E3	SAC [1]
11.	All treated	OSP3	Listing of Prior Anti-Cancer Related Surgical Procedures	ICH E3	SAC [1]
12.	All treated	CM3	Listing of Concomitant Medications	ICH E3	SAC [1]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
13.	All treated	BP4	Listing of Prior Blood Products or Blood Supportive Products	ICH E3	SAC [1]
14.	All treated	BP4	Listing of Blood Products or Blood Supportive Products On Treatment	ICH E3	SAC [1]
Adverse Events					
15.	All treated	AE8	Listing of All Adverse Events	ICH E3	SAC [1]
16.	All treated	AE7	Listing of Subject Numbers for Individual Adverse Events	ICH E3	SAC [1]
Serious and Other Significant Adverse Events					
17.	All treated	AE8	Listing of Fatal Serious Adverse Events	ICH E3	SAC [1]
18.	All treated	AE8	Listing of Non-Fatal Serious Adverse Events	ICH E3	SAC [1]
19.	All treated	AE14	Listing of Reasons for Considering as a Serious Adverse Event	ICH E3	SAC [1]
20.	All treated	AE8	Listing of Adverse Events Leading to Withdrawal from Study / Permanent Discontinuation of Study Treatment	ICH E3	SAC [1]
21.	All treated	AE8	Listing of Other Significant Adverse Events	ICH E3	SAC [1]
All Laboratory					
22.	All treated	LB5	Listing of All Laboratory Data for Participants with Any Value of Potential Clinical Importance/Outside Normal Range	ICH E3	SAC [1]
23.	All treated	LB5	Listing of Laboratory Values of Potential Clinical Importance	ICH E3	SAC [1]
24.	All treated	LB14	Listing of Laboratory Data with Character Results	ICH E3	SAC [1]
25.	All treated	UR2A	Listing of Urinalysis Data for Participants with Any Value of Potential Clinical Importance	ICH E3	SAC [1]
26.	All treated	OAE4	Listing of Dose Limit Toxicity	FDAAA, EudraCT	SAC [1]

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Efficacy					
27.	All treated	EFF_L1	Listing of Investigator-Assessed Responses (with and without confirmation) (IMWG 2016)	ICH E3	SAC [1]
28.	All treated	TTE9	Listing of Duration of Response	ICH E3	SAC [1]
29.	All treated	TTE9	Listing of Progression-Free Survival	ICH E3	SAC [1]
30.	All treated	TTE9	Listing of Overall Survival	ICH E3	SAC [1]
31.	All treated	TTE9	Listing of Time to Response	ICH E3	SAC [1]
Pharmacokinetic					
32	PK	PK07	Listing of GSK2879552 Plasma PK Concentration-Time Data	ICH E3	SAC [1]

5.8. Appendix 13: Example Mock Shells for Data Displays

5.8.1 Investigator-Assessed Responses Listing

Example: EFF_L1
Protocol: GSK2879552 Page 1 of 1
Population: All Treated (Data as of: DDMMMYYYY)

Listing 27
Listing of Investigator-Assessed Responses (with and without confirmation)

Centre/ Subj.	Age(y)/ Sex/ Race	Cycle	Visit	New Lesion	Response assessment (without confirmation)/ (with confirmation)
PPD	65/ F/ White - White/Caucasian/ European Heritage		UNSCHEDULED	N	Stable disease/
		3	DAY 1	N	Stable disease/ Stable disease
		4	DAY 1	N	Partial response/ Stable disease
		5	DAY 1	N	Complete response/ Partial response

Example: [Insert IDSL Or Example Shell Reference]
Protocol: [Insert Protocol Number]
Population: [Insert Population]

Table [Insert Table Number]
[Insert Title]