Division	:	Worldwide Development
Information Type	:	Reporting and Analysis Plan (RAP)
Title	:	Reporting and Analysis Plan for A Pilot Study of NY-ESO-1^{c259}T Cells in Participants with Advanced Myxoid/ Round Cell Liposarcoma
Study Number	:	208469
Compound Number	:	GSK3377794
Approval Date	:	05 May 2022

Description:

- The purpose of this RAP is to describe the planned analyses and output to be included in the final Clinical Study Report for Protocol 208469.
- This RAP is intended to describe the planned efficacy and safety analyses required for the study.
- This RAP will be provided to the study team members to convey the content of interim analysis deliverables as well as deliverables for the primary and final analyses.

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1. INTRODUCTION

The purpose of this Reporting and Analysis Plan (RAP) is to describe the analyses to be included in the Clinical Study Report for Protocol 208469:

Protocol Revision Chronology:		
Version 01	23-MAY-2016	Original
Version 02 (Amendment 1)	03-OCT-2016	Change in scope to Phase I/II pilot study NY-ESO-1^{c259}T has not previously been used in myxoid/ round cell liposarcoma, therefore the scope of ADP-0011-007 has been changed to comprise a pilot study to evaluate efficacy and safety. The study will recruit up to 15 participants.
Version 03 (Amendment 2)	24-JUL-2018	The following changes have been made: • Updates to time periods that must elapse between cessation of various therapies prior to leukapheresis and prior to initiation of lymphodepleting chemotherapy ("wash-out" periods) • Typographical errors have been corrected and timings of assessments have been clarified • Option to increase the sample size, as well as the option to change the lymphodepletion regimen based on emerging data • Administrative changes to align with GSK processes and procedures. • Language relating to serious adverse event (SAE) reporting and safety monitoring has been updated.
Version 04 (Amendment 3)	17-OCT-2018	Changes made to the protocol were requested by FDA as a result of safety events which included 2 reports of Guillain-Barré syndrome in participants who have received chemotherapy and GSK3377794 during clinical trials
Version 05 (Amendment 4)	18-JUN-2019	Clarification on definitions of enrollment and intent to treat population. Definition of evaluable changed to require at least 3 post baseline disease assessments (or progressed or died or withdrawn from the study) rather than 2.
Version 06 (Amendment 5)	13-DEC-2019	The following updates have been made: • Addition/clarification of delayed AE definition • Revised guidelines for the management of CCI [redacted] CCI • Revised guidelines for the management of encephalopathy syndrome • Adjustment to lymphodepletion regimen for safety purposes

Protocol Revision Chronology:		
Version 07 (Amendment 6)	17-FEB-2021	The following updates have been made: • Primary endpoint to be ORR based upon investigator assessment rather than independent reviewer assessment. • Added secondary endpoint of ORR as assessed by independent review. • Inserted secondary endpoint for PK profile. • Removed secondary endpoint for development of companion diagnostic assay. • Included guidance for monitoring of response post 2-years on trial. • Updated definition of evaluable subjects in Protocol Section 3.3 to match that provided in Protocol Section 11.2. • Deleted statement in Section 3.3 that continuous interim assessment of participants beyond 10 would "be used to continuously assess ORR and inform decisions regarding enrollment of additional subjects". • Clarified definition of completion of interventional phase. • Clarified completion of study definition. • Removed requirement for confirmation of disease progression. • Clarified and made consistent descriptions of ITT and mITT populations (with no change to population definitions). • Updated definition of Intent-to-Treat population. • Added statement describing planned second interim analysis in "at least 8 evaluable" in the high lymphodepletion cohort. • Clarified description for Time to Response endpoint.
Version 08 (Amendment 7)	17-FEB-2021	This amendment was site specific only. The following changes have been made: • Protocol Section 7.6 has been added describing the potential for retreatment for those subjects who have had a confirmed CCI [redacted] CCI [redacted] CCI [redacted]
Version 09 (Amendment 8)	18-MAY-2021	Changes to protocol have been made in reference to Dear Investigator Letter dated 03 May 2021 and Protocol and ICF clarification memorandum dated 11 May 2021 regarding mitigations put in place on active studies of GSK3377794 (letetresgene autoleucel, lete-cel), following the recent SAEs of fatal neutropenia (1 event) and decreased vision (1 event)

Protocol Revision Chronology:		
Version 10 (Amendment 9)	04-NOV-2021	Changes to the protocol made in reference to Dear Investigator Letter dated 21 Oct 2021 and Protocol and ICF clarification memorandum dated 25 Oct 2021 regarding safety mitigations implemented on active studies of GSK3377794.
Version 11 (Amendment 10)	17-Dec-2021	This amendment was site specific only. Changes made to subject eligibility criteria to allow second infusion with lete-cel (GSK3377794) in patients who have received other anticancer therapy after progression post first lete-cel infusion.

1.1. RAP Amendments

Revision chronology:

RAP Section	Amendment Details
Reporting and Analysis Plan_208469_Final_V1 [05-OCT-2018]	
Reporting and Analysis Plan_208469_Amendment_Final_V2 [20-NOV-2020]	
Section 1	Updated for protocol amendments 3, 4 & 5.
Section 2	• Changes to protocol defined analysis plan described. • Added CCI [redacted] • Updated for protocol amendments 3, 4 & 5.
Section 3	• Updated for outcome of interim analysis for futility on 1st 10 treated participants. • Described interim analyses of second "High Lymphodepletion" cohort. • Clarified timing of primary and final analyses.
Section 4	• Added enrolled population required for disclosure displays. • Updated ITT population in line with amended protocol.
Section 5.1	• Changed reporting standard to include second "High Lymphodepletion" cohort. • Baseline definitions updated to accommodate timing of new high lymphodepletion regimen.
Section 6	• Prior anti-cancer therapy reporting updated to only count full lines of therapy between diagnosis of advanced/metastatic disease and lymphodepletion, excluding bridging therapies administered between leukapheresis and lymphodepletion. • Updated to use GSK drug rather than WHO Drug coding. • Updated reporting in line with current GSK standards for NY-ESO.

RAP Section	Amendment Details
Section 7	• Clarified that responses (CR, PR) must be confirmed, per protocol. • Clarified that only responses from treatment start until disease progression or initiation of new anti-cancer therapy should be considered for ORR, TTR, DOR, CCI endpoints, via definition of best overall response (BOR). • Clarified consideration of unconfirmed CR & unconfirmed PR as evidence for stable disease. • Clarified that to be considered evidence for stable disease, a disease assessment must be at least 28 days after T-cell infusion. • Specified handling of participants with no measurable disease at baseline if such an inclusion criteria deviation should occur. • Clarified use of independent vs. investigator disease assessments. • Updated PFS censoring rules in line with current GSK oncology analysis plan template. • Added CCI [redacted] • Clarified use and methods for calculation of 95% confidence intervals. • Interim Analyses sub-section updated for interim analysis for futility on 1st 10 "Low Lymphodepletion" participants and interim analyses of second "High Lymphodepletion" cohort. • Updated reporting in line with current GSK standards for NY-ESO.
Section 8	• Updated list of Adverse Events of Special Interest (AESI) to current GSK standard for NY-ESO. • Moved description of "Deaths and Serious Adverse Events" to main "Adverse Events Analysis" section to avoid repetition and deleted section. • Updated reporting in line with current GSK standards for NY-ESO. • Analyses of cytokines, anti-NY-ESO-1 antibodies and (most) persistence moved to separate biomarker section. • Analyses of Replication Competent Lentivirus (RCL) added.
Section 10	• Clarified analyses of persistence, cytokines and anti-NY-ESO-1 antibodies.
Appendix 2	• Schedule of activities updated per protocol amendment 5.
Appendix 4	• Study phase definitions updated.
Appendix 6	• Added derivations for study population measures. • Added derivations for time in months and date of last contact. • Removed definitions duplicated in main sections.

RAP Section	Amendment Details
Appendix 7	• Updated reporting standards for missing data in line with current GSK reporting for NY-ESO.
Appendix 8	• Updated values of potential clinical importance in line with current GSK reporting for NY-ESO.
Appendix 11	• New abbreviations updated.
Appendix 12	• Updated reporting in line with current GSK standards for NY-ESO. • Identified displays to be produced for second interim analysis.
Appendix 13	• Updated mock shells in line with current GSK standards for NY-ESO.
Appendix 14	• New appendix detailing combined preferred terms.
Appendix 15	• New appendix detailing Adverse Event collapsing rules.
Entire RAP	• Made general edits in line with protocol and RAP template. • Typographical and grammatical corrections.

Reporting and Analysis Plan_208469_Amendment_Final_V3 [13-DEC-2021]	
Section 1	• Updated for protocol amendments 7, 8 & 9.
Section 2	• Updated for protocol amendments 7, 8 & 9, including description of retreatment and retreatment interventional phase.
Section 3	• Detail on previous analyses added. • Primary analysis no longer optional and to exclude retreatment.
Section 4	• Updated enrolled population definition in line with amended protocol. • Updated description of analyses evaluated using each population. • Added mITT2 population for retreatment 2nd T-cell infusion.
Section 5	• Clarified that all analyses are by planned cohort. • Added definitions for retreatment baseline.
Section 6	• Specified derivation of study status using new “End of Study” CRF. • BSA calculation method specified as Dubois-Dubois. • Reporting of retreatment data at final analysis added. • Minor clarifications to anti-cancer therapy specifications.
Section 7.1	• Primary endpoint changed to be based on investigator assessment of response following protocol amendment 6. • Participants with no measurable disease at baseline by independent review to be considered as not evaluable (rather than considering non-target response), matching handling for similar investigator assessments. • Clarified that confirmation of CR/PR must occur at least 28 days later inclusive (per GSK IDSL standards). • Clarified that minimum of 4 weeks for a BOR of SD is inclusive of day of T-cell infusion. • Clarified identification and handling of new anti-cancer therapy. • Following addition of retreatment, clarified that analysis is over the interventional phase (i.e. excluding retreatment). • Clarified requirements for confirmation of response, and added separate specification for Best Overall Response (BOR) without confirmation required for some displays.
Section 7.2 & Section 7.3	• BOR & ORR based on independent review now secondary endpoints following protocol amendment 6.

Reporting and Analysis Plan_208469_Amendment_Final_V3 [13-DEC-2021]	
	• Noted that PFS censoring rules do not need updating for retreatment since only participants that progress during the interventional phase are considered for retreatment. • Specified that confidence intervals for Kaplan-Meier estimates should use a generalization of the Brookmeyer-Crowley method under a log-log transformation. • Clarified tha CCI [redacted] is with confirmation. • Added CCI [redacted] • Clarified that CCI [redacted] is limited to follow-up in this study.
Section 8	• Clarified that safety analyses will group leukapheresed participants according to the lymphodepletion cohort the participant was enrolled into. • Reporting of retreatment data at final analysis added. • Identification and analysis of Adverse Events of Special Interest (AESI) updated in line with current GSK NY-ESO standards. • List of Clinical Laboratory Tests updated. • Clarified timepoints for summaries of change from baseline and worst case post-baseline, including exclusion of retreatment data. • Added Plot of Hematology Data Over Time. • Identification of participants showing >1% gene marked PBMCs at 1 year or beyond post 1st T-cell infusion to exclude retreatment data. • COVID-19 reporting added. • Identified AE displays that use collapsed events.
Section 9	• Persistence moved from biomarker section to this PK section. • Pharmacokinetic analysis of persistence added.
Section 10	• Persistence moved to from this biomarker to the PK section. • CCI [redacted]
Appendix 4	• Concomitant medications during retreatment defined. • On-Study Anti-Cancer Therapy/Surgery during retreatment defined. • Retreatment emergent adverse events defined as those with onset on or after start of retreatment lymphodepletion. • Retreatment assessments/data defined (for exclusion from primary analysis).
Appendix 5	• Updated references to GSK IDSL Standards.
Appendix 6	• Retreatment Day defined to indicate time since 2nd T-cell infusion (inclusive) in listings including retreatment data.

Reporting and Analysis Plan_208469_Amendment_Final_V3 [13-DEC-2021]	
	• Specified methods for calculation of Body Mass Index (BMI) and Body Surface Area (BSA).
Appendix 8	• Corrected specification of values of potential clinical concern for lab test values than can be graded as grade 2 or above (not grade 1 or above as previously stated), and deleted Grade 1 hypertension from table of values of values of potential clinical importance (PCI) for blood pressure.
Appendix 12	• Previous "Statistical Analysis Complete" deliverable replaced by separate primary and final analysis deliverables. • Instructions for displays to refresh or repeat/extend to include retreatment data at final analysis added. • Retreatment specific displays added for final analysis. • Clarifications to programming notes arising from dry run. • Minor refinements to some display titles. • Adjustments to AE18 displays required for CSR in-text tables following feedback from stakeholders. • Fatal AE reporting updated in line with current GSK standards. • Persistence (previously reported as a biomarker) now reported as PK. • CCI [redacted] • Treatment dates listing dropped as detail incorporated into subject status listing. • Listings of laboratory values of potential clinical concern dropped (as also have listings of all laboratory values for subjects with any value of potential clinical importance). • Listings of response assessments with and without confirmation consolidated. • CCI [redacted] only to be analysed at final analysis.
Appendix 13	• Clarifications and corrections arising from dry run. • Mock identifiers updated in line with draft NY-ESO standard mocks. • CCI [redacted] • Updated POP_L5 "Listing of Subject Status". • AESI mocks updated. • Mocks for PK analyses of persistence added. "Distribution of Peak Cell Expansion" changed from box plot to dot plot. • High Level Race added to listings. • Custom POP_T4 mock added for "Summary of Total Transduced T-cells". • Custom SAFE_L6 mock added for "Listing of QTc Values of Potential Clinical Importance" as replacement for OECG5A which is now archived. • Added SAFE_F3 "Plot of Hematology Data Over Time".

Reporting and Analysis Plan_208469_Amendment_Final_V3 [13-DEC-2021]	
Appendix 14	• Minor update to combined preferred terms for MedDRA v23.1 from GSK Safety Review Team 09-NOV-2020.
Entire RAP	• Minor clarifications and corrections. • Typographical and grammatical corrections.

Reporting and Analysis Plan_208469_Amendment_Final_V4	
Section 1	• Updated for protocol amendment 10.
Section 4	• Added Screened2 population for 2nd T-cell infusion.
Section 5	• Clarified that retreated participants are to be summarized by the lymphodepletion cohort the participant was enrolled into.
Section 6	• Clarified that retreatment screen failures will be reported for the final analysis. • Clarified that for retreatment participants the final end of study form will be considered for subject status. • Clarified that listings of protocol deviations will be extended to include retreatment data. • Updated to include the following listings on the mITT2 population at the final analysis: listing of demographic characteristics, listing of prior and concomitant medications, listing of blood products, listings of lymphodepletion and T-cell exposure, listing of anti-cancer radiotherapies, listing of on-study anti-cancer therapies and cancer-related surgical procedures. • Clarified that listings of resection biopsies will be extended to include retreatment data.
Section 7	• CCI [redacted] • Clarified PFS wording to remove 'acceptable' from the description of the imaging modalities. • Clarified PFS Censoring rules Table 1 to reference 'two or more' missed scheduled assessments instead of 'more than two'. • Added KM PFS and OS rates at specific timepoints to the PFS summary and OS summary tables. • Added PFS and OS follow-up time summaries using the reverse KM method. • Removed spider plot for retreatment.

Reporting and Analysis Plan_208469_Amendment_Final_V4	
Section 8	• Updated to include the following listings on the mITT2 population at the final analysis: AE listings, listing of symptoms and treatments related to [redacted]isting of tocilizumab, listing of laboratory data, listing of ECOG performance status, listing of ECG values, listing of vital signs, and listing of RCL. Clarified that AE tables at the final analysis will include retreatment AEs.
Section 9	• Updated to include the listing of persistence on the mITT2 population at the final analysis.
Section 10	• Updated to include the listing of integration site analysis data on the mITT2 population at the final analysis. • Updated to include the listing of anti-NY-ESO-1 antibodies on the mITT2 population at the final analysis.
Appendix 12	• Retreatment specific displays added or modified for final analysis. In particular, listings were added on the mITT2 population. • Efficacy figures removed for the final analysis. • Efficacy KM tables updated from TTE1 mock to EFF_T2. • Added new efficacy tables for follow-up under EFF_T3 mock. • Minor refinements to some display titles.
Appendix 13	• Update to POP_L4 text in 4th column to specify 'Time since Leukapheresis' • Update to BIO_L4 to remove '(Normal Range)' from Shannon Index column header. • Update to POP_L2 to add columns for cumulative dose for lymphodepletion chemotherapy. • Added EFF_T2 and EFF_T3 mocks.

2. SUMMARY OF KEY PROTOCOL INFORMATION

2.1. Changes to the Protocol Defined Statistical Analysis Plan

CCI [redacted]

Protocol Section 3.3 states that "*Enrolled subjects will be considered those subjects who sign the treatment consent, meet all eligibility requirements, and undergo apheresis*". In this RAP the enrolled population is defined in Section 4 as "*all participants who underwent leukapheresis*".

Protocol Section 7.6.9 states defines a "*Safety Retreatment Analysis Set*" which "*will consist of all subjects who undergo retreatment with GSK3377794*". Since this is identical to the mITT2 population also defined in that section of the protocol, and since Section 11.2 of the protocol specifies that safety analyses overall will be conducted in the mITT or ITT populations and does not specify a corresponding safety population, 2nd infusion safety is reported in the mITT2 population for consistency and the Safety Retreatment Analysis Set defined in the protocol is not used in this RAP.

The protocol specifies (in the schedule of procedures) that "*Baseline assessments must be conducted < 7 days prior to lymphodepleting chemotherapy.*" This interval has been used in data display labels but to accommodate scheduling of labs and disease assessments (and for consistency with the original version of this RAP used for the interim analysis of futility) the day before this window has been included and (as described in Section 5.2 of this RAP) the last assessment with a non-missing value prior to initiating lymphodepletion will be used as baseline even if it occurred more than 7 days prior to initiating lymphodepletion.

According to GSK standards, Listing of Race (DM9) is required per ICH E3. Due to differences in Adaptimmune data collection, only Listing of Demographic Characteristics (DM2) will be displayed which will include high level race information.

Protocol Section 11.1 notes that "*if the mITT and ITT populations are identical, only results associated with the ITT population will be reported*". This is clarified in this RAP in that for study population analyses (where the ITT population is the primary analysis population) results planned for both ITT and mITT populations will only be reported for the ITT population, and for efficacy analyses (where the mITT population is the primary analysis population) results planned for both ITT and mITT populations will only be reported for the mITT population.

Protocol Section 11.3 states that "*ORR will be summarized by two-sided 95% confidence intervals using exact and Wilson methods. 95% (Bayesian) credible intervals may also be used to summarize the ORR.*" In this analysis plan only exact confidence intervals are specified.

Protocol Section 11.4 states that "*Adverse events with missing date of onset will be considered to have occurred on treatment.*" In this RAP AEs with missing date of onset but non-missing end date before lymphodepletion start are not considered as treatment emergent. (See Section 14.4.1.3 for details.)

Protocol appendix 4 "*RECIST 1.1 Criteria for Evaluating Response in Solid Tumors*" in the table "*Summary of the overall response status calculation at each time point*" states "*>4 wks. Confirmation*" is required for CR and PR. In this analysis plan confirmation must be at least 28 days later (i.e. ≥4 wks. confirmation), in line with GSK IDSL standards and the timing specified in the protocol schedule of activities.

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

Objectives	Endpoints
Primary Objectives	**Primary Endpoints**
• To evaluate the efficacy of autologous genetically modified T-cells (NY-ESO-1^{c259}T) in HLA-A*02:01, HLA-A*02:05 and/or HLA-A*02:06 subjects with NY-ESO-1 expressing advanced myxoid/ round cell liposarcoma	• Overall Response Rate[1] (ORR) per RECIST v1.1 by investigator assessment
Secondary Objectives	**Secondary Endpoints**
• To evaluate the efficacy of autologous genetically modified T-cells (NY-ESO-1^{c259}T) in HLA-A*02:01, HLA-A*02:05 and/or HLA-A*02:06 subjects with NY-ESO-1 expressing advanced myxoid/ round cell liposarcoma	• Overall Response Rate[1] (ORR) per RECIST v1.1 by independent review • Time to Response[2] • Duration of Response[2] • Progression Free Survival[2]
• To evaluate the safety and tolerability of autologous genetically modified T-cells (NY-ESO-1^{c259}T) in HLA-A*02:01, HLA-A*02:05 and/or HLA-A*02:06 subjects with NY-ESO-1 expressing advanced myxoid/ round cell liposarcoma	• AEs, including SAEs and AESIs • Laboratory assessments, including chemistry and hematology • Replication competent lentivirus (RCL) • Instances of insertional oncogenesis • Incidence of anti-NY-ESO-1^{c259}T antibodies • ECG
• To characterize the in vivo PK profile (levels, expansion, persistence) of NY-ESO-1 specific (c259) cells	• Maximum transgene expansion (C_{max}) • Time to C_{max} (T_{max}) • Area under the time curve from zero to time t AUC_{0-t}, as data permit
CCI [redacted]	

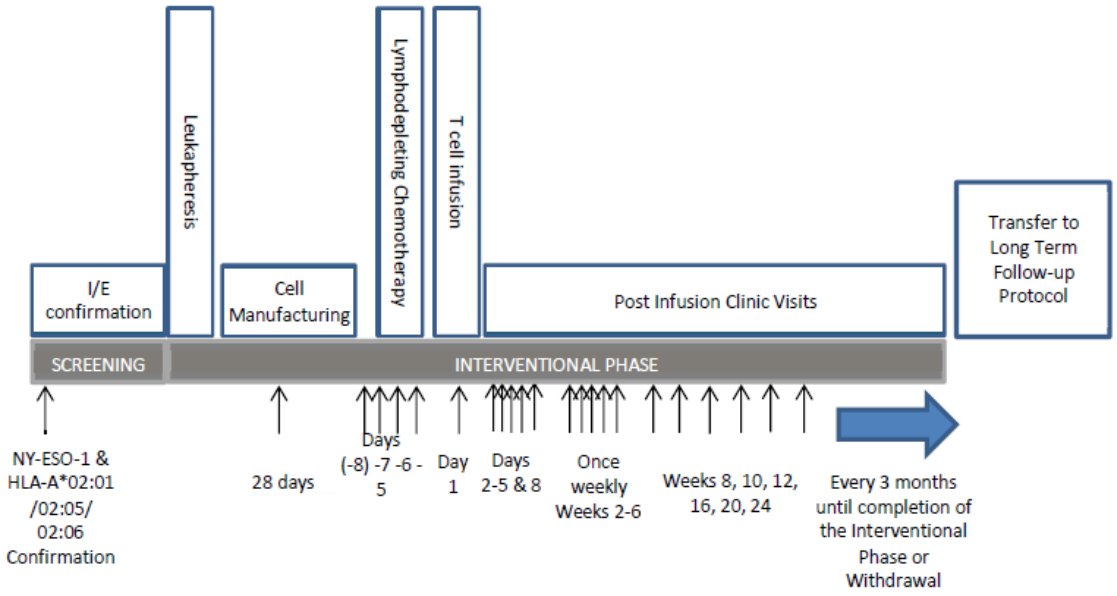
CCI

[redacted]

[1]Overall Response Rate is based on confirmed response determined at least 4 weeks post initial identification of response.
[2]Secondary response endpoints may be based on investigator assessment and independent review.

2.3. Study Design

Overview of Study Design and Key Features



Design Features	• This is a pilot, open-label study of genetically engineered NY-ESO-1^{c259}T cells in HLA-A*02:01, HLA-A*02:05 and/or HLA-A*02:06 participants with Advanced Myxoid/ Round Cell Liposarcoma. • Participants with the HLA-A*02:01, HLA-A*02:05 and/or HLA-A*02:06 allele, whose tumor expresses the NY-ESO-1 antigen above the cut-off level according to the applied immunohistochemistry, and who meet study entry criteria will be eligible for enrollment. • The study is divided into three distinct phases:1) Screening, 2) Interventional, and 3) Long Term Follow-up. • The Screening Phase starts from the time the participant signs the screening ICF until the subject attends for second screening following antigen positivity. • Eligible participants then enter the Interventional Phase of the study (T-cell infusion) on signing the Treatment Informed Consent Form. • During the Interventional Phase, participants undergo leukapheresis to obtain cells for the manufacture of autologous NY-ESO-1^{c259} TCR bearing T-cells. • When the NY-ESO-1^{c259}T cells are available, eligible participants undergo lymphodepleting chemotherapy with cyclophosphamide and fludarabine followed by infusion of a NY-ESO-1^{c259}T cells on Day 1. • A NY-ESO-1^{c259}T infused subject will be considered to have completed the interventional phase of the study when he/she has progression of disease, death, or has been followed-up for 2 years after NY-ESO-1^{c259}T cell infusion, whichever is shorter. If necessary and upon discussion with the Sponsor, those patients who have not progressed after 2 years on study and who are continuing in Study 208469 may continue to undergo response assessments every 3 months as defined in Study 208469 per institutional standard of care. • All participants alive on completing the Interventional Phase of the study will be rolled over to a long-term follow-up (LTFU) Protocol (GSK208750) for observation of delayed AEs for 15 years post-infusion in accordance Food

Overview of Study Design and Key Features	
	and Drug Administration (FDA) and European Medicines Agency (EMA) requirements for gene therapy clinical trials (or under the current protocol until the LTFU is available). • Up to 20 participants may be treated in total.
Dosing	• Lymphodepleting chemotherapy: o For the first 10 subjects, Fludarabine and Cyclophosphamide will be given at 30 mg/m^2 and 600 mg/m^2, respectively. The intervention will be 3 consecutive days, starting 7 days prior to the T-cell infusion. Refer to Section 5.2 in protocol for the details. o For the next 10 subjects: Fludarabine will be given at 30mg/m^2 for 4 consecutive days starting 8 days prior to the T-cell infusion and Cyclophosphamide will be given at 900 mg/m^2 for 3 consecutive days starting 7 days prior to the T-cell infusion. Refer to Section 5.2 in protocol for the details. • T-cell infusion: Within the range of 1 x 10^9 – 8 x 10^9 transduced cells
Time & Events	• [Refer to Appendix 2: Schedule of Activities]
Treatment Assignment	• Autologous T-cells transduced with lentivirus encoding enhanced TCR specific for NY-ESO-1
Interim Analysis	• There is no planned interim analysis before the first 10 participants are treated. • An interim analysis for futility was conducted after the first 10 participants had been treated and had at least 2 post baseline disease assessments or progressed (according to investigator assessment) or died or withdrawn from the study. • An interim analysis in the second "High lymphodepletion" cohort was performed to provide data for internal decision making after at least 8 participants had at least 3 post baseline disease assessments or progressed (according to investigator assessment) or died or withdrawn from the study.

2.3.1. Retreatment

Section 7.6 of (site specific) protocol amendment 7 of 17-FEB-2021 introduced the option for participants to receive a second course of conditioning chemotherapy and NY-ESO-1^{c259}T cell infusion under certain conditions:

Conditions for retreatment include (see Protocol Section 7.6 for the complete list):

- Subject had a confirmed CR or PR or SD ≥3 months following first GSK3377794 infusion.
- Subject's disease subsequently progressed in >3 months after first infusion.
- Sufficient cell dose is available from the original manufacturing procedure to allow for retreatment (i.e. subjects will not undergo repeat leukapheresis) and within shelf-life specifications.

Subjects being considered for retreatment will enter the retreatment interventional phase on completion of the interventional phase.

All study procedures should be carried out as defined for initial treatment, including safety and response assessment, with the exception of leukapheresis which is not part of retreatment.

Retreated subjects will receive the "option 2" high lymphodepletion regimen regardless of what was received on the first infusion.

Subjects who meet eligibility for and undergo retreatment will be considered to have completed the retreatment interventional phase of the study when they have progression of disease following retreatment, death, or have been followed-up for 2 years after re-treatment, whichever is shorter. The sponsor may terminate the study before all retreated subjects have completed the retreatment interventional phase.

2.4. Statistical Analyses

The study is not powered to conduct any hypothesis testing on either primary or secondary endpoints. All analyses will be descriptive in nature. Continuous data will be summarized by statistics including n, mean, median, standard deviation, minimum and maximum. Categorical data will be summarized using frequency counts and percentages or proportions. Graphical summaries of the data will be presented as appropriate. Time-to-event endpoints will be summarized as the median, and the 25^{th} and 75^{th} percentiles and displayed graphically using Kaplan-Meier (product-limit) curves if data warrant.

3. PLANNED ANALYSES

3.1. Interim Analyses

Protocol Section 11.2 specifies interim analyses of futility for ORR to start "once at least 10 participants are evaluable". This analysis was carried out under v1.0 of this RAP and is described in Section 3.1.1 below.

The study having passed the futility boundary and the decision having been made to continue (after protocol amendment 2) to enroll a further 10 participants to be treated with a higher dose lymphodepletion regimen prior to infusion, no further formal interim analyses for futility are necessary.

Interim analyses of accruing efficacy in the second group of participants may be conducted for internal decision making. These data looks will use the methods described in protocol Section 11.2 for the interim analyses of futility and will proceed as described in Section 3.1.2 below.

3.1.1. Interim Analysis of Futility

After the first 10 participants were treated (received T-cell infusion) and had at least 2 post baseline disease assessments or progressed (according to investigator assessment) or died or were withdrawn from the study, the investigator-assessed Overall Response Rate (ORR) was evaluated to inform the decision of continuing enrollment up to 20 treated participants.

This analysis was carried out under v1.0 of this RAP, on data as of 26-OCT-2018.

The enrollment rules at the interim analysis are defined based on a Bayesian predictive adaptive design [Lee, 2008] that allows the study to be monitored more frequently at multiple stages. The criteria were based on a historical response rate of approximately 20% versus a response rate of interest of 40%, but the sample size is not powered for any formal hypothesis testing. Bayesian statistics were employed to calculate the predictive probability that the response rate was ≥40% and ≥20% at interim, assuming a weak beta (0.02, 0.08) prior for the binomially distributed data, equivalent to the information present in 0.1 participant.

The protocol specified that if there were 1 or no confirmed responses in the 10 participants assessed, then enrollment may stop after review of all available data; but that if there were 2 or more confirmed responses in the 10 participants, enrollment would continue up to 20 participants, with the final decision based on the totality of data.

The overall response rate (according to investigator assessment) for these first 10 participants was 2/10, above the futility stopping threshold. Based on the review of the totality of data it was decided to exercise the option introduced in protocol amendment 2 of 24-JUL-2018 and continue enrollment with a second group of 10 participants to receive a higher dose "option 2" lymphodepletion regimen, referred to in this RAP as the "high lymphodepletion cohort".

After the interim analysis of futility but before any interim analyses of efficacy in the second "high lymphodepletion" cohort, protocol amendment 4 updated the minimum number of post baseline disease assessments (for participants who had not progressed or died or withdrawn from the study) from 2 to 3. This amendment made the minimum follow-up required to be considered evaluable more consistent with other studies at around 12 weeks.

3.1.2. Interim Analyses of Second "High Lymphodepletion" Cohort for Internal Decision Making

Interim Analyses in the second "High lymphodepletion" cohort may be performed to provide data for internal decision making after at least 8 participants in this cohort are evaluable, where evaluable is defined as: received T-cell infusion and had at least 3 post baseline disease assessments or have progressed (according to investigator assessment) or died or withdrawn from the study. (Note that the definition of evaluable was updated in protocol amendment 4 – after the interim analysis of futility in the first ten infused participants but before any interim analyses of efficacy in the second cohort – to require at least 3 post baseline disease assessments rather than 2.)

Such an analysis was carried out under v2.0 of this RAP and v6 (amendment 5) of the Protocol, on data as of 04-DEC-2020.

The null hypothesis for the population represented by the high lymphodepletion cohort is H_0: ORR=20%, versus alternative hypothesis H_1: ORR=40%, the same as for the low lymphodepletion cohort.

Further development may be approved if the posterior probability that the Overall Response Rate (ORR) by investigator assessment is greater than or equal to 0.2 is at least 0.95, assuming the same weak beta (0.02, 0.08) prior for the binomially distributed data as used for the interim analysis of futility in the low lymphodepletion cohort. Thresholds for the corresponding minimum number of confirmed responders required are given in table below. These rules are for guidance only. The final decision will be based on the totality of the data available.

Analyses may be performed earlier with fewer than 8 evaluable participants if it is clear from the accumulated data what the decision at 8 evaluable participants would be. For example, if 4 participants in the second high lymphodepletion cohort have confirmed response (by investigator assessment) before 8 participants are evaluable, then an early interim analysis may be conducted.

Operating characteristics for these decision rules are as follows:

Number of Evaluable Participants	Threshold (#responders) for Go decision[1]	Posterior Probability ORR≥0.2 at threshold.	Probability of Go if true ORR=0.2	Posterior Probability ORR≥0.4 at threshold.	Probability of Go if True ORR=0.4
4	4	1.000	0.002	0.999	0.026
5	4	0.998	0.007	0.971	0.087
6	4	0.993	0.017	0.908	0.179
7	4	0.982	0.033	0.815	0.290
8	4	0.966	0.056	0.704	0.406
9	5	0.989	0.020	0.821	0.267
10	5	0.980	0.033	0.728	0.367
11	5	0.967	0.050	0.628	0.467
12	6	0.988	0.019	0.749	0.335

[1] For 8 or more evaluable participants, the threshold is the smallest number of responders such that the posterior probability that the population ORR is ≥0.2 is at least 0.95. For less than 8 evaluable participants, the threshold is set to that which would be required for a go decision with 8 evaluable participants.

Summaries of DOR and PFS will be presented to support decision making if data warrant. Displays planned for these interim analyses are indicated in Appendix 12.

The results of these data looks will guide further development of NY-ESO-1^{c259}T but will not impact the conduct of the study.

Such an interim analysis was conducted under version 2.0 of this RAP, version 6 of the protocol, on data as of 04-DEC-2020.

3.2. Primary Analyses

The planned primary analyses was performed after the completion of the following sequential steps:

1. Enrollment is complete and all the enrolled participants that will receive NY-ESO-1^{c259}T have received their first infusion.
2. At least 9 or 90% of the NY-ESO-1^{c259}T infused participants in each cohort (whichever is smaller) have completed the interventional phase (defined as confirmed disease progression [according to investigator assessment], death or follow-up for 2 years after first NY-ESO-1^{c259}T infusion) or were withdrawn

(including lost to follow-up), and the remaining infused participants have at least three disease assessments after first NY-ESO-1^{c259}T infusion.

3. All required database cleaning activities have been completed and final database release (DBR) and database freeze (DBF) has been declared by Data Management.

Note that whilst protocol amendment 6 (and later) Section 4.3 allow "*patients who have not progressed after 2 years on study and who are continuing in Study 208469 may continue to undergo response assessments every 3 months as defined in Study 208469 per institutional standard of care*", the protocol definition of completion of interventional phase is unchanged. Thus for the purposes of criteria 2 above, such subjects would be considered to have completed the interventional phase.

Section 7.6 of (site specific) protocol amendment 7 of 17-FEB-2021 introduced the possibility for retreatment of participants under certain conditions, with exploratory objectives for safety and efficacy: Any retreatment data (as defined in Section 14.4.1.5) will be excluded from the primary analysis.

3.3. Final Analyses

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

1. Enrollment is complete and all the enrolled participants that will receive NY-ESO-1^{c259}T have done so, including any retreatment 2nd infusion in this study.
2. All of the NY-ESO-1^{c259}T infused participants are no longer in follow-up in the study, having either transferred to the separate long-term follow-up protocol GSK208750 (ADP-0000-002), completed 15 years of long term follow-up in this study, has declined LTFU, died or withdrawn (including lost to follow-up).
3. All required database cleaning activities have been completed and final database release (DBR) and database freeze (DBF) has been declared by Data Management.

Details of the planned displays for the final analysis are presented in Appendix 12: List of Data Displays.

4. ANALYSIS POPULATIONS

Population	Definition / Criteria	Analyses Evaluated
Screened	• All participants that signed screening informed consent.	• Screening • Population inclusion/exclusion
Enrolled	• All participants who underwent leukapheresis.	• Specific required Study Population displays.
Intent-to-Treat (ITT)	• All participants who underwent leukapheresis.	• Study Population • Primary Safety (where appropriate) • Sensitivity for Primary Efficacy Endpoint (ORR)
Modified Intent-to-Treat (mITT)	• All ITT participants who received NY-ESO-1^{c259}T cell infusion.	• Primary Efficacy (except at interim analyses) • Primary Safety (where appropriate) • Sensitivity Safety (where appropriate) • Supportive Study Population
All Evaluable	• All participants who received T-cell infusion and (had at least 3 post baseline disease assessments or [have progressed or died or withdrawn from the study]).	• Interim Futility Analysis (conducted under RAP v1 which required only 2 post-baseline disease assessments) • Interim Assessments of ORR
CCI		

Appendix 12 details the population to be used for each display.

4.1. Protocol Deviations

Protocol deviations will be tracked in accordance with the Protocol Deviation Specification Form by the study team throughout the conduct of the study and sent to the Data Manager and Biostatistics Leads in a spreadsheet. Protocol deviations will not be identified programmatically.

Inclusion/exclusion criteria deviations 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

This is a single arm study with NY-ESO-1^{c259}T. Data will be listed and summarized according to the GSK reporting standards, where applicable. For participants that entered the interventional phase and underwent leukapheresis, data will be summarized by the lymphodepletion cohort the participant was enrolled into and by study total:

- Low lymphodepletion cohort: participants enrolled into the original lymphodepletion regimen specified prior to protocol amendment 2 consisting of 3 days of cyclophosphamide 600mg/m^2/day starting on day -7 and 3 days of fludarabine 30 mg/m^2/day starting on day -7.
- High lymphodepletion cohort: participants enrolled into the "option 2" lymphodepletion regimen introduced in protocol amendment 2 consisting of 3 days of cyclophosphamide 900mg/m^2/day starting on day -7 and 4 days of fludarabine 30 mg/m^2/day) starting on day -8.

Treatment Group Descriptions	
Data Displays for Reporting	
Description	**Order in TLF**
LOW LYMPHO DOSE + GSK794	1
HIGH LYMPHO DOSE + GSK794	2
Total	3

Note that for leukapheresed participants, grouping is by lymphodepletion cohort the participant was enrolled into, regardless of the actual lymphodepletion chemotherapy or NY-ESO-1^{c259}T cell infusion subsequently received (or not).

No analyses in this RAP are grouped according to the actual treatment received.

For analyses in the screened population, participants who did not proceed to leukapheresis will be grouped as "No Treatment".

All data displays (Tables, Figures & Listings) will use the term "Subject" which reflects CDISC and GSK Data Display Standards terminology.

5.1.1. Retreatment

Participants that are retreated with a second course of conditioning chemotherapy and NY-ESO-1^{c259}T cell infusion, will continue to be summarized by the lymphodepletion cohort the participant was enrolled into.

This analysis plan and the treatment group descriptors described above do not accommodate for participants that were enrolled into the low lymphodepletion cohort and received the "option 2" high dose lymphodepletion regimen for retreatment, since there are no such retreated participants in which this scenario occurred.

5.2. Baseline Definitions

Unless specified otherwise, the baseline value will be the latest assessment with a non-missing value (including unscheduled visits) prior to initiating lymphodepletion. Per-protocol, baseline assessments should occur less than 7 days prior to initiating lymphodepletion on day -8 (high lymphodepletion cohort) or day -7 (low lymphodepletion cohort).

The initial identification of baseline will consider assessments within 7 days (inclusive) of initiating lymphodepletion. If a non-missing assessment within 7 days of initiating lymphodepletion is not available, then the last assessment with a non-missing value prior to initiating lymphodepletion would be used even if it occurred more than 7 days prior to initiating lymphodepletion. If an assessment is performed on the same date as the start of lymphodepleting chemotherapy and the time of assessment is not recorded, then the assessment will be assumed to have occurred prior to lymphodepletion and used as baseline.

For participants who did not receive lymphodepleting chemotherapy during the study, baseline will be defined as the latest, non-missing collected value.

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

For participants retreated with a second T-cell infusion, a baseline associated with retreatment lymphodepletion and infusion will be derived and used for all retreatment displays. For all endpoints except laboratory data, baseline will be as described for the initial infusion albeit the window for baseline will be $\leq$28 days prior to the initiation of retreatment lymphodepletion chemotherapy, instead of 7 days. For laboratory data (lymphocyte subset (CD3/CD4/CD8), hematology, chemistry, coagulation and urinalysis), baseline will be as described above for the initial infusion but prior to initiation of retreatment lymphodepletion.

5.3. Multicenter Studies

Data from all participating centers will be pooled prior to analysis.

It is anticipated that participant accrual will be spread thinly across centers and summaries of data by center would be unlikely to be informative and will not, therefore, be provided.

5.4. Examination of Covariates, Other Strata, and Subgroups

No covariates or strata will be incorporated into analyses and no subgroup analysis will be performed.

5.5. Multiple Comparison and Multiplicity

No formal statistical testing will be performed; therefore, no adjustments for multiple comparisons or multiplicity are planned.

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
14.3	Appendix 3: Assessment Windows
14.4	Appendix 4: Study Phases and Treatment Emergent Adverse Events
14.5	Appendix 5: Data Display Standards & Handling Conventions
14.6	Appendix 6: Derived and Transformed Data
14.7	Appendix 7: Reporting Standards for Missing Data
14.8	Appendix 8: Values of Potential Clinical Importance

6. STUDY POPULATION ANALYSES

6.1. Overview of Planned Study Population Analyses

The study population analyses will be based on the Intent-to-Treat (ITT) population, unless otherwise specified. Some study population analyses will be repeated in the mITT population. If the mITT and ITT populations are identical, then results planned for both ITT and mITT populations will only be reported for the ITT population.

Study population analyses including analyses of participant's disposition, protocol deviations, demographic and baseline characteristics, prior and concomitant medications, disease characteristics at initial diagnosis and at screening, prior and on-study anti-cancer therapy, prior anti-cancer radiotherapy, prior and on-study surgical procedures, disease burden at baseline and study treatment exposure will be based on GSK Core Data Standards. Details of the planned displays are presented in Appendix 12: List of Data Displays.

6.2. Disposition of Participants

A summary of the number of participants in each of the analysis populations described in Section 4 will be provided. A listing of participants excluded from analysis populations will also be provided detailing reason for exclusion.

A summary of screening status and reasons for screen failure together with a listing of reasons for screen failure will be provided using the screened population. Per GSK reporting standards, participants who were rescreened will appear once in these displays according to their final status, with an additional listing detailing their multiple screenings.

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Overall study disposition will be summarized. For participants who have received T-cell infusion, this will be based on study status as recorded on the "End of Study" form. If any participants return from the long-term follow-up study and are retreated with 2nd T-cell infusion, this will be based on study status as recorded on the second "End of Study" form. Participants whose end of study status is "TRANSFERRED TO SEPARATE LONG-TERM FOLLOW-UP STUDY" will be considered to have completed this study. For participants who do not receive T-cell infusion (for whom no "End of Study" form is completed), the "End of Treatment" form records their final study disposition.

Interventional phase status will be summarized with reasons for non-completion as captured in the eCRF.

A listing of subject status (including leukapheresis, lymphodepletion, T-cell infusion, interventional phase and overall study status) will be provided. At the final analysis this listing will be extended to include the final status from retreated participants.

CCI [redacted]

CCI [redacted]

6.3. Protocol Deviations

Important protocol deviations will be summarized and listed.

A separate listing of inclusion/exclusion deviations will also be provided.

At the final analysis both listings will be extended to include retreatment data.

6.4. Demographic and Baseline Characteristics

The demographic characteristics (e.g., race, age, ethnicity, sex, height, baseline body weight, body mass index (BMI) and body surface area (BSA) calculated by the formula of Dubois-Dubois [Dubois, 1916]) will be summarized and listed. Age, height, weight, BMI and BSA will be summarized as continuous variables, while sex, race and ethnicity will be summarized as categorical variables. Age will also be categorized and summarized by GSK IDSL standard as ≤18, 19-64, ≥65. See Appendix 6 for details of calculation of age.

In a separate summary, age will also be categorized and summarized by 18-64, 65-84 and ≥85 using EudraCT.

Disease characteristics at initial diagnosis including location of disease, time since initial diagnosis to screening in months, % of myxoid cells, % of round cells, histological grade, stage, and reciprocal chromosomal translocation will be summarized and listed. Disease characteristics at screening including HLA-A status, NY-ESO-1 status, stage, time since metastatic disease to screening in months, and numbers of prior radiotherapy regimens between diagnosis of advanced disease and leukapheresis and numbers of prior systemic therapy regimens between diagnosis of advanced disease and leukapheresis will also be summarized and listed. Date of (first) screening consent will be taken as date of screening, with calculation of elapsed time in months as detailed in Appendix 6.

A summary of disease burden at baseline, including number of organs involved and location of disease at baseline, will be produced. Both target and non-target lesions at baseline will be included. These will be based on the investigator's baseline disease assessment.

Medical conditions (history and ongoing) at screening will be listed and summarized.

At the final analysis the listing of demographics will be repeated on the ITT population excluding retreatment data. CCI [redacted]

6.5. Prior and Concomitant Medications

All concomitant medications will be summarized (for the mITT Population only), and all prior and concomitant medications will be included in a single listing. Definition of prior and concomitant medication study phases are provided in Appendix 4. Note all summaries exclude retreatment.

Medications will be coded using GSK Drug coding dictionary, summarized and listed. The summary of concomitant medications will show the number and percentage of participants taking concomitant medication by Ingredient. Multi-ingredient products will be summarized by their separate ingredients rather than as a combination of ingredients. Anatomical Therapeutic Chemical (ATC) classification Level 1 (Body System) information will be included in the dataset created but will not appear on the listing or summary.

Medications will also be coded using the WHODrug dictionary in a separate dataset but this will not be used for any of the reporting planned in this document.

In the summary of concomitant medications, each participant will be counted once within each unique ingredient. For example, if a participant takes Amoxycillin on two separate occasions, the participant will be counted only once under the ingredient 'Amoxycillin'. In the summary of concomitant medications, the ingredients will be summarized by the base only.

At the final analysis the prior and concomitant medications listing will be repeated on the mITT population excluding retreatment data. CCI [redacted]

Blood products will be summarized and listed. CCI [redacted]

6.6. Study Treatment Exposure

Study treatments – described in Section 5 of the protocol – are leukapheresis, lymphodepleting chemotherapy and NY-ESO-1^{c259}T cell infusion.

Dose administration data for lymphodepleting chemotherapy, including cyclophosphamide and fludarabine, will be presented in a data listing. At the final analysis this listing will be repeated on the ITT population excluding retreatment data. A separate listing of retreatment lymphodepletion on the mITT2 population will also be presented. Both listings will include the cumulative dose of lymphodepletion per participant.

At the final analysis the cumulative dose (mg/m^2) for the 1st lymphodepleting chemotherapy across all participants will be summarized using n, mean, standard deviation, median, min and max.

Number and percentage of participants receiving leukapheresis procedure, lymphodepleting chemotherapy, and T-cell infusion will be summarized (excluding retreatment).

A listing of study treatment will be provided, including overall T-cell infusion start and stop date/time (over all bags), average vector copy number per cell in the cell product, total number of transduced cells, and percent of cells transduced. At the final analysis this listing will be repeated on the ITT population excluding retreatment data. CCI [redacted] CCI [redacted] CCI [redacted]

The total number of transduced T-cells will be summarized using n, mean, standard deviation, median, min and max. Also, the total number of transduced T-cells will be categorized into <1, >=1 to <=8, and >8 (x 10^9 cells). This summary will exclude any retreatment 2nd T-cell infusions.

6.7. Anti-Cancer Therapies

Anti-cancer therapies will be classified into prior and on-study phases as described in Appendix 4. Only therapies initiated on or after the first day of lymphodepletion chemotherapy are considered on-study. Note that anti-cancer therapies given after first disease progression but before first day of retreatment lymphodepletion chemotherapy to participants remaining on-study for retreatment after their first disease progression but before the first day of retreatment lymphodepletion are considered on-study. Prior therapy regimens will be further classified into sub-phases at date of diagnosis of advanced (metastatic/unresectable) disease and date of leukapheresis.

6.7.1. Prior Anti-Cancer Therapies

Prior therapy types as defined below are systemic therapy (coded using the GSK Drug coding dictionary), radiotherapy, and cancer-related surgery.

Regimens initiated before diagnosis of advanced disease will not be included in summaries of prior therapies.

Summaries of the numbers of radiotherapy and systemic anti-cancer regimens initiated between diagnosis of advanced disease and leukapheresis will be presented as part of the summary of disease characteristics at screening.

Systemic anti-cancer therapy regimens initiated between leukapheresis and lymphodepletion (as defined in Appendix 4) will be categorized as either bridging (regimens administered to maintain/stabilize the participant until T-cell infusion) or full lines (regimens administered with the intent of disease effect) through GSK study physician review.

Bridging therapies will be excluded from summaries of prior anti-cancer therapy.

Thus, unless otherwise stated, summaries of prior systemic anti-cancer therapies will include all therapies initiated from diagnosis of advance disease to lymphodepletion

except those in the leukapheresis to lymphodepletion period identified as bridging therapies. (Note that this is equivalent to all therapies from diagnosis of advanced disease to leukapheresis plus therapies initiated between leukapheresis and lymphodepletion identified as full lines.)

A breakdown of the number of participants who received each category of prior anti-cancer therapy (surgery, radiotherapy, chemotherapy, etc.) will be presented.

Anti-cancer therapy will be coded using GSK Drug coding dictionary. The number of participants receiving prior anti-cancer therapies will be summarized by ATC Level 1 and ingredient. Bridging therapies will be similarly summarized.

A summary of the number of prior anti-cancer therapy regimens will also be produced.

All prior anti-cancer therapy will be listed, with sub-phase indicated and bridging therapies flagged.

All anti-cancer radiotherapy (including on-study) will be listed, with on-study or prior sub-phase indicated. At the final analysis this listing will be repeated on the ITT population excluding retreatment data. CCI [redacted] CCI [redacted] CCI [redacted]

All prior cancer-related surgical procedures will be listed, with sub-phase indicated. Those surgeries carried out between diagnosis of advanced disease and lymphodepletion will be summarized by intent and site.

6.7.2. On-Study Anti-Cancer Therapies

The number and percentage of participants that received any on-study anti-cancer therapy will be summarized together with the time from T-cell infusion to start of subsequent anti-cancer therapy for those that received on-study anti-cancer therapy (excluding retreatment).

On-study systemic therapies will be coded using the GSK Drug coding dictionary, then summarized by ATC Level 1 and ingredient.

Participant-level data describing all on-study anti-cancer therapies and cancer-related surgical procedures will be provided in separate listings. At the final analysis this listing will be repeated on the ITT population excluding on-study therapies after retreatment lymphodepletion. CCI [redacted] CCI [redacted] CCI [redacted]

All resection biopsies will be listed. At the final analysis this listing will be extended to include retreatment data.

7. EFFICACY ANALYSES

The primary and secondary efficacy analyses are only conducted on the 1st infusion data.

CCI [redacted]

Lesion assessment method and timing, and response determination for all efficacy analyses will be conducted according to RECIST (version 1.1) (Eisenhauer, 2009) per Section 16.4 of the Protocol. As this is a non-comparative study, responses must be confirmed.

- To be assigned a confirmed response assessment of Partial Response (PR) or Complete Response (CR), a confirmatory disease assessment should be performed no less than 4 weeks (28 days) after the criteria for response are first met.

7.1. Primary Efficacy Analyses

Listings of RECIST v1.1 response as assessed by the investigator and independent review at each assessment during the interventional phase (i.e. excluding any retreatment assessments) will be provided, including visit number, date of assessment, response day, target and non-target lesion response, new lesion, and overall response.

7.1.1. Endpoint / Variables

7.1.1.1. Best Overall Response (BOR) with Confirmation per RECIST v1.1 by Investigator Assessment

The Best Overall Response (BOR) with confirmation for a participant is defined as the best confirmed response (Confirmed Complete Response [CR] > Confirmed Partial Response [PR] > Stable Disease [SD] > Progressive Disease [PD] > Not Evaluable [NE]) from treatment start date until disease progression or initiation of new anti-cancer therapy, whichever is earlier, as assessed by the investigator per RECIST v1.1 Criteria during the interventional phase.

- Inclusion criteria 6 requires participants to have measurable disease according to RECIST v1.1 criteria. If a participant has no measurable disease at baseline (and therefore no target lesions) then the participant will be treated as a non-responder with BOR of NE (not evaluable), regardless of any non-target response (of CR, Non-CR/Non-PD or PD).
- A response of CR or PR is confirmed if the criteria for each are met at a subsequent time point at least 28 days later (but before disease progression or initiation of new anti-cancer therapy), excluding assessments that are not evaluable (NE) or were not done.
- Responses of CR/PR that do not meet the requirements of confirmed CR/PR are still eligible to be considered for a BOR with confirmation of SD.

- To be considered evidence for a BOR with confirmation of Stable Disease (SD), a disease assessment meeting the RECIST 1.1 SD (or unconfirmed CR or unconfirmed PR) criteria must be after at least 28 days of follow-up post T-cell infusion (where the day of T-cell infusion is day 1). If the minimum of 4 weeks (28 days) for SD (or unconfirmed CR or unconfirmed PR) is not met, best response will depend on the subsequent assessments. For example, if an assessment of PD follows the assessment of SD and SD does not meet the minimum 4-week requirement the best response will be PD. Alternatively, participants lost to follow-up after an SD assessment not meeting the minimum time criteria will be considered not evaluable (NE) for BOR.
- Disease assessments after new anti-cancer therapy will not be considered when deriving best overall response.
    - Anti-cancer therapies are per protocol Section 6.1 & Section 6.2: non- protocol chemotherapy, immune therapy, biological therapy (including targeted therapies with tyrosine kinase inhibitors or monoclonal antibodies), investigational anti-cancer therapy, locoregional therapies such as surgical resection or non-palliative radiotherapy.
    - If time is not collected and anti-cancer therapy starts on the same day as the disease assessment, it is assumed that the disease assessment occurred first.
    - New anti-cancer therapies are those classified as on-study (as defined in Appendix 4).

7.1.1.2. Overall Response Rate (ORR) with Confirmation per RECIST v1.1 by Investigator Assessment

The primary efficacy endpoint is the Overall Response Rate (ORR) with confirmation per RECIST v1.1 by investigator assessment, defined as the percentage of participants with a confirmed complete response (CR) or confirmed partial response (PR) as the BOR with confirmation, as assessed by the investigator per RECIST v1.1 Criteria during the interventional phase.

7.1.1.3. Best Overall Response (BOR) without Confirmation per RECIST v1.1 by Investigator Assessment

The Best Overall Response (BOR) without confirmation is required as supporting evidence for some displays. This is defined for a participant as the best response (Complete Response [CR] > Partial Response [PR] > Stable Disease [SD] > Progressive Disease [PD] > Not Evaluable [NE]) from treatment start date until disease progression or initiation of new anti-cancer therapy, whichever is earlier, as assessed by the investigator per RECIST v1.1 Criteria during the interventional phase.

- Inclusion criteria 6 requires participants to have measurable disease according to RECIST v1.1 criteria. If a participant has no measurable disease at baseline (and therefore no target lesions) then the participant will be treated as a non-responder with BOR of NE (not evaluable), regardless of any non-target response (of CR, Non-CR/Non-PD or PD).
- To be considered evidence for a BOR of Stable Disease (SD), a disease assessment meeting the RECIST 1.1 SD criteria must be after at least 28 days of follow-up post

T-cell infusion (where the day of T-cell infusion is day 1). If the minimum of 4 weeks (28 days) for SD is not met, best response will depend on the subsequent assessments, as described in Section 7.1.1.1 above for BOR with confirmation.

- Disease assessments after new anti-cancer therapy will not be considered when deriving best overall response, as described in Section 7.1.1.1 above for BOR with confirmation.

7.1.2. Summary Measure

The number and percentage of participants in the analysis population of interest with the best overall response with confirmation in the following response categories at each assessment will be summarized: CR, PR, SD, PD and NE. The overall response rate and the corresponding two-sided exact (Clopper-Pearson) 95% CI will also be provided. Participants with unknown or missing responses will be treated as non-responders, i.e., these participants will be included in the denominator when calculating percentages of response.

Percent change in the sum of target lesion diameters from baseline over the interventional phase for each subject will be shown in a spider plot. A waterfall plot showing the maximum percent reduction from baseline in target tumor measurement will be produced.

Details of the planned displays are provided in Appendix 12 and are based on GSK data standards and statistical principles.

7.1.3. Population of Interest

The primary efficacy analyses will be based on the modified Intent-to-Treat (mITT) population. The Intent-to-Treat (ITT) is the sensitivity analysis population for the primary efficacy endpoint, ORR with confirmation by investigator assessment. If the mITT and ITT populations are identical, then results planned for both ITT and mITT populations will only be reported for the mITT population.

7.1.4. Strategy for Intercurrent Events

A composite strategy will be followed for participants who are not evaluable or have missing response who will be treated as non-responders; i.e. they will be included in the denominator when calculating the percentage.

7.1.5. Statistical Analyses / Methods

The study is not powered for either primary or secondary endpoints, therefore no statistical testing will be done.

7.2. Secondary Efficacy Analyses

7.2.1. Endpoint / Variables

7.2.1.1. Best Overall Response (BOR) with Confirmation per RECIST v1.1 by Independent Review

The BOR with confirmation described in Section 7.1.1.1 for the primary analysis based on the investigator assessments of response will be repeated based on response as assessed by independent review.

7.2.1.2. Overall Response (ORR) with Confirmation per RECIST v1.1 by Independent Review

The ORR with confirmation described in Section 7.1.1.2 for the primary analyses for BOR with confirmation based on the investigator assessments of response will be repeated for BOR with confirmation based on independent review as defined in Section 7.2.1.1.

7.2.1.3. Time to (Confirmed) Response (TTR)

Time to (confirmed) response (TTR) is defined as the interval of time (in months) between the date of 1st T-cell infusion and the first documented evidence of the confirmed response (PR or CR), in the subset of participants with a confirmed response of PR or CR as the BOR with confirmation.

TTR with confirmation will be calculated for both investigator assessment and independent review.

7.2.1.4. Duration of (Confirmed) Response (DOR)

Duration of (confirmed) response (DOR) is defined as the interval of time (in months) from first documented evidence of the confirmed response (PR or CR) to the date of disease progression per RECIST 1.1 Criteria or death due to any cause, among participants with a confirmed response of PR or CR as the BOR.

Censoring rules for DOR will follow those of the PFS (see Section 7.2.2).

DOR with confirmation will be calculated for both investigator assessment and independent review.

7.2.2. Progression Free Survival (PFS)

Progression-free survival (PFS) is defined as the interval of time (in months) between the date of 1st T-cell infusion and the earlier of the date of disease progression per RECIST v1.1 Criteria or death due to any cause.

PFS will be calculated for both investigator assessment and independent review.

If a participant has neither progressed nor died nor started new anti-cancer therapy, PFS will be censored at the date of the last adequate disease assessment. The imaging modalities for this study are:

- Diagnostic-quality CT scan with oral and/or i.v. iodinated contrast of the chest and abdomen/pelvis (CT is the preferred modality for tumor assessments)
- MRI of the abdomen/pelvis acquired before and after gadolinium contrast agent administration and a non-contrast enhanced CT of the chest, if a participant is contraindicated for contrast enhanced CT
- MRI of the extremities per site standard of care, if clinically indicated.
- Digital photographs of skin lesions including a ruler for estimating the size of the lesion.

For participants who receive on-study anti-cancer therapy the following rules will apply:

- If anti-cancer therapy is started without documented disease progression or is started prior to documented disease progression, PFS will be censored at the date of the last adequate disease assessment that is no later than the date of initiation of anti-cancer therapy (i.e. if an assessment occurs on the same day as the start of new anti-cancer therapy, the assessment will be used, as it will be assumed the assessment occurred prior to the administration of new anti-cancer therapy).
- If a participant has only a baseline visit or does not have an adequate disease assessment that is no later than the date of initiation of on-study anti-cancer therapy, PFS will be censored at the date of T-cell infusion.
- If the start date of the on-study anti-cancer therapy is partial (i.e. either missing the day but has the month and year available or missing both day and month), the imputation rules described in Section 14.7 will be applied. No imputation will be made for completely missing dates.

Anti-cancer therapy for efficacy censoring is as described in Section 7.1.1.1 above for BOR with confirmation.

Inclusion criteria 6 requires participants to have measurable disease according to RECIST v1.1 criteria. If a participant has no measurable disease at baseline (and therefore no target lesions) then the participant will be considered censored at Day 1 for PFS (PFS follow-up ended), regardless of any non-target progression or new lesions.

Per Protocol Section 7.6, only participants that progress during the interventional phase are considered for retreatment. Assuming such progression is per RECIST v1.1, no additional censoring rules are required to exclude retreatment disease assessments or deaths after retreatment.

A summary of the assignments for progression and censoring dates for PFS are specified in Table 1.

Table 1 PFS Censoring Rules

Scenario	Date of Event (Progression/Death) or Censored	Event (Progression/Death) or Censored
No baseline assessments[4] and the participant has not died	Day 1 (NY-ESO-1^{c259}T cell infusion)	Censored (PFS follow-up ended)
No adequate post-baseline assessments before start of new anti-cancer therapy and the participant has not died	Day 1 (NY-ESO-1^{c259}T cell infusion)	Censored (PFS follow-up ended)
Progression documented at or between scheduled visits	Date of assessment of progression[1]	Event
With adequate post-baseline assessment but no progression (or death)	Date of last 'adequate' assessment of response[2]	Censored (PFS follow-up ongoing if still in interventional phase follow-up)
With adequate post-baseline assessment and new anticancer treatment started (prior to documented disease progression).[3]	Date of last 'adequate' assessment of response[2] (on or prior to starting anti-cancer therapy)	Censored (PFS follow-up ended)
Death before first scheduled assessment	Date of death	Event
Death (regardless of having baseline assessment) before missing two scheduled assessments and no progression	Date of death (Use rule below to determine missing two scheduled assessments)	Event

Scenario	Date of Event (Progression/Death) or Censored	Event (Progression/Death) or Censored
Death (regardless of having baseline assessment) or progression after two or more missed scheduled assessments	Day 1 (NY-ESO-1^{c259}T cell infusion) if there is no adequate post-baseline assessment or date of last 'adequate' assessment of response (Prior to missed assessments): As the assessment schedule changes through the course of the protocol (i.e. every 4 weeks until week 12 and then at week 24, month 9 and every 3 months until month 24), the following rules will be used for identifying extended loss to follow up or extended time without an adequate assessment (i.e. two or more missed assessments). • If PFS event is on or prior to day 91 (week 12 + 7-day window), then a participant will be identified as an extended loss to follow up if the participant did not have an adequate assessment during the time period of 66 days (4 weeks + 4 weeks + 7-day window + 3-day window) prior to PFS event; • Else if PFS event is after day 91 (week 12 + 7-day window) and on or prior to day 175 (week 24 + 7 day window), then a participant will be identified as an extended loss to follow up if the participant did not have an adequate assessment during the time period of 126 days (4 weeks + 12 weeks + 7-day window + 7-day window) prior to PFS event; • Else if PFS event is after day 175 (week 24+ 7-day window) and on or prior to day 288 (month 9 + 14-day window), then a participant will be identified as an extended loss to follow up if the participant did not have an adequate assessment during the time period of 211 days (Month 9 – Week 12 + 14-day window + 7-day window) prior to PFS event; • Else if PFS event is after day 288 (month 9 + 14-day window), then a participant will be identified as an extended loss to follow up if the participant did not have an adequate assessment during the time period of 218 days (Month 12 – Week 24 + 14-day window + 7-day window) prior to PFS event. PFS will be censored at the date of last adequate disease assessment of response or Day 1, whatever is later, prior to PD/death.	Censored (PFS follow-up ended)

[1] The earliest of (i) Date of radiological assessment showing new lesion (if progression is based on new lesion); or (ii) Date of radiological assessment showing unequivocal progression in non-target lesions, or (iii) Date of last radiological assessment of measured lesions (if progression is based on increase in sum of measured lesions)
[2] An adequate assessment is defined as an assessment where the response is CR, PR, or SD.
[3] If PFS event and new anti-cancer therapy occur on the same day assume the progression was documented first (e.g. outcome is progression and the date is the date of the assessment of progression).
[4] No baseline assessment defined as baseline scan performed outside of the window specified in Section 5.2 or no baseline scan at all.

7.2.3. Summary Measure

7.2.3.1. Best Overall Response (BOR) with Confirmation per RECIST v1.1 by Independent Review

The primary analyses will be repeated for BOR with confirmation as assessed by independent review.

Investigator-assessed and independent reviewer-assessed BOR with confirmation will be compared.

7.2.3.2. Overall Response (ORR) with Confirmation per RECIST v1.1 by Independent Review

The primary analyses will be repeated for BOR with confirmation as assessed by independent review.

7.2.3.3. Time to (Confirmed) Response (TTR)

If there are sufficient number of responses at time of primary or final analysis, time to (confirmed) response will be summarized descriptively using n, median, mean, min, max and quartiles in the subset of participants with a confirmed response of PR or CR as the BOR with confirmation.

TTR will be presented for both investigator assessment and independent review, if data warrant.

7.2.3.4. Duration of (Confirmed) Response (DOR)

Duration of (Confirmed) Response (DOR) will be listed and summarized in months among the participants with confirmed response of PR or CR as the BOR with confirmation, using Kaplan-Meier quartile estimates along with two-sided 95% CIs using a generalization of the Brookmeyer-Crowley method [Brookmeyer, 1982] under a log-log transformation, if data warrant.

Kaplan-Meier curve will also be produced.

DOR will be presented for both investigator assessment and independent review.

7.2.3.5. Progression Free Survival (PFS)

PFS will be listed and summarized in months using Kaplan-Meier quantile estimates along with two-sided 95% CIs using a generalization of the Brookmeyer-Crowley method [Brookmeyer, 1982] under a log-log transformation, if data warrant. At the Final analysis, the PFS rate at 3 monthly intervals (3, 6, 9, 12, etc) and the corresponding two-sided 95% CIs (under a log-log transformation) will also be estimated from the Kaplan-Meier analysis.

Kaplan-Meier curve will also be produced.

PFS will be presented for both investigator assessment and independent review.

Investigator and independent reviewer-assessed PFS event or censoring and timing will be compared. A time window of plus or minus 7 days will be applied when determining agreement in timing. A summary of the agreement will be produced, together with a supporting listing.

At the Final analysis, the median follow-up time for PFS for investigator assessment will be summarized in months using the reverse Kaplan-Meier method. Patients who had a PD or died will be censored for further follow-up in the reverse KM PFS follow-up estimates. The Kaplan-Meier quantiles will be summarised as above for PFS.

7.2.4. Population of Interest

The secondary efficacy analyses will be based on the mITT population.

7.2.5. Statistical Analyses / Methods

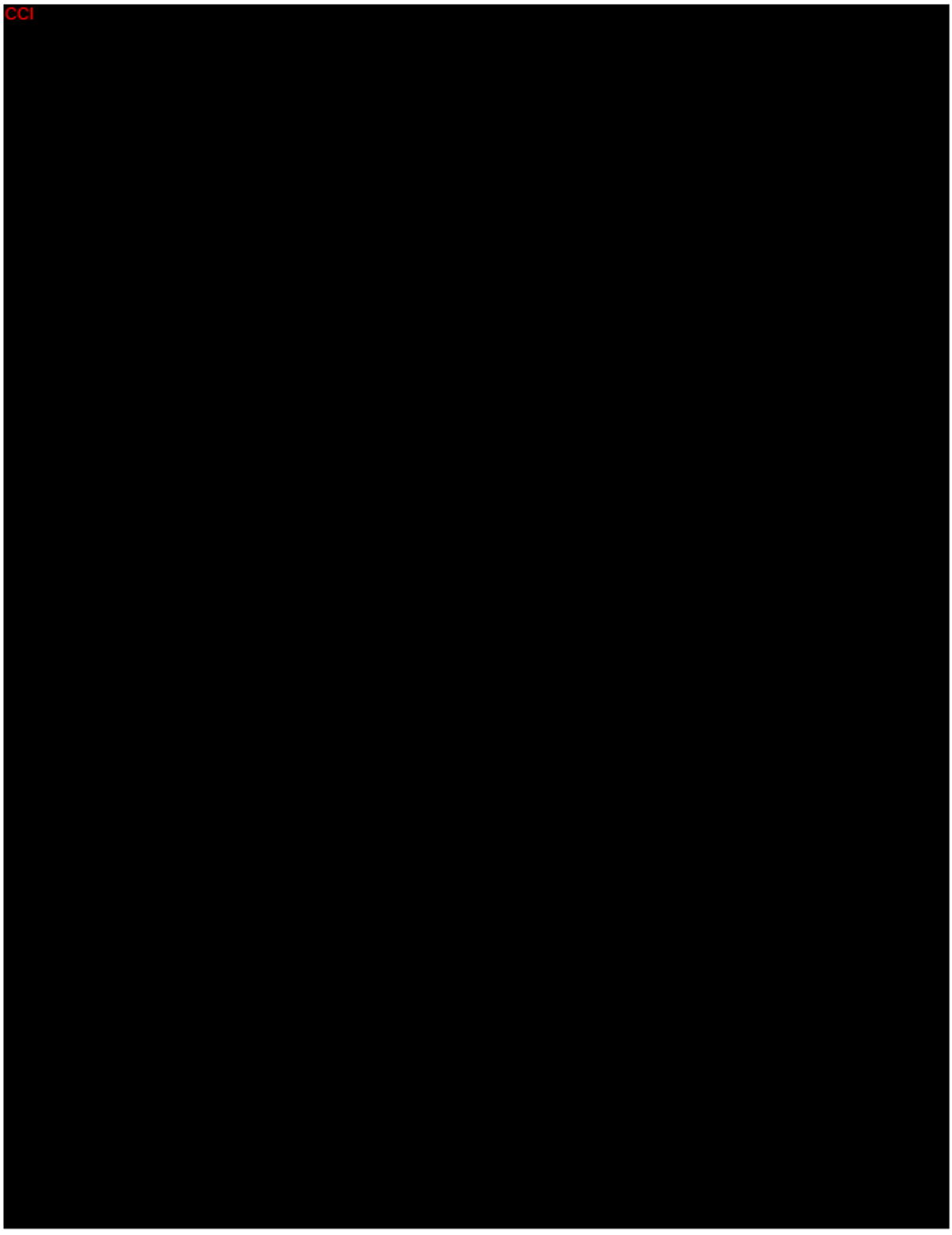
Details of the planned displays are provided in Appendix 12 and are based on GSK data standards and statistical principles.

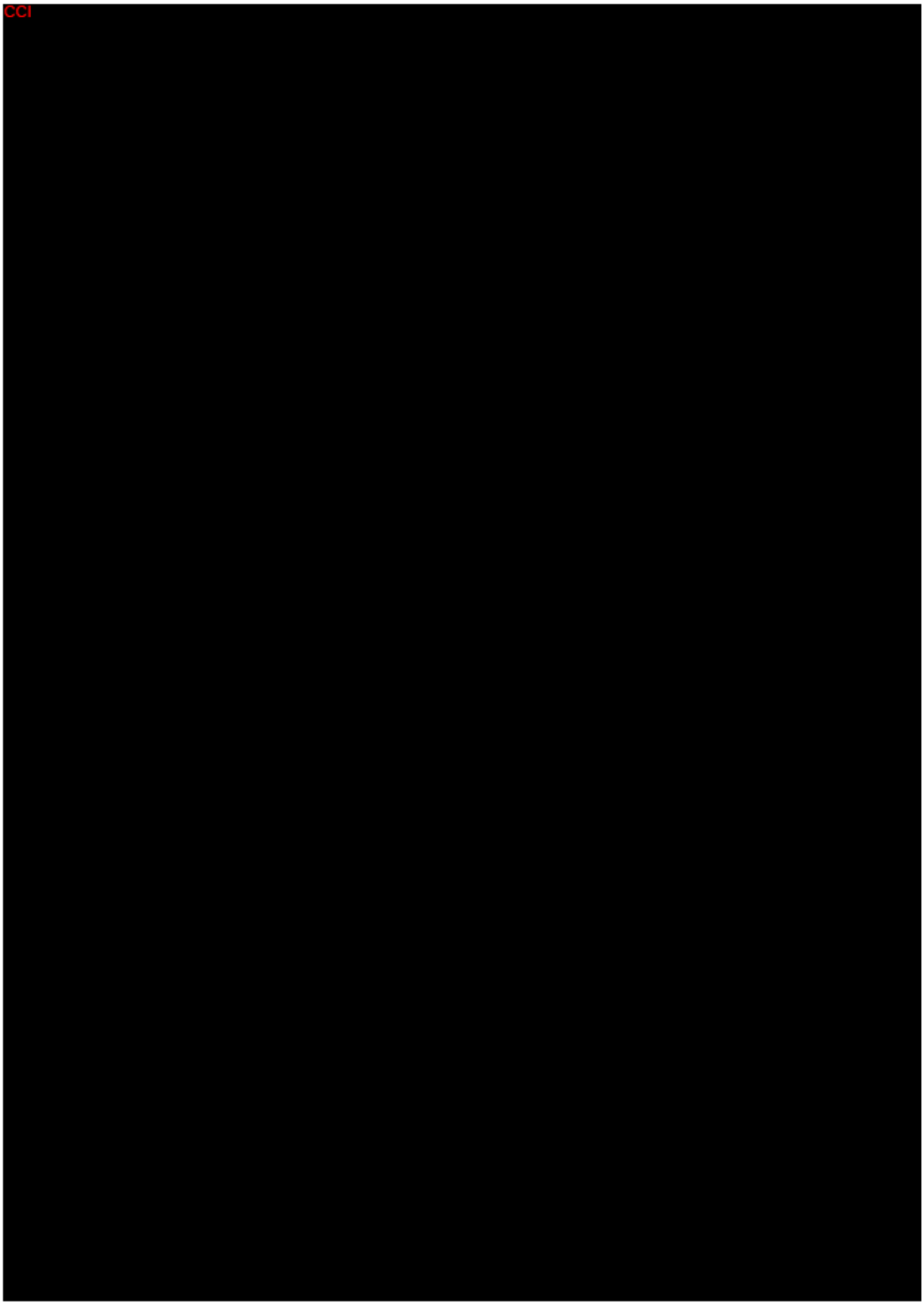
Unless otherwise specified, endpoints / variables defined in Section 7.2.1 will be summarized using descriptive statistics, graphically presented (where appropriate) and listed.

7.3. Exploratory Efficacy Analysis

CCI

CCI




CCI

CCI [redacted]

7.4. Interim Analyses

An interim analysis for futility was conducted after the first 10 participants had been treated and all 10 participants were evaluable, as described in Section 3.1.1, when the Overall Response Rate (ORR) as assessed by the investigator was evaluated.

Interim analyses of the second "high lymphodepletion" cohort for internal decision making were also conducted as described in Section 3.1.2, when the Overall Response Rate (ORR) as assessed by the investigator was evaluated.

7.4.1. Overall Response Rate (ORR) with Confirmation per RECIST v1.1 by Investigator Assessment

The endpoint assessed at interim analyses is the Overall Response Rate (ORR) with confirmation per RECIST v1.1 as assessed by the investigator, defined as the proportion of participants with an investigator-assessed confirmed complete response (CR) or confirmed partial response (PR) as the BOR, as assessed by the investigator per RECIST v1.1 Criteria during the interventional phase.

7.4.2. Population of Interest

The interim analyses of ORR will be based on the all evaluable population.

7.4.3. Strategy for Intercurrent Events

A composite strategy will be followed for participants who are not evaluable or have missing response who will be treated as non-responders; i.e. they will be included in the denominator when calculating the ORR.

7.4.4. Statistical Analyses / Methods

A summary of investigator-assessed best response will be provided including number and percentage of participants in each category of best response. The ORR and the corresponding two-sided exact (Clopper-Pearson) 95% confidence interval will also be provided.

DOR and PFS (assessed per RECIST 1.1) will be summarized in months using Kaplan-Meier quartile estimates along with two-sided 95% CIs, if data warrant. Kaplan-Meier curves of PFS will also be produced. A listing of participant best response including number of post-baseline assessments, evaluable for interim analysis, and confirmed and unconfirmed best response will be provided. A waterfall plot showing the maximum percent reduction from baseline in tumor measurement will be produced.

Details of the planned displays are provided in Appendix 12 and are based on GSK data standards and statistical principles.

8. SAFETY ANALYSES

The safety analyses will be based on the Intent-to-Treat population except for displays that are treatment dependent where the modified Intent-to-Treat population will be used, as detailed in Appendix 12.

Safety analyses will group leukapheresed participants according to the lymphodepletion cohort the participant was enrolled into, as described in Section 5.1, regardless of the actual lymphodepletion chemotherapy or NY-ESO-1^{c259}T cell infusion subsequently received (or not).

Unless otherwise specified, summaries will include totals across both the low and high lymphodepletion dose treatment groups as described in Section 5.1.

A plot of duration of the interventional phase including SAEs, death, progression, and response will be produced (excluding retreatment).

8.1. 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 Appendix 12.

AEs will be coded to the Preferred Term (PT) level using the latest version of the Medical Dictionary for Regulatory Affairs (MedDRA). The relationship between MedDRA SOC, PT, and Verbatim Text will be listed.

Tables that summarize AEs by SOC and PT will use MedDRA preferred terms, as well as any adverse event tables required for disclosure. Most other AE tables will summarize AEs by using the combined terms defined in Appendix 14, as detailed in the programming notes in Appendix 12. A summary of incidence of adverse events by MedDRA preferred grouped by combined preferred term will be produced to indicate the combined preferred terms.

AEs will be graded by the investigator according to the National Cancer Institute-Common Toxicity Criteria for Adverse Events (NCI-CTCAE) v4.03. Refer to Section 8.5 and Section 8.6 of Protocol for the definitions and the grading of CCI [redacted] CCI [redacted] and Graft versus Host Disease (GvHD). Following protocol amendment 5 CCI [redacted] vents are graded using the American Society for Transplantation and Cellular Therapy grading system [Lee, 2019].

In the eCRF for this study Adverse Events for which the grade changes over the course of the event are entered as multiple records, one record per grade. (If multiple grades are experienced on the same day then the highest grade for that day is reported.) Similarly, events where other attributes such as relatedness change over the course of the event will also be entered as multiple records. For analyses requiring summaries of numbers or characteristics of individual events, these multiple sequential segments will be collapsed back into a single event record prior to analysis using the algorithm detailed in Appendix 15.

At the final analysis retreatment data will be included. Summaries of AEs will report on combined 1st and 2nd infusion AE data. AE listings will be repeated excluding the retreatment data. CCI [redacted] CCI

Adverse Events with onset on or after lymphodepletion chemotherapy start date are considered treatment emergent. (See Appendix 4 for details.) The frequency and percentage of all AEs (all grades) and (separately) all treatment emergent AEs will be summarized and displayed in descending order of total incidence by System Organ Class (SOC) and Preferred Term (PT). In the SOC row, the number of participants with multiple events under the same system organ class will be counted once. A separate summary of SAEs by SOC and PT will be produced detailing numbers of participants and number of occurrences.

Summaries of the number and percentage of participants with AEs by maximum grade will be produced as indicated in Appendix 12. In these displays AEs will be sorted by combined PT in descending order of total incidence and will use the following algorithms for counting participants:

- **Preferred term row**: Participants experiencing the same AE preferred term several times with different grades will only be counted once with the maximum grade.
- **Any event row**: Each participant with at least one AE will be counted only once at the maximum grade no matter how many events they have.

Separate summaries will be provided for AEs (and SAEs) related to study treatments: one for lymphodepleting chemotherapy-related (S)AEs, one for T-cell infusion-related (S)AEs, and one for all study treatment related (S)AEs.

A study treatment-related AE is defined as an AE for which the investigator classifies the relationship to study treatment as "Yes", which includes "Definitely Related", "Probably Related" or "Possibly Related". A worst-case scenario approach will be taken to handle missing relatedness data, i.e. the summary table will include events with the relationship to study treatment as 'Yes' or missing.

Summaries of total incidence and frequency and percentage of grade 3, 4, and 5 events will be presented for: all AEs, all treatment emergent AEs, all study-treatment related AEs, all T-cell related AEs, all lymphodepletion related AEs, and all serious AEs.

A summary of non-serious AEs that occurred in strictly 5% of the participants or above will be provided (no rounding for the percentage will be used in terms of 5% threshold, e.g. events with 4.9% incidence rate should not be included in this table). This summary will contain the number and percentage of participants and the number of occurrences of common non-serious adverse events. The summary table will be displayed by SOC and PT.

A listing of delayed AEs as adjudicated by GSK will be provided. GSK adjudicated AEs will be provided as an additional data source.

In the event that a participant has withdrawn consent for primary research use, no data after the withdrawal of consent date from this participant including death is supposed to appear in the database and should be part of the data cleaning process. All deaths will be summarized based on the number and percentage of participants. This summary will classify participants by time of death relative to the date of T-cell infusion (>30 days or ≤30 days) and primary cause of death (disease under study, treatment related toxicity, or other). A supportive listing will be generated.

8.2. Adverse Events of Special Interest Analyses

The adverse events of special interest (AESI) are as follows:

- CCI [redacted]
- Haematopoietic cytopenias (including pancytopenia and aplastic anaemia)
- Graft versus host disease (GvHD)
- Immune Effector-Cell Associated Neurotoxicity Syndrome (ICANS)
- Guillain-Barre syndrome

Lists of MedDRA terms based on clinical review will be used to identify each type of event. For each type of event, both focused and comprehensive lists will be used. In addition, for haematopoietic cytopenias, three distinct subsets of the focused list corresponding to Neutropenia, Thrombocytopenia and Anemia will be considered, as well as Febrile neutropenia identified by single preferred term. Changes to the MedDRA dictionary may occur between the start of the study and the time of reporting and/or emerging data from on-going studies may highlight additional adverse events of special interest, therefore the list of terms to be used for each event of interest and the specific events of interest will be based on the safety review team (SRT) agreements in place at the time of reporting.

AESI tables will be reported for the mITT population, considering only treatment-emergent events.

The details of the planned displays are provided in Appendix 12.

Listings of AESIs will be produced for each AESI category using the focused list, which will include leukapheresis date, lymphodepletion start date, T-cell infusion date, AE start date, AE end date, SAE code, grade, relationship to study treatment and outcome of event. A corresponding listing of haematopoietic cytopenias identified using the comprehensive list will also be provided.

At the final analysis retreatment data will be included. Summaries of AESIs will report on combined 1st and 2nd infusion AE data. AESI listings will be repeated excluding the retreatment data. CCI [redacted]
CCI [redacted]

The number and percentage of participants with these events will be summarized by categories of AESI and preferred term, with one table for AESIs identified using the focused lists (using combined preferred terms) and another for AESIs identified using the comprehensive lists (not using combined preferred terms).

A summary of event characteristics for each category of treatment emergent AESI as identified using the focused lists will be provided, including number of participants with any event, number of events, number of participants with any event that is serious, number of participants with any event that is related to study treatment, the outcome of the event and the maximum grade for the event. The percentage will be calculated in two ways, one with number of participants with event as the denominator and the other with total number of participants as the denominator. The worst-case approach will be applied at participant level for the event outcome and maximum grade, i.e. a participant will only be counted once as the worst-case from all the events experienced by the participant. For action taken to an event, participant will be counted once under each action, e.g. if a participant has an event leading to both study treatment discontinuation and dose reduction, the participant will be counted once under both actions.

Summaries of onset and duration of the first occurrence will be created for each AESI, identified using the focused lists. For Haematopoietic cytopenias this will include an overall analysis of events in the focused list as well as separate analyses for cell lines describing events of Neutropenia, Thrombocytopenia and Anemia. A summary of onset and duration of the last occurrence of Haematopoietic cytopenias identified using the focused list will also be created. These summaries will exclude any retreatment emergent AESIs.

In addition, summaries of time to resolution of clinically significant (Grade 3 and above) Haematopoietic cytopenias will be created separately for the focused list of PTs, Neutropenia, Anemia, Thrombocytopenia, and Febrile Neutropenia. This analysis will use Kaplan-Meier methodology to report the median time to resolution and probability of resolution of adverse events by study day 30 and study day 90 for three types of clinically significant events: Initial occurrences, Recurrences, and delayed onset events. These summaries will exclude any retreatment emergent AESIs.

- Time to resolution is defined as the time (in days) between the date of 1st T-cell infusion and the AE resolution end date inclusive.
- Initial occurrences are defined as treatment-emergent Grade 3 and above cytopenias which start on or before Day 30.
- Recurrences are defined as treatment-emergent Grade 3 and above cytopenias which start after Day 30, in subjects which had an initial occurrence.
- Delayed onset events are defined as treatment-emergent Grade 3 and above cytopenias which start after Day 30, in subjects which *did not* have an initial occurrence.

For subjects which have multiple events, the worst-case event will be summarized. If the subject had an unresolved event, this is considered worst-case and the subject will be censored. If not, the adverse event that resolved at the latest study day is the worst-case

event. Additionally, the duration of the chosen worst-case event will be summarized separately for all three types of AEs.

Subjects with unresolved events will be censored at the completion/withdrawal of the interventional phase or date of last contact if the subject has not completed/withdrawn from the interventional phase. See below for detailed censoring rules.

Scenario	Date of Event (AE Resolution), or Censored	Event (AE Resolution), Censored
Adverse event resolves (AE end date is populated)	Adverse event end date	Event
Adverse event does not resolve, and participant completes or withdrawals from the interventional phase of the study	Interventional phase completion/withdrawal date	Censored
Adverse event does not resolve, and participant is ongoing in the interventional phase of the study	Date of last contact	Censored

Characteristics, Onset and Duration, and Time to Resolution summaries will not be created if there are 0 or 1 AESI in total.

8.2.1. CCI [redacted] and Graft versus Host Disease (GvHD)

Refer to Section 8.5 and Section 8.6 of Protocol for the definitions and the grading of CCI [redacted] and GvHD. The listing of CCI [redacted] ESIs will also include time from infusion to first CCI [redacted] (days) and time from infusion to max CCI [redacted] (days). Listings of symptoms and treatments related to CCI [redacted] and (separately) GvHD will be produced from the AESI forms, and a listing of all tocilizumab administrations recorded as concomitant medications presented as detailed in Appendix 12.

At the final analysis the listing of symptoms and treatments related to CCI [redacted] and listing of tocilizumab administrations will be repeated on the ITT population excluding retreatment data. CCI [redacted]
CCI [redacted]

8.3. Clinical Laboratory Analyses

Laboratory evaluations including the analyses of Chemistry laboratory tests, Hematology laboratory tests, and other laboratory tests will be based on GSK Core Data Standards. The details of the planned displays are in Appendix 12.

The laboratory assessments conducted to monitor participant safety are in Table 2.

Table 2 List of Clinical Laboratory Tests

Hematology, Chemistry and Urinalysis Variables	
Clinical Chemistry	**Hematology**
Total Calcium Calcium corrected for Albumin Phosphorus Magnesium Albumin Bilirubin Alanine aminotransferase Aspartate aminotransferase Alkaline phosphatase LDH Sodium Potassium Bicarbonate Creatinine* Chloride Glucose BUN or Urea * In participants ≥65 years, add GFR	Red blood cell count Hemoglobin Hematocrit Mean cell volume Mean corpuscular hemoglobin Mean corpuscular hemoglobin concentration Platelet count White blood cell count White blood cell differential absolute counts of lymphocytes, monocytes, and neutrophils White blood cell differential percentages of lymphocytes, monocytes, and neutrophils
	Lymphocyte subsets
	Lymphocyte subsets including CD3 T-cell (absolute) count
Other Tests	**Coagulation Screen**
Uric Acid C-reactive protein	Prothrombin time or International Normalized Ratio Activated partial tissue thromboplastin time
Pregnancy Test	**Thyroid Function Tests**
Serum beta-HCG or Urine test	Thyroid Stimulating Hormone (TSH) Free T3 Free T4
Urinalysis	**Microbiology**
Glucose Ketones Specific gravity Protein Blood Microscopy Bilirubin pH	**Infectious disease screen** HIV 1+2 antibody Hepatitis B surface antigen Hepatitis B core antibody – if positive, test for HBV DNA Hepatitis C antibody – if positive, test for HCV RNA HTLV 1+2 IgG CMV IgG EBV (EBNA) Treponema (Syphilis) **Viral reactivation** CMV DNA PCR – peripheral blood for detection of reactivation. In the event of suspected end organ CMV disease a biopsy may be required

Laboratory grades will be reported using the CTCAE v4.03.

Summary of the change from baseline using n, mean, median, standard deviation, minimum, and maximum will be provided. These summaries will exclude any retreatment assessments.

Supporting line graphs of neutrophils, platelets, hemoglobin, and lymphocytes over time will also be produced. These figures will exclude any retreatment assessments.

Summaries of worst-case grade increase from baseline grade at Week 4, Week 12 and across all post-baseline assessments will be provided for all the lab tests that are gradable by CTCAE v4.03. These summaries will display the number and percentage of participants with a maximum post-baseline grade increase from their baseline grade. [redacted] as grade 0. For laboratory tests that are graded for both low and high values, summaries will be done separately and labeled by direction, e.g. sodium will be summarized as hyponatremia and hypernatremia. These summaries will exclude any retreatment assessments.

For lab tests that are not gradable by CTCAE v4.03, summaries of worst-case changes from baseline with respect to normal range will be generated. The worst-case will be chosen from all available tests, including scheduled and unscheduled visits. Decreases to low, changes to normal or no changes from baseline, and increases to high will be summarized for the worst-case post-baseline. If a participant has a decrease to low and an increase to high during the same time interval, then the participant is counted in both the "Decrease to Low" categories and the "Increase to High" categories. These summaries will exclude any retreatment assessments.

Separate summary tables for hematology, chemistry, other laboratory tests will be produced.

A supporting listing of laboratory data for participants with any value outside normal range will be provided. A separate listing of laboratory data with character values will also be provided. At the final analysis these listings will be repeated on the ITT population excluding retreatment data. [redacted]

Detailed derivation of baseline assessment is specified in Section 5.2.

Unless otherwise specified, the denominator in percentage calculation at each scheduled visit will be based on the number of participants with non-missing value at each particular visit.

8.3.1. Analyses of Liver Function Tests (LFT)

Listings of hepatobiliary laboratory events including possible Hy's law cases will be provided in addition to what has been described above, including listings of liver monitoring and stopping events as well as a listing of subjects meeting hepatobiliary laboratory criteria post-baseline.

Possible Hy's law cases are defined as any elevated (ALT≥3×ULN **and** total bilirubin≥2×ULN (with direct bilirubin ≥35% of total bilirubin, if direct bilirubin is measured)) **OR** (ALT ≥3×ULN **and** INR >1.5, if INR is measured). Note that INR measurement is not required, and the threshold value stated will not apply to participants receiving anticoagulants.

A scatter plot of maximum total bilirubin versus maximum ALT will be generated. Also a scatter plot of maximum vs baseline for ALT will be produced. These figures will exclude any retreatment assessments.

8.4. 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 Appendix 12.

8.4.1. ECOG Performance Status

Eastern Cooperative Oncology Group (ECOG) performance status will be summarized at baseline and last assessment by frequency and percentage of participants. A summary of change from baseline by scheduled visits will be performed, as well as the worst-case post-baseline and the best-case post-baseline changes during the study (improved, no change, deteriorated). These summaries will exclude any retreatment assessments.

A supporting listing will also be provided. At the final analysis this listing will be repeated on the ITT population excluding retreatment data. CCI [redacted]

8.4.2. ECG

A summary of the number and percentage of participants who had normal and abnormal (clinically significant and not clinically significant) ECG findings will be displayed by scheduled visits as well as for the worst-case post-baseline. The worst-case will be chosen from all available ECG findings, including scheduled and unscheduled visits. These summaries will exclude any retreatment assessments.

A summary of change from baseline in ECG values will be produced. This summary will exclude any retreatment assessments.

The number of participants with maximum QTc values (i.e., worst-case) post-baseline relative to baseline will be summarized by test (e.g., QTcF Interval, Aggregate) and category. Also, a summary by a categorization of participants' maximum increase (i.e., worst-case) in QTc value (e.g., QTcF Interval, Aggregate) post-baseline relative to baseline will be produced by category (e.g. Increase of 31-60 msec from baseline value). These summaries will exclude any retreatment assessments.

Summaries of QTc values will incorporate corrections based on Friderica's or Bazett's formula separately (with values referred to as QTcF and QTcB, respectively).

Listings of abnormal ECG findings and a listing of ECG values will be provided. At the final analysis the listing of ECG values will be repeated on the ITT population excluding retreatment. CCI [redacted]

A figure plotting QTc shift from baseline to worst-case post baseline will be produced, with separate plots for the 2 correction methods (QTcF and QTcB). Plots within the figure will have reference lines at 480 and 500 msec for both the ordinate and the abscissa axes. There will be diagonal reference lines at equality (i.e. a 45-degree line), at equality plus 30 msec, and at equality plus 60 msec. These figures will exclude any retreatment assessments.

8.4.3. Vital Signs

A summary of change from baseline in vital signs will be provided. Also, a summary of worst-case vital signs results by Potential Clinical Importance (PCI, defined in Appendix 8) criteria post-baseline relative to baseline will be generated. These summaries will exclude any retreatment assessments.

A listing of vital signs with values of PCI will be provided. At the final analysis this listing will be repeated on the ITT population excluding retreatment data. CCI [redacted] CCI [redacted] CCI [redacted]

8.4.4. Pregnancies

Pregnancy (or pregnancy of a male participant's partner) is not considered an AE/SAE unless there is reason to believe that the pregnancy may be the result of failure of the contraceptive being used due to interaction with the study drug. However, the investigator shall report all pregnancies immediately to the Sponsor. If participants or participants' partner become pregnant while on the study, the information will be included in the narratives and no separate table or listing will be produced.

8.4.5. Replication Competent Lentivirus (RCL)

The proportion of participants who are RCL positive will be summarized. RCL is reported as "Negative" if copies of VSV-G are <50 copies/µg gDNA.

RCL results will also be presented in a data listing. At the final analysis, this listing will be repeated on the mITT population excluding retreatment data. CCI [redacted] CCI [redacted] retreatment day as defined in Section 14.6.1.

8.4.6. PBMCs

The proportion of patients showing >1% gene marked Peripheral Blood Mononuclear Cells (PBMCs) at one year or beyond post 1st T-cell infusion (excluding persistence measurements after 2nd infusion in retreated participants) will be summarized if data warrant.

Further details of the handling of persistence data are given in the Pharmacokinetic Section 9.

8.4.7. COVID-19

A listing of all COVID-19 assessments, including test date and result, along with symptom assessments will be provided.

9. PHARMACOKINETIC ANALYSES

9.1. Persistence of NY-ESO-1^{c259}T

Following protocol amendment 6, characterization of the in vivo pharmacokinetic profile (levels, cell expansion, persistence) of NY-ESO-1 specific (c259) cells is a secondary objective of the study.

9.1.1. Endpoint/Variables

GSK3377794 T-cell vector copies (persistence) in the peripheral blood will be measured in participants by quantitation of transduced cells by PCR of transgene from DNA extracted from PBMC.

9.1.1.1. Drug Concentration Measures

The following calculations will be performed:

copies/cell is calculated with the following formula:

copies/cell=(copies/µg) x (0.0000063 µg gDNA/cell)

Percent gene marked peripheral blood mononuclear cells (PBMCs) = (copies/cell) *100

The final reported result of copies/µg gDNA is calculated as follows:

copies/µg gDNA=copies per well/µg gDNA per well

For persistence value below the lower limit of quantification (LLOQ), the following rules will be applied:

Reported Copies per cell Result	Reported Copies per µg gDNA Result	Reported Result	Set Value for Copies per cell	Set Value for Copies per µg gDNA
<0.0003	<50.0	Negative	0	0
<0.0003	<50.0	Detectable, <LLOQ	0.0003	50

Note, sometimes values for copies per cell and copies per µg gDNA might be different than above as it depends on the input of DNA, but rule would be the same:

- If interpretive reported result is negative, set values at 0.
- If interpretive reported result is “Detectable, <LLOQ”, set values at LLOQ (If <XXX, set at XXX)

The unit for persistence will be "Copies/µg of gDNA"

Time to loss of 25% of peak cell expansion will be calculated as the time since 1st T-cell infusion corresponding to observing at least 25% loss of peak cell expansion. If time to 25% loss of peak cell expansion is not observed, the last observed time will be reported with a "+" appended to the numerical result. The same procedure will be followed for 50% and 75%.

Duration of detectable persistence is defined as time from 1st T-cell infusion until persistence is no longer detectable. Persistence above the assay limit of detection but below the lower limit of quantification is considered for the duration determination, i.e. the time window from infusion until the first instance persistence falls below the detection limit and the interpretive reported result is "Negative." If persistence for a given subject remains detectable ("Positive" or "Detectable, LLOQ") at their last sample collection timepoint, the last observed time is reported and considered as right-censored with a "+" appended to the numerical result. Note, transduced T-cells frequently persist beyond the follow-up period, and hence, the reported duration is directly influenced by length of time the patient is on-study.

9.1.1.2. Derived Pharmacokinetic Parameters

The following PK parameters will be derived:

- C_{max}: Peak cell expansion during the interventional phase (i.e. excluding retreatment)
- T_{max}: Time to peak cell expansion during the interventional phase (i.e. excluding retreatment)
- $AUC_{0–28d}$: Area under the plasma concentration-time curve from 1st T-cell infusion to day 28

The area under the plasma concentration-time curve from 1st T-cell infusion to day 28 ($AUC_{0–28d}$) will be determined using the linear trapezoidal rule for each increasing concentration trapezoid and the logarithmic trapezoidal rule for each decreasing concentration trapezoid. $AUC_{0–28d}$ will not be calculated for participants without a concentration measurement within 4 days of day 28.

Derivation will be the responsibility of the Statistics and Programming group at PAREXEL under the direction of the Clinical Pharmacology Modelling and Simulation (CPMS) Department at GSK.

Peak cell expansion during the interventional phase (C_{max}), time to peak cell expansion (T_{max}), and as data permit, $AUC_{0–28d}$ will be summarized overall and for responders and non-responders using descriptive statistics and dot plots.

9.1.2. Summary Measure

Spider plots will be used to graphically summarize persistence (copies/µg gDNA) over time for each participant by responders and non-responders. These figures will exclude any retreatment assessments.

A listing of persistence will be provided and will include coefficient of variation, number of positive replicates, copies/cell, copies/µg gDNA, percent gene marked cells of PBMCs (%), interpretive result, C_{max}, T_{max}, AUC_{0-28d}, duration of detectible persistence and time to loss of 25%/50%/75% peak cell expansion.

For each of these parameters, except T_{max}, the following summary statistics will be calculated: n, median, minimum, maximum, arithmetic mean, 95% confidence interval for the arithmetic mean, standard deviation, coefficient of variation (coefficient of variation (CV) = 100*(sqrt (exp(SD^2) - 1))) [NOTE: SD = SD of natural log transformed data]), geometric mean, 95% confidence interval for the geometric mean and standard deviation of natural logarithmically transformed data. Data will be summarized by lymphodepletion regimen and overall.

For T_{max}, calculations will include n, median, maximum, minimum, arithmetic mean, 95% confidence interval, and standard deviation. Data will be summarized by lymphodepletion regimen and overall.

These summaries will exclude any retreatment assessments.

At the final analysis the listing of persistence will be repeated on the mITT population excluding retreatment data. CCI [redacted] CCI [redacted]

9.1.3. Population of Interest

All analyses of persistence will be based on the mITT population, unless otherwise specified.

CCI [redacted]

10. BIOMARKER ANALYSES

10.1. Biomarker Analyses

10.1.1. Endpoint/Variables

[redacted], immunohistochemistry and anti-NYESO antibody formation may be reported if data warrant. Any additional [redacted]

10.1.2. Summary Measure

10.1.2.1. Integration Site Analysis

If persistence, as detected by the presence of vector sequences (WPRE or Psi DNA copies), is present in >1% of PBMC at 1 year or beyond post 1st T-cell infusion, Next-Gen Sequencing of DNA from the participant's PBMCs will be performed for integration site analysis to assess clonality and possible insertional oncogenesis.

A summary of the number of subjects with any number of clones with >20% abundance will be summarized (excluding any retreatment assessments). A supporting listing will be provided.

Two diversity indices, Shannon diversity index and Gini index, will be reported in the data listing. These indices can help summarize the composition of a population of clones. Shannon diversity is a measurement that represents the uncertainty about the identity of a single species within the population [Shannon, 1948]. The Gini index can help detect the similarity in abundance of different clones across the population [Gini, 1914].

At the final analysis the listing of integration site analysis will be repeated on the mITT population excluding the retreatment data. [redacted]

[redacted]

CCI

10.1.3. Population of Interest

The primary biomarker analyses will be based on the mITT population, unless otherwise specified.

11. POPULATION PHARMACOKINETIC (POPPK) ANALYSES

Not applicable in this RAP but may be described in a separate Biomarker Analysis Plan.

12. PHARMACOKINETIC / PHARMACODYNAMIC ANALYSES

Not applicable in this RAP but may be described in a separate Biomarker Analysis Plan.

13. REFERENCES

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14. APPENDICES

14.1. 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 Specification document.

14.2. Appendix 2: Schedule of Activities

14.2.1. Protocol Defined Schedule of Events

See protocol Section 7.3.

14.3. Appendix 3: Assessment Windows

No assessment window will be applied.

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

14.4.1. Study Phases

14.4.1.1. Study Phases for Concomitant Medication

Study Phase	Definition
Prior	End date of medication is not missing and is before the start date of lymphodepletion OR lymphodepletion chemotherapy start date is missing
Concomitant	Any medication that is not a prior

NOTES:

- Please refer to Appendix 7 for handling of missing and partial dates for concomitant medication. Use the rules in this table if concomitant medication date is completely missing.

Concomitant medications during retreatment will be identified those concomitant medications (as defined above) for which: End date of medication is missing OR End date of medication is non-missing and is on or after start date of retreatment lymphodepletion.

14.4.1.2. Study Phases for Anti-Cancer Therapy/Surgery

Study Phase	Definition
On-Study	Start date is on or after the first day of lymphodepletion chemotherapy (both start date and lymphodepletion chemotherapy start date not missing).
Prior	Not classified as On-Study.

NOTES:

- Please refer to Appendix 7 for handling of missing and partial dates for anti-cancer therapy

The prior phase will be further subdivided into sub-phases as follows:

Study Phase	Definition
prior to advanced diagnosis	If classified as prior and entered on the screening visit 2 eCRF with start date missing or before the date of diagnosis of metastatic disease.
advanced diagnosis to leukapheresis	If classified as prior and entered on the screening visit 2 eCRF with start date on or after the date of diagnosis of metastatic disease.
leukapheresis to lymphodepletion	If classified as prior and not entered on the screening visit 2 eCRF.

NOTES:

- Please refer to Appendix 7 for handling of missing and partial dates for anti-cancer therapy

On-Study Anti-Cancer Therapy/Surgeries during retreatment will be identified those on-study Anti-Cancer Therapy/Surgeries (as defined above) for which the start date is on or after the first day of retreatment lymphodepletion chemotherapy (both start date and retreatment lymphodepletion chemotherapy start date not missing).

14.4.1.3. Treatment Emergent Flags for Adverse Events

Flag	Definition
Treatment Emergent	• If AE onset date is on or after lymphodepletion chemotherapy start date. (Lymphodepletion Start Date ≤ AE Start Date) • If AE onset date is missing and AE end date is before the lymphodepletion start date, then the AE will not be classified as Treatment-Emergent. If AE onset date is missing and AE end date is either missing or on or after lymphodepletion start date, then the AE will be classified as treatment-emergent • Partially missing AE onset and end dates will be imputed following rules in Section 14.7.2.1 for determining Treatment Emergent AEs.
Retreatment Emergent	• If AE onset date is on or after retreatment lymphodepletion chemotherapy start date. (Retreatment Lymphodepletion Start Date ≤ AE Start Date) • If AE onset date is missing and AE end date is before the retreatment lymphodepletion start date, then the AE will not be classified as Retreatment Treatment-Emergent. If AE onset date is missing and AE end date is either missing or on or after retreatment lymphodepletion start date, then the AE will be classified as retreatment-emergent. • Partially missing AE onset and end dates will be imputed following rules in Section 14.7.2.1 for determining Treatment Emergent AEs, but using retreatment lymphodepletion start date as the reference date. • If the participant did not start retreatment lymphodepletion chemotherapy then no AEs are retreatment emergent. • Note that retreatment emergent AEs are also treatment emergent.

14.4.1.4. Medical History

Study Phase	Definition
Past	Medical condition is not marked as ongoing on eCRF
Current	Medical condition is not past

14.4.1.5. Retreatment Assessments/Data

Retreatment assessments/data will be identified for a participant as:

- data entered on a retreatment specific eCRF (even if the participant was not retreated), and
- records for events entered on other eCRF forms (e.g. Adverse Events) with start dates on or after the date of start of retreatment lymphodepletion chemotherapy (for participants who start retreatment lymphodepletion chemotherapy).

Detailed specifications (including handling of partial event dates) will be included in dataset specifications.

14.5. Appendix 5: Data Display Standards & Handling Conventions

14.5.1. Reporting Process

Software	
• The currently supported versions of SAS software will be used.	
Reporting Area	
HARP Server	: US1SALX00259
HARP Compound	: arprod\GSK3377794\mid208469
Analysis Datasets	
• Analysis datasets will be created according to CDISC standards (SDTM IG Version 3.2 & ADaM IG Version 1.1].	
Generation of RTF Files	
• RTF files will be generated for IA2 and the primary and final analyses.	

14.5.2. 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 4.24: General Principles
  • 5.01 to 5.09: Principles Related to Data Listings
  • 6.01 to 6.11: Principles Related to Summary Tables
  • 7.01 to 7.13: Principles Related to Graphics
• Do not include participant level listings in the main body of the GSK Clinical Study Report. All participant level listings should be located in the modular appendices as ICH or non-ICH listings.
• While text within this RAP uses the term “participant”, all data displays (Tables, Figures, and Listings) will use the term “subject”, reflecting CDISC and GSK Data Display Standards terminology.

Formats
• GSK IDSL Statistical Principles (4.24) 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	
• Unscheduled visits will not be included in summary tables and figures, except in cases where worse-case post-baseline is calculated. • All unscheduled visits will be included in listings.	
Descriptive Summary Statistics	
Continuous Data	Refer to IDSL Statistical Principle 6.06.1
Categorical Data	N, n, frequency, %
Graphical Displays	
• Refer to IDSL Statistical Principals 7.01 to 7.13.	

14.6. Appendix 6: Derived and Transformed Data

14.6.1. General

Multiple Measurements at One Analysis Time Point
• For cytokines, as some samples taken at baseline were analyzed repeatedly alongside samples from subsequent visits, where there are multiple analyses of the baseline sample, the first analysis should be taken as the baseline value. • Mean of the measurements will be calculated and used in any derivation of summary statistics but if listed, all data will be presented. • For character variables, if multiple assessments on different days are reported for the same scheduled assessment, then the worst-case assessment for that scheduled assessment will be analyzed. • Participants having both High and Low values for Normal Ranges at any post-baseline visit for safety parameters will be counted in both the High and Low categories of "Any visit post-baseline" row of related summary tables. This will also be applicable to relevant Potential Clinical Importance summary tables.
Study Day

• Calculated as the number of days from 1st T-cell infusion date:
  • Ref Date = Missing → Study Day = Missing
  • Ref Date < 1st T-cell infusion Date → Study Day = Ref Date – 1st T-cell infusion Date
  • Ref Data ≥ 1st T-cell infusion Date → Study Day = Ref Date – 1st T-cell infusion Date + 1

Retreatment Day

• Calculated as the number of days from 2nd T-cell infusion date:
  • Ref Date = Missing → Study Day = Missing
  • Ref Date < 2nd T-cell infusion Date → Study Day = Ref Date – 2nd T-cell infusion Date
  • Ref Data ≥ 2nd T-cell infusion Date → Study Day = Ref Date – 2nd T-cell infusion Date + 1

Change from Baseline
• Change from Baseline = Post-Baseline Visit Value – Baseline • % Change from Baseline= 100 x (Post-Baseline Visit Value – Baseline) / Baseline • Maximum Increase/Decrease from Baseline = maximum (Increase/Decrease from Baseline) • If either the Baseline or Post-Baseline Visit Value is missing, Change from Baseline and % Change from Baseline is set to missing
Date of Response
• For post-baseline disease assessments, the date of response (PR, CR) is assigned to the latest date of disease assessments; for other response categories (SD, NE, PD), the date of response is assigned to the earliest date of disease assessments.
Date of New Anti-Cancer Therapy
• Derived as the earliest date of on-study anti-cancer therapy, radiotherapy (where applicable) or cancer-related surgical procedure (where applicable). • Missing or partial dates will be imputed for derivation of new anti-cancer therapy following rules specified in section Appendix 7.

14.6.2. Study Population

Age
• For participants with a 1st T-cell infusion date, age is derived using 1st T-cell infusion date as the reference date. For ITT participants without a 1st T-cell Infusion date, date of eligibility for leukapheresis is used as the reference date.
Body Mass Index (BMI)
• (Weight in kg) / (Height in meters)^2
Body Surface Area (BSA) (m^2) (Dubois-Dubois Formula)
• 0.007184 * Height(cm)$^{0.725}$ * Weight(kg)$^{0.425}$
Time Since Initial Diagnosis to Screening
• Time (in months) since initial diagnosis to screening will be calculated as: (Date of (last) Screening Consent - Date of Initial Diagnosis +1) / 30.4375
Time Since Metastatic Disease to Screening
• Time (in months) since metastatic disease to screening will be calculated as: (Date of (last) Screening Consent - Date of Diagnosis of Metastatic Disease +1) / 30.4375
On-study Treatment Follow-up Time
• Time (in months) from T-cell infusion to end of follow-up will be calculated as: (Date of Death/Last Contact - T-cell Infusion Date -+1) / 30.4375

14.6.3. Efficacy

Refer to Section 7 for endpoint derivation information.

Secondary and Exploratory Duration and Time to Endpoints
Durations and intervals in months
• Durations and intervals to be presented in months will be calculated in days and converted to months by dividing by 30.4375.
Secondary Endpoints
Date of Last Contact
• Last date in all SDTM domains • If patient died, the last contact date should be death date. • Dates after date of death will be excluded. Future dates will be excluded. • SDTM domain SE and SUPPBE will be excluded and SDTM variables DM.BRTHDTC, MH.MHSTDTC, SV.SVENDTC, SV.SVSTDTC, DM.RFPENDTC, _ALL_.ANALDTC, DV.DVDTC, DV.DVSTDTC and any other external source data dates (such as RS.RSDTC where RSEVAL='INDEPENDENT ASSESSOR') as necessary will be excluded • Partial and missing dates will not be imputed for the purpose of deriving date of last contact

14.6.4. Safety

Adverse Events
AEs of Special Interest
See Section 8.2.
Duration of AE
• Calculated as the number of days from AE Start Date to AE Stop Date: ○ AE Start Date = Missing → Elapse Time = Missing ○ AE Stop Date = Missing → Elapse Time = Missing ○ Otherwise → Elapsed Time = AE Stop Date – AE Start Date + 1 Imputed dates will not be used to calculated AE duration

14.7. Appendix 7: Reporting Standards for Missing Data

14.7.1. Premature Withdrawals

Element	Reporting Detail
General	• Completion of the interventional phase is defined for the purposes of analysis as having received NY-ESO-1^{c259}T cell infusion and been followed-up until confirmed progression of disease, death or for 2 years after NY-ESO-1^{c259}T cell infusion, whichever is shorter. • 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.

14.7.2. Handling of Missing Data

Element	Reporting Detail
General	• Missing data occurs when any requested data is not provided, leading to blank fields on the collection instrument: o These data will be indicated by the use of a "blank" in participant listing displays. Unless all data for a specific visit are missing in which case the data is excluded from the table. o Answers such as "Not applicable" and "Not evaluable" are not considered to be missing data and should be displayed as such.
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.

14.7.2.1. Handling of Missing and Partial Dates

Imputed partial dates can be used to derive study day, duration, or elapsed time variables unless otherwise specified. CCI [redacted] CCI [redacted]

Imputed dates will not be displayed in listings, nor will any study days, durations or elapsed time variables derived from imputed dates. For listings the SDTM character date variables will be displayed. The imputed dates can be used for sorting the data for listings. In addition, partial dates may be imputed for 'slotting' data to study phases (see Section 14.4.1) or for specific analysis purposes as outlined below.

The partial date imputation will follow ADaM conventions. The ADaM approach is to populate the numeric date variables with the imputed date and add a flag variable to the dataset that indicates the level of imputation.

The flag variable can contain the values: blank, 'D', 'M', 'Y'.

blank: indicates that no imputation was done

D='Day': indicates that the day portion of the date is imputed

M='Month': indicates that the month and day portions of the date are imputed

Y='Year': indicates that the entire date (year, month, and day) is imputed

Example of date variables:

XYZDTC − character date variable

XYZDT − numeric date variable

XYZDTF − date imputation flag variable

Details on imputing partial dates for specific datasets are outlined below.

<table>
<tr><th>Element</th><th>Reporting Detail</th></tr>
<tr><td>General</td><td>• Partial dates will be displayed as captured in participant listing displays.</td></tr>
<tr><td>Adverse Events</td><td>• Imputations in the adverse events dataset are used for slotting events to the appropriate study time periods and for sorting in data listings. Imputed dates will not be used to calculated AE duration.
• Partial dates for AE recorded in the CRF will be imputed using the following conventions:

<table>
<tr><td>Missing start day</td><td>• If lymphodepletion start date is missing (i.e. participant did not start lymphodepletion), then set start date = 1st of month.
• Else if lymphodepletion start date is not missing:
o If month and year of start date = month and year of lymphodepletion start date then
▪ If stop date contains a full date and stop date is earlier than lymphodepletion start date then set start date= 1st of month.
▪ Else set start date = lymphodepletion start date.
o Else set start date = 1st of month.</td></tr>
<tr><td>Missing start day and month</td><td>• If lymphodepletion start date is missing (i.e. participant did not start lymphodepletion), then set start date = January 1st.
• Else if lymphodepletion start date is not missing:
o If year of start date = year of lymphodepletion start date then
▪ If stop date contains a full date and stop date is earlier than lymphodepletion start date then set start date = January 1st.
▪ Else set start date = lymphodepletion start date.
o Else set start date = January 1st.</td></tr>
<tr><td>Missing stop day</td><td>Last day of the month will be used.</td></tr>
<tr><td>Missing stop day and month</td><td>No Imputation</td></tr>
<tr><td>Completely missing start/end date</td><td>No imputation</td></tr>
</table>
</td></tr>
<tr><td>Anti-Cancer Therapy and Radiotherapy</td><td>• Completely missing start or end dates will remain missing, with no imputation applied.
• If partial start date contains a year only set to January 1st.
• If partial start date contains a month and year set to the 1st of the month.
• No imputation for partial end dates will be performed.</td></tr>
<tr><td>Surgical Procedures</td><td>• No Imputation for completely missing dates
• If partial date contains a year only set to January 1st.
• If partial date contains a month and year set to the 1st of the month</td></tr>
</table>

<table>
<tr><th>Element</th><th>Reporting Detail</th></tr>
<tr><td>Concomitant Medications/ Blood Products</td><td>

These imputation rules will be used for classifying a medication as prior or concomitant
Completely missing start dates will not be imputed
Partial dates for any concomitant medications recorded in the CRF will be imputed using the following convention:

<table>
<tr><td>Missing start day</td><td>• If study lymphodepletion date is missing (i.e. participant did not start lymphodepletion), then set start date = 1st of month.
• Else if lymphodepletion start date is not missing:
o If month and year of start date = month and year of lymphodepletion start date then
▪ If stop date contains a full date and stop date is earlier than lymphodepletion start date then set start date= 1st of month.
▪ Else set start date = lymphodepletion start date.
o Else set start date = 1st of month.</td></tr>
<tr><td>Missing start day and month</td><td>• If lymphodepletion start date is missing (i.e. participant did not start lymphodepletion), then set start date = January 1st.
• Else if lymphodepletion start date is not missing:
o If year of start date = year of lymphodepletion start date then
▪ If stop date contains a full date and stop date is earlier than lymphodepletion start date then set start date = January 1st.
▪ Else set start date = lymphodepletion start date.
• Else set start date = January 1st.</td></tr>
<tr><td>Missing end day</td><td>A '28/29/30/31' will be used for the day (dependent on the month and year)</td></tr>
<tr><td>Missing end day and month</td><td>A '31' will be used for the day and 'Dec' will be used for the month.</td></tr>
<tr><td>Completely missing start/end date</td><td>No imputation</td></tr>
</table>
</td></tr>
<tr><td>New Anti-Cancer Therapy/ Radiotherapy/ Surgical Procedures for Efficacy Evaluation (e.g., response rate, time to event)</td><td>

Start dates for on-study anti-cancer therapy, radiotherapy (where applicable), and surgical procedures (where applicable) will be temporarily imputed in order to define event and censoring rules for progression-free survival, response rate, or duration of response (i.e. start date for new anti-cancer therapy). Dates will only be imputed when a month and year are available but the day is missing. The imputed dates will not be stored on the anti-cancer therapy, radiotherapy, or surgical procedure datasets. The following rules will be used to impute the date when partial start dates are present on anti-cancer therapy radiotherapy, and/or surgical procedures datasets.
Completely missing start dates will remain missing, with no imputation applied;
Partial start dates will be imputed using the following convention:

If both month and day are missing, no imputation will be applied (note the eCRF should only allow for missing day);
If only day is missing:

If partial start date falls in the same month as the T-cell infusion, then assign to earlier of (date of T-cell infusion+1, last day of month).
If partial start date falls in the same month as the participant’s last assessment and the participant’s last assessment is progressive disease (PD), then assign to earlier of (date of disease assessment+1, last day of month).
If both conditions above are met, then assign to later of the 2 dates;
Otherwise, impute missing day to the first of the month.

</td></tr>
</table>

Element	Reporting Detail
	• Completely or partial missing end dates will remain missing, with no imputation applied.

14.8. Appendix 8: Values of Potential Clinical Importance

To identify values of potential clinical importance, National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE v 4.03) will be used to assign grades for laboratory parameters including clinical chemistry, hematology, liver function tests, thyroid function tests, pancreatic enzyme tests, QTc (Bazett's or Fridericia's) values, and vital signs (heart rate, blood pressure, temperature).

14.8.1. Laboratory Values

Reference ranges for all laboratory parameters collected throughout the study are provided by the laboratory. A laboratory value that is outside the reference range is considered either high abnormal (value above the upper limit of the reference range) or low abnormal (value below the lower limit of the reference range). The laboratory reference ranges will be provided on the listings of laboratory data. Clinical laboratory test results outside of the reference range will be flagged in the listings.

To identify laboratory values of potential clinical importance, National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE v4.03) will be used to assign grades to the relevant laboratory parameters. NCI-CTCAE v4.03 can be found at http://ctep.cancer.gov/reporting/ctc.html.

For laboratory data which are not listed in the NCI-CTCAE v4.03, a summary of values outside the normal range will be provided.

For lab test values that can be graded, values of grade 2 or above are defined as [redacted] For lab test values that cannot be graded, values out of the normal range are defined as values of potential clinical concern. For lab tests reported descriptively as 'Normal', 'Abnormal, not clinically significant', or 'Abnormal, clinically significant' (such as urinalysis), responses of 'Abnormal, clinically significant' will be considered as of potential clinical concern.

14.8.2. ECG Parameters:

To identify QTc (Bazett's or Fridericia's) values of potential clinical importance, NCI-CTCAE v4.03 will be used to assign grades (see adverse event 'Electrocardiogram QT corrected interval prolonged'). The eCRF collects either QTcB or QTcF. Note that there is a slight inconsistency between NCI-CTCAE v4.03 and ICH E14 (Absolute QTc interval prolongation). It was decided to align with CTCAE for the oncology standard categories.

The following criteria will be used to flag electrocardiogram (ECG) values that are values of potential clinical importance:

CCI

[redacted]

14.8.3. Vital Signs

To identify heart rate values of potential clinical importance, NCI-CTCAE v4.03 will be used to assign categories that align with the grades for 'Sinus bradycardia', 'Sinus tachycardia', 'Supraventricular tachycardia', and 'Ventricular tachycardia'.

The following criteria will be used to flag vital sign values that are values of potential clinical importance:

Vital Sign Parameter	Potential Clinical Importance (PCI) Range
Decrease from baseline Heart Rate	Decrease to <60 bpm
Increase from baseline Heart Rate	Increase to >100 bpm

To identify blood pressure values of potential clinical importance, NCI-CTCAE v4.03 will be used to assign categories that align with the grades for 'Hypertension':

CCI

[redacted]

To identify temperature values of potential clinical importance, NCI-CTCAE v4.03 will be used to assign categories that align with the grades for 'Hypothermia' and 'Fever':

Vital Sign Parameter	Potential Clinical Importance (PCI) Range	Unit
Increase from baseline temperature	Increase to ≥38	Degrees C
Decrease from baseline temperature	Decrease to ≤35	Degrees C

To identify respiratory rate of potential clinical importance, NCI-CTCAE v4.03 will be used to assign categories that align with the grades for 'Respiratory':

Vital Sign Parameter	Potential Clinical Importance (PCI) Range	Unit
Increase from baseline respiratory rate	Increase to >30	Breaths/ minute

14.9. Appendix 9: Population Pharmacokinetic (PopPK) Analyses

Not applicable.

14.10. Appendix 10: Pharmacokinetic / Pharmacodynamic Analyses

Not applicable.

14.11. Appendix 11: Abbreviations & Trademarks

14.11.1. Abbreviations

Abbreviation	Description
ADaM	Analysis Data Model
AE	Adverse Event
AESI	Adverse Events of Special Interest
ALT	Alanine aminotransferase
A&R	Analysis and Reporting
ATC	Anatomical Therapeutic Chemical
BMI	Body Mass Index
BSA	Body Surface Area
BOR	Best Overall Response
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
CMV	Cytomegalovirus
CR	Complete Response
CRP	C-reactive Protein
CCI [redacted]	
CS	Clinical Statistics
CSR	Clinical Study Report
CTCAE	Common Toxicity Criteria for Adverse Events
CTR	Clinical Trial Register
CV	Coefficient of Variation
DBF	Database Freeze
DBR	Database Release
CCI [redacted]	
DOR	Duration of Response
DP	Decimal Places
ECG	Electrocardiogram
ECOG	Eastern Cooperative Oncology Group
eCRF	Electronic Case Report Form
EMA	European Medicines Agency
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Clinical Results Disclosure Requirements
GSK	GlaxoSmithKline
GvHD	Graft versus Host Disease
IA	Interim Analysis
ICANS	Immune Effector-Cell Associated Neurotoxicity Syndrome
ICH	International Conference on Harmonization
IDSL	Integrated Data Standards Library
IMMS	International Modules Management System
IP	Investigational Product
ITT	Intent-to-Treat
INR	International Normalized Ratio

Abbreviation	Description
LFT	Liver Function Test
LLOQ	Lower Limit of Quantitation
LTFU	Long-Term Follow-Up
LVEF	Left Ventricular Ejection Fraction
MedDRA	Medical Dictionary for Regulatory Affairs
mITT	Modified Intent-to-Treat
NCI	National Cancer Institute
NE	Not Evaluable
ORR	Overall Response Rate
CCI [redacted]	
PBMCs	Peripheral Blood Mononuclear Cells
PCI	Potential Clinical Importance
PCR	Polymerase Chain Reaction
PD	Progressive Disease
PFS	Progression Free Survival
PR	Partial Response
PT	Preferred Term
QC	Quality Control
QTcF	Frederica's QT Interval Corrected for Heart Rate
QTcB	Bazett's QT Interval Corrected for Heart Rate
RAP	Reporting & Analysis Plan
RCL	Replication Competent Lentivirus
RECIST	Response Evaluation Criteria in Solid Tumors
RTF	Rich Text Format
SAC	Statistical Analysis Complete
SAE	Serious Adverse Event
SD	Stable Disease
SDTM	Study Data Tabulation Model
SOC	System Organ Class
SOP	Standard Operation Procedure
SRT	Safety Review Team
TA	Therapeutic Area
TCR	T-cell Receptors
TFL	Tables, Figures & Listings
TTR	Time to Response
ULN	Upper Limit of Normal
ULOQ	Upper Limit of Quantification
WHO	World Health Organization

14.11.2. Trademarks

Trademarks of the GlaxoSmithKline Group of Companies
NONE

Trademarks not owned by the GlaxoSmithKline Group of Companies
SAS

14.12. Appendix 12: List of Data Displays

14.12.1. Data Display Numbering

The following numbering will be applied for RAP generated displays:

Section	Tables	Figures
Study Population	1.0010 to 1.0310	
Efficacy	2.0010 to 2.0175	2.0180 to 2.0390
Safety	3.0010 to 3.0716	3.0720 to 3.0780
Biomarker	3.0830 to 3.0840	
Pharmacokinetic	4.0010 to 4.0020	4.0030 to 4.0070
Section	**Listings**	
ICH Listings	0010 to 0570	
Other Listings	0580 to 0730	

Note that display numbering from the previous version of the RAP has been retained for compatibility across reporting efforts, resulting in non-uniform increments between successive displays where displays have been dropped, added or moved.

14.12.2. Mock Example Shell Referencing

Non IDSL specifications will be referenced as indicated and if required example mock-up displays provided in Appendix 13.

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
Biomarker	BIO_Fn	BIO_Tn	BIO_Ln
Pharmacokinetic	PK_Fn	PK_Tn	PK_Ln

NOTES:

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

14.12.3. Deliverables

Delivery	Description
IFA	Interim Futility Analysis
IA2	Second Interim Analyses for Internal Decision Making
PRY	Primary Analysis (excluding retreatment)
FNL*	Final Analysis (if there are participants ongoing in interventional phase follow-up at time of primary analysis then these displays are to be refreshed at the final analysis but still excluding retreatment data)
FNL	Final Analysis

At the primary analysis, displays should be marked as "Protocol: 208469 Primary Analysis (excluding retreatment)".

14.12.4. Study Population Tables

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Subject Disposition					
1.0010	ITT	[Non-Standard] POP_T2	Summary of Subject Status (ITT)	ICH E3, FDAAA, EudraCT Note (in footnote) any deaths after lymphodepletion start before T-cell infusion. Repeat at final analysis including retreatment data and append " - Including Retreatment" to the title.	PRY, FNL
1.0020	mITT	[Non-Standard] POP_T2	Summary of Subject Status (mITT)	ICH E3, FDAAA, EudraCT If same population as ITT, don't produce Repeat at final analysis including retreatment data and append " - Including Retreatment" to the title.	PRY, FNL
1.0025	mITT	[Non-Standard] POP_T3	Summary of Interventional Phase Status	Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	IA2, PRY, FNL*
1.0030	Screened	ES6	Summary of Screening Status and Reasons for Screen Failure	Journal Requirements Show only categories collected in eCRF, in order presented in the eCRF. Since eCRF only allows selection of one reason, change ES6 label "Reason(s) for Failure" to "Reason for Failure" and omit "Subjects may have more than on reason…" footnote. Refresh at the final analysis and only include 1st T-cell infusion data. Append " – Excluding Retreatment" to the title.	PRY, FNL*

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
1.0040	ITT	[Non-Standard] POP_T1	Summary of Leukapheresis, Lymphodepletion, and T-cell Infusion	Add number of participants infused with minimum dose of 1 x10^9 transduced cells	IFA, IA2, PRY
1.0050	Enrolled	NS1	Summary of Number of Subjects by Country and Site ID (Enrolled Population)	EudraCT/Clinical Operations Refresh at the final analysis and only include 1st T-cell infusion data. Append " – Excluding Retreatment" to the title.	PRY, FNL*
1.0052	mITT	NS1	Summary of Number of Subjects by Country and Site ID (mITT)	Plain Language Summary (PLS)	PRY
Populations Analyzed					
1.0060	Screened	SP1A	Summary of Study Populations	IDSL Screened, Enrolled, ITT, mITT. Include "All Evaluable" for IFA & IA2. Extend at final analysis to include additional rows for "Screened for Second T-cell infusion" (Screened2) and "Modified Intent-to-Retreat (mITT2)" population and append " – Including Retreatment" to the title.	IFA, IA2, PRY, FNL
Protocol Deviations					
1.0070	ITT	DV1	Summary of Important Protocol Deviations	ICH E3	PRY
Demographic and Baseline Characteristics					
1.0080	ITT	DM1	Summary of Demographic Characteristics (ITT)	ICH E3, FDAAA, EudraCT Report baseline height, weight, BMI, and BSA Include footnote "Note: BSA was calculated using the Dubois-Dubois formula."	IFA, IA2, PRY, FNL*

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				Report High Level Race not Race Detail Refresh at the final analysis and only include 1st T-cell infusion data. Append " – Excluding Retreatment" to the title.	
1.0090	mITT	DM1	Summary of Demographic Characteristics (mITT)	ICH E3, FDAAA, EudraCT Report baseline height, weight, BMI and BSA Include footnote: "Note: BSA was calculated using the Dubois-Dubois formula." Report High Level Race not Race Detail If same population as ITT, don't produce Refresh at the final analysis and only include 1st T-cell infusion data. Append " - Excluding Retreatment" to the title.	IA2, PRY, FNL*
1.0100	Enrolled	DM11	Summary of Age Ranges	EudraCT Refresh at the final analysis and only include 1st T-cell infusion data. Append " - Excluding Retreatment" to the title.	PRY, FNL*
Disease Characteristics					
1.0110	ITT/mITT	LA1	Summary of Disease Burden at Baseline	ICH E3 Includes target and non-target lesions Use ITT for IFA and IA2 and use mITT for PRY	IFA, IA2, PRY
1.0120	ITT	DC1	Summary of Disease Characteristics at Initial Diagnosis (ITT)	ICH E3 Primary Neoplasm Type Under Study, location of disease, time since initial diagnosis to screening (months), % of myxoid cells, % of round cells, histological	IFA, IA2, PRY

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				grade, stage, and reciprocal chromosomal translocation. Add footnote "Time from initial diagnosis to date of screening informed consent is displayed."	
1.0130	mITT	DC1	Summary of Disease Characteristics at Initial Diagnosis (mITT)	ICH E3 Primary Neoplasm Type Under Study, location of disease, time since initial diagnosis to screening (months), % of myxoid/round cells, histological grade, stage, and reciprocal chromosomal translocation. Add footnote "Time from initial diagnosis to date of screening informed consent is displayed." If same population as ITT, don't produce	IA2, PRY
1.0140	ITT	DC2	Summary of Disease Characteristics at Screening (ITT)	ICH E3 HLA status (Positive/Negative), HLA allele status (One HLA allele positive, Two HLA alleles positive), NY-ESO-1 status, disease stage at screening, time since metastatic disease to screening (months), number of prior radiotherapy regimens between advanced diagnosis and leukapheresis, number of prior systemic therapy regimens between advanced diagnosis and leukapheresis. Break down "Number of Prior Systemic Therapy Regimens…" into {0,1,2,3,4,5,6,>6}.	IFA, IA2, PRY, FNL

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				Refresh at the final analysis and only include 1st T-cell infusion data. Append " - Excluding Retreatment" to the title.	
1.0150	mITT	DC2	Summary of Disease Characteristics at Screening (mITT)	ICH E3 HLA status (Positive/Negative), HLA allele status (One allele positive, two alleles positive, Positive – ambiguous), NY-ESO-1 status, disease stage at screening, time since metastatic disease to screening (months), number of prior radiotherapy regimens between advanced diagnosis and leukapheresis, number of prior systemic therapy regimens between advanced diagnosis and leukapheresis. Break down “Number of Prior Systemic Therapy Regimens…” into {0,1,2,3,4,5,6,>6}. If same population as ITT, don’t produce. Refresh at the final analysis and only include 1st T-cell infusion data. Append " - Excluding Retreatment" to the title.	IA2, PRY, FNL
Medical Conditions and Concomitant Medications					
1.0160	ITT	MH4	Summary of Medical Conditions (ITT)	ICH E3 Include conditions pre-printed on the CRF that occur (as printed unless coded) and other conditions specified by the investigator (as coded).	PRY
1.0170	mITT	MH4	Summary of Medical Conditions (mITT)	ICH E3	PRY

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				Include conditions pre-printed on the CRF that occur (as printed unless coded) and other conditions specified by the investigator (as coded). If same population as ITT, don't produce	
1.0180	mITT	CM8	Summary of Concomitant Medications (mITT)	ICH E3 Summarise only concomitant (as defined in Section 14.4.1.1) Concomitant Medications, with footnote "Note: Concomitant medications are those initiated after (or ongoing at) lymphodepletion." Use GSK Drug Coding Dictionary	PRY
1.0190	mITT	BP1A	Summary of Blood Products on Treatment		PRY
Anti-Cancer Therapy					
1.0200	ITT	AC1	Summary of Prior Anti-Cancer Therapy (ITT)	IDSL Add footnote: "Note: Includes all anti-cancer therapy from regimens initiated between diagnosis of advanced disease and lymphodepletion except bridging therapies."	IA2, PRY
1.0210	mITT	AC1	Summary of Prior Anti-Cancer Therapy (mITT)	IDSL Add footnote: "Note: Includes all anti-cancer therapy from regimens initiated between diagnosis of advanced disease and lymphodepletion except bridging therapies." If same population as ITT, don't produce	IA2, PRY
1.0220	mITT	FAC1	Summary of On-Study Anti-Cancer Therapy	IDSL	PRY

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				Summarise "Time From T-cell Infusion to Start of Subsequent Anti-Cancer Therapy" where FAC1 shell has "Time from Study Treatment Discontinuation".	
1.0230	ITT	CM1	Summary of Prior Dictionary Coded Anti-Cancer Therapy (ITT)	IDSL Use GSK Drug Coding Dictionary Add footnote: "Note: Includes all anti-cancer therapy from regimens initiated between diagnosis of advanced disease and lymphodepletion except bridging therapies."	IA2, PRY
1.0240	mITT	CM1	Summary of Prior Dictionary Coded Anti-Cancer Therapy (mITT)	IDSL Use GSK Drug Coding Dictionary Add footnote: "Note: Includes all anti-cancer therapy from regimens initiated between diagnosis of advanced disease and lymphodepletion except bridging therapies." If same population as ITT, don't produce	IA2, PRY
1.0245	mITT	CM1	Summary of Dictionary Coded Bridging Therapy (mITT)	Use GSK Drug Coding Dictionary Summarise all prior therapies identified as bridging per Section 6.7.1. Add footnote: "Note: Includes all anti-cancer therapy initiated between leukapheresis and lymphodepletion identified as bridging."	IA2, PRY
1.0250	mITT	CM1	Summary of On-Study Dictionary Coded Anti-Cancer Therapy	IDSL Use GSK Drug Coding Dictionary	PRY

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
1.0260	ITT	AC3	Summary of Number of Prior Anti-Cancer Therapy Regimens (ITT)	IDSL Break down "Number of Chemotherapy Regimens" into {0,1,2,3,4,5,6,>6}. Add footnote: "Note: Includes all anti-cancer regimens initiated between diagnosis of advanced disease and lymphodepletion except bridging therapies."	PRY
1.0270	mITT	AC3	Summary of Number of Prior Anti-Cancer Therapy Regimens (mITT)	IDSL Break down "Number of Chemotherapy Regimens" into {0,1,2,3,4,5,6,>6}. Add footnote: "Note: Includes all anti-cancer regimens initiated between diagnosis of advanced disease and lymphodepletion except bridging therapies." If same population as ITT, don't produce	PRY
Surgical Procedures					
1.0280	ITT	OSP1	Summary of Prior Cancer Related Surgical Procedures (ITT)	IDSL Report Surgery Intent and Site of Surgery Add footnote: "Note: Includes all cancer related surgeries between diagnosis of advanced disease and lymphodepletion." For surgeries recorded at the baseline visit on the "On Study Cancer Related Surgery Since Screening" where intent is not collected, report intent as UNKNOWN, with footnote "Note: UNKNOWN intent includes procedures recorded at the	IA2, PRY

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				baseline visit for which intent is not collected."	
1.0290	mITT	OSP1	Summary of Prior Cancer Related Surgical Procedures (mITT)	IDSL Report Surgery Intent and Site of Surgery Add footnote: "Note: Includes all cancer related surgeries between diagnosis of advanced disease and lymphodepletion." For surgeries recorded at the baseline visit on the "On Study Cancer Related Surgery Since Screening" where intent is not collected, report intent as UNKNOWN, with footnote "Note: UNKNOWN intent includes procedures recorded at the baseline visit for which intent is not collected." If same population as ITT, don't produce	IA2, PRY
1.0300	mITT	OSP1	Summary of On-Study Cancer Related Surgical Procedures	IDSL Report Site of Surgery	PRY
Exposure					
1.0310	mITT	POP_T4	Summary of Total Transduced T-cells	Add total column. Report total number of transduced T-cells in 10^9 cells and categorize it into: <1, >=1 to <=8, >8	IA2, PRY
1.0312	mITT	POP_T4	Summary of Exposure to Lymphodepletion Chemotherapy	Add total column. Remove sections on T-cell infusion. Add summary statistics (n, mean, SD, median, Min, Max) for cumulative dose (mg/m^2) for Cyclophosphamide and Fludarabine separately, with row labels	FNL*

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				'Cyclophosphamide Cumulative Dose (mg/m^2)' and 'Fludarabine Cumulative Dose (mg/m^2). For the final analysis only, include 1st T-cell infusion data. Append " - Excluding Retreatment" to the title.	

14.12.5. Efficacy Tables

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Overall Response Rate (ORR)					
2.0010	mITT	RE1a	Summary of Independent Reviewer-Assessed Best Response with Confirmation (RECIST 1.1 Criteria) (mITT)	Add total column Add Overall Response Rate (CR+PR) Include exact (Clopper Pearson) 95% CI for overall response rate (CR+PR) Per Section 2.3.1, omit all hypothesis testing sections: p-value for response rate and sections for response rate differences, odds ratio and homogeneity (marked as optional in IDSL shell). Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	PRY, FNL*

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.0020	ITT	RE1a	Summary of Independent Reviewer-Assessed Best Response with Confirmation (RECIST 1.1 Criteria) (ITT)	If same population as mITT, don't produce. Add total column Add Overall Response Rate (CR+PR) Include exact (Clopper Pearson) 95% CI for overall response rate (CR+PR) Per Section 2.3.1, omit all hypothesis testing sections.	PRY
2.0030	mITT / All Evaluable	RE1a	Summary of Investigator-Assessed Best Response with Confirmation (RECIST 1.1 Criteria) (mITT)	Use mITT for PRY & FNL and All Evaluable for IFA & IA2. For IA2, remove "(mITT)" from title. Add total column Add Overall Response Rate (CR+PR) Include exact (Clopper Pearson) 95% CI for overall response rate (CR+PR) Per Section 2.3.1, omit all hypothesis testing sections. Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	IFA, IA2, PRY, FNL*
2.0040	ITT	RE1a	Summary of Investigator-Assessed Best Response with Confirmation (RECIST 1.1 Criteria) (ITT)	If same population as mITT, don't produce. Add total column Add Overall Response Rate (CR+PR) Include exact (Clopper Pearson) 95% CI for overall response rate (CR+PR) Per Section 2.3.1, omit all hypothesis testing sections.	IA2, PRY

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.0050	mITT	RE4	Summary of Comparison of Investigator-Assessed and Independent Reviewer-Assessed Best Response (with Confirmation) (RECIST 1.1 Criteria)	Add total column	PRY, FNL*
2.0060	mITT	RE1a	Summary of Independent Reviewer-Assessed Best Response without Confirmation (RECIST 1.1 Criteria)	Add total column Per Section 2.3.1, omit all hypothesis testing sections.	PRY
2.0070	mITT	RE1a	Summary of Investigator-Assessed Best Response without Confirmation (RECIST 1.1 Criteria)	Add total column Per Section 2.3.1, omit all hypothesis testing sections.	PRY
CCI					

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Time to Event					
2.0100	mITT	[Non-Standard] EFF_T1	Summary of Independent Reviewer-Assessed Time to Response (RECIST 1.1 Criteria)	Subset of subjects with confirmed BOR of CR or PR Add mean Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	PRY, FNL*
2.0110	mITT	[Non-Standard] EFF_T1	Summary of Investigator-Assessed Time to Response (RECIST 1.1 Criteria)	Subset of subjects with confirmed BOR of CR or PR Add mean Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	IA2, PRY, FNL*

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.0120	mITT	TTE1a	Summary of Independent Reviewer-Assessed Duration of Response (RECIST 1.1 Criteria)	Subset of subjects with confirmed response Add total column Unit = Months Per Section 2.3.1, omit all hypothesis testing sections. Include footnotes: • "Note: Duration of Response is defined as the interval between the initial date of confirmed response (Partial Response / Complete Response) and the date of progressive disease or death among subjects with a confirmed response per RECIST 1.1." • 'Censored, follow-up ongoing' includes subjects that had not progressed or died but were still in interventional phase follow-up and had not initiated new anti-cancer therapy. Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	PRY, FNL*

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.0130	mITT	TTE1a	Summary of Investigator-Assessed Duration of Response (RECIST 1.1 Criteria)	Subset of subjects with confirmed response Add total column Unit = Months Per Section 2.3.1, omit all hypothesis testing sections: Hazard Ratio estimate and 95%CI (marked as optional in IDSL shell). Include footnotes: • "Note: Duration of Response is defined as the interval between the initial date of confirmed response (Partial Response / Complete Response) and the date of progressive disease or death among subjects with a confirmed response per RECIST 1.1." • 'Censored, follow-up ongoing' includes subjects that had not progressed or died but were still in interventional phase follow-up and had not initiated new anti-cancer therapy. Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	PRY, FNL*

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.0140	mITT	[Non-Standard] EFF_T2	Summary of Independent Reviewer-Assessed Progression Free Survival (RECIST 1.1 Criteria)	Include total column Unit = Months For the PFS rates include a separate section for each 3 month interval (3, 6, 9, 12, etc). Use the latest PFS time to determine which intervals to include. Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	PRY, FNL*
2.0150	mITT	[Non-Standard] EFF_T2	Summary of Investigator-Assessed Progression Free Survival (RECIST 1.1 Criteria)	Include total column Unit = Months For the PFS rates include a separate section for each 3 month interval (3, 6, 9, 12, etc). Use the latest PFS time to determine which intervals to include. For IA2: If at time of data cut there are <5 PDs in the high lympho cohort then do not present (leave blank) percentiles for that cohort and footnote "Note: Percentiles (median, quartiles) and the corresponding CIs for the HIGH LYMPHO + GSK794 group are not presented as data are immature.". Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	IFA, IA2, PRY, FNL*
2.0155	mITT	[Non-Standard] EFF_T3	Summary of Interventional Phase Follow-up	Follow the reverse KM method as described in Section 7.2.3.5. EXCLUDING retreatment data and append " - Excluding Retreatment" to the title	FNL

Efficacy: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.0160	mITT	OTTE1	Summary of Comparison of Investigator-Assessed and Independent Reviewer-Assessed Progression Event Timing or Censoring Timing (RECIST 1.1 Criteria)	Include [optional] footnote text: "The time window for complete agreement in timing is plus/minus 7 days." Where INV is PD and IRC is censored, classify under "INV PD earlier than IRC" as "PD by INV, Censored by IRC", even if censoring date is before the PD date (e.g. due to incomplete IRC reads for in-stream data). Similarly, if IRC is PD and INV is censored.	PRY
CCI [redacted]					

14.12.6. Efficacy Figures

Efficacy: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Overall Response Rate (ORR)					
2.0180	mITT	[Non-Standard] EFF_F1	Spider Plot of Independent Reviewer-Assessed Percent Change from Baseline in Sum of Target Lesion Diameters (by Lymphodepletion Regimen)	Plot by cohort. Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	PRY
2.0190	mITT	[Non-Standard] EFF_F1	Spider Plot of Independent Reviewer-Assessed Percent Change from Baseline in Sum of Target Lesion Diameters	Plot both cohorts combined on same axes.	PRY
2.0200	mITT / All Evaluable	[Non-Standard] EFF_F1	Spider Plot of Investigator-Assessed Percent Change from Baseline in Sum of Target Lesion Diameters (by Lymphodepletion Regimen)	Use mITT for PRY & FNL and All Evaluable for IFA & IA2 Plot by cohort. Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	IFA, IA2, PRY,
2.0210	mITT / All Evaluable	[Non-Standard] EFF_F1	Spider Plot of Investigator-Assessed Percent Change from Baseline in Sum of Target Lesion Diameters	Use mITT for PRY and All Evaluable for IFA & IA2 Plot both cohorts combined on same axes, with cohort differentiated by color and best confirmed response by symbol.	IFA, IA2, PRY
2.0220	mITT	RE8b	Independent Reviewer-Assessed Maximum Percent Reduction from Baseline in Sum of Target Lesion Diameters (by Lymphodepletion Regimen)	Label with participant ID Plot by cohort. Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	PRY

Efficacy: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.0230	mITT	RE8b	Independent Reviewer-Assessed Maximum Percent Reduction from Baseline in Sum of Target Lesion Diameters	Label x-axis with participant ID Plot both cohorts combined on same axes, with cohort differentiated by color and best confirmed response by shading. Annotate end of bar with participants best confirmed response.	PRY
2.0240	mITT / All Evaluable	RE8b	Investigator-Assessed Maximum Percent Reduction from Baseline in Sum of Target Lesion Diameters (by Lymphodepletion Regimen)	Label x-axis with participant ID Use mITT for PRY and All Evaluable for IFA & IA2 Plot by cohort. Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	IFA, IA2, PRY
2.0250	mITT / All Evaluable	RE8b	Investigator-Assessed Maximum Percent Reduction from Baseline in Sum of Target Lesion Diameters	Label x-axis with participant ID Use mITT for PRY and All Evaluable for IFA & IA2 Plot both cohorts combined on same axes, with cohort differentiated by color and best confirmed response by shading. Annotate end of bar with participants best confirmed response.	IFA, IA2, PRY

Efficacy: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Time to Event					
2.0260	mITT	TTE10	Graph of Kaplan-Meier Survival Curves of Independent Reviewer-Assessed Duration of Response (RECIST 1.1 Criteria) (by Lymphodepletion Regimen)	Subset of subjects with confirmed response Plot by cohort. Include 95% (Hall-Wellner) confidence Bands if data warrant. Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	PRY
2.0270	mITT	TTE10	Graph of Kaplan-Meier Survival Curves of Independent Reviewer-Assessed Duration of Response (RECIST 1.1 Criteria)	Subset of subjects with confirmed response Plot both cohorts on same axes, with cohort differentiated by color and labelled so clear which is which even in monochrome print.	PRY
2.0290	mITT	TTE10	Graph of Kaplan-Meier Survival Curves of Investigator-Assessed Duration of Response (RECIST 1.1 Criteria) (by Lymphodepletion Regimen)	Subset of subjects with confirmed response Plot by cohort. Include 95% (Hall-Wellner) confidence Bands if data warrant. Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	PRY
2.0300	mITT	TTE10	Graph of Kaplan-Meier Survival Curves of Investigator-Assessed Duration of Response (RECIST 1.1 Criteria)	Subset of subjects with confirmed response Plot both cohorts on same axes, with cohort differentiated by color and labelled so clear which is which even in monochrome print.	PRY

Efficacy: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
2.0320	mITT	TTE10	Graph of Kaplan-Meier Survival Curves of Independent Reviewer-Assessed Progression Free Survival (RECIST 1.1 Criteria) (by Lymphodepletion Regimen)	Plot by cohort. Include 95% (Hall-Wellner) confidence Bands if data warrant. Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	PRY
2.0330	mITT	TTE10	Graph of Kaplan-Meier Survival Curves of Independent Reviewer-Assessed Progression Free Survival (RECIST 1.1 Criteria)	Plot both cohorts on same axes, with cohort differentiated by color and labelled so clear which is which even in monochrome print.	PRY
2.0350	mITT	TTE10	Graph of Kaplan-Meier Survival Curves of Investigator-Assessed Progression Free Survival (RECIST 1.1 Criteria) (by Lymphodepletion Regimen)	Plot by cohort. Include 95% (Hall-Wellner) confidence Bands if data warrant. For IA2: If at time of data cut there are <5 PDs in the high lympho cohort then do not present (leave blank) K-M curves for that cohort and footnote "Note: Curves for the HIGH LYMPHO + GSK794 group are not presented as data are immature." Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	IFA, IA2, PRY,
2.0360	mITT	TTE10	Graph of Kaplan-Meier Survival Curves of Investigator-Assessed Progression Free Survival (RECIST 1.1 Criteria)	Plot both cohorts on same axes, with cohort differentiated by color and labelled so clear which is which even in monochrome print.	IA2, PRY

14.12.7. Safety Tables

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Adverse Events (AEs)					
3.0010	ITT	AE13	Adverse Event Overview (ITT)	Add total column. Remove “AEs leading to permanent discontinuation of study treatment”.	IFA
3.0020	mITT	AE13	Adverse Event Overview (mITT)	Add total column. Remove “AEs leading to permanent discontinuation of study treatment”.	IFA
3.0030	ITT	AE1	Summary of Adverse Events by System Organ Class and Preferred Term	ICH E3 Add total column. Do not use combined PT terms.	IA2, PRY
3.0040	mITT	AE1	Summary of Treatment Emergent Adverse Events by System Organ Class and Preferred Term	ICH E3 Add total column. Do not use combined PT terms. Include footnote “Note: Treatment Emergent is defined as onset on or after lymphodepletion chemotherapy start date.” Repeat at final analysis including retreatment data and append " - Including Retreatment" to the title.	IA2, PRY, FNL
3.0050	ITT	OAE07	Summary of Adverse Events by Maximum Grade and by Preferred Term – Post-Lymphodepletion Period (ITT)	• Add total “by group” page with subheading “Treatment: Total (N=XXX)”. • Present grades 3+4+5 combined (as in AE5B) rather than 3+4.	IFA

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0060	mITT	OAE07	Summary of Adverse Events by Maximum Grade and by Preferred Term – Post-Lymphodepletion Period (mITT)	• Add total "by group" page with subheading "Treatment: Total (N=XXX)". • Present grades 3+4+5 combined (as in AE5B) rather than 3+4.	IFA
3.0070	ITT	OAE07	Summary of Adverse Events by Maximum Grade	• Add total "by group" page with subheading "Treatment: Total (N=XXX)". • Use combined PT with footnote "Preferred terms are combined as shown in Table 3.0140" and "Adverse Event" (rather than "Preferred Term") as header. • Present grades 3+4+5 combined (as in AE5B) rather than 3+4.	IA2, PRY
3.0075	ITT	AE18	Summary of Adverse Events by Maximum Grade Category	• Summarise by combined PT (only – not within SOC) with footnote "Preferred terms are combined as shown in Table 3.0140" and "Adverse Event" (rather than "System Organ Class" & "Preferred Term") as header. • Present grades 3+4+5 combined (as in AE5B) rather than 3+4 (as AE18 IDSL mock had prior to v21). • Include Total columns (overall Total & 3+4+5 over both cohorts).	PRY

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0080	mITT	OAE07	Summary of Treatment Emergent Adverse Events by Maximum Grade	• Add total “by group” page with subheading “Treatment: Total (N=XXX)”. • Use combined PT with footnote “Preferred terms are combined as shown in Table 3.0140” and “Adverse Event” (rather than “Preferred Term”) as header. • Present grades 3+4+5 combined (as in AE5B) rather than 3+4. • Footnote definition of treatment emergent per Table 3.0040. • Repeat at final analysis including retreatment data and append " - Including Retreatment" to the title.	IA2, PRY, FNL
3.0085	mITT	AE18	Summary of Treatment Emergent Adverse Events by Maximum Grade Category	• Summarise by combined PT (only – not within SOC) with footnote “Preferred terms are combined as shown in Table 3.0140” and “Adverse Event” (rather than “System Organ Class” & “Preferred Term”) as header. • Present grades 3+4+5 combined (as in AE5B) rather than 3+4 (as AE18 IDSL mock had prior to v21). • Include Total columns (overall Total & 3+4+5 over both cohorts). • Footnote definition of treatment emergent per Table 3.0040.	PRY

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0090	mITT	OAE07	Summary of Study-Treatment Related TEAEs by Maximum Grade	ICH E3 • Add total “by group” page with subheading “Treatment: Total (N=XXX)”. • Treatment related including all lymphodepletion regimens and T-cell infusion. • Use combined PT with footnote “Preferred terms are combined as shown in Table 3.0140” and “Adverse Event” (rather than “Preferred Term”) as header. • Add footnote: Note: Study-treatment related AEs are defined as adverse events that are related to either T-cell infusion, cyclophosphamide or fludarabine. • Present grades 3+4+5 combined (as in AE5B) rather than 3+4. • Repeat at final analysis including retreatment data and append " - Including Retreatment" to the title.	IA2, PRY, FNL

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0095	mITT	AE18	Summary of Study-Treatment Related Adverse Events by Maximum Grade Category	• Summarise by combined PT (only – not within SOC) with footnote "Preferred terms are combined as shown in Table 3.0140" and "Adverse Event" (rather than "System Organ Class" & "Preferred Term") as header. • Present grades 3+4+5 combined (as in AE5B) rather than 3+4 (as AE18 IDSL mock had prior to v21). • Include Total columns (overall Total & 3+4+5 over both cohorts). • Footnote definition of study-treatment related AEs per Table 3.0090.	PRY
3.0100	mITT	OAE07	Summary of T-cell Infusion Related TEAEs by Maximum Grade	ICH E3 • Add total "by group" page with subheading "Treatment: Total (N=XXX)". • Use combined PT with footnote "Preferred terms are combined as shown in Table 3.0140" and "Adverse Event" (rather than "Preferred Term") as header. • Present grades 3+4+5 combined (as in AE5B) rather than 3+4. • Repeat at final analysis including retreatment data and append " - Including Retreatment" to the title.	IA2, PRY, FNL

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0110	mITT	OAE07	Summary of Lymphodepletion-Related Adverse Events by Maximum Grade	ICH E3 • Add total "by group" page with subheading "Treatment: Total (N=XXX)". • Use combined PT with footnote "Preferred terms are combined as shown in Table 3.0140" and "Adverse Event" (rather than "Preferred Term") as header. • Present grades 3+4+5 combined (as in AE5B) rather than 3+4. • Repeat at final analysis including retreatment data and append " - Including Retreatment" to the title.	PRY, FNL
3.0120	ITT	AE15	Summary of Common (>=5%) Non-serious Adverse Events by System Organ Class and Preferred Term (Number of Subjects and Occurrences)	FDAAA, EudraCT Add total column. • Do not combine PT Terms. • Add footnote - Multiple events recorded with a common preferred term and continuous or overlapping start/end dates are considered as a single event. Repeat at final analysis including retreatment data and append " - Including Retreatment" to the title.	PRY, FNL
3.0130	mITT	AE3	Summary of Non-Serious Study-Treatment Related TEAEs by Overall Frequency	Add total column. • Do not combine PT Terms. • Add footnote - "Multiple events recorded with a common preferred term and continuous or overlapping start/end dates are considered as a single event." • Footnote definition of study-treatment related AEs per Table 3.0090.	PRY, FNL

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0140	ITT	AE1	Summary of Adverse Events Grouped by Similarity of Preferred Terms	Add total column. Use combined PT term AEs Only include all combined PT term AEs. Remove overall “ANY EVENT” and synonym level “Any Event” rows. SOC from AE1 should be combined PT Term. PT term from AE1 should be the MEDDRA PT term. Label column “Synonym/Preferred Term” rather than “System Organ Class/Preferred Term” (where / indicates newline and indent as in AE1) If combined AE does not appear then include a 0 count. Repeat at final analysis including retreatment data and append " - Including Retreatment" to the title.	IA2, PRY, FNL
Adverse Events of Special Interest (AE of SI)					
3.0150	ITT	AE5B	Summary of Adverse Events of Special Interest	Add total “by group” page with subheading “Treatment: Total (N=XXX)”. Replace SOC with AESI category (use AESI category names from current SRT AESI specification document if these differ to those in Section 8.2). Use combined PT with footnote “Preferred terms are combined as shown in Table 3.0140” and “Adverse Event” (rather than “Preferred Term”) as header.	IFA

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0160	mITT	AE5B	Summary of Adverse Events of Special Interest – Post-Lymphodepletion Period	Add total "by group" page with subheading "Treatment: Total (N=XXX)". Replace SOC with AESI category (use AESI category names from current SRT AESI specification document if these differ to those in Section 8.2). Use combined PT with footnote "Preferred terms are combined as shown in Table 3.0140" and "Adverse Event" (rather than "Preferred Term") as header.	IFA
3.0170	mITT	AE5B	Summary of Treatment Emergent Adverse Events of Special Interest by Maximum Grade (Focused List)	Add total "by group" page with subheading "Treatment: Total (N=XXX)". Use combined PT identified in the focused list with footnote "Preferred terms are combined as shown in Table 3.0140" and "Adverse Event" (rather than "Preferred Term") as header. Replace SOC with AESI category (use AESI category names from current SRT AESI specification document if these differ to those in Section 8.2). Footnote definition of treatment emergent per Table 3.0040. Repeat at final analysis including retreatment data and append " - Including Retreatment" to the title.	IA2, PRY, FNL

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0180	mITT	AE5B	Summary of Treatment Emergent Adverse Events of Special Interest by Maximum Grade (Comprehensive List)	• Add total "by group" page with subheading "Treatment: Total (N=XXX)". • Do Not Use combined PT. • Replace SOC with AESI category (use AESI category names from current SRT AESI specification document if these differ to those in Section 8.2). • Footnote definition of treatment emergent per Table 3.0040.	IA2, PRY
3.0190	mITT	ESI1	Summary of Characteristics of Treatment Emergent Graft versus Host Disease (GvHD)	• Add total column. • Use Focused Scope List. • Footnote – "Preferred terms identified in the Focused list are summarized". • Footnote – "Multiple events recorded with a common preferred term and continuous or overlapping start/end dates are considered as a single event." • Report for all subjects and for all subjects with event. • Report characteristics, outcome, number of occurrences and max grade • Do not create if 1 or fewer participants have event (default to listing). • Footnote definition of treatment emergent per Table 3.0040.	PRY

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0200	mITT	ESI1	Summary of Characteristics of Treatment Emergent Haematopoietic Cytopenias (Focused List)	Add total column. Use Focused Scope List. Footnote – "Preferred terms identified in the Focused list are summarized". Footnote – "Multiple events recorded with a common preferred term and continuous or overlapping start/end dates are considered as a single event." Report for all subjects and for all subjects with event. Report characteristics, outcome, number of occurrences and max grade. Do not create if 1 or fewer participants have event (default to listing). Footnote definition of treatment emergent per Table 3.0040. Repeat at final analysis including retreatment data and append " - Including Retreatment" to the title.	PRY, FNL

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0220	mITT	ESI1	Summary of Characteristics of Treatment Emergent Immune Effector-Cell Associated Neurotoxicity Syndrome (ICANS)	Add total column. Use Focused Scope List. Footnote – "Preferred terms identified in the Focused list are summarized". Footnote – "Multiple events recorded with a common preferred term and continuous or overlapping start/end dates are considered as a single event." Report for all subjects and for all subjects with event. Report characteristics, outcome, number of occurrences and max grade. Do not create if 1 or fewer participants have event (default to listing). Footnote definition of treatment emergent per Table 3.0040.	PRY

Safety: Tables					
No.	Population	IDSL / Example Shell	Title	Programming Notes	Deliverable
CCI [redacted]					

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0240	mITT	ESI1	Summary of Characteristics of Treatment Emergent Guillain-Barre Syndrome	Add total column. Use Focused Scope List. Footnote – "Preferred terms identified in the Focused list are summarized". Footnote – "Multiple events recorded with a common preferred term and continuous or overlapping start/end dates are considered as a single event." Report for all subjects and for all subjects with event. Report characteristics, outcome, number of occurrences and max grade. Do not create if 1 or fewer participants have event (default to listing). Footnote definition of treatment emergent per Table 3.0040.	PRY
3.0250	mITT	ESI2B	Summary of Onset and Duration of the First Treatment Emergent Occurrence of Graft versus Host Disease (GvHD)	Add total column. Use Focused Scope List. Footnote – "Preferred terms identified in the Focused list are summarized". Footnote – "Multiple events recorded with a common preferred term and continuous or overlapping start/end dates are considered as a single event." Time to onset (days) (-8 - -1, 1-14, 15-30, 31-60, >60) Duration (days) (1-30, 31-90, >90) Onset from first T-cell infusion Do not create if 1 or fewer participants have event (default to listing). Footnote definition of treatment emergent per Table 3.0040.	PRY

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0260	mITT	ESI2B	Summary of Onset and Duration of the First Treatment Emergent Occurrence of Haematopoietic Cytopenia (Focused List)	Add total column. Use Focused Scope List. Footnote – "Preferred terms identified in the Focused list are summarized". Footnote – "Multiple events recorded with a common preferred term and continuous or overlapping start/end dates are considered as a single event." Time to onset (days) (-8 - -1, 1-14, 15-30, 31-60, >60) Duration (days) (1-30, 31-90, >90) Onset from first T-cell infusion Do not create if 1 or fewer participants have event (default to listing). Footnote definition of treatment emergent per Table 3.0040.	PRY
3.0272	mITT	ESI2B	Summary of Onset and Duration of the First Treatment Emergent Occurrence of Haematopoietic Cytopenia (Neutropenia)	Add total column. Use Focused Scope Sub-List. Footnote – "Preferred terms identified in the Focused sub-list are summarized". Footnote – "Multiple events recorded with a common preferred term and continuous or overlapping start/end dates are considered as a single event." Time to onset (days) (-8 - -1, 1-14, 15-30, 31-60, >60) Duration (days) (1-30, 31-90, >90) Onset from first T-cell infusion Do not create if 1 or fewer participants have event (default to listing). Footnote definition of treatment emergent per Table 3.0040.	PRY

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0274	mITT	ESI2B	Summary of Onset and Duration of the First Treatment Emergent Occurrence of Haematopoietic Cytopenia (Thrombocytopenia)	Add total column. Use Focused Scope Sub-List. Footnote – "Preferred terms identified in the Focused sub-list are summarized". Footnote – "Multiple events recorded with a common preferred term and continuous or overlapping start/end dates are considered as a single event." Time to onset (days) (-8 - -1, 1-14, 15-30, 31-60, >60) Duration (days) (1-30, 31-90, >90) Onset from first T-cell infusion Do not create if 1 or fewer participants have event (default to listing). Footnote definition of treatment emergent per Table 3.0040.	PRY
3.0276	mITT	ESI2B	Summary of Onset and Duration of the First Treatment Emergent Occurrence of Haematopoietic Cytopenia (Anemia)	Add total column. Use Focused Scope Sub-List. Footnote – "Preferred terms identified in the Focused sub-list are summarized". Footnote – "Multiple events recorded with a common preferred term and continuous or overlapping start/end dates are considered as a single event." Time to onset (days) (-8 - -1, 1-14, 15-30, 31-60, >60) Duration (days) (1-30, 31-90, >90) Onset from first T-cell infusion Do not create if 1 or fewer participants have event (default to listing). Footnote definition of treatment emergent per Table 3.0040.	PRY

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0278	mITT	ESI2B	Summary of Onset and Duration of the First Treatment Emergent Occurrence of Haematopoietic Cytopenia (Febrile Neutropenia)	Add total column. Use Focused Scope Sub-List. Footnote – "Preferred terms identified in the Focused sub-list are summarized". Footnote – "Multiple events recorded with a common preferred term and continuous or overlapping start/end dates are considered as a single event." Time to onset (days) (-8 - -1, 1-14, 15-30, 31-60, >60) Duration (days) (1-30, 31-90, >90) Onset from first T-cell infusion Do not create if 1 or fewer participants have event (default to listing). Footnote definition of treatment emergent per Table 3.0040.	PRY
3.0280	mITT	ESI2B	Summary of Onset and Duration of the First Treatment Emergent Occurrence of Immune Effector-Cell Associated Neurotoxicity Syndrome (ICANS)	Add total column. Use Focused Scope List. Footnote – "Preferred terms identified in the Focused list are summarized". Footnote – "Multiple events recorded with a common preferred term and continuous or overlapping start/end dates are considered as a single event." Time to onset (days) (-8 - -1, 1-14, 15-30, 31-60, >60) Duration (days) (1-30, 31-90, >90) Onset from first T-cell infusion Do not create if 1 or fewer participants have event (default to listing). Footnote definition of treatment emergent per Table 3.0040.	PRY

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
CCI [redacted]					
3.0300	mITT	ESI2B	Summary of Onset and Duration of the First Treatment Emergent Occurrence of Guillain-Barre Syndrome	Add total column. Use Focused Scope List. Footnote – "Preferred terms identified in the Focused list are summarized". Footnote – "Multiple events recorded with a common preferred term and continuous or overlapping start/end dates are considered as a single event." Time to onset (days) (-8 - -1, 1-14, 15-30, 31-60, >60) Duration (days) (1-30, 31-90, >90) Onset from first T-cell infusion Do not create if 1 or fewer participants have event (default to listing). Footnote definition of treatment emergent per Table 3.0040.	PRY

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0320	mITT	ESI2B	Summary of Onset and Duration of the Last Treatment Emergent Occurrence of Haematopoietic Cytopenias (Focused List)	Add total column. Use Focused Scope List. Footnote – "Preferred terms identified in the Focused list are summarized". Footnote – "Multiple events recorded with a common preferred term and continuous or overlapping start/end dates are considered as a single event." Time to onset (days) (-8 - -1, 1-14, 15-30, 31-60, >60) Duration (days) (1-30, 31-90, >90) Onset from first T-cell infusion Do not create if 1 or fewer participants have event (default to listing). Footnote definition of treatment emergent per Table 3.0040.	PRY
3.0380	mITT	[Non-Standard] SAFE_T1	Summary of Time to Resolution and Recurrence of Grade 3 or Above Treatment Emergent Haematopoietic Cytopenias (Focused List)	Use Focused Scope List. Footnote – "Preferred terms identified in the Focused list are summarized". Footnote – "Multiple events recorded with a common preferred term and continuous or overlapping start/end dates are considered as a single event." Do not create if 1 or fewer participants have event (default to listing). Footnote definition of treatment emergent per Table 3.0040.	PRY

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0382	mITT	[Non-Standard] SAFE_T1	Summary of Time to Resolution and Recurrence of Grade 3 or Above Treatment Emergent Haematopoietic Cytopenias (Neutropenia)	Use Focused Scope Sub-List. Footnote – "Preferred terms identified in the Focused sub-list are summarized". Footnote – "Multiple events recorded with a common preferred term and continuous or overlapping start/end dates are considered as a single event." Do not create if 1 or fewer participants have event (default to listing). Footnote definition of treatment emergent per Table 3.0040.	PRY
3.0384	mITT	[Non-Standard] SAFE_T1	Summary of Time to Resolution and Recurrence of Grade 3 or Above Treatment Emergent Haematopoietic Cytopenias (Thrombocytopenia)	Use Focused Scope Sub-List. Footnote – "Preferred terms identified in the Focused sub-list are summarized". Footnote – "Multiple events recorded with a common preferred term and continuous or overlapping start/end dates are considered as a single event." Do not create if 1 or fewer participants have event (default to listing). Footnote definition of treatment emergent per Table 3.0040.	PRY

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0386	mITT	[Non-Standard] SAFE_T1	Summary of Time to Resolution and Recurrence of Grade 3 or Above Treatment Emergent Haematopoietic Cytopenias (Anemia)	Use Focused Scope Sub-List. Footnote – "Preferred terms identified in the Focused sub-list are summarized". Footnote – "Multiple events recorded with a common preferred term and continuous or overlapping start/end dates are considered as a single event." Do not create if 1 or fewer participants have event (default to listing). Footnote definition of treatment emergent per Table 3.0040.	PRY
3.0388	mITT	[Non-Standard] SAFE_T1	Summary of Time to Resolution and Recurrence of Grade 3 or Above Treatment Emergent Haematopoietic Cytopenias (Febrile Neutropenia)	Use Focused Scope Sub-List. Footnote – "Preferred terms identified in the Focused sub-list are summarized". Footnote – "Multiple events recorded with a common preferred term and continuous or overlapping start/end dates are considered as a single event." Do not create if 1 or fewer participants have event (default to listing). Footnote definition of treatment emergent per Table 3.0040.	PRY
Serious and Other Significant Adverse Events					
3.0425	ITT	ESI1	Summary of Characteristics of Serious Adverse Events	Add total column. Report for all subjects and for all subjects with event. Report characteristics, outcome, number of occurrences and max grade.	IA2

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0430	ITT	AE16	Summary of Serious Adverse Events by System Organ Class and Preferred Term (Number of Subjects and Occurrences)	FDAAA, EudraCT Add total column. Do not use combined PT term. Update row text to "Number of Study-treatment related SAEs" and "Number of Study-treatment related Fatal SAEs" instead of drug-related. Footnote definition of study-treatment related AEs per Table 3.0090. Add Footnote – "Multiple events recorded with a common preferred term and continuous or overlapping start/end dates are considered as a single event." Repeat at final analysis including retreatment data and append " - Including Retreatment" to the title.	IA2, PRY, FNL
3.0440	ITT	OAE07	Summary of Serious Adverse Events by Maximum Grade	Add total "by group" page with subheading "Treatment: Total (N=XXX)". Use combined PT with footnote "Preferred terms are combined as shown in Table 3.0140" and "Adverse Event" (rather than "Preferred Term") as header. Present grades 3+4+5 combined (as in AE5B) rather than 3+4.	IA2, PRY

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0445	ITT	AE18	Summary of Serious Adverse Events by Maximum Grade Category	Summarise by combined PT (only – not within SOC) with footnote "Preferred terms are combined as shown in Table 3.0140" and "Adverse Event" (rather than "System Organ Class" & "Preferred Term") as header. Present grades 3+4+5 combined (as in AE5B) rather than 3+4 (as AE18 IDSL mock had prior to v21). Include Total columns (overall Total & 3+4+5 over both cohorts).	PRY
3.0450	mITT	OAE07	Summary of Serious Treatment Emergent Adverse Events by Maximum Grade	Add total "by group" page with subheading "Treatment: Total (N=XXX)". Use combined PT with footnote "Preferred terms are combined as shown in Table 3.0140" and "Adverse Event" (rather than "Preferred Term") as header. Present grades 3+4+5 combined (as in AE5B) rather than 3+4. Footnote definition of treatment emergent per Table 3.0040. Repeat at final analysis including retreatment data and append " - Including Retreatment" to the title.	IA2, PRY, FNL

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0455	mITT	AE18	Summary of Serious Treatment Emergent Adverse Events by Maximum Grade Category	Summarise by combined PT (only – not within SOC) with footnote "Preferred terms are combined as shown in Table 3.0140" and "Adverse Event" (rather than "System Organ Class" & "Preferred Term") as header. Present grades 3+4+5 combined (as in AE5B) rather than 3+4 (as AE18 IDSL mock had prior to v21). Include Total columns (overall Total & 3+4+5 over both cohorts). Footnote definition of treatment emergent per Table 3.0040.	PRY
3.0460	mITT	OAE07	Summary of Study-Treatment Related Serious TEAEs by Maximum Grade	Add total "by group" page with subheading "Treatment: Total (N=XXX)". Treatment related including all lymphodepletion regimens and T-cell infusion. Use combined PT with footnote "Preferred terms are combined as shown in Table 3.0140" and "Adverse Event" (rather than "Preferred Term") as header. Present grades 3+4+5 combined (as in AE5B) rather than 3+4. Footnote definition of study-treatment related AEs per Table 3.0090. Repeat at final analysis including retreatment data and append " - Including Retreatment" to the title.	IA2, PRY, FNL

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0465	mITT	AE18	Summary of Study-Treatment Related Serious Adverse Events by Maximum Grade Category	Summarise by combined PT (only – not within SOC) with footnote "Preferred terms are combined as shown in Table 3.0140" and "Adverse Event" (rather than "System Organ Class" & "Preferred Term") as header. Present grades 3+4+5 combined (as in AE5B) rather than 3+4 (as AE18 IDSL mock had prior to v21). Include Total columns (overall Total & 3+4+5 over both cohorts). Footnote definition of study-treatment related AEs per Table 3.0090.	PRY
3.0470	mITT	OAE07	Summary of T-cell Infusion Related Serious TEAEs by Maximum Grade	Add total "by group" page with subheading "Treatment: Total (N=XXX)". Use combined PT with footnote "Preferred terms are combined as shown in Table 3.0140" and "Adverse Event" (rather than "Preferred Term") as header. Present grades 3+4+5 combined (as in AE5B) rather than 3+4. Repeat at final analysis including retreatment data and append " - Including Retreatment" to the title.	IA2, PRY, FNL

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0480	mITT	OAE07	Summary of Lymphodepletion-Related Serious Adverse Events by Maximum Grade	Add total “by group” page with subheading “Treatment: Total (N=XXX)”. Use combined PT with footnote “Preferred terms are combined as shown in Table 3.0140 and “Adverse Event” (rather than “Preferred Term”) as header. Present grades 3+4+5 combined (as in AE5B) rather than 3+4. Repeat at final analysis including retreatment data and append " - Including Retreatment" to the title.	PRY, FNL
3.0525	mITT	AE20	Summary of Serious Fatal and Non-Fatal Study-Treatment Related TEAEs by Overall Frequency	Plain Language Summary (PLS) Add total column. Do NOT use combined PT. Add Footnote – “Multiple events recorded with a common preferred term and continuous or overlapping start/end dates are considered as a single event.” Footnote definition of study-treatment related AEs per Table 3.0090. Repeat at final analysis including retreatment data and append " - Including Retreatment" to the title.	PRY, FNL

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Deaths					
3.0530	mITT	DD1	Summary of Deaths	IDSL Add total column. Report “Time from T-cell Infusion to Death” with median, min, max, 1st Q, 3rd Q in months, >30 days or <=30 days (rather than “Time from Last Dose to Death”). Only report Alive at Last Contact (do not report follow up ongoing/ended) Report primary cause of death categories corresponding to those captured on eCRF. -Disease Under Study -Treatment Related toxicity -Other Extend at final analysis to include retreatment data, replace "Time from T-cell Infusion to Death" with "Time from Last T-cell Infusion to Death" and append " - Including Retreatment" to the title.	PRY, FNL
Laboratory: Chemistry					
3.0540	mITT	LB1	Summary of Chemistry Changes from Baseline	ICH E3. Don’t show baseline for tests with no post-baseline values. Add total panel. Add footnote “Summary statistics for baseline are summarizing the baseline value, while at subsequent times the change from baseline is summarized.”	PRY

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0550	mITT	OLB9C	Summary of Worst-Case Chemistry Results by Maximum Grade Increase Post-Baseline Relative to Baseline	ICH E3 Include total panel. Report Week 4 & Week 12 visits plus Worst-case post-baseline only. For labs that are gradable by CTCAE v4.03. Refresh at the final analysis and only include 1st T-cell infusion data. Append " – Excluding Retreatment" to the title.	PRY, FNL*
3.0560	mITT	OLB11C	Summary of Worst-Case Chemistry Results Relative to Normal Range Post-Baseline Relative to Baseline	ICH E3 Include total panel. Report Week 4 & Week 12 visits plus Worst-case post-baseline only. For labs that are not gradable by CTCAE Add footnote “Only tests that are not gradable by CTCAE are summarized.”	PRY
Laboratory: Hematology					
3.0570	mITT	LB1	Summary of Hematology Changes from Baseline	ICH E3. Don’t show baseline for tests with no post-baseline values. Add total panel. Add footnote “Summary statistics for baseline are summarizing the baseline value, while at subsequent times the change from baseline is summarized.”	PRY

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0580	mITT	OLB9C	Summary of Worst-Case Hematology Results by Maximum Grade Increase Post-Baseline Relative to Baseline	ICH E3 Include total panel. Report Week 4 & Week 12 visits plus Worst-case post-baseline only. For labs that are gradable by CTCAE v4.03. Refresh at the final analysis and only include 1st T-cell infusion data. Append " – Excluding Retreatment" to the title.	PRY, FNL*
3.0590	mITT	OLB11C	Summary of Worst-Case Hematology Results Relative to Normal Range Post-Baseline Relative to Baseline	ICH E3 Include total panel. Report Week 4 & Week 12 visits plus Worst-case post-baseline only. For labs that are not gradable by CTCAE Add footnote “Only tests that are not gradable by CTCAE are summarized.”	PRY
Laboratory: Other Tests					
3.0600	mITT	LB1	Summary of Other Laboratory Changes from Baseline	ICH E3 Don’t show baseline for tests with no post-baseline values. Add total panel. Add footnote “Summary statistics for baseline are summarizing the baseline value, while at subsequent times the change from baseline is summarized.”	PRY

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0610	mITT	OBL9C	Summary of Worst-Case Other Laboratory Results by Maximum Grade Increase Post-Baseline Relative to Baseline	ICH E3 Include total panel. Report Week 4 & Week 12 visits plus Worst-case post-baseline only. For labs that are gradable by CTCAE If there are no "other" labs gradable by CTCAE then do not produce this display.	PRY
3.0620	mITT	OLB11C	Summary of Worst-Case Other Laboratory Results Relative to Normal Range Post-Baseline Relative to Baseline	ICH E3 Include total panel. Report Week 4 & Week 12 visits plus Worst-case post-baseline only. For labs that are not gradable by CTCAE If there are no "other" labs not gradable by CTCAE then do not produce this display. Add footnote "Only tests that are not gradable by CTCAE are summarized.	PRY
Performance Status					
3.0630	mITT	PS1A	Summary of ECOG Performance Status	ICH E3 Add total column. Just summarize at baseline and last-assessment	IA2, PRY
3.0640	mITT	PS3A	Summary of Change in ECOG Performance Status from Baseline	ICH E3 Add total column. Include best and worst case	PRY

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
ECG					
3.0650	mITT	EG1	Summary of ECG Findings	IDSL Add total column. Do not include screening visit. "Clinically significant change from baseline" in this standard shell is not collected in this study so cannot be reported: drop from display.	PRY
3.0660	mITT	EG10A	Summary of Maximum QTc Values Post-Baseline Relative to Baseline by Category	IDSL Use CTCAE grade categories rather than the standard ICH E14 categories given in the body of the mock, and include all optional "increase" categories, with CTCAE grade footnote. Include total panel. Report Baseline and Worst Case Post-Baseline only. Do not report by visit. QTcB and QTcF reported in the same table but summarized separately. QTcB and QTcF values should not be derived.	PRY
3.0670	mITT	EG2	Summary of Change from Baseline in ECG Values by Visit	IDSL Include total panel. QTcF and QTcB reported separately Add footnote "Summary statistics for baseline are summarizing the baseline value, while at subsequent times the change from baseline is summarized." Refresh at the final analysis and only include 1st T-cell infusion data. Append " – Excluding Retreatment" to the title.	PRY, FNL*

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0680	mITT	EG11A	Summary of Maximum Increase in QTc Values Post-Baseline Relative to Baseline by Category	IDSL Include total panel. Report Worst Case Post-Baseline only. Do not report by visit. QTcB and QTcF reported in the same table but summarized separately. QTcB and QTcF values should not be derived.	PRY
Vital Signs					
3.0690	mITT	VS1	Summary of Change from Baseline in Vital Signs	ICH E3 Don't show baseline for tests with no post-baseline values. Include total panel. Include weight, temp, DBP, SBP pulse rate, respiratory rate. Add footnote "Summary statistics for baseline are summarizing the baseline value, while at subsequent times the change from baseline is summarized."	PRY
3.0700	mITT	OVT1C	Summary of Worst-Case Heart Rate Results Relative to Normal Range Post-Baseline Relative to Baseline	IDSL Include total panel. Do not summarize by visit	PRY
3.0710	mITT	OVT2C	Summary of Worst-Case Blood Pressure Results by Maximum Grade Increase Post-Baseline Relative to Baseline	IDSL Include total panel. Do not summarize by visit	PRY

Safety: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Replication Competent Lentivirus (RCL) & Gene Marked PBMCs					
3.0714	mITT	[Non-Standard] SAFE_T3	Summary of Replication Competent Lentivirus Positive	Add footnote “Note: n reflects the number of subjects with RCL assessed post T-cell infusion.” Count number of subjects with a “RCL Interpretation” POSITIVE at any assessment post-infusion, and present with “Count” row label in SAFE_T3 mock replaced with “Positive”. Refresh at the final analysis and only include 1st T-cell infusion data. Append " – Excluding Retreatment" to the title.	PRY, FNL*
3.0716	mITT	[Non-Standard] SAFE_T3	Summary of Subjects Showing >1% Gene Marked PBMCs 1 Year Post-Treatment	Label- >1% Gene Marked PBMCs 1 Year Post-treatment Define 1 year conservatively as at least 360 days since infusion or month 12 visit. Use n row to indicate #subjects with persistence captured 1 year post-treatment. Add footnote “Note: n reflects the number of subjects with persistence measured 1 year post T-cell infusion.”	PRY

14.12.8. Safety Figures

Safety: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Duration Plots					
3.0720	mITT	[Non-Standard] SAFE_F1	Plot of Duration on Interventional Phase with Prior Therapy Information (by Lymphodepletion Regimen)	Add T-cell Dose Plot by cohort.	IFA, IA2, PRY
Laboratory					
3.0730	mITT	LIVER9	Scatter Plot of Maximum ALT vs. Maximum Total Bilirubin – eDISH (by Lymphodepletion Regimen)	IDSL Plot by cohort.	PRY
3.0740	mITT	LIVER9	Scatter Plot of Maximum ALT vs. Maximum Total Bilirubin – eDISH	IDSL Plot both cohorts combined on same axes, with cohort differentiated by color.	PRY
3.0750	mITT	LIVER14	Scatter Plot of Maximum vs. Baseline for ALT (by Lymphodepletion Regimen)	IDSL Plot by cohort.	PRY
3.0760	mITT	LIVER14	Scatter Plot of Maximum vs. Baseline for ALT	IDSL Plot both cohorts combined on same axes, with cohort differentiated by color.	PRY
3.0765	mITT	[Non-Standard] SAFE_F3	Plot of Hematology Data Over Time (by Lymphodepletion Regimen)	Plot by parameter by cohort. Produce a separate plot for neutrophils, lymphocytes, platelets, and hemoglobin. X-axis units should be days starting at day -14.and ending at day 90, with day 1 (T-cell) indicated as axis tick and vertical line.	PRY
ECG					
3.0770	mITT	EG12	QTc Shifts from Baseline to Worst-Case Post Baseline (by Lymphodepletion Regimen)	IDSL Plot by QTc type (Bazett or Fridericia) and cohort.	PRY

Safety: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
3.0780	mITT	EG12	QTc Shifts from Baseline to Worst-Case Post Baseline	IDSL Plot by QTc type (Bazett or Fridericia). Plot both cohorts combined on same axes, with cohort differentiated by color.	PRY

14.12.9. Biomarkers Tables

Biomarker: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Biomarkers					
3.0830	mITT	[Non-Standard] SAFE_T3	Summary of Subjects Showing Monoclonality of Genetically Modified T-cell Population	Label: Monoclonality of Genetically Modified T-cell Population Use n row to indicate #subjects with clonality data. Add footnote “Note: n reflects the number of subjects with clonality assessed.”	PRY
Anti-NY-ESO-1 Antibodies					
3.0840	mITT	[Non-Standard] BIO_T4	Summary of Anti-NY-ESO-1 TCR(c259) Antibodies (ATA)	Refresh at the final analysis and only include 1st T-cell infusion data. Append " – Excluding Retreatment" to the title.	PRY, FNL*

14.12.10. Biomarker Figures

None.

14.12.11. Pharmacokinetic Tables

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Persistence of NY-ESO-1^{c259}T					
4.0010	mITT	[Non-Standard] PK_T1	Summary of Derived Persistence Parameters	Report overall and by responders vs. non-responders per investigator-assessed best response with confirmation. Add total "by group" page with subheading "Treatment: Total (N=XXX)". Add footnote: "Note: Samples collected within 4 days of day 28 are treated as day 28 when calculating $AUC_{0\text{-}28d}$" Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	PRY, FNL*
4.0020	mITT	[Non-Standard] PK_T2	Summary of Log-Transformed Derived Persistence Parameters	Report overall and by responders vs. non-responders per investigator-assessed best response with confirmation. Add total "by group" page with subheading "Treatment: Total (N=XXX)".. Add footnote: "Note: Samples collected within 4 days of day 28 are treated as day 28 when calculating $AUC_{0\text{-}28d}$" Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	PRY, FNL*

14.12.12. Pharmacokinetic Figures

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Persistence of NY-ESO-1^{c259}T					
4.0030	mITT	[Non-Standard] PK_F4	Distribution of Peak Cell Expansion (by Lymphodepletion Regimen)	Side by side dot-plots for responders vs. non-responders, per investigator-assessed best response with confirmation. Include footnote "Note: Responders are subjects with investigator-assessed best response with confirmation (per RECIST 1.1 criteria) of Partial Response or Complete Response.". Plot by cohort. X-axis and Y-axis should be same for each cohort.	PRY
4.0040	mITT	[Non-Standard] PK_F1	Persistence Profile by Subject (by Lymphodepletion Regimen)	By responders and non-responders per investigator-assessed best response with confirmation. Plot by cohort. Present with x-axis sufficient to see all follow-up. X-axis and Y-axis should be same for each cohort. Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	IA2, PRY, FNL*
4.0050	mITT	[Non-Standard] PK_F1	Persistence Profile by Subject	By responders and non-responders per investigator-assessed best response with confirmation. Plot both cohorts combined on same axes, with cohort differentiated by color. Present with x-axis sufficient to see all follow-up.	IA2, PRY

Pharmacokinetic: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				X-axis and Y-axis should be same as for corresponding "by Lymphodepletion Regimen" plot.	
4.0060	mITT	[Non-Standard] PK_F1	Persistence Profile by Subject (Truncated at 20 Days) (by Lymphodepletion Regimen)	By responders and non-responders per investigator-assessed best response with confirmation. Plot by cohort. Y-axis should be same as for complete profile plot in Figure 4.0040.	IA2, PRY
4.0070	mITT	[Non-Standard] PK_F1	Persistence Profile by Subject (Truncated at 20 Days)	By responders and non-responders per investigator-assessed best response with confirmation. Plot both cohorts combined on same axes, with cohort differentiated by color. X-axis and Y-axis should be same as for corresponding "by Lymphodepletion Regimen" plot.	IA2, PRY

14.12.13. ICH Listings

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Subject Disposition					
0010	Screened	ES7	Listing of Reasons for Screen Failure	Journal Guidelines Only include subjects that entered screening; do not include "Run-In" elements or optional column "Type of Failure" Include subjects that passed screening but were not enrolled as well as screen failures, with footnote: "Note: Includes screen failures (subjects who did not meet HLA or antigen criteria) as well as subjects that passed screening but were not enrolled (signed treatment informed consent, met eligibility criteria and leukapheresed) for other reasons." Report as captured on CRF.	PRY
CCI [redacted]					

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
CCI [redacted]					
0015	Screened	ES9	Listing of Subjects Who Were Rescreened	Include footnote: "Note: Date Subject Entered into Trial is date of leukapheresis." Include footnote: "Note: Includes screen failures (subjects who did not meet HLA or antigen criteria) as well as subjects that passed screening but were not enrolled (signed treatment informed consent, met eligibility criteria and leukapheresed) for other reasons."	PRY
0020	ITT	ES2	Listing of Reasons for Study Withdrawal	ICH E3 Do not include columns "Reason Term(s)", "Was a follow-up phone contact attempted 3 times?" & " Was a follow-up certified letter mailed?" from GSK standard mock as not collected in this study. Where primary reason is OTHER, append "Other, Specify" text (separated by ": ").	PRY, FNL

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				Include footnote: "Primary reason for study withdrawal is as indicated by the investigator on the "End of Study" CRF (for subjects that received T-cell infusion) or the "End of Treatment" CRF. The options available on these CRFs are as presented in the Summary of Subject Status (Table 1.0010)." Extend at final analysis to include retreatment data, flag mITT2 subjects with an asterisk, and footnote: "* = mITT2 subjects. Append '/Retreatment Day' to each study day and only populate on records during retreatment assessment period . Append " - Including Retreatment" to the title.	
0030	ITT	[Non-Standard] POP_L5	Listing of Subject Status	ICH E3 Extend at final analysis to include retreatment data, flag mITT2 subjects with an asterisk, and footnote: "* = mITT2 subjects., and append " - First Infusion and Study Completion" to the title.	IA2, PRY, FNL
CCI					

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Populations Analysed					
0040	Screened	SP3	Listing of Subjects Excluded from Any Population	ICH E3 Include columns to indicate exclusion ('Y') from Enrolled, ITT, and mITT populations. Drop "Date of Deviation/ Study day" and "Category/Coded Term" columns. Populate "Criteria" column with reason for exclusion from first: "SUBJECT NOT LEUKAPHERESED", "SUBJECT NOT LEUKAPHERESED", "SUBJECT NOT INFUSED". Extend at final analysis to include additional column for exclusion from "Modified Intent-to-Retreat" (mITT2) population with reason for exclusion (if participant is in mITT) of "SUBJECT NOT REINFUSED" and append " - Including Retreatment" to the title.	PRY, FNL
Protocol Deviations					
0050	ITT	DV2	Listing of Important Protocol Deviations	ICH E3 Extend at final analysis to include retreatment data, flag mITT2 subjects with an asterisk, and footnote: "* = mITT2 subjects. Append '/Retreatment Day' to each study day and only populate on records during retreatment assessment period . Append " – Including Retreatment" to the title.	PRY, FNL
0060	ITT	IE3	Listing of Subjects with Inclusion/Exclusion Criteria Deviations	ICH E3	PRY, FNL

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				Extend at final analysis to include retreatment data and append " – Including Retreatment " to the title.	
Demographic and Baseline Characteristics					
0070	ITT	DM2	Listing of Demographic Characteristics	ICH E3 Add BMI, BSA and High Level Race Include footnote: "Note: BSA was calculated using the Dubois-Dubois formula." List OTHER High Level Race with "If Other, please specify" free text appended (eg. "OTHER: MORE THAN ONE RACE"). Refresh at the final analysis and only include 1st T-cell infusion data and append " – Excluding Retreatment" to the title.	PRY, FNL*
CCI [redacted]					
Prior and Concomitant Medications					
0080	ITT	BP4	Listing of Blood Products	Refresh at the final analysis and only include 1st T-cell infusion data, and append " – Excluding Retreatment" to the title.	PRY, FNL*

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
CCI					
0090	ITT	CM3	Listing of Medications	IDSL Include all collected medications, do not subset on concomitant medications study phase. Replace "Started Pre-Trial" column with "Prior / Concomitant" (identified per Appendix 4). Refresh at the final analysis and only include 1st T-cell infusion data, and append " – Excluding Retreatment" to the title.	PRY, FNL*
CCI					
Exposure					
0110	ITT	[Non-Standard] POP_L2	Listing of Exposure to Lymphodepletion Chemotherapy	ICH E3 Cyclophosphamide & Fludarabine only. Include dose per unit body surface area (mg/m2). Cumulative dose is to only be populated on the first row for each subject. Refresh at the final analysis and only include 1st lymphodepletion data, and append " - Excluding Retreatment" to the title.	IA2, PRY, FNL*

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
CCI [redacted]					
0120	ITT	[Non-Standard] POP_L1	Listing of Exposure to T-cell Infusion	ICH E3 Refresh at the final analysis and only include 1st T-cell infusion data, and update title "Listing of Exposure to T-cell Infusion – Excluding Retreatment".	IA2, PRY, FNL*
CCI [redacted]					
Adverse Events (AEs)					
0130	ITT	AE8	Listing of All Adverse Events	ICH E3 Include "High Level Race" rather than "Race Detail" since latter not collected. Report time from first T-cell Infusion Use "Time Since T-cell Infusion" instead of "Time Since 1st Dose/Time Since Last Dose". Refresh at the final analysis and only include 1st T-cell infusion data, and append "- Excluding Retreatment" to the title.	PRY, FNL*
CCI [redacted]					

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
0140	ITT	[Non-Standard] SAFE_L1	Listing of Delayed Adverse Events	ICH E3 List events collapsed per Appendix 15. Sort by USUBJID, AEDECOD, ASTDT, AENDT Refresh at the final analysis and only include 1st T-cell infusion data, and append " – Excluding Retreatment" to the title.	PRY, FNL*
CCI [redacted]					
0150	ITT	AE7	Listing of Subject Numbers for Individual Adverse Events	ICH E3 All AEs Repeat at final analysis including retreatment data and append " - Including Retreatment" to the title.	PRY, FNL
0160	ITT	AE2	Listing of Relationship Between Adverse Event System Organ Classes, Preferred Terms, and Verbatim Text	IDSL Repeat at final analysis including retreatment data and append " - Including Retreatment" to the title.	PRY, FNL
Adverse Events of Special Interest (AE of SI)					
0170	mITT	[Non-Standard] SAFE_L1	Listing of Treatment Emergent Graft versus Host Disease (GvHD) Adverse Events	Use Focused Scope List Sort by USUBJID, AEDECOD, ASTDT, AENDT Footnote definition of treatment emergent per Table 3.0040.	IA2, PRY, FNL*

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				Refresh at the final analysis to include 1st T-cell Infusion data only, append " – Excluding Retreatment" to title.	
CCI [redacted]					
0180	mITT	[Non-Standard] SAFE_L1	Listing of Treatment Emergent Haematopoietic Cytopenias (Focused List)	Use Focused Scope List Sort by USUBJID, AEDECOD, ASTDT, AENDT Footnote definition of treatment emergent per Table 3.0040. Refresh at the final analysis to include 1st T-cell Infusion data only, append " – Excluding Retreatment" to title.	IA2, PRY, FNL*
CCI [redacted]					
0190	mITT	[Non-Standard] SAFE_L1	Listing of Treatment Emergent Haematopoietic Cytopenias (Comprehensive List)	Use Comprehensive Scope List Sort by USUBJID, AEDECOD, ASTDT, AENDT	IA2, PRY, FNL*

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				Footnote definition of treatment emergent per Table 3.0040. Refresh at the final analysis to include 1st T-cell Infusion data only, append " – Excluding Retreatment" to title.	
CCI [redacted]					
0200	mITT	[Non-Standard] SAFE_L1	Listing of Treatment Emergent Immune Effector-Cell Associated Neurotoxicity Syndrome (ICANS)	Use Focused Scope List Sort by USUBJID, AEDECOD, ASTDT, AENDT Footnote definition of treatment emergent per Table 3.0040. Refresh at the final analysis to include 1st T-cell Infusion data only, append " – Excluding Retreatment" to title.	IA2, PRY, FNL*
CCI [redacted]					

ICH: Listings					
No.	Population	IDSL / Example Shell	Title	Programming Notes	Deliverable
CCI [redacted]					
0220	mITT	[Non-Standard] SAFE_L1	Listing of Treatment Emergent Guillain-Barre Syndrome (GBS) Adverse Events	Use Focused Scope List Sort by USUBJID, AEDECOD, ASTDT, AENDT Footnote definition of treatment emergent per Table 3.0040. Refresh at the final analysis to include 1st T-cell Infusion data only, append " – Excluding Retreatment" to title.	IA2, PRY, FNL*

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
CCI [redacted]					
Serious and Other Significant Adverse Events					
0235	ITT	[Non-Standard] SAFE_L1	Listing of Serious Adverse Events		IA2
0240	ITT	AE8	Listing of Non-Fatal Serious Adverse Events	ICH E3 Include "High Level Race" rather than "Race Detail" since latter not collected. Report time from first T-cell Infusion Use "Time Since T-cell Infusion" instead of "Time Since 1st Dose/Time Since Last Dose". Refresh at the final analysis to include 1st T-cell Infusion data only, append " – Excluding Retreatment" to title.	PRY, FNL*
CCI [redacted]					
0250	ITT	AE14	Listing of Reasons for Considering as a Serious Adverse Event	ICH E3 Include "High Level Race" rather than "Race Detail" since latter not collected.	PRY, FNL

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				Refresh at the final analysis to include 1st T-cell Infusion data only, append " – Excluding Retreatment" to title.	
CCI [redacted]					
0255	ITT	PAN12	Listing of COVID-19 Assessments and Symptoms Assessments	If data exists Repeat at final analysis including retreatment data and append " - Including Retreatment" to the title.	PRY, FNL
Deaths					
0260	ITT	DTH3	Listing of Deaths	ICH E3 Replace "Time From Last Dose" column of standard mock with "Time From T-cell Infusion" and exclude "No. of Cycles/ Last Dose (unit)" column.	IA2
0262	ITT	DD3	Death Profile	ICH E3 Include "High Level Race" rather than "Race Detail" since latter not collected. If data warrant. eCRF only collects YES|NO for secondary cause of death. Repeat at final analysis including retreatment data and append " - Including Retreatment" to the title.	PRY, FNL
Hepatobiliary (Liver)					
0270	ITT	LIVER5	Listing of Liver Monitoring/Stopping Event Reporting	IDSL Replace columns "Time Since First/Last Dose (days)" of LIVER5 mock with "Time Since T-cell Infusion".	PRY

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
0280	ITT	LIVER13	Listing of Subjects Meeting Hepatobiliary Laboratory Criteria Post-Baseline	IDSL	PRY
0282	ITT	LIVER15	Liver Stopping Event Profile	IDSL Include "High Level Race" rather than "Race Detail" since latter not collected. Replace "Start Date of Treatment" and "End Date of Treatment" of LIVER15 mock with "Date of T-cell Infusion" and report "Time Since First T-cell Infusion…" & "Time from Last T-cell Infusion…" for "Time Since First Dose…" & "Time from Last Dose…".	PRY
Laboratory					
0290	ITT	LB5A	Listing of All Chemistry Data for Subjects with Any Value of Potential Clinical Importance/Outside Normal Range	ICH E3 Include "High Level Race" rather than "Race Detail" since latter not collected. Refresh at the final analysis to include 1st T-cell Infusion data only, append " – Excluding Retreatment" to title	PRY, FNL*
CCI [redacted]					
0300	ITT	LB5A	Listing of All Hematology Data for Subjects with Any Value of Potential Clinical Importance/Outside Normal Range	ICH E3 Include "High Level Race" rather than "Race Detail" since latter not collected. Refresh at the final analysis to include 1st T-cell Infusion data only, append " – Excluding Retreatment" to title.	PRY, FNL*

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
CCI					
0310	ITT	LB5A	Listing of All Other Laboratory Data for Subjects with Any Value of Potential Clinical Importance/Outside Normal Range	ICH E3 Include "High Level Race" rather than "Race Detail" since latter not collected. Refresh at the final analysis to include 1st T-cell Infusion data only, append " – Excluding Retreatment" to title.	PRY, FNL*
CCI					
0350	ITT	LB14	Listing of Laboratory Data with Character Results	ICH E3 Include "High Level Race" rather than "Race Detail" since latter not collected. Refresh at the final analysis to include 1st T-cell Infusion data only, append " – Excluding Retreatment" to title.	PRY, FNL*
CCI					
0360	ITT	UR2	Listing of Urinalysis Data for Subjects with Any Value of Potential Clinical Importance	ICH E3 Include "Age (Years)/Sex/High Level Race" to the right of the Subject Id. column (as in other listings), even though not included in the UR2 standard mock. Refresh at the final analysis to include 1st T-cell Infusion data only, append " – Excluding Retreatment" to title.	PRY, FNL*

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
CCI					
Replication Competent Lentivirus (RCL)					
0365	mITT	LB5A	Listing of VSV-G DNA (RCL) Data	Include "High Level Race" rather than "Race Detail" since latter not collected. Refresh at the final analysis and only include 1st T-cell infusion data, and append " – Excluding Retreatment" to the title.	PRY, FNL*
CCI					
Biomarkers and Pharmacokinetic					
0368	ITT	[Non-Standard] BIO_L2	Listing of Immunohistochemistry Data		PRY
0380	mITT	[Non-Standard] PK_L1	Listing of Persistence Data	Add C_{max}, T_{max}, duration of detectable persistence, $AUC_{0\text{-}28d}$, time to loss of 25%, 50% and 75% of peak cell expansion. Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	IA2, PRY, FNL*
CCI					

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
0385	mITT	[Non-Standard] BIO_L4	Listing of Integration Site Analysis Data	Refresh at the final analysis and only include 1st T-cell infusion data, and append " – Excluding Retreatment" to the title.	PRY, FNL*
CCI [redacted]					
0400	mITT	[Non-Standard] BIO_L3	Listing of Anti-NY-ESO-1 TCR(c259) Antibodies (ATA)	Refresh at the final analysis and only include 1st T-cell infusion data, and append " – Excluding Retreatment" to the title.	PRY, FNL*
CCI [redacted]					
Performance Status					
0410	ITT	PS5A	Listing of ECOG Performance Status	Refresh at the final analysis and only include 1st T-cell infusion data, and append " – Excluding Retreatment" to the title.	IA2, PRY, FNL*
CCI [redacted]					
ECG					
0420	ITT	EG3	Listing of All ECG Values for Subjects with Any Value of Potential Clinical Importance	IDSL Include "High Level Race" rather than "Race Detail" since latter not collected. Update PCI footnote to use oncology definition "…Clinical Importance is defined as Grade 2 or Higher (QTc>480), or QTc increase of >30 msec…" (as in OECG5A).	PRY, FNL*

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				Refresh at the final analysis and only include 1st T-cell infusion data, and append " – Excluding Retreatment" to the title	
CCI					
0430	ITT	EG5	Listing of All ECG Findings for Subjects with an Abnormal ECG Finding	IDSL Include "High Level Race" rather than "Race Detail" since latter not collected. "Clinically significant change from baseline" and "Clinically Significant Abnormality" in this standard shell are not collected in this study so cannot be reported: drop from display.	PRY
0440	ITT	SAFE_L6	Listing of QTc Values of Potential Clinical Importance	List "High Level Race" rather than "Race". List by QTc correction method, Bazett or Fridericia.	PRY
Vital Signs					
0450	ITT	OVT7A	Listing of Vital Signs with Values of Potential Clinical Importance	IDSL In addition to OVT7A specified vital signs, include "Respiratory Rate (breaths/min)".	PRY, FNL*

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				Include footnote for blood pressure grade columns per IDSL spec. of "[1] Grades were derived based on numeric criteria as defined in CTCAE V4.03 and did not take into consideration of clinical signs or symptoms, concomitant medication usage which is needed for the final grade associated with the adverse event." Refresh at the final analysis and only include 1st T-cell infusion data, and append " – Excluding Retreatment" to the title.	
CCI					
Response					
0460	mITT / All Evaluable	RE12	Listing of Investigator-Assessed Subject Best Response for Interim Review (RECIST 1.1 Criteria)	Sort by T-cell infusion date. Use mITT for IA2 and All Evaluable for IFA	IFA, IA2
0490	ITT	RE5	Listing of Independent Reviewer-Assessed Responses without and with Confirmation (RECIST 1.1 Criteria)	Do not include the optional "CA[2]" (Progressive Disease by clinical assessment) or "Organs of PD" columns. Rather than one "Best Resp" row, include two, one "Best Unconfirmed Response", the second "Best Confirmed Response". Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	PRY, FNL*
0500	ITT	RE5	Listing of Investigator-Assessed Responses without and with Confirmation (RECIST 1.1 Criteria)	Do not include the optional "CA[2]" (Progressive Disease by clinical assessment) or "Organs of PD" columns.	PRY, FNL*

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				Rather than one "Best Resp" row, include two, one "Best Unconfirmed Response", the second "Best Confirmed Response". Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	
CCI					
Time to Event					
0510	mITT	TTE9	Listing of Investigator-Assessed Time to Response (RECIST 1.1 Criteria)	Use T-cell infusion date Include optional "Age/Sex/Race" column with "High Level Race" rather than "Race Detail" since latter not collected. Omit "Status" from the header. Include optional "New Anti-Cancer Therapy Start Date" column. As TTR is not a survival analysis and are only listing time to response for responders, remove "or Censoring" from "Event or Censoring Date". Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	IA2, PRY, FNL*
0520	mITT	TTE9	Listing of Independent Reviewer-Assessed Time to Response (RECIST 1.1 Criteria)	Use T-cell infusion date	PRY, FNL*

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				Include optional “Age/Sex/Race” column with “High Level Race” rather than “Race Detail” since latter not collected. Omit “Status” from the header. Include optional “New Anti-Cancer Therapy Start Date” column. As TTR is not a survival analysis and are only listing time to response for responders, remove “or Censoring” from “Event or Censoring Date”. Refresh at final analysis EXCLUDING retreatment data and append “ - Excluding Retreatment” to the title.	
0530	mITT / All Evaluable	TTE9	Listing of Investigator-Assessed Duration of Response (RECIST 1.1 Criteria)	Include optional “Age/Sex/Race” column with “High Level Race” rather than “Race Detail” since latter not collected. Add Initial Confirmed Response Use mITT for PRY & IA2 and All Evaluable for IFA Use T-cell infusion date Include optional “New Anti-Cancer Therapy Start Date” column. Include footnotes: • “Note: Duration of Response is defined as the interval between the initial date of confirmed response (Partial Response / Complete Response) and the date of progressive disease or death among subjects with a confirmed response per RECIST 1.1.” • 'Censored, follow-up ongoing' includes subjects that had not progressed or died	IFA, IA2, PRY, FNL*

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				but were still in interventional phase follow-up and had not initiated new anti-cancer therapy. Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	
0540	mITT	TTE9	Listing of Independent Reviewer-Assessed Duration of Response (RECIST 1.1 Criteria)	Include optional "Age/Sex/Race" column with "High Level Race" rather than "Race Detail" since latter not collected. Add Initial Confirmed Response Use T-cell infusion date Include optional "New Anti-Cancer Therapy Start Date" column. Include footnotes: • "Note: Duration of Response is defined as the interval between the initial date of confirmed response (Partial Response / Complete Response) and the date of progressive disease or death among subjects with a confirmed response per RECIST 1.1." • 'Censored, follow-up ongoing' includes subjects that had not progressed or died but were still in interventional phase follow-up and had not initiated new anti-cancer therapy. Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	PRY, FNL*
0550	mITT	TTE9	Listing of Investigator-Assessed Progression Free Survival (RECIST 1.1 Criteria)	Include optional "Age/Sex/Race" column with "High Level Race" rather than "Race Detail" since latter not collected.	IA2, PRY, FNL*

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				Use T-cell infusion date Include optional "New Anti-Cancer Therapy Start Date" column. Include footnote: • 'Censored, follow-up ongoing' includes subjects that had not progressed or died but were still in interventional phase follow-up and had not initiated new anti-cancer therapy. Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	
0560	mITT	TTE9	Listing of Independent Reviewer-Assessed Progression Free Survival (RECIST 1.1 Criteria)	Include optional "Age/Sex/Race" column with "High Level Race" rather than "Race Detail" since latter not collected. Use T-cell infusion date Include optional "New Anti-Cancer Therapy Start Date" column. Include footnote: • 'Censored, follow-up ongoing' includes subjects that had not progressed or died but were still in interventional phase follow-up and had not initiated new anti-cancer therapy. Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	PRY, FNL*
CCI [redacted]					

ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
				Exclude optional “New Anti-Cancer Therapy Start Date” column. Include retreatment data, flag mITT2 subjects with an asterisk, and footnote: "* = mITT2 subjects. Append "Including Retreatment" to the title.	

14.12.14. Non-ICH Listings

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Disease Characteristics					
0580	ITT	DC3	Listing of Disease Characteristics at Initial Diagnosis	Report Primary Neoplasm Type Under Study, location of disease, date of initial diagnosis / time since initial diagnosis to screening (months), % of myxoid cells, % of round cells, histological grade, stage, and reciprocal chromosomal translocation. Add footnote "Time from initial diagnosis to date of screening informed consent is displayed."	PRY
0590	ITT	[Non-Standard] POP_L4	Listing of Disease Characteristics at Screening	Report HLA status (date, allele 1, allele 2), NY-ESO-1 biopsy date and status, stage, date of metastatic disease / time since metastatic disease to screening (months), and number of radiotherapy / systemic therapy regimens prior to lymphodepletion Refresh at the final analysis and only include anti-cancer radiotherapy up until end of first interventional phase and append " – Excluding Retreatment" to the title.	PRY, FNL
Anti-Cancer Therapy					
0600	ITT	AC6	Listing of Prior Systemic Anti-Cancer Therapy	Include prior sub-phase (per Appendix 4) and flag bridging therapies. Include "Best Response" (from eCRF) but not "Reason for Stopping" (as not collected for prior systemic therapy).	PRY

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
0610	ITT	AC7	Listing of Anti-Cancer Radiotherapy	Include prior sub-phase or "on-study" (per Appendix 4). Include "Dose" but not "Best Response" (as not collected for prior radiotherapy). Refresh at the final analysis and only include anti-cancer radiotherapy up until end of first interventional phase, and append " – Excluding Retreatment" to the title.	PRY, FNL*
CCI [redacted]					
0620	ITT	FAC3	Listing of On-Study Anti-Cancer Therapy	Include "Time to Progression (Days)" but not CCI [redacted] Days)". Note: Includes both radiotherapy and systemic therapy and surgery. Refresh at the final analysis and only include anti-cancer therapy up until end of first interventional phase, and append " – Excluding Retreatment" to the title.	PRY, FNL*
CCI [redacted]					

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Medical Conditions					
0630	ITT	MH2	Listing of Medical Conditions	Remove "Status" column of standard mock and replace with "Ongoing?" flag as collected on eCRF.	PRY
Symptoms, Concomitant Medications and Procedures Related to Adverse Events of Special Interest					
CCI [redacted]					
0642	ITT	[Non-Standard] SAFE_L4	Listing of Symptoms and Medications Related to Graft versus Host Disease (GvHD)		PRY
0650	ITT	CM3	Listing of Tocilizumab	List only tocilizumab administrations. Replace "Started Pre-Trial" column with "Prior / Concomitant" (identified per Appendix 4). Refresh at the final analysis and only include 1st T-cell infusion data, and append " – Excluding Retreatment" to the title.	IA2, PRY, FNL*
CCI [redacted]					

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Surgical Procedures					
0660	ITT	OSP3	Listing of Prior Cancer-Related Surgical Procedures	List Surgery Intent and Site and Date of Surgery. Include prior sub-phase or "on-study" (per Appendix 4) in place of "Time Point". Include footnote: "Surgery Intent is not collected for procedures recorded at the baseline visit."	PRY
0670	ITT	OSP3	Listing of On-Study Cancer-Related Surgical Procedures	List Site and Date of Surgery. Include prior sub-phase or "on-study" (per Appendix 4) in place of "Time Point". Omit "Surgery Intent" as not collected on on-study forms. Refresh at the final analysis and only include on-study surgical procedures up until end of first interventional phase, and append " – Excluding Retreatment" to the title.	PRY, FNL*
CCI [redacted]					

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
0672	ITT	OSP3	Listing of Resection Biopsies	Use Listing 0660 as base and: • remove timepoint, classification, and transition surgery column. • replace "Surgery Intent" with "Type of Sample Obtained", and "Site of Surgery" with "Anatomical Location" Extend at final analysis to include retreatment data, flag mITT2 subjects with an asterisk, and footnote: "* = mITT2 subjects. Append '/Retreatment Day' to each study day and only populate on records during retreatment assessment period . Append "Including Retreatment" to the title	PRY, FNL
Response					
0680	ITT	LA5	Listing of Investigator-Assessed Lesion Assessments (RECIST 1.1 Criteria)	Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	IA2, PRY, FNL*
CCI [redacted]					
0690	ITT	LA5	Listing of Independent Reviewer-Assessed Lesion Assessments (RECIST 1.1 Criteria)	Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	PRY, FNL*

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
0700	ITT	RE9	Listing of Subjects with a Difference between Investigator-Assessed and Independent Reviewer-Assessed Best Response (with Confirmation) (RECIST 1.1 Criteria)	Do not include (optional) "Comment" columns. RE9 mock has "Best Response [1] without CT Scans…" for independent reviewer. Since the independent reviewer for this study does not assess response with and without CR scans, delete "without CT Scans" from column header. Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	PRY, FNL*
0710	ITT	RE7	Listing of Response Assessments for Subjects with a Difference between Investigator-Assessed and Independent Reviewer-Assessed Best Response (with Confirmation) (RECIST 1.1 Criteria)	Do not include the optional "CA[2]" (Progressive Disease by clinical assessment), "PD" or "Organs of PD" columns. Use "Planned Time" rather than "Time". Refresh at final analysis EXCLUDING retreatment data and append " - Excluding Retreatment" to the title.	PRY, FNL*
0720	ITT	RE7	Listing of Response Assessments for Subjects with a Difference between Investigator-Assessed and Independent Reviewer-Assessed Best Response (without Confirmation) (RECIST 1.1 Criteria)	Do not include the optional "CA[2]" (Progressive Disease by clinical assessment), "PD" or "Organs of PD" columns. Use "Planned Time" rather than "Time".	PRY

Non-ICH: Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable**
Time to Event					
0730	mITT	OTTE2	Listing of Comparison of Investigator-Assessed and Independent Reviewer-Assessed Progression Event Timing or Censoring Timing (RECIST 1.1 Criteria)	Add “High Level Race” to Age/Sex column. Change randomization date to “Date of T-cell Infusion” Include footnote: “Note: The time window for complete agreement in timing is plus/minus 7 days.” Refresh at final analysis EXCLUDING retreatment data and append “ - Excluding Retreatment” to the title.	PRY, FNL*

14.13. Appendix 13: Example Mock Shells for Data Displays

Data Display Specification will be made available on request.

14.14. Appendix 14: Combined Preferred Terms

The combined terms for MedDRA Version 24.1 are listed below. Changes to the MedDRA dictionary may occur between the start of the study and the time of reporting and/or emerging data from on-going studies may highlight additional combined terms, therefore the list of combined preferred terms will be based on the safety review team (SRT) agreements in place at the time of reporting.

Combined Term	MedDRA Preferred term	PT Code
Anaemia/Red blood cell count decreased	Anaemia	10002034
	Red blood cell count decreased	10038153
CCI		10052015
	Cytokine storm	10050685
Acute GVHD - Skin	Acute graft versus host disease in skin	10066262
Acute GVHD - Gut (Liver and Intestine)	Acute graft versus host disease in liver	10066263
	Acute graft versus host disease in intestine	10066264
Acute GVHD - Other (Lung, Bone Marrow, not specified)	Acute graft versus host disease	10066260
	Acute graft versus host disease oral	10083513
Chronic GVHD - Skin	Chronic graft versus host disease in skin	10072159
Chronic GVHD - Gut (Liver and Intestine)	Chronic graft versus host disease in liver	10072160
	Chronic graft versus host disease in intestine	10072158
Chronic GVHD Other - (Lung, Bone Marrow, not specified)	Chronic graft versus host disease	10066261
	Chronic graft versus host disease in eye	10083757
	Chronic graft versus host disease oral	10083514
	Chronic graft versus host disease in lung	10086041
Unspecified GVHD - Skin	Graft versus host disease in skin	10064675
Unspecified GVHD - Gut (Liver and Intestine)	Graft versus host disease in liver	10064676
	Graft versus host disease in gastrointestinal tract	10075160
Unspecified GVHD - Other (Lung, Bone Marrow, not specified)	Graft versus host disease	10018651
	Graft versus host disease in eye	10074563
	Graft versus host disease in lung	10067742
	Prophylaxis against graft versus host disease	10053239
	Transfusion associated graft versus host disease	10070895
	Engraftment syndrome	10050684
Leukopenia/White blood cell decreased	White blood cell count decreased	10047942
	Leukopenia	10024384

Combined Term	MedDRA Preferred term	PT Code
Lymphopenia/Lymphocyte count decreased	Lymphocyte count decreased	10025256
	CD4 lymphocytes decreased	10007839
	CD8 lymphocytes decreased	10056283
	Lymphopenia	10025327
Neutropenia/Neutrophil count decreased	Neutrophil count decreased	10029366
	Neutropenia	10029354
Rash/Rash maculo-papular	Rash maculo-papular	10037868
	Rash	10037844
	Rash erythematous	10037855
Thrombocytopenia/Platelet count decreased	Platelet count decreased	10035528
	Thrombocytopenia	10043554
Immune effector cell-associated neurotoxicity syndrome (ICANS)	Immune effector cell-associated neurotoxicity syndrome	10083347
	Encephalopathy	10014625

14.15. Appendix 15: Adverse Event Collapsing Rules

1. Collapsing AE Segments with a Common AE Preferred Term (PT) into Unique Events based on the Start and End Dates

For each unique subject, the AE records (segments) with the same AE preferred term will be collapsed into one unique AE event based on the start and end dates below.

1.1. Multiple AE Segments with Overlapped or Continuous Start/End Dates

Multiple AE segments with a common preferred term (PT, variable=ADAE.AEDECOD) that occurred around the same time; defined as:

If a segment starts no more than one day (i.e., ≤ 1 day) prior, on, or after the previous segment's end date, it is considered as an 'event'.

If the gap between the start date of a segment and the end date of previous segment is greater than one complete day (i.e., > 1 day), then consider these segments as different events.

If partial start or end dates for any AE segments, then consider these segments as separate events.

*** **NOTE: Handling of partial dates or completely missing dates**

Partial dates or completely missing dates will not be imputed.

The reason for not using imputed dates is due to the small number of partial / or completely missing dates. Furthermore, using imputed dates might create additional error of up to 30 days off for the AE start or AE end dates, and can be up to 60 days off for the duration of AE.

1.2. Sort Adverse Events (AE)

For any AE event identified above:

Sort the AEs segments by study ID (ADAE.STUDYID), unique subject ID (ADAE.USUBJID), AE preferred term (ADAE.AEDECOD), AE start date (ADAE.AESTDTC), and AE end date (ADAE.AEENDTC). The sorting will include all AE segments with complete or partial start / end dates.

1.3. Create Derived Variables in ADAE ADaM SAS Dataset

Based on the ADAE dataset after sorting per step 1.2 above, for each unique subject, create the following derived variables in the ADAE ADaM SAS dataset:

1) **ANL01FL: Flag for the unique AE**

a) Collapsed AE Segments

For collapsed AE segments. based on the ADAE dataset after sorting per step 1.2 above:

- derive the flag variable: **ANL01FL="Y" on the first record for each collapsed AE (i.e. the earliest segment within each collapsed AE with the same ADAE.AEDECOD)** . In case if the AE segment of the collapsed AEs started before Lymphodepletion and ending after it, then populate the ANL01FL='Y' on very first Treatment emergent record. If there is only one record (segment) which started before lymphodepletion and ended after lymphodepletion then populate ANL01FL='Y' on that record only.
- **Otherwise ANL01FL="" (Missing).**

b) AE Events Comprised of a Single Row (No Collapsing Needed)

- derive the flag variable: **ANL01FL="Y" for each single segment AE event**.

2) EVTSEQ: Sequence number of each unique AE with the same PT

Create a sequence number, EVTSEQ, for each unique AE within the same ADAE.AEDECOD.

For each unique subject within each unique AE preferred term, this variable will be recorded as **the sequential number to identify all unique adverse events (including both single segment events (i.e., no collapsing needed) and collapsed events from multiple segments) based on the sorting order chronologically addressed under step 1.2 above.**

a) Collapsed AE Segments

Each collapsed AE and its corresponding composed segments will have the same sequence numbers (i.e., if multiple segments/records are qualified for being collapsed into one unique AE (i.e., all those records will have same value for the derived variable EVTSEQ for that corresponding subject within the same collapsed AE).

b) Single Segment AE Records

Each single segment AE event (i.e., un-collapsed event) will have different unique sequence number separately.

c) AE Segments with partial start or end dates

Each AE segment with partial start or end dates will have different unique sequence number starting from 99XXX, where XXX=001, 002, ...

*** NOTE:** For those subjects who received 2 T-cell infusions, the sequential number will be based on both infusion periods combined (i.e., the assigned sequential number will be independent of T-cell infusion periods).

3) EVTENDT: End Date for each unique AE

a) Collapsed AE Segments

- =ADAE.AENDT (end date) of the last segment of the collapsed event (i.e., the segment with the latest ADAE.AENDT within the same collapsed AE for each unique subject).
- This should be populated on the segment with ANL01FL='Y' only (i.e., the segment with earliest ADAE.ASTDT of each collapsed AE).
- Note: If any of the segments have missing end date (i.e., unresolved) then the derived EVTENDT will be missing, and hence cannot calculate duration of event (please see derived variable: EVTDUR under item 4) below).

b) Single Segment AE Records
=ADAE.AENDT (end date) of each single segment event (i.e. un-collapsed record).

4) EVTDUR: Duration of each unique AE

a) Collapsed AE Segments when AE segment started on or after lymphodepletion or Un-collapsed AEs.

- **Collapsed AE Segments**
  - Where ANL01FL='Y' then EVTDUR = AESTDT-EVTENDT+ 1.
  - = Missing, if missing end date for the derived variable EVTENDT (i.e., AEOUT=unresolved with missing AEENDTC for any of the segments within the same collapsed AE).
- **Single Segment AE records**
  - EVTDUR = AESTDT-EVTENDT (i.e., = AEENDT) + 1.
  - = Missing, if missing end date (i.e., missing AEENDT and hence EVTENDT due to

AEOUT=unresolved for the corresponding, single segment record (i.e., un-collapsed AE record).

b) Collapsed AE Segments when AE segment started before lymphodepletion and ends after it.

- Where ANL01FL='Y' then EVTDUR = LYMPHDT(Lymphodepletion date) - EVTENDT+ 1.
- = Missing, if missing end date for the derived variable EVTENDT (i.e., AEOUT=unresolved with missing AEENDTC for any of the segments within the same collapsed AE).

5) EVTOUT: Outcome of each unique AE

a) Collapsed AE Segments

Derive this variable for the record with ANL01FL="Y" only

- EVTOUT should be derived variable as worst output for an event based on the hierarchy: Fatal > Not Recovered/Not Resolved > Recovering/Resolving with sequale > Recovering/Resolving > Recovered/Resolved, with Fatal being the worst.

b) Un-collapsed AE records

- EVTOUT=ADAE.AEOUT for each unique, un-collapsed AE record.

6) EVTREL: Relatedness of each unique AE to Study Drug

a) Collapsed AE Segments

Derive this variable for the record with ANL01FL="Y" only

- EVTREL='Y' when any of the segments within the same collapsed AE was related to any study drug (i.e., ADAE.AREL="Y" for any segment within the same collapsed AE).
- Otherwise EVTREL="N" if all of the segments within the same collapsed AE were not related to any study drug (ADAE.AREL="N" for all segments within the same collapsed AE).

b) Un-collapsed AE Records

- EVTREL='ADAE.AREL for each unique, un-collapsed AE record.

7) EVTSAE: Seriousness of each unique AE Event (take the worst)

a) Collapsed AE Segments

Derive this variable for the record with ANL01FL="Y" only

- EVTSAE='Y' when any of the segments within the same collapsed AE EVENT(i.e., ADAE.AESER="Y" for any segment within the same collapsed AE).

- Otherwise EVTSAE="N" if all of the segments within the same collapsed AE were not SERIOUS (ADAE.AESER="N" for all segments within the same collapsed AE).

b) Un-collapsed AE Records

- EVTSAE='ADAE.AESER for each unique, un-collapsed AE record.

8) EVTSDY: Event start day

a) Collapsed AE Segments when AE segment started before lymphodepletion and ends after it.

Derive this variable for the record with ANL01FL="Y" only

- Populate as day on the study lymphodepletion started w.r.t T -cell as follows: LYMPH1DT-TRTSDT.
- If in case any of the date is missing (1st lymphodepletion date or t-cell infusion date use -8.

b) Collapsed AE Segments when AE segment started on or after lymphodepletion.

- EVTSDY =ASTDY.

c) Un-collapsed AE Records

- EVTSDY=ASTDY.

9) EVTMGR: Maximum grade of each unique AE Event (take the worst)

a) Collapsed AE Segments

Derive this variable for the record with ANL01FL="Y" only

- Populate EVTMGR with grade out of each segment(record) within the event.

b) Un-collapsed AE Records

- EVTMGR=ADAE.AETOXGR for each unique, un-collapsed AE record.

Additional Notes:

- **For any collapsed AEs and single segment records with missing or partial start and/or end dates,**
  - EVTDUR= missing and will be excluded from the calculation for the summary statistics of AE duration.

- **AOCCPFL: Flag for the first (ONSET) occurrence of preferred term**
  - This variable is a GSK standard variable in the ADAE ADaM SAS data set, which can be used to capture the first AE onset date for each unique AE preferred term.
  - If there are multiple AEs (AEDECODs) within same AESI on the same date, select the record with the max. duration. This is as per the GSK std. Macro. Macro remove the missing dates records.
  - We are not creating the Last occurrence of AESI as can be done for sorting the AE start date and Duration and take the last record.

- For Onset Day and Last Onset Day, please use EVTSDAY for table programming.