Reporting and Analysis Plan

Study ID: 208467

Main Study Title: Master Protocol to Assess the Safety and Antitumor Activity of Genetically Engineered NY-ESO-1-Specific (c259) T Cells, Alone or in Combination With Other Agents, in HLA-A2+ Participants With NY-ESO-1 and/or LAGE-1a Positive Solid Tumors (IGNYTE-ESO)

Sub-study 1 Title: Evaluation of Safety and Antitumor Activity of Lete-Cel (GSK3377794) in HLA-A2+ Participants With NY-ESO-1 Positive Previously Untreated Advanced (Metastatic or Unresectable) Synovial Sarcoma and Myxoid/Round Cell Liposarcoma

NCT ID for Sub-study 1: NCT05993299

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

Title	:	Reporting and Analysis Plan for the Substudy 1 of study 208467: To Assess the Safety and Antitumor Activity of Genetically Engineered T Cells in NY-ESO-1 and/or LAGE-1a Positive Solid Tumors
Compound Number	:	GSK3377794
Effective Date	:	Refer to Document Date

Description:

- The purpose of this RAP is to describe the planned analyses and output to be included in the Clinical Study Report for Protocol 208467 Substudy 1.
- This RAP is intended to describe the planned efficacy, safety and tolerability analyses required for the study.
- Given the status of the study, this RAP will be provided to the study team members to convey the content of the Statistical Analysis Complete (SAC) deliverable to support an abbreviated primary / final CSR post substudy termination. Only a subset of the original planned analysis designed to support full CSR will be performed. Substudy 1 was terminated due to enrollment challenges and feasibility of completing the study in the first line Synovial Sarcoma and Myxoid Round Cell Liposarcoma patient population.

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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 the Substudy 1 of Protocol:

Revision Chronology:		
Original/ 2018N385677_00	05-APR-2019	Original
Amendment 01/ 2018N385677_01	21-JUN-2019	The overall rationale for this amendment is addition or clarification of aspects related to participant safety and rationale for Substudy 1 patient population. These additions included modification of lymphodepleting regimen for older participants, and changes related to FDA requests including addition of study stopping rules, and update to both the Encephalopathy (now Immune Effector Cell-Associated Neurotoxicity or ICANS) and the CRS grading and management criteria.
Amendment 02/ 2018N385677_03	05-FEB-2020	The primary rationale for protocol Amendment 2 is clarification of aspects related to drug product supply used for treatment on Substudy 2. Per protocol Amendment 1, for Substudy 2, at least 45 participants will be treated using the intended commercial vector supply and cell manufacturing processes (application supplement to be submitted). In the event participants eligible for Substudy 2 require treatment before commercial drug product supply is available, protocol Amendment 2 allows for treatment to begin with the currently registered drug product supply. Such participants, if any, will be replaced to ensure that at least 45 participants receive the intended commercial drug product supply. An additional rationale for protocol Amendment 2 is clarification of dosing regimen and drug product supply used for treatment of participants weighing less than 40 kg on Substudies 1 and 2. This protocol Amendment 2 implements an updated dose range per body weight for participants weighing less than 40 kg as per the Investigator's Brochure version 11 update [GlaxoSmithKline Document Number 2018N369930_03, 2019]. Clarification is also provided that participants weighing less than 40 kg will only be treated with the intended commercial cell manufacturing process, and that screening of such participants may begin before commercial drug product supply is available.
Amendment 03/ 2018N385677_05	06-APR-2020	The primary rationale for protocol Amendment 3 is to address regulatory agency's requests and integrate protocol clarification letters that were issued to date. Protocol amendment 3 addresses feedback from regulatory agencies by defining an end of study for the Master Protocol, by clarifying the hospitalization and monitoring requirements

Revision Chronology:		
		for T-cell infusion, and by clearly defining contraception requirements. Protocol amendment 3 also further clarifies schedule of assessments, washout periods prior to leukapheresis and prior to lymphodepletion for Substudy 1 and 2, requirement for availability of tocilizumab and treatment/management of pediatric participants. Further data collection for all screened participants, assessment of TGF-β levels and on-study collection of stool samples for microbiome analysis have been added. Protocol amendment 3 also updates eligibility criteria that participants from Substudies 1 and 2 who are enrolled under clinical drug product supply need to weigh ≥40 kg. Conditions for rescreening of participants who have failed screening or withdrawn have been clarified such that, for patients who have previously completed protocol-specified target expression testing and/or leukapheresis, the Sponsor will confirm the eligibility and use of any cryopreserved leukapheresis and/or manufactured product on evaluation for an applicable substudy.
Amendment 04/ 2018N385677_07	03-DEC-2020	The primary rationale for protocol Amendment 4 is to: 1. Include Myxoid/Round Cell Liposarcoma (MRCLS) as a second translation-related sarcoma indication to Substudies 1 and 2. 2. Allow fresh biopsies for NY-ESO-1 antigen expression screening, 3. Allow for participants with high-risk locally advanced disease to be screened on Substudy 1, 4. Amend analysis population definitions to align with program definitions.
Amendment 05/ TMF-13778474	19-MAY-2021	Amendment 05 The primary rationale for protocol Amendment 5 is to: 1. Inclusion of updated safety language: a. for increased monitoring of coagulation and cardiotoxicity biomarkers b. for management of CRS and ICANS c. for lymphodepleting regimen dose adjustments and assessment of renal function 2. Update on Disease-specific translocation requirements Clarification of End of Interventional Phase, End of Follow-up phase and End of substudy definitions

Revision Chronology:		
Amendment 06/ TMF-14132897	04-NOV-2021	The primary rationale for protocol Amendment 6 is: 1. Implementation of additional safety monitoring measures in accordance with a recent Dear Investigator Letter and safety events. 2. An increase in the number of participants in Substudy 2 from 70 planned to 87 participants (with 72 expected to receive the intended commercial drug product supply) was made to ensure greater statistical power for the purpose of registration. 3. For participants treated as of protocol Amendment 6, the cyclophosphamide dose in the lymphodepleting chemotherapy was reduced on Day -7 thru Day -4 to further optimize and reduce potential for acute and prolonged cytopenias while also minimizing impact on efficacy. 4. For participants treated as of protocol Amendments 6, the upper end of the target dose range of transduced T cells was increased from to 8×10^9 to 15×10^9 in order to maximize the delivery of cells for participants whose manufacture yields $>8\times10^9$ transduced T cells.

2. SUMMARY OF KEY PROTOCOL INFORMATION

2.1. Changes to the Protocol Defined Statistical Analysis Plan

Changes or deviations to the originally planned statistical analysis specified in the Protocol Amendment 06 (Dated: 04-NOV-2021) include:

- Efficacy sensitivity analysis will not be performed due to study termination
- Most exploratory endpoints will not be analyzed. Further details are given in the RAP.
- As appropriate, listings may be produced in lieu of tables and figures given low sample size due to study termination. Further details are given in the RAP.

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

Most exploratory endpoints detailed in the Protocol will not be analyzed as part of this statistical analysis plan. If additional analyses are considered necessary for selected endpoints, separate analyses according to exploratory analysis plan may be drafted.

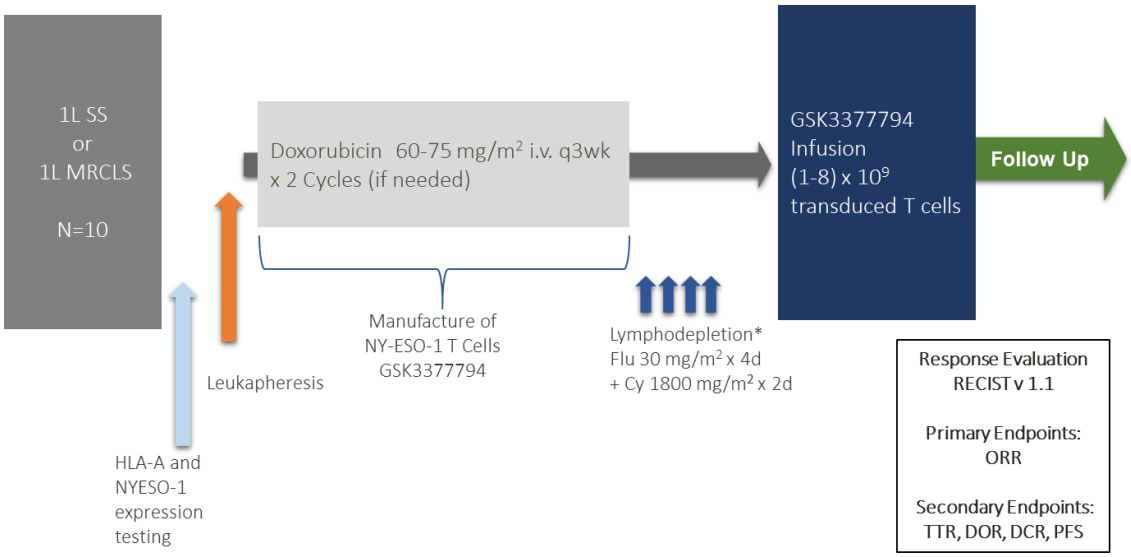
Objectives	Endpoints
Primary Objectives	**Primary Endpoints**
To evaluate the efficacy of lete-cel in HLA-A*02:01, HLA-A*02:05 and/or HLA-A*02:06 participants with NY-ESO-1 positive advanced synovial sarcoma or myxoid/round cell liposarcoma	• Overall Response Rate (ORR) per RECIST v1.1 assessed by investigator
Secondary Objectives	**Secondary Endpoints**
To further evaluate the efficacy of lete-cel in HLA-A*02:01, HLA-A*02:05 and/or HLA-A*02:06 participants with NY-ESO-1 positive advanced synovial sarcoma or myxoid/round cell liposarcoma	• Time to Response (TTR) • Duration of Response (DoR) • Disease Control Rate (DCR) • Progression Free Survival (PFS)
To evaluate the safety and tolerability of lete-cel in HLA-A*02:01, HLA-A*02:05 and/or HLA-A*02:06 participants with NY-ESO-1 positive advanced synovial sarcoma or myxoid/round cell liposarcoma	• Frequency and severity of Adverse events (AEs), serious adverse events (SAEs) and AEs of special interest (AESI; as defined in protocol) • Replication Competent Lentivirus (RCL) • Instances of Insertional oncogenesis (IO)
To characterize in vivo cellular PK profile (levels, expansion, persistence) of NY-ESO-1 specific (c259) T cells	• Maximum transgene expansion (Cmax) • Time to Cmax (Tmax) • Area under the time curve from zero to time t AUC(0-t), as data permit
Exploratory Objectives	**Exploratory Endpoints**
CCI [redacted]	

Objectives	Endpoints
CCI	

AE/s = adverse event/s; AESI/s: adverse event/s of special interest; AUC (0-t) = area under the time curve from zero to time t; Cmax = maximum concentration; DOR = duration of response; HLA = human leukocyte antigen; ORR = overall response rate; OS = overall survival; PFS = progression-free survival; RECIST = Response Evaluation Criteria in Solid Tumors; SAE = serious adverse event; Tmax = Time to Cmax; TTR = Time to Response.

2.3. Study Design

Overview of Study Design and Key Features



* The lymphodepleting regimen was adjusted as described in Section 7.1.3 of the Substudy 1 section of ⩾Amendment 06 of the Protocol

Design Features	• This is a single arm, non-randomized substudy to investigate Lete-Cel (GSK3377794) in previously untreated participants with advanced (metastatic or unresectable) synovial sarcoma and Myxoid/Round Cell Liposarcoma • Participants identified by the Investigator as possible candidates for the study must have completed target expression screening for HLA-typing and NY-ESO-1 antigen expression; participants with the HLA-A*02:01, HLA-A*02:05 and/or HLA-A*02:06 alleles and whose tumor expresses the NY-ESO-1 antigen above the cut-off according to the applied immunohistochemistry assay are eligible to undergo further screening for this study. • This study is divided into four distinct parts:1) Screening, 2) Leukapheresis/manufacture,3) Lymphodepletion/Treatment,4) Long-term follow-up (LTFU) • Participants will undergo stepwise enrollment on the study followed by treatment according to defined phases within this substudy which will include: ○ Part 1: Screening 1) Target expression screening for the presence of HLA-A*02:01, HLA-A*02:05 and/or HLA-A*02:06 type and tumor expression of NY-ESO-1, 2) Leukapheresis screening phase to determine eligibility for undergoing leukapheresis beginning up to 28 days prior to leukapheresis, ○ Part 2: Leukapheresis/Manufacture 3) Leukapheresis procedure. (Note: Leukapheresis may have been performed under another GSK-sponsored protocol or substudy of this protocol) ○ Part 3: Lymphodepletion/Treatment 4) Treatment fitness assessment and eligibility confirmation

Overview of Study Design and Key Features	
	5) Interventional phase including Lymphodepletion from Days -7 to -4, GSK3377794 infusion on Day 1 and follow-up until the end of study (as defined in Protocol Section 5.3 of this Substudy) (Note:T-cell receptor (TCR) engineered T-cell may have been manufactured under another GSK-sponsored protocol or substudy of this protocol) o Part 4: Long-Term Follow-Up (LTFU) 6) Long-term follow-up phase for up to 15 years from the date of GSK3377794 infusion. • A participant is considered to have completed the Substudy when one of the following occurs (whichever is sooner): o The substudy ends when all treated participants have transferred to the separate LTFU protocol (GSK study 208750), declined consenting to the LTFU protocol, completed LTFU requirement in this study, have been lost to follow-up, or withdrawn early, or died. • If participant withdraws consent or is withdrawn for other reasons prior to substudy end, they will be considered early withdrawal. • All participants alive after confirmed disease progression will be followed in a separate long term follow up (LTFU) protocol (GSK study 208750) for observation of delayed AEs and survival for a duration of 15 years post-T-cell infusion in accordance with FDA (FDA, 2020) and EMA guidance (EMA, 2009). If LTFU protocol is not yet available at the particular clinical site, participants may be temporarily followed per LTFU schedule until LTFU protocol becomes available. The transfer of any individual participant to the LTFU protocol 208750 should not exceed 6 months. This substudy will enroll approximately 10 participants to support the primary analysis.
Dosing	• When the NY-ESO-1c259T cells are available, participants will undergo lymphodepleting chemotherapy, followed by infusion of NY-ESO-1c259 transduced T cells on day 1 in the range of 1 x 10^9 to 15 x 10^9 transduced cells. • The lymphodepleting regimen in this study consists of fludarabine 30 mg/m^2/day x 4 days (Day -7 to -4) and cyclophosphamide 900 mg/m^2/day x 3 days (Day -6 to -4). • T-cell dose and lymphodepletion regimen may be adjusted based on criteria specified in Section 7.1.3 and Section 7.1.4 of the Protocol.
Time & Events	• [Refer to Appendix 2: Schedule of Activities]
Treatment Assignment	• This is a single arm, non-randomized substudy. Participants will receive Genetically Engineered NY-ESO-1 Specific (c259) T Cells (GSK3377794 / lete-cel}
Interim Analysis	• Detailed safety reports will be provided to the IDMC on a regular basis and the intervals will be specified in the IDMC charter

2.4. Statistical Hypotheses / Statistical Analyses

No formal statistical hypotheses are being tested in this study.

3. PLANNED ANALYSES

3.1. Interim Analyses

Detailed interim safety reports will be provided to the IDMC (see Section 5.4.1 of the Core Protocol) on a regular basis and the intervals will be specified in the IDMC charter.

3.2. Primary Analyses

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

1. All the enrolled participants have received T-cell infusion (mITT population) or withdrawn earlier and have completed at least 2 post-baseline disease assessments since infusion or discontinued earlier (due to death, loss to follow-up, or permanent study withdrawal).

2. All required database cleaning activities have been completed and final database release (DBR) and database lock (DBL) has been declared by Data Management.

3.3. Final Analyses

In the case that the primary analysis occurs close to the final analysis, only the final analysis will occur.

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

1. All participants who have received the T-cell infusion have either confirmed disease progression, died, or have withdrawn early from the study or have been lost to follow-up and the substudy has ended.

2. All required database cleaning activities have been completed and final database release (DBR) and database lock (DBL) has been declared by Data Management.

4. ANALYSIS POPULATIONS

Population	Definition / Criteria	Analyses Evaluated
Screened	• All patients who signed an ICF to participate in the study.	• Study Population
Enrolled	• All participants who started leukapheresis procedure.	• Study Population
Intent-To-Treat (ITT)	• All participants who started leukapheresis procedure.	• Study Population Safety, Efficacy
Lymphodepletion Population	• All participants who received any dose of lymphodepletion chemotherapy.	• Safety
Safety Population	• All participants who received any dose of GSK3377794.	• Primary Safety
Modified ITT Population (mITT)	• All participants who received any dose of GSK3377794.	• Primary Efficacy, Study Population
Pharmacokinetic (PK)	• Participants in the Safety population from whom at least one persistence sample was obtained, analyzed and was measurable.	• PK
Patient Reported Outcomes (PRO)	• All adult participants in the Safety population (≥18 years of age)	• Patient Reported Outcomes

Refer to Appendix 12: List of Data Displays which details the population used for each display.

The PRO population will not be used for any analysis to support the abbreviated CSR.

4.1. Protocol Deviations

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

Protocol deviations will be tracked by the study team throughout the conduct of the study in accordance with the Protocol Deviation Management Plan [Version 2.0 11-May-2021]. There are no data-driven protocol deviations tracked.

- Data will be reviewed prior to locking the database to ensure all important deviations are captured and categorized in the protocol deviations dataset.
- This dataset will be the basis for the listings of protocol deviations.

A separate listing of all inclusion/exclusion criteria deviations will also be provided using the ITT population. This listing 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, non-randomized substudy, in which each participant will receive Genetically Engineered NY-ESO-1 Specific (c259) T Cells (GSK3377794/lete-cel). Data will be listed and summarized according to the GSK reporting standards, where applicable. The GSK794 column represents all participants planned to be treated with GSK3377794.

Treatment Group Descriptions	
Data Displays for Reporting	
Description	**Order in TLF**
GSK794	1

5.2. Baseline Definitions

For all endpoints, unless otherwise stated below in this section, the baseline value will be the latest assessment with a non-missing value (including unscheduled visits) prior to initiating lymphodepletion. If time is not collected, assessments taken on the day of lymphodepleting chemotherapy are assumed to be taken prior to lymphodepletion and used as baseline. Per protocol, baseline assessments should occur less than 10 days prior to initiating lymphodepletion. If a non-missing assessment within 10 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 10 days prior to initiating lymphodepletion.

For laboratory data, baseline will be defined as the most recent, non-missing value from a central laboratory prior to the initiating lymphodepleting chemotherapy. If there are no central laboratory tests collected for a participant and a laboratory test prior to the lymphodepletion, the most recent, non-missing value from a local laboratory prior to initiating lymphodepletion will be defined as the baseline value. For summaries of laboratory data by CTCAE (version 5.0) grade, missing baseline grade will be assumed as grade 0. For cytokine analyses, some samples taken at baseline may be 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.

For ECG analyses, participant level baseline is defined as the mean of triplicate baseline assessments

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

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

5.4.1. Covariates and Other Strata

Not applicable for this study.

5.4.2. Examination of Subgroups

Due to the small sample size, subgroups will not be examined in this study.

5.5. Multiple Comparisons 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

Limited study population summaries and listings will be created to support the abbreviated primary / final CSRs. The section below details all original planned analyses which may not be performed. Appendix 12 will reflect the limited scope of displays to support the terminated substudy, as well as conditional displays.

6.1. Overview of Planned Study Population Analyses

The study population analyses will be based on the Screened, Enrolled, modified Intent-to-Treat (mITT) and Intent-To Treat (ITT) populations. Some study population analyses will be performed using both the mITT and ITT populations. If the mITT and ITT populations are identical, then results planned for both populations will only be reported for the MITT population. All listings will be based on the ITT population, unless otherwise specified.

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

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.

A summary and listing of screening status and screen failures at target expression screening and leukapheresis eligibility 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.

The interventional phase begins at lymphodepletion and is completed at time of confirmed progressive disease or death. A summary of interventional phase status will be produced, with reasons for completion and study withdrawal summarized in the order they are displayed in the CRF in the lymphodepletion population.

Overall study disposition, including long-term follow up, will be summarized for the mITT and ITT populations. An additional table will be created to summarize the number of participants in the ITT population who did and did not receive T-cell infusion, as well as the reason for not receiving T-cell infusion. A supporting listing of reason for study withdrawal will be created

Lastly, the number of participants in the Enrolled Population and mITT population will be summarized by country and study site ID.

6.3. Demographic and Baseline Characteristics

Disease characteristics at initial diagnosis will be summarized and listed, as collected in the CRF. Example categories may include primary tumor type under study, specific translocation or % round cell component, primary site at initial diagnosis, time since initial diagnosis in months, and disease stage, grade, and TNM (tumor, nodes, metastases) staging at initial diagnosis. In addition to those stated above, date of initial

diagnosis will be listed. Refer to Section 14.6.2 for time since initial diagnosis derivation rules.

Disease characteristics at screening will be summarized and listed, as collected in the CRF. Example categories may include the extent of disease at screening, time since last recurrence (months), grade, TNM staging, and disease stage at screening, tumor histology, visceral/non-visceral disease, HLA and NY-ESO-1 status (Y/N), and NY-ESO-1 expression level.

A summary of metastatic disease at Screening will be provided for the mITT population and will summarize time from diagnosis of metastatic disease to leukapheresis eligibility screening and status of metastases at different body sites. A supportive listing in the ITT population will be provided.

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.

The demographic characteristics (e.g., race, age, ethnicity, sex, height, and body weight at leukapheresis eligibility screening, body mass index [kg/m^2]), and body surface area (BSA) as per the DuBois & DuBois formula (DuBois, 1916) will be summarized and listed according to GSK standards. A supportive summary of age ranges and listing of race will be produced.

Past and current medical conditions will be summarized separately for the ITT and mITT population. All medical conditions recorded will be summarized, even if they are not pre-specified in the CRF. A supportive listing will be provided.

6.4. Concomitant Medication

Concomitant medications will be coded using both WHO Drug and GSK Drug coding dictionary and will be summarized using the mITT population. Concomitant medications will be reported using GSK Drug for all deliveries. 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. Concomitant medication is defined in Section 14.4.1.2. A supportive listing in the ITT population will be provided.

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

Blood products will be summarized as recorded in the CRF. A supporting listing will also be provided.

6.5. Study Treatment Exposure

A listing of study treatment will be provided, including overall T-cell infusion start and stop date/time over all bags and for each bag separately, average vector copy number per cell in the cell product, total number of transduced cells, percentage of cells transduced, and product status (conforming vs. nonconforming product). The listing will also include information pertaining to why a bag was partially infused, estimated percentage of bag infused, and reason for halting infusion. The total number of transduced T-cells and actual cumulative fludarabine and cyclophosphamide dose will be summarized using n, mean, standard deviation, median, minimum, and maximum. The total number of transduced T-cells will be categorized into <1, ≥1 to ≤8, >8 to ≤15, and >15 (x 10^9 cells), cumulative cyclophosphamide will be categorized into ≤1800 mg/m^2, >1800 to ≤2400 mg/m^2, >2400 to ≤2700 mg/m^2, >2700 to ≤3600 mg/m^2, and >3600 mg/m^2, and cumulative fludarabine will be categorized into ≤60mg/m2, >60 to ≤80 mg/m^2, >80 to ≤90 mg/m^2, >90 to ≤120 mg/m^2, and >120 mg/m^2. Time from leukapheresis to T-cell infusion will also be summarized.

Assigned Lymphodepletion Regimen (LDR) will be programmed based on participants lymphodepleted prior to 25Oct2021 (2x1800 = 3600 mg/m2) vs. lymphodepleted on or after 25Oct2021 (3x900 = 2700 mg/m2) – reflecting the date of the LDR change for the study (Protocol Amendment 6 issued on 04Nov2021 and a Protocol Clarification Letter prior to that).

All dose administration data for lymphodepletion, including cyclophosphamide and fludarabine, for T-cell infusion will be presented by participant in a data listing. Supportive listings to report dose reductions and delay of lymphodepletion chemotherapy will be provided also.

Duration of lymphodepletion dose delays over planned consecutive days is defined as period from the expected start date of dose to actual start date of current dose. The calculation of the duration of delay is actual start date of current dose - expected start date of dose. Expected start date of dose = actual start date of previous dose + 1.

6.6. Anti-Cancer Therapies and Surgery

Anti-cancer therapies include systemic therapy (coded using the GSK Drug coding dictionary), radiotherapy, and cancer-related surgery.

Anti-cancer systemic therapies will be classified into prior, bridging and on-study phases as described below. Therapies will be identified using the corresponding CRF pages.

Type of Systemic Therapy	Definition[1]
Prior	Prior therapy is defined as any line of systemic therapy (including intermediate therapy after leukapheresis), radiotherapy, and cancer-related surgeries given before start of lymphodepletion. Prior therapies will be identified as any therapy recorded on the Prior Therapy CRF forms or Intermediate and Supportive Therapy CRF form and labeled as Intermediate Standard of Care.
Bridging	Bridging therapies (supportive chemotherapy) are defined as prior systemic therapy given between leukapheresis and start of lymphodepletion to maintain disease control (not considered a line of therapy) Bridging therapies will be identified as any therapy recorded on the Intermediate and Supportive Therapy CRF form and labeled as Supportive Chemotherapy.
On-Study/Follow-up	On-study and follow-up therapies are defined as systemic therapy, radiotherapy, or cancer-related surgery given on or after the start of lymphodepletion. On-study / Follow-up therapies will be identified as any therapy recorded on the On-study therapy and Follow-up therapy CRF forms

[1] Type of Systemic Therapy will be reported based on CRF form. Forms will not be re-assigned programmatically for text or dates.

6.6.1. Prior and Bridging Anti-Cancer Therapies

Bridging therapies are defined as prior systemic therapy given between leukapheresis and start of lymphodepletion to maintain disease control. Bridging therapy will be coded using GSK Drug coding dictionary and summarized by ATC Level 1 and ingredient.

Full lines of systemic therapy in the advanced/metastatic setting prior to treatment are not expected in this substudy. Full lines of systemic therapy will not be included in summaries of bridging therapy.

A breakdown of the number of participants who received prior surgery and prior radiotherapy in the mITT population will be summarized.

A listing of systemic therapy will be provided and labelled as prior, bridging, or on-study. Radiotherapies and cancer-related surgeries will be listed separately and labelled as prior or on-study (as defined in Section 6.6.2).

6.6.2. On-Study Anti-Cancer Therapies

On-study anti-cancer therapies will be summarized using the mITT population. The number and percentage of participants that received any on-study systemic anti-cancer therapy, radiotherapy, or cancer-related surgery will be summarized together with the time from T-cell infusion to first post-treatment anti-cancer therapy. On-study systemic therapies will be coded using GSK Drug coding dictionary and summarized. On-study anti-cancer therapy will be listed. As described in Section 6.6.1, a listing of systemic therapy will be provided and labelled as prior, bridging, or on-study.

7. EFFICACY ANALYSES

Limited efficacy summaries and listings will be created to support the abbreviated primary / final CSRs. The section below details all original planned analyses which may not be performed. Appendix 12 will reflect the limited scope of displays to support the terminated substudy, as well as conditional displays

7.1. Primary Efficacy Analyses

Sensitivity analysis evaluating the Overall Response Rate using the ITT population will not be performed.

7.1.1. Endpoints/Variables

ORR

Overall response rate (ORR) is defined as the percentage of participants with a confirmed CR or a PR relative to the total number of participants within the analysis population at any time per RECIST v1.1 (Eisenhauer, 2009) as determined by the local Investigators.

ORR will be reported in the ITT and mITT populations at the time of primary analysis. The primary analysis for ORR will be based on the mITT population

Best Overall Response **(**BOR) is defined as the best confirmed response (Complete Response (CR) > Partial Response (PR) > Stable Disease (SD) > Progressive Disease (PD) > Not Evaluable (NE)) from T cell infusion date until disease progression or initiation of new anti-cancer therapy, whichever is earlier, as assessed by the RECIST v1.1.

RECIST (version 1.1) criteria

With respect to best overall responses, RECIST will be derived on local investigator assessed overall response at each visit:

- To be assigned a status of PR, or CR, a confirmatory disease assessment should be performed no less than 4 weeks (28 days) after the criteria for response are first met
- To be assigned a status of SD, follow-up disease assessment must have met the SD criteria at least once after the first dose at a minimum of 4 (28 days) weeks (Protocol Section 12.6.1)
- If the minimum of 4 weeks for SD 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
- Responses of CR/PR that do not meet the requirements of confirmed CR/PR are still eligible to be considered SD if it has met the SD criteria.
- If PR assessments are separated by more than one SD assessment (e.g., PR-SD-SD-PR), the PR is not considered confirmed. PR separated by only one SD assessment (PR-SD-PR) will be considered a confirmed PR.

- Assessments that are not done or not evaluable should be disregarded.
- The date of disease progression is defined as the date of radiological disease progression based on imaging data per RECIST v1.1. For cases where symptomatic progression is documented by the investigator, the derived overall response based on RECIST v1.1 tumor assessment data will be utilized.
- Disease assessments after new on-study anti-cancer therapy will not be considered when deriving best overall response. On-study anti-cancer therapy is defined as systemic therapy, radiotherapy (excluding palliative radiotherapy), or anti-cancer surgery of target/non-target lesions given on or after the start of T-cell infusion
- 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.
- Inclusion criteria 19 requires participants to have measurable disease according to RECIST v1.1 criteria. If this is violated and a participant has no measurable disease at baseline, then the participant will be treated as a non-responder and included in the denominator when calculating ORR. Participants with no disease assessments on study will be also treated as a non-responder and included in the denominator when calculating ORR.

7.1.2. Summary Measure

ORR

The number and percentage of participants with the BOR in the following response categories will be summarized: CR, PR, SD, PD, NE, and overall response rate (CR+PR). The observed confirmed ORR will be reported at the primary analysis along with 95% Clopper-Pearson exact CI. Analysis will be based on mITT and ITT population.

An overall listing of participant response data and supporting lesion data will be provided.

Change in target lesions from baseline over time will be shown in a spider plot. A waterfall plot showing the maximum percentage of reduction from baseline in tumor measurement will be also 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 mITT population. ORR will be reported in the mITT population at the time of the primary analysis.

The ITT is the sensitivity analysis population for ORR. If the mITT and ITT populations are identical, only results associated with the mITT population will be reported.

7.1.4. Strategy for Intercurrent Events

A composite strategy will be followed for participants who experience death prior to response assessments or have only missing responses or not-evaluable assessments or have non-measurable disease at baseline. These participants will be treated as non-responders (NE); i.e., they will be included in the denominator when calculating the percentage.

Start of new anti-cancer therapy is addressed using a while-on-treatment strategy, as the interest lies in the treatment effect of the investigational treatments before the start of a new anti-cancer therapy.

7.1.5. Statistical Analyses / Methods

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

Unless otherwise specified, endpoints / variables defined in Section 7.1.1 will be summarized using descriptive statistics, graphically presented (where appropriate) and listed

7.2. Secondary Efficacy Analyses

Sensitivity analysis evaluating the Disease Control Rate using the ITT population will not be performed.

7.2.1. Endpoint / Variables

DCR

Disease Control Rate (DCR) is defined as the percentage of participants with a confirmed CR, PR, or SD with a minimal 12 weeks (84 days ± 7-day window) duration relative to the total number of participants within the analysis population at the time of primary analysis as determined by local investigators per RECIST v1.1. DCR will be analyzed based on the mITT population. The observed DCR will be reported along with 95% Clopper-Pearson exact confidence interval (CI).

A BOR of SD will be considered to have had a duration of at least 12 weeks (SD durability) if there is at least one follow-up disease assessment that has met the RECIST 1.1 SD, PR, or CR criteria on or after Week 12 (Day 84 ± 7-day window), but before disease progression or initiation of new anti-cancer therapy.

Inclusion criteria 19 requires participants to have measurable disease according to RECIST v1.1 criteria. If this is violated and a participant has no measurable disease at baseline, then the participant will be treated as a non-responder and included in the denominator when calculating DCR. Participants with no disease assessments on study will be also treated as a non-responder and included in the denominator when calculating DCR.

PFS

Progression-free survival (PFS) is defined as the interval of time (in months) between from the date of T-cell infusion to the earliest date of radiological progression of disease (PD) as assessed by local investigator per RECIST v1.1, or death due to any cause. Determination of dates of PFS events and dates for censoring are described in Table 1.

On-study anti-cancer therapy is defined in Section 6.6.2.

For participants that receive on-study anticancer therapy, the following rules will apply:

- If there is no or incomplete baseline assessment, the participants will be censored at the date of T-cell infusion.
- Participants without any adequate post-baseline disease assessments prior to the date of initiation of anti-cancer therapy will be censored at the date of T-cell infusion
- If the participant has adequate post-baseline disease assessments prior to initiation of anti-cancer therapy, PFS will be censored at the last adequate disease assessment (e.g., assessment when visit level response was CR, PR, or SD) prior to the initiation of the new anticancer therapy.

If the start date of anticancer therapy is partial, the imputation rules described in Section 14.7.2.1 will be applied. If new anti-cancer therapy occurs on the same day as a radiological disease assessment, assume the disease assessment was performed first.

Extended Loss to Follow-up

Since missing scheduled radiological disease assessments prior to radiological progression or death increases the uncertainty when the event actually occurs, PFS will be censored for participants who have radiological progression or die after missing two or more scheduled radiological disease assessments. Specifically, if there are two or more scheduled radiological assessments which are missing followed by radiological progression or death, PFS will be censored at the last adequate radiological assessment prior to radiological progression or death. If a participant does not have an adequate post-baseline disease assessment prior to the date of radiological progression or death, PFS will be censored at the date of the T-cell infusion date.

As the assessment schedule and windows change through the course of the study (i.e., every 6 weeks during the first 24 weeks and then every 3 months thereafter), the following rules will be used for identifying extended loss to follow up.

- If the PFS event is on or prior to Day 127 (Week 18 + 7-day window), then a participant will be identified as extended lost to follow-up without an adequate assessment if the participant did not have an adequate disease assessment or T-cell infusion during the period of 94 days (12 weeks + 1 week window +3-day window) prior to PFS event
- Else if the PFS event is after Day 127 (Week 18 + 7-day window) and on or before Day 169 (Week 24 + 7 day window) then a participant will be identified as extended lost to follow-up without an adequate assessment if the participant did not have an adequate disease assessment during the period of 98 days (12 weeks + 2-week window)

- Else if the PFS event is after Day 169 (Week 24 + 7-day window) and on or before Day 274 (Month 9/Week 36 + 1 month window) then a participant will be identified as extended lost to follow-up without an adequate assessment if the participant did not have an adequate disease assessment during the period of 161 days (Month 9/Week 36-Week 18 + 1 month window + 1 week window)
- Else if the PFS event is after Day 274 (Month 9/Week 36 + 1 month window) and on or before Day 358 (Month 12/Week 48 + 1 month window), then a participant will be identified as extended lost to follow-up without an adequate assessment if the participant did not have an adequate disease assessment during the period of 203 days (Month 12/Week 48-Week 24 + 1 month window + 1 week window
- Else if the PFS event is after Day 358 (Month 12/Week 48 + 1 month window) then a participant will be identified as extended lost to follow-up without an adequate assessment if the participant did not have an adequate disease assessment during the period of 224 days (Month 15/Week 60-Month 9/Week 36 + 1 month window + 1 month window).

The "month" used in these algorithms is 28 days long.

If the participant has a missing or incomplete baseline assessment and dies before missing two scheduled disease assessments, the death will be considered an event.

A summary of the assignments for progression and censoring dates for PFS are specified in table below.

Table 1 Assignments for Progression and Censoring Dates for PFS Analysis

Situation	Date of Event (Progression/Death) or Censored	Event (Progression/Death) or Censored
No or incomplete baseline tumor assessments, and the participant has not died	Date of T-cell infusion	Censored
No adequate post-baseline adequate disease assessments before start of new anti-cancer therapy, and the participant has not died	Date of T-cell infusion	Censored
Progression documented between scheduled visits	Date of radiological assessment of progression[1]	Event
With adequate post-baseline assessment but no progression (or death)	Date of last adequate radiological disease assessment of response[2]	Censored
With adequate post-baseline assessment and new anticancer treatment started (prior to documented disease progression) [3]	Date of last adequate radiological disease assessment of response[2] (on or prior to starting anti-cancer therapy)	Censored
Death before first scheduled assessment	Date of death	Event

Situation	Date of Event (Progression/Death) or Censored	Event (Progression/Death) or Censored
Death (regardless of having baseline assessment) before missing two scheduled assessments and no progression[4]	Date of death (Use rule above to determine missing two scheduled assessments)	Event
Death (regardless of having baseline assessment) or progression after two or more missed scheduled disease assessment[4]	Date of last adequate radiological disease assessment of response[2] (prior to missed assessments)	Censored

[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 Investigator determined response is CR, PR, or SD.
[3] If PD 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] Refer to Section 7.2.1 for details of extended time without an adequate assessment

DOR

Duration of response (DOR) is defined as the interval in months from first documented evidence of confirmed PR or better to the date of disease progression as assessed by RECIST v1.1 or death due to any cause in the subset of participants with a confirmed CR or PR as assessed by local investigators per RECIST v1.1. Censoring rules and analysis details will follow those for PFS as specified in Table 1.

TTR

Time to response (TTR) is defined as the time between T-cell infusion to initial date of confirmed response (PR or CR) as assessed by local investigator per RECISTv1.1 in the subset of participants who achieved a confirmed PR or CR.

7.2.2. Summary Measure

DCR

The number and percentage of participants with the BOR in the following response categories will be summarized: CR, PR, SD ≥12 weeks, clinical benefit response (CR+PR+SD ≥12 weeks), PD and NE. The corresponding Clopper-Pearson exact 95% CI for DCR will also be provided. DCR will be summarized for the ITT and mITT population.

PFS

The distribution of PFS will be estimated using the Kaplan-Meier method if data warrant. The median, 25th and 75th percentiles of PFS will be estimated and corresponding 95% confidence intervals will be estimated using the Brookmeyer-Crowley method (Brookmeyer, 1982) under a log-log transformation. A Kaplan-Meier curve will be produced with 95% confidence bands, if data warrant. A supporting listing will be provided.

The median follow-up time for PFS will be summarized in months using the reverse Kaplan-Meier method. Patients who died will be censored for further follow-up in the reverse Kaplan-Meier PFS follow-up estimates. The Kaplan-Meier quantiles will be summarized as above for PFS.

DOR

If there are sufficient number of responses at time of primary or final analysis, the distribution of DOR will be estimated using the Kaplan-Meier method if data warrant. The median, 25th and 75th percentiles of DOR will be estimated and corresponding 95% confidence intervals will be estimated using the Brookmeyer-Crowley method (Brookmeyer, 1982) under a log-log transformation. A Kaplan-Meier curve will be produced with 95% confidence bands, if data warrant. DOR will be summarized among the participants with confirmed response of PR or CR as the BOR. A supporting listing will be provided.

The median follow-up time for DOR will be summarized in months using the reverse Kaplan-Meier method. Patients who died will be censored for further follow-up in the reverse Kaplan-Meier DOR follow-up estimates. The Kaplan-Meier quantiles will be summarized as above for DOR.

TTR

If there are sufficient number of responses at time of primary or final analysis, time to response at will be summarized descriptively using median, minimum, maximum, and quartiles in the subset of participants with a confirmed response of PR or CR as the BOR. A supportive listing will be provided.

A plot of study duration including study days of any SAE, death, progression, response, and on study anti-cancer therapy will be produced.

7.2.3. Population of Interest

The secondary efficacy analyses will be based on the mITT population, unless otherwise specified. The ITT is the sensitivity analysis population for DCR. If the mITT and ITT populations are identical, only results associated with the mITT population will be reported.

7.2.4. Strategy for Intercurrent Events

For DCR:

A composite strategy will be followed for participants who experience death prior to response assessments, or have only missing responses or not-evaluable assessments, or have non-measurable disease at baseline. These participants will be treated as non-responders (NE); i.e., they will be included in the denominator when calculating the percentage.

Start of new anti-cancer therapy is addressed using a while-on-treatment strategy, as the interest lies in the treatment effect of the investigational treatments before start of new anti-cancer therapy.

For PFS and DOR:

New anti-cancer therapy started before documented PD or death is addressed with the hypothetical strategy, because the interest lies in the treatment effect attributable to the investigational treatments and not confounded by other anti-cancer therapies. Palliative radiotherapy is not considered as an anti-cancer therapy since it is permitted per protocol.

Refer to Table 1 for censoring rules and intercurrent event strategy.

7.2.5. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 12 and will be 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 Analyses

CCI [redacted]

7.3.1. Endpoint/Variables

CCI [redacted]

CCI

[redacted]

CCI

[redacted]

Table 3 Comparison of RECIST 1.1 and iRECIST

	RECIST 1.1	iRECIST
Definitions of measurable and non-measurable disease; numbers and site of target disease	Measurable lesions are ≥10 mm in diameter (≥15 mm for nodal lesions); maximum of five lesions (two per organ); all other disease is considered non-target (must be ≥10 mm in short axis for nodal disease)	No change from RECIST 1.1; however, new lesions are assessed as per RECIST 1.1 but are recorded separately on the case report form (but not included in the sum of lesions for target lesions identified at baseline)
Complete response, partial response, or stable disease	Cannot have met criteria for progression before complete response, partial response, or stable disease	Can have had iUPD (one or more instances), but not iCPD, before iCR, iPR, or iSD
Confirmation of complete response or partial response	Only required for non-randomised trials	As per RECIST 1.1
Confirmation of stable disease	Not required	As per RECIST 1.1
New lesions	Result in progression; recorded but not measured	Results in iUPD but iCPD is only assigned on the basis of this category if at next assessment additional new lesions appear or an increase in size of new lesions is seen (≥5 mm for sum of new lesion target or any increase in new lesion non-target); the appearance of new lesions when none have previously been recorded, can also confirm iCPD
Independent blinded review and central collection of scans	Recommended in some circumstances—eg, in some trials with progression-based endpoints planned for marketing approval	Collection of scans (but not independent review) recommended for all trials
Confirmation of progression	Not required (unless equivocal)	Required
Consideration of clinical status	Not included in assessment	Clinical stability is considered when deciding whether treatment is continued after iUPD

"i" indicates immune responses assigned using iRECIST. RECIST=Response Evaluation Criteria in Solid Tumours. iUPD=unconfirmed progression. iCPD=confirmed progression. iCR=complete response. iPR=partial response. iSD=stable disease.

7.3.2. Summary Measure

CCI

[redacted]

CCI

[redacted]

7.3.3. Population of Interest

CCI

[redacted]

7.3.4. Strategy for Intercurrent Events

CCI

[redacted]

7.3.5. Statistical Analyses / Methods

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

8. SAFETY ANALYSES

Limited safety summaries and listings will be created to support the abbreviated primary / final CSRs. The section below details all original planned analyses which may not be performed. Appendix 12 will reflect the limited scope of displays to support the terminated substudy.

The primary safety analysis will be based on the Safety population. Additional analyses will be presented using the ITT and Lymphodepletion populations.

8.1. Adverse Events Analyses

Adverse event analyses including the analysis of adverse events (AEs), serious AEs (SAEs), AEs related to study-treatment (lymphodepletion chemotherapy and T-cell infusion), SAEs related to study-treatment, and AEs of special interest will be based on GSK Core Data Standards. The details of the planned displays are provided in Appendix 12.

AEs will be graded according to National Cancer Institute-Common Toxicity Criteria for Adverse Events (NCI-CTCAE) version 5.0 unless otherwise specified in the protocol. For instance, the grading of Cytokine Release Syndrome (CRS) and ICANS will be performed using ASTCT grading criteria (Lee, 2019); see protocol Sections 12.7.5 and 12.7.8.1, respectively. For the grading of Graft versus Host Disease (GvHD), see protocol Section 12.7.6.2. AEs will be coded using the latest version of the Medical Dictionary for Regulatory Affairs (MedDRA).

Per GSK standard, AEs that have grade changes over the course of the event are entered in the same CRF record, with grade changes indicated within the overall event. Other attributes of the event (e.g., seriousness, relatedness) are attributed to the overall event.

For specific AE displays, Preferred Terms (PT) are combined and will be reported together as one term. The combined terms for MedDRA Version 25.0 are listed in Appendix 6: Derived and Transformed Data. 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. The most recent version of MedDRA will be used at the time of reporting. A table showing the relationship between the combined preferred term and contributing preferred terms will be produced. Tables that summarize AEs by System Organ Class (SOC) and PT will use MedDRA preferred terms. Most other tables will summarize AEs using the combined term specified in Appendix 6: Derived and Transformed Data, unless otherwise specified.

AEs will be summarized in the following phases among participants who have entered the phase:

Phase	Definition	Population
Pre-Lymphodepletion Phase	AEs which start prior to lymphodepletion chemotherapy	Intent-to-Treat Population
Lymphodepletion Phase	AEs which start or worsen on or after the start of lymphodepletion chemotherapy until the start of T-cell infusion	Lymphodepletion Population
T-cell Phase (Treatment-Emergent)	AEs which start or worsen on or after T-cell infusion	Safety Population

These phases are defined in more detail in Section 14.4.2.

AEs which start within the phase or worsen after initiation of the phase (maximum grade after initiation of the phase is larger than the maximum grade before initiation of the phase) will qualify to be summarized in the phase. AEs may be summarized in multiple phases (e.g., A Grade 2 AE after lymphodepletion increases to Grade 3 after T-cell infusion and is summarized as a Grade 2 in the lymphodepletion phase and a Grade 3 in the T-cell Phase).

The primary analysis of AEs will be performed for AEs that started or worsened in the T-cell Phase (i.e., treatment-emergent AEs). However additional analyses will be performed in the phases above.

All AEs collected in the ITT population will be listed, and the phase assigned to the AE will be indicated in the listing. AEs that led to study treatment withdrawal, interruption, delay, or reduction of any study treatment (cyclophosphamide, fludarabine, or T-cell infusion) will be flagged in the listing as collected in the CRF. Additionally, a listing of participant IDs for each individual AE will be produced.

SAEs will be included in the listing of all AEs, but also separate supportive listings with participant-level details will be generated for the following:

- Non-fatal SAEs
- Reasons for considering AE as serious

AEs will be summarized and displayed in descending order of total incidence by SOC and PT. In the SOC row, the number of participants with multiple events under the same SOC will be counted once.

Summaries of number and percentage of participants with AEs by maximum grade will also be produced. AEs will be sorted by combined PT in descending order of total incidence. The summary will use the following algorithms for counting the participant:

- **Combined preferred term row**: Participants experiencing the same combined 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.

Summaries will be provided for lymphodepletion-related and T cell-related AEs separately. Study treatment-related AE is defined as an AE for which the investigator classifies the relationship to study treatment as "Yes". 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).

Analyses for AEs in the Pre-Lymphodepletion Phase will include the following:

- Summary of AEs by System Organ Class and Preferred Term (using PT term)
  - AEs
- Summary by maximum grade
  - AEs
  - SAEs

Analyses for AEs in the Lymphodepletion Phase will include the following:

- Summary of AEs by System Organ Class and Preferred Term (using PT term)
  - AEs
- Summary by maximum grade
  - AEs
  - SAEs
  - Lymphodepletion-related AEs

Analyses for treatment-emergent AEs will include the following:

- Summary of AEs by System Organ Class and Preferred Term (using PT term)
  - AEs
  - SAEs
  - T-cell related
  - Common non-serious AEs (number of participants and occurrences)
  - SAEs (number of participants and occurrences)
- Summary by maximum grade
  - AEs
  - SAEs
  - T-cell related AEs
  - Lymphodepletion related AEs
  - T-cell related SAEs
  - Lymphodepletion related SAEs
- Descending frequency (using Preferred Term)
  - Non serious T-cell related AEs
  - Serious fatal and non-fatal T-cell related AE

The summary of common non-serious treatment-emergent AEs will summarize events that occurred in 5% of the participants or above (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 of participants and occurrences of participants with common non-serious adverse events. The summary table will be displayed by SOC and PT. A summary of All Treatment-Emergent Serious Adverse Events by System Organ Class (SOC) and Preferred Term (PT) will also be created to detail the number of participants and occurrences of each event.

Delayed AEs, as defined in the FDA 2020 Guidance- Long Term Follow-Up After Administration of Human Gene Therapy Products (FDA, 2020) are identified through sponsor adjudication as the primary method of reporting. Sponsor adjudication will focus on AEs starting 90 days after administration of T-cell therapy that fall into one of following categories:

- New malignancies
- New incidence or exacerbation of a pre-existing neurological disorder
- New incidence or exacerbation of a prior rheumatologic or other autoimmune disorder
- New incidence of a hematologic disorder
- New incidence of infection (potentially related to gene modified cell therapy)
- Unanticipated illness or hospitalization deemed related to gene modified cell therapy

Events that meet the criteria above, are study-treatment related events, and are serious and/or Grade ≥3 will be the primary focus of sponsor adjudication, although adjudication is not limited to these criteria. A listing of delayed AEs as adjudicated by the sponsor, including delayed AE category, will be produced using the Safety population.

Delayed AEs are also identified by the investigator and captured in the CRF. Delayed AEs as adjudicated by the sponsor (provided from external data source) and identified by the investigator will be listed separately.

8.2. Adverse Events of Special Interest Analyses

Adverse events of special interest (AESIs) evaluated in this RAP include the following:

- Cytokine Release Syndrome (CRS)
- Hematopoietic cytopenias (including pancytopenia and aplastic anemia)
- Graft versus Host Disease (GvHD)
- Immune Effector-Cell Associated Neurotoxicity Syndrome (ICANS)
- Guillain-Barre Syndrome (GBS)
- Treatment-related inflammatory response at tumor site(s)
- Neutropenia G4 lasting ≥ 28 days

All analysis of AESIs will be performed in the T-cell Phase using the Safety population, unless otherwise stated.

A focused list of MedDRA terms based on clinical review will be used to identify each type of event. In addition, a comprehensive list of MedDRA terms aligning with MedDRA SMQ list will also be used for AESI reporting. 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. The details of the planned displays are provided in Appendix 12.

The protocol-identified AESI, Treatment-related inflammatory response at tumor site and Neutropenia G4 lasting ≥ 28 days will not be identified using the focused or comprehensive list. Investigator identified AEs identified in the CRF which may be related to this event will be used to characterize this AESI in the table described below.

A summary of AEs linked to the AESI identified by the investigator will be summarized by AESI and maximum grade. A summary of the concomitant medications linked to the AESI will also be provided by AESI.

The number and percentage of participants with treatment emergent AESIs will be summarized by categories of AESI, combined preferred term, and maximum grade using both the comprehensive list and focused list (if applicable). Hematopoietic cytopenias will be summarized using the focused list and presented overall as well as by cell line.

A summary of event characteristics for each category of AESI 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, maximum grade, and the action taken for the event. The percentage will be calculated in 2 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 for an event, the 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). This summary will only be created if there are a sufficient number of events.

Cytokine Release Syndrome

The following analyses will be provided:

- Summary of event characteristics (as detailed above) using the focused list
- Among participants who experienced CRS, a summary of onset and duration of the first occurrence of CRS identified using the focused list will be provided, if at least 5 events
- Time to onset and duration of serious adverse events, if at least 5 events
- Summary of the procedures associated with CRS

A supporting CRS listing profile will be provided to detail the CRS adverse event, display the procedures and medications administered to treat CRS, and display symptoms associated with the event.

Hematopoietic cytopenias

The following analyses will be provided:

- Summary of event characteristics of treatment-emergent cytopenias using the focused list (as detailed above).
- Summary of onset and duration of the first occurrence of febrile neutropenia if at least 5 events
- Summary of persistent cytopenias

Summary of persistent cytopenias will be based on laboratory values. Please refer to Section 8.3

A supporting pancytopenia listing profile will be provided to detail these events.

Graft versus Host Disease (GvHD)

The following analyses will be provided:

- Summary of event characteristics using the focused list (as detailed above)
- Summary of onset and duration of the first occurrence of GvHD identified using the focused list if at least 5 events

A supporting GvHD listing profile will be provided to detail these events.

Immune Effector-Cell Associated Neurotoxicity Syndrome (ICANS)

The following analyses will be provided:

- Summary of event characteristics using the focused list (as detailed above)
- Summary of onset and duration of the first occurrence of ICANS identified using the focused list if at least 5 events

A supporting ICANS listing profile will be provided to detail these events.

Guillain-Barre Syndrome (GBS)

A supporting GBS listing profile will be provided to detail these events.

8.3. Clinical Laboratory Analyses

Laboratory evaluations including the analyses of chemistry laboratory tests, hematology laboratory tests, urinalysis, and liver function tests will be based on GSK Core Data Standards. The details of the planned displays are in Appendix 12.

Clinical Hematology:	Platelet Count RBC Count Hemoglobin Hematocrit	RBC Indices: • MCV • MCH • Reticulocytes		WBC count with Differential: • Neutrophils • Lymphocytes • Monocytes • Eosinophils • Basophils
Flow cytometry:	CD3/CD4/CD8			
Clinical Chemistry:	BUN[b]	Potassium	AST (SGOT)	Total and direct bilirubin
	Creatinine	Sodium	ALT (SGPT)	Total Protein
	Glucose [nonfasting]	Calcium	Alkaline phosphatase	Chloride
	Albumin	Phosphorus	LDH	Urea[a]
		Magnesium	Bicarbonate	
Coagulation:	INR, PT, aPTT, and Fibrinogen			
Routine Urinalysis:	• Specific gravity • pH, glucose, protein, blood, ketones, bilirubin, urobilinogen, nitrite, leukocyte esterase by dipstick • Microscopic examination (if blood or protein is abnormal)			

Other Tests:	• CMV IgG and PCR • TSH with free T4 • CRP • Uric acid • GFR or 24 Urine • Follicle-stimulating hormone and estradiol (as needed in women of non-childbearing potential only) • Highly sensitive serum or urine human chorionic gonadotropin (hCG) pregnancy test (as needed for women of childbearing potential)[c] • HIV, HBV, HCV, HTLV, EBV, and syphilis (spirochete bacterium) • Ferritin • Serum troponin • NT-proBNP/BNP

a. Details of liver chemistry monitoring criteria and required actions and follow-up assessments after liver monitoring event are given in Protocol Section 8.2. All events of ALT ≥3 × ULN and bilirubin ≥2 × ULN (>35% direct bilirubin) or ALT ≥3 × ULN and INR >1.5, if INR measured, which may indicate severe liver injury (possible Hy's Law), must be reported as an SAE.
b. Either BUN or UREA tests are acceptable.
c. Local urine testing will be standard for the protocol unless serum testing is required by local regulation or IRB/IEC.

Laboratory grades will be reported using the CTCAE 5.0.

A summary of post-baseline change of laboratory values by visit will be provided. Separate summary tables for hematology and chemistry laboratory tests will be produced. 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.

Supporting line graphs of neutrophils, platelets, hemoglobin, and lymphocytes over time will be produced. Plots will be produced by type of laboratory value. Spider plots including neutrophils, platelets, and hemoglobin in the same plot will be created by participant.

Summaries of worst-case grade increase from baseline grade will be provided for all the laboratory tests that are gradable by CTCAE 5.0. These summaries will display the number and percentage of participants with a maximum post-baseline grade increasing from their baseline grade, as well as post-baseline increase at all planned visits for hematology parameters. Missing baseline grade will be assumed 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).

For laboratory tests that are not gradable by CTCAE 5.0., summaries of worst-case changes from baseline with respect to reference 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 change. 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. A missing baseline value will be assumed to be normal.

The number of participants with worst-case protein or occult blood urinalysis (discrete or character) results will be summarized by the combination of specimen, method and test, and category

A supporting listing of all laboratory data and urinalysis data for participants will be provided. All laboratory values, including pre-baseline values, will be included in the listing.

Persistent cytopenias
Persistent cytopenias are defined as neutropenia, thrombocytopenia, or anemia persisting at Grade 3 or above at the Week 5 visit (Day 29 ± 3 days). If the participant does not have a Week 5 laboratory assessment, the latest assessment before the Week 5 visit will be analyzed. The percentage of participants with any cytopenia, as well as any persistent neutropenia, thrombocytopenia, or anemia at Week 5 will be provided separately. If a participant has multiple laboratory values within the Week 5 visit window, the worst-case grade will be used to define persistent cytopenia. Unscheduled visits will be incorporated in the analysis. Grading of cytopenias are reported according to CTCAE 5.0 criteria for neutropenia, anemia, and thrombocytopenia.

Among the subset of participants with persistent cytopenias defined above, a summary of time to resolution to grade 2 or below will be provided using Kaplan Meier methodology. The time from T-cell infusion to the first reduction to Grade 2 after Week 5 will be analyzed. If the patient did not achieve resolution to grade 2 at the last laboratory assessment, they will be censored at the last laboratory assessment. If a participant is censored, the result for unresolved cytopenia will be displayed (death, interventional phase follow-up ended, cytopenia ongoing). Cytopenias may worsen to Grade 3 again at a later point in time. Recurrences are not captured in this analysis

The probability of resolution at Day 90 will be provided, as well as the estimated median and IQR of time to resolution post-T-cell infusion.

8.3.1. Analysis of Liver Function Test (LFT)

A summary of liver monitoring/stopping event reporting will be provided, with a corresponding listing.

A listing of participants meeting hepatobiliary laboratory abnormalities aligned with the Protocol liver monitoring criteria will be provided. The intent of this listing is to identify participants, in particular possible Hy's Law participants, for clinical review. A summary of participants meeting hepatobiliary laboratory abnormalities may be provided if enough participants have events.

The percentage of participants that met the following criteria will be summarized : ALT ≥3 x ULN and BIL ≥2 x ULN, ALT ≥3 x ULN and INR >1.5, ALT ≥3 x ULN and BIL ≥2 x ULN and (ALP <2 x ULN), Hepatocellular injury, Hepatocellular injury and BIL ≥2 x ULN, ALT ≥3 x ULN, ALT ≥5 x ULN, ALT ≥8 x ULN, ALT ≥10 x ULN, ALT ≥20 x ULN:

- To be counted in the denominator, the participant must have at least one post-baseline lab chemistry measurement for the specified lab tests (e.g., in the 'ALT ≥3 x ULN and BIL ≥2 x ULN' category, the denominator should include participants who had both a post-baseline ALT value AND a post-baseline BIL value that was up to 28 days after ALT).
- Categories are not mutually exclusive. For example, a participant with ALT 20 x ULN will be included in each of the 3x, 5x, 8x, 10x, and 20x categories.
- If Direct Bilirubin is available on the same day, then Direct Bilirubin as a portion of total bilirubin must be ≥35% when total Bilirubin is ≥2 x ULN, in order to satisfy the criteria. If all criteria for Hy's law are satisfied except Direct Bilirubin exists and is <35% then the record will not be considered a possible Hy's Law event. The total Bilirubin elevation must occur on or up to 28 days after the ALT elevation (as this is the standard for DILI cases of Hy's Law). This was deemed an acceptable window through discussion with the GSK Hepatic Safety Panel.
- **Note:** In the rare event that total Bilirubin value is not provided within 28 days on or after ALT value, Direct Bilirubin cannot be used in place of total Bilirubin in the Hy's law criteria therefore a separate optional category can be included if needed to analyze these cases.
- Hepatocellular injury is defined as ((ALT/ALT ULN)/(ALP/ALP ULN)) ≥5 and ALT ≥3 x ULN. ALT and ALP values must occur on the same day. The denominator should include participants who had both a post-baseline ALT and ALP on the same day. In addition, the denominator for Hepatocellular injury and BIL ≥2 x ULN should include participants who had both a post-baseline ALT and ALP on the same day as well as BIL on or up to 28 days of that day.
- For the row 'ALT >3 x ULN and BIL >2 x ULN and (ALP <2 x ULN)', the ALP value must occur on or up to 28 days after the ALT elevation.

An additional liver stopping event profile will be provided to facilitate medical review of participants with liver stopping events.

A scatter plot of maximum total bilirubin versus maximum ALT will be generated, as well as a scatter plot of maximum vs baseline for ALT.

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. Deaths

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 as a categorical (> 30 days or ≤ 30 days) and primary cause of death displayed in the order it appears in the CRF.

An individual participant profile for patients who died will be generated, which will report fatal SAEs.

8.4.2. Performance Status

The performance status will be assessed using Lansky (for participants <16 years of age) or Karnofsky (for participants ≥ 16 and < 18 years of age) or ECOG (for participants ≥18 years of age) scale.

The frequency and percentage of participant's ECOG score (0, 1, 2, 3, 4-5) at baseline and last assessment on study will be summarized, as well as improvement and deterioration from baseline at each scheduled assessment, including best and worst case change. Due to small sample size, Lansky and Karnofsky performance status will only be listed.

8.4.3. ECG

The QTc values based on the Fridericia formula (QTcF) will be categorized into the following CTCAE v5.0 grade and ranges: Grade 0 (<450 milliseconds [msec]), Grade 1 (≥450 to <481 msec), Grade 2 (≥481 to <501 msec), and Grade 3 (≥501 msec) at baseline. Summaries of worst-case grade increase will be provided. These summaries will display the number and percentage of participants with no change or improvement, any grade increase, increase to Grade 1, increase to Grade 2 and increase to Grade 3 for worst case post-baseline only. Participants with missing baseline grade will be assumed to be Grade 0 at baseline.

The changes in QTcF values will be categorized into the clinical concern ranges which are specific to changes in QTcF from baseline: Increase of ≤30 msec, increase of 31 to 60 msec, and increase of >60 msec. A summary of change in QTc value will display the number and percentage of participants with a change within each range for worst case post-baseline only. Participants with missing baseline values will be excluded from this summary.

If QTcF is missing, it will be calculated using the formula in Section 14.6.3. QTcB values will only be listed.

QRS duration will be categorized into the following categories approximately based on the limits determined by Ramirez et al (Ramirez, 2011): Low (<70 msec), Normal (≥70 msec to ≤105 msec) and High (>105 msec). Additionally, these summaries will display the number and percentage of participants with no change or improvement to Normal, worsening to Low, and worsening to High for the worst case (both minimum and

maximum) post-baseline values only. Participants with missing baseline QRS duration will be assumed to be Normal at baseline.

A listing of Left Ventricular Ejection Fraction results will be provided

8.4.4. Vital Signs

A summary of change in vital signs (heart rate, diastolic blood pressure, systolic blood pressure, pulse oximetry, temperature) from baseline by planned visit and worst-case change will be provided by categories of potential clinical importance. A supportive listing may be provided.

8.4.5. Pregnancies

The investigator will 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. A supportive listing of participants or partners of participants who became pregnant during the study will be produced to support the case narratives.

8.4.6. Cardiovascular Events

As required by the GSK Global Safety Board, profile displays for the following nine cardiovascular events will be produced if an event occurs and the appropriate CV event form has been completed:

- Arrythmias
- Congestive Heart Failure
- Cerebrovascular Events, Stroke and Transient Ischemic Attack
- Deep Vein Thrombosis/Pulmonary Embolism
- Unstable Angina / Myocardial Infarction
- Peripheral Arterial Thromboembolism
- Pulmonary Hypertension
- Revascularisation
- Valvulopathy

8.4.7. Replication Competent Lentivirus and Integration Site Analysis

The results of Replication Competent Lentivirus (RCL) and Integration Site Analysis will be summarized descriptively.

The proportion of participants who are RCL positive will be summarized. RCL results will also be presented in a data listing.

The proportion of participants showing >1% gene marked PBMCs 1-year post-infusion will be summarized. Percentage will be based on the participants with persistence value available one-year or later post-infusion.

For any participant who has greater than 1% gene marked PBMCs at least 1 year or beyond post-infusion, Integration Site Analysis will be performed on PBMCs to assess clonality and will be summarized to identify participants with any clones representing >20% of the total.

For participants that undergo Integration Site Analysis, a supportive listing will be provided to report the data. Two diversity indices, Shannon diversity index and Gini index (GI), will be reported in the data listing. Shannon diversity is a measurement that represents the uncertainty about the identity of a single species within a population. Therefore, the greater number of unique species within a population, the less certain the measure is of the "identity" of any one species, resulting in a higher value of Shannon diversity. Likewise, the less complex the population, the lower the value of Shannon diversity. When Shannon diversity is calculated it takes into account the number of distinct clones ("species") as well as the abundance of each clone. A low value of Shannon diversity has been previously reported in the literature as being associated with clonal expansion and a reduction in overall clonal diversity (Braun, 2014).

The GI is a measure for detecting inequality in the distribution of clone sizes. A GI value of 0 indicates complete equality across the population i.e., all clones have the same abundance. A value of 1 would indicate complete inequality i.e., one clone is much more abundant than the others. Therefore, as GI approaches 1 this indicates that one clone is highly abundant. It has previously been used for insertion site analysis as the oligoclonality index (Gillet, 2011) to describe clonal populations where the dominance of a single clone is seen (e.g., leukemia).

8.4.8. Anti-GSK3377794 Antibodies

The anti-GSK3377794 antibody results, including titers, will be reported for all participants in a data listing if data is available at the time of analysis. Additionally, the overall incidence of participants with all negative or confirmed positive results pre-infusion and at any post-treatment time point will be summarized if data warrant.

9. PHARMACOKINETIC ANALYSES

Limited pharmacokinetic summaries and listings will be created to support the abbreviated primary / final CSRs. The section below details all original planned analyses which may not be performed. Appendix 12 will reflect the limited scope of displays to support the terminated substudy. All exploratory analyses detailed in Section 9.3 will not be performed.

9.1. Primary Pharmacokinetic Analyses

There are no primary pharmacokinetic analyses for this study.

9.2. Secondary Pharmacokinetic Analyses

9.2.1. Endpoint / Variables

9.2.1.1. Drug Persistence

GSK3377794 T-cell vector copies (persistence) in the peripheral blood will be measured in participants either by quantitation of transduced cells by PCR of transgene from DNA extracted from frozen PBMC or quantitation of transduced cells by flow cytometry from frozen PBMC. Persistence will be measured to establish the relationships with response to GSK3377794 as well as a long-term safety measure. For all PK analyses, persistence of the engineered T-cells will be applied in lieu of "concentration" to derive PK parameters.

Persistence data will also be used to inform a population PK model that is the subject of a separate analysis and RAP.

9.2.1.2. Derived Pharmacokinetic Parameters

Pharmacokinetic parameters will be calculated by the Clinical Pharmacology Modelling and Simulation (CPMS) group using standard non-compartmental analysis according to current working practices and using appropriate software. All calculations of non-compartmental parameters will be based on actual sampling times.

Pharmacokinetic parameters listed will be determined from the persistence–time data, as data permits.

Parameter	Parameter Description
AUC (0-28d)	Area under the persistence–time curve from time zero to Day 28 will be calculated using the linear trapezoidal rule for each incremental trapezoid and the log trapezoidal rule for each decremental trapezoid.
Cmax	Maximum observed persistence, determined directly from the persistence–time data.
Tmax	Time to reach Cmax, determined directly from the persistence–time data.

NOTES: Additional parameters may be included as required.

9.2.2. Summary Measure

All raw persistence data and derived PK parameters will be listed.

For each of these parameters, except Tmax, the following summary statistics will be calculated: 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 log transformed data]), geometric mean, 95% confidence interval for the geometric mean and standard deviation of logarithmically transformed data.

For Tmax, n median, maximum, minimum, arithmetic mean, 95% confidence interval, and standard deviation will be calculated.

All PK parameters will be reported to at least 3 significant digits, but to no more significant digits than the precision of the original data.

For persistence value below LLOQ, the following rules will be applied:

Reported Copies per cell Result	Reported Copies per µg DNA Result	Interpretive 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)

Spider plots will be used to graphically summarize persistence (copies/µg gDNA) over time for each participant.

9.2.3. Population of Interest

All pharmacokinetic analyses will be based on the PK population, unless otherwise specified.

9.2.4. Statistical Analyses / Methods

Displays will be based on GSK Data Standards and statistical principles.

9.3. Exploratory Pharmacokinetic Analyses

CCI [redacted]

10. BIOMARKER ANALYSES

Details of the exploratory biomarker analyses to address the following exploratory endpoints may be reported under a Biomarker Clinical Study Plan (BCSP).

- To explore mechanisms of clinical benefit
- To explore the relationship between antigen expression and treatment response
- To investigate the relationship between genetic variants in the host and disease under study, as well as response to study treatment

11. ADDITIONAL ANALYSES DUE TO THE COVID-19 PANDEMIC

Limited COVID-19 analyses will be performed to support the abbreviated primary / final CSRs. The section below details all original planned analyses which may not be performed. Appendix 12 will reflect the limited scope of displays to support the terminated substudy.

11.1. Study Population

11.1.1. Subject Disposition

A country level listing of the dates of the COVID-19 pandemic measures will be produced. For the definition of the phases of the COVID-19 pandemic measures see Section 14.4.1.3.

If participants withdrew/discontinued from the study due to the COVID-19 pandemic (based on information collected in the COVID-19 Pandemic Study Impact form), this information will be present on the study withdrawal listing. The summaries will be based on GSK Core Data Standards, and details are provided in Appendix 12. Study treatment that is discontinued due to the COVID-19 pandemic will be flagged in the listing.

11.1.2. Protocol Deviations

Important protocol deviations related to COVID-19 and important protocol deviations not related to COVID-19 will be summarized separately. A listing of non-important protocol deviations related to COVID-19 will also be produced.

Visits and assessments missed due to the COVID-19 pandemic, together with visits conducted remotely, will be summarized in both a table and a figure, and listed by participant. The summaries will be based on GSK Core Data Standards, and details are provided in Appendix 12.

11.1.3. Additional Displays for Participants with a COVID-19 Infection

A participant is defined as having a suspected, probable, or confirmed COVID-19 infection during the study if the answer is “Confirmed”, “Probable” or “Suspected” to the case diagnosis question from the COVID-19 coronavirus infection assessment eCRF.

Analysis of participants with a suspected, probable, or confirmed COVID-19 infection, and of COVID-19 test results will be based on GSK Core Data Standards.

A comprehensive profile listing of COVID-19 assessments and symptom assessments for participants with COVID-19 adverse events will be provided.

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

11.2. Efficacy

Listing of participants with visits and assessments impacted by the COVID-19 pandemic will be produced.

11.3. Safety

11.3.1. Assessment of COVID-19 AEs

A Standardized MedDRA Query (SMQ) will be used to identify all COVID-19 AEs. COVID-19 AEs will either be listed or summarized by overall frequency, depending on the number of COVID-19 AEs observed in the ITT population.

The incidence of COVID-19 AEs and SAEs (Fatal and Non-Fatal) will be obtained from standard AE and SAE summaries. COVID-19 AEs leading to study drug discontinuation and study withdrawal can be found in the associated listing.

All of the above displays will be based on GSK Core Data Standards. The details of the planned displays are provided in Appendix 12.

12. HEALTH OUTCOMES ANALYSIS

CCI [redacted]

12.1. Exploratory Analyses

CCI [redacted]

CCI

[redacted]

CCI

[redacted]

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14. APPENDICES

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

This study does not have per protocol population.

14.2. Appendix 2: Schedule of Activities

14.2.1. Protocol Defined Schedule of Events

Table 4 Substudy 1 Schedule of Activities– Screening and Leukapheresis

	Screening Phase[1]		
	Target Expression Screening[2]	Leukapheresis Eligibility Screening, within 28 days prior to leukapheresis[3]	Leukapheresis
Informed Consent for Screening	X		
Informed Consent for Leukapheresis and Treatment[1]		X	
Inclusion/Exclusion for Screening	X		
Inclusion/Exclusion for Leukapheresis		X	
Demographics	X		
Central Lab HLA -A genotyping[3]	X		
Tumor expression of NY-ESO- 1[3]	X		
Liquid biopsy (blood)[4]	X		
Medical History[5]	X	X	
Prior/Concomitant Medications[6]	X	X	X
Height and Weight[7]		X	
Physical Exam (complete)		X	X[8]
ECOG or Lansky or Karnofsky[10]	X	X	
Vital Signs[11]		X	X[8]
12-lead ECG (in triplicate)		XXX	XXX[8]
ECHO/MUGA		X[12]	
CT / MRI		X[13]	
Brain MRI[14]		X[13]	
Hematology		X[12]	X[8]
Clinical Chemistry		X[12]	X[8]
Coagulation Tests		X[12]	X[8]
Lymphocyte Subset (CD3/CD4/CD8)		X[8]	X[8,9]
Estradiol and FSH, if needed to determine CBP		X	

Notes

1. Written informed consent must be obtained prior to performing any study assessments or procedures, except as stated in footnote 12. Informed Consent for Leukapheresis and Treatment must be repeated if given more than 90 days prior to leukapheresis procedure.
2. This visit may be performed under a separate protocol when it is introduced.
3. Participants must be HLA-A*02:01, HLA-A*02:05, and/or HLA-A*02:06 positive and have NY-ESO-1 positive tumor prior to conducting leukapheresis eligibility screening procedures.
4. Only collect this sample if optional Genetics Research Consent has been signed by the participant. Sample may be collected any time from signature of optional consent until leukapheresis. Liquid biopsy is a blood sample from which circulating cell-free DNA (cfDNA), circulating tumor DNA (ctDNA), and exosomes may be extracted.
5. Medical history will be recorded in the eCRF at Target Expression Screening and at Lymphodepletion Screening/Baseline visits; however, any changes in medical history must be recorded in source documents throughout the conduct of the study.
6. Includes all prescription, over-the-counter medications, and herbal remedies. Any use of mutagenic agents or investigational agents must also be reported.
7. In pediatric participants height and weight will also be evaluated as a percentile vs national growth charts (based on sex and age) and vs genetic height target (expected height based on parental heights) and evaluation will be performed on whether growth is normal or abnormal.
8. To be performed within 7 days prior to the day of leukapheresis.
9. CD3 count prior to leukapheresis should be preferably performed within 24 hours from leukapheresis procedure.

	Screening Phase[1]			
	Target Expression Screening[2]	**Leukapheresis Eligibility Screening, within 28 days prior to leukapheresis[3]**	**Leukapheresis**	**Notes**
Pregnancy Test[15]		X[15]	X[15]	10. Lansky will be used for participants <16 years of age; Karnofsky will be used for participants ≥16 and <18 years of age; and ECOG will be used for participants ≥18 years of age. 11. Includes temperature, blood pressure, pulse rate, respiratory rate, and oxygen saturation. 12. ECHO/MUGA and laboratory assessments performed as standard of care prior to study consent will be acceptable as long as assessment is done within 28 days before leukapheresis. 13. CT/MRI scan performed as standard of care prior to study consent will be acceptable as long as assessment is done within 90 days before leukapheresis. Any FDG PET/CT performed as part of clinical routine within 90 days before leukapheresis, will also be collected. 14. In addition to the Brain MRI, MRI of the spine will be performed when clinically indicated. 15. WOCBP must have a highly sensitive negative urine or serum pregnancy test at screening for leukapheresis and within 24 h prior to leukapheresis. 16. Includes HIV, HBV, HCV, HTLV, EBV, CMV, and syphilis (spirochaete bacterium). 17. See Section 6.1 Table 5 in the Protocol for specifics on renal assessment. 18. SAEs and AEs assessed as related to study participation (e.g., study intervention, protocol-mandated procedures, invasive tests, or change in existing therapy) or leading to study withdrawal will be collected from signing informed consent for target expression screening. All SAEs and AEs will be collected starting at leukapheresis (See Section 9.4.1 in the Core Protocol).
Urinalysis		X[12]	X[8]	
Infectious disease markers[16]		X[12]		
Creatinine clearance by GFR or 24h urine[17]		X		
Adverse Events and Serious Adverse Events	X[18]	X[18]	X	
Leukapheresis			X	

AE=adverse event; CBP=child-bearing potential; CT = computerized tomography; EBV = Epstein Barr virus; ECG = electrocardiogram; ECHO = echocardiogram; ECOG = Eastern Cooperative Oncology Group; FDG = Fluorodeoxyglucose; FSH=follicle-stimulating hormone; GFR = glomerular filtration rate; HBV = hepatitis B virus; HCV = hepatitis C virus; HIV = human immunodeficiency virus; HTLV = human T-lymphotropic virus; MRI = magnetic resonance imaging; MUGA = multigated acquisition; SAE=serious adverse event; WOCBP = Women of childbearing potential.

Table 5 Substudy 1 Schedule of Activities – Interventional Phase (Lymphodepletion and Treatment)

	Treatment Fitness & Eligibility / Baseline	Lymphodepletion				T-cell Infusion[1]	Post T-cell Infusion												
Month (1 month = 4 weeks)	-1					1								2				3-6	Q3M from month 9 until confirmed PD
Week (Week N visit for N≥1 is scheduled on 1st day of the week = Day 7N-6)	-3 to -2	-1				1					2	3	4	5	6	7	8	10, 12, 18, 24 or until confirmed PD, whichever is sooner	
Day	-17 to -8	-7	-6	-5	-4	1	2	3	4	6	8	15	22	29	36	43	50	64, 78, 120, 162	
Visit Window	N/A								±1 day					±3 days				±7 days	±1 month
Treatment Fitness and Inclusion/Exclusion for Treatment Eligibility	X																		
Request lete-cel shipment	X[2]																		
Med. History[3]	X																		
Physical Exam (complete)	X	X				X	X	X	X	X	X		X			X	X	X	X
Physical Exam (dedicated)												X		X	X				
Prior/Con Meds[4]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
ECOG, Karnofsky or Lansky[5]	X					X					X		X		X		X	X	X
Developmental exam, height, and puberty assessment[6,7]	X																		X[8]
Vital Signs[9] and weight[7]	X	X	X	X	X	X[10]	X	X	X	X	X	X	X	X	X	X	X	X	X
ECHO/MUGA[11]	X																		
Pulse oximetry						X[12]	X	X	X	X	X	X[13]	X	X[13]		X	X	X	
12-lead ECG[14]	XXX					X			X		X								
CT/MRI[15]	X														X			X[16]	X[16]
Brain MRI[17]	X[17]																		

	Treatment Fitness & Eligibility / Baseline	**Lymphodepletion**				**T-cell Infusion[1]**	**Post T-cell Infusion**												
Month (1 month = 4 weeks)	**-1**					**1**								**2**				**3-6**	**Q3M from month 9 until confirmed PD**
Week (Week N visit for N≥1 is scheduled on 1st day of the week = Day 7N-6)	**-3 to -2**	**-1**				**1**					**2**	**3**	**4**	**5**	**6**	**7**	**8**	**10, 12, 18, 24 or until confirmed PD, whichever is sooner**	
Day	**-17 to -8**	**-7**	**-6**	**-5**	**-4**	**1**	**2**	**3**	**4**	**6**	**8**	**15**	**22**	**29**	**36**	**43**	**50**	**64, 78, 120, 162**	
Visit Window	**N/A**								**±1 day**					**±3 days**				**±7 days**	**±1 month**
ICE or CAPD[18]						X[19]	X	X	X	X	X								
Chest X-Ray	X																		
Hematology[20]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Clinical Chemistry[20]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Uric acid	X					X										X			
Creatinine clearance by GFR or 24 h urine[21]	X																		
Coagulation Tests[20, 22]	X					X	X	X	X	X	X	X							
Ferritin[20]	X																		
Troponin and NT-proBNP / BNP test[23]	X																		
Pregnancy	X					X[24]							X				X	X[25]	X[25]
Urinalysis[26]	X		X	X	X														
Infectious disease markers[27]	X																		
CMV IgG and PCR[28]	X					X						X		X		X			
Thyroid function tests	X																		
CRP[20]	X					X			X		X	X	X	X	X	X	X	X	X
Adverse Events and Serious Adverse Events	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Transgene Copies (Persistence for Safety) and VSV-G DNA (RCL)[29]	X																	Week 12 and 24	Month 12 and Q6M[30]

	Treatment Fitness & Eligibility / Baseline	Lymphodepletion				T-cell Infusion[1]	Post T-cell Infusion												
Month (1 month = 4 weeks)	-1					1								2				3-6	Q3M from month 9 until confirmed PD
Week (Week N visit for N≥1 is scheduled on 1st day of the week = Day 7N-6)	-3 to -2	-1				1					2	3	4	5	6	7	8	10, 12, 18, 24 or until confirmed PD, whichever is sooner	
Day	-17 to -8	-7	-6	-5	-4	1	2	3	4	6	8	15	22	29	36	43	50	64, 78, 120, 162	
Visit Window	N/A								±1 day					±3 days				±7 days	±1 month
Genetic sample	X																		
Survival follow-up																		X	X
Lymphodepletion																			
Fludarabine		X[31]	X	X	X														
Cyclophosphamide			X	X	X														
Investigational Product Administration																			
Lete-cel (GSK3377794)						X													
Patient-Reported Outcomes[32]																			
Post-lete-cel infusion interview (adult participants only)											X[33]								
EOT interview (adult participants only)																			X[34]

CCI [redacted]

	Treatment Fitness & Eligibility / Baseline	Lymphodepletion				T-cell Infusion[1]	Post T-cell Infusion												
Month (1 month = 4 weeks)	-1					1								2				3-6	Q3M from month 9 until confirmed PD
Week (Week N visit for N≥1 is scheduled on 1st day of the week = Day 7N-6)	-3 to -2	-1				1					2	3	4	5	6	7	8	10, 12, 18, 24 or until confirmed PD, whichever is sooner	
Day	-17 to -8	-7	-6	-5	-4	1	2	3	4	6	8	15	22	29	36	43	50	64, 78, 120, 162	
Visit Window	N/A								±1 day					±3 days				±7 days	±1 month
CCI	[redacted]																		

1. On Day 1, all samples will be collected and assessments performed prior to T-cell infusion (within 24 h), unless otherwise specified.
2. As lete-cel needs to be on site prior to lymphodepletion, request lete-cel no later than 4 working days prior to the day of lymphodepletion. The mechanism of request will be provided in and the Drug Product and Infusion Manual.
3. Medical history will be recorded in the eCRF at Treatment Eligibility Screening / Baseline visit; however, any changes in medical history must be recorded in source documents throughout the conduct of the study.
4. Includes all prescription, over-the-counter medications, and herbal remedies. Any use of mutagenic agents or investigational agents must also be reported.
5. Lansky will be used for participants <16 years of age; Karnofsky will be used for participants ≥16 and <18 years of age; and ECOG will be used for participants ≥18 years of age.
6. To be assessed in pediatric participants only.
7. In pediatric participants height and weight will also be evaluated as a percentile vs national growth charts (based on sex and age) and vs genetic height target (expected height based on parental heights) and evaluation will be performed on whether growth is normal or abnormal.
8. To be assessed once a year.
9. Vital signs include temperature, blood pressure, pulse rate, and respiratory rate.
10. Vital signs on day of T-cell infusion should be taken pre-infusion, and approximately at 5, 15 and 30 minutes, and 1, 1.5, 2, and 4 hours after the infusion has started.
11. If suspected CRS Grade ≥2, an ECHO/MUGA is required at onset of Grade ≥2 CRS. Additional monitoring must be conducted (including inpatient continuous cardiac telemetry monitoring) for a minimum of 3 days post onset and as long as deemed necessary by the Investigator (refer to Section 12.7.5 of the Protocol)
12.
13. On T-cell infusion day, pulse oximetry should be taken pre-infusion, and at approximately 5, 15 and 30 minutes, and 1, 1.5, 2, and 4 hours after the infusion has started.
14. Pulse oximetry at these visits will be performed if medically indicated.
15. ECG can also be performed at other time points if medically indicated. Triplicate ECG will be collected at Treatment Eligibility Screening / Baseline visit and single ECGs at other timepoints. Participants with an increased burden of cardiovascular risk factors (as per Section 9.3.6 in the Protocol) will undergo evaluation by a cardiologist prior to lymphodepletion.

16. See Section 9.1.1 in the core protocol for scan description and areas to scan. If a participant is found to have a tumor response or PD by imaging and considered to be clinically stable by iRECIST criteria (see Section 12.6.2 in the Protocol), a follow-up confirmation scan must be done no earlier than 4 weeks and no later than 8 weeks following the scan when response or PD first seen. A participant is not considered to have a response or PD until follow-up scan confirms the finding.
17. CT/MRI will not be performed at Week 10. CT/MRI assessments only need to continue until confirmed PD.
18. Brain MRI should be performed at baseline if more than 4 months have elapsed from last MRI. Brain MRI will be performed at other time points, if clinically indicated. MRI of the spine will be performed, if clinically indicated.
19. All participants will be monitored as shown in the SoA. If a participant is found to have Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), the ICE neurological assessment tool should be used at least twice per day until ICANS is resolved or stable. It can also be used at later visits if indicated. In participants < 12 years of age, CAPD should be used in place of ICE.
20. To be administered prior to T-cell infusion.
21. If CRS and/or ICANS is suspected, chemistry, hematology, ferritin, coagulation, and CRP tests should be performed locally every day for the first week and approximately every other day thereafter until symptoms are improving or an alternative diagnosis is confirmed. In addition, if CRS is suspected, cytokine samples will be collected for central analysis following same schedule (as per SOA)
22. See Section 6.1 Table 5 in the Protocol for specifics on renal assessment.
23. Coagulation tests include INR, PTT or aPTT and fibrinogen. Coagulation tests should be taken at baseline, Day 1, 2, 3, 4, 6, 8 and 15.
24. Troponin and NT-proBNP / BNP tests should be monitored for participants with CRS Grade ≥2 as clinically indicated.
25. WOCBP must have a negative urine or serum pregnancy test prior to lete-cel infusion.
26. WOCBP will need to have pregnancy tests performed at all visits indicated in the table for the duration of the contraception period (Section 6.1 in the Protocol).
27. In addition to the specified time points, urinalysis will be done at other timepoints if warranted by the symptoms.
28. Includes HIV, HBV, HCV, HTLV, EBV, and syphilis (spirochaete bacterium).
29. Only participants who are CMV positive at Baseline will continue to be monitored for CMV viremia. CMV will also be assessed if GBS is suspected.
30. If possible, this sample also needs to be obtained in case of any SAE that occurs after T-cell infusion, unless the sample has been collected recently due to a scheduled visit assessment.
31. If no gene modified cells are detected for two consecutive assessments post-infusion, and the participant is ≥2 years after T-cell infusion, samples for VSV-G DNA (RCL) and persistence of gene modified cells will be discontinued (Section 9.3.11.1 of the Core Protocol).
32. On Day -7 fludarabine will not be administered to participants ≥60 years old.
33. Patient-Reported Outcomes instruments are only for adult participants.
34. Contact participant about one week after T-cell infusion to schedule the phone interview to be conducted by Day 21 of the study. If phone interview cannot be scheduled at this time, contact participant every two weeks until successful or the 60-day limit is reached from T-cell infusion. Beyond 60 days from T-cell infusion, no need to conduct the participant interview as recall may not be reliable.
35. To be conducted within approximately 21 days following the last study visit.
36. To be administered prior to infusion.

BNP = B-type natriuretic peptide; CAPD = Cornell Assessment of Pediatric Delirium; CMV = Cytomegalovirus; Con Meds = concomitant medications; CRS=cytokine release syndrome; CT = computerized tomography; EBV = Epstein Barr virus; ECG = electrocardiogram; ECHO = echocardiogram; ECOG = Eastern Cooperative Oncology Group; EDC = electronic data capture; CCI [redacted]; CCI [redacted] EOT = end of treatment; CCI [redacted]; GFR = glomerular filtration rate; HBV = hepatitis B virus; HCV = hepatitis C virus; HIV = human immunodeficiency virus; HTLV =

human T-lymphotropic virus; ICANS = Immune Effector Cell-Associated Neurotoxicity Syndrome; ICE=Immune Effector Cell-Associated Encephalopathy; Med history=medical history; MRI = magnetic resonance imaging; MUGA = multigated acquisition; NT-proBNP = N-terminal pro-BNP; PCR = Polymerase chain reaction; PD=progressive disease; CCI [redacted]; Q3M = every 3 months; RCL=replication competent lentivirus; TSH = Thyroid stimulating hormone; VSV-G =vesicular stomatitis virus G protein; WOCBP = Women of childbearing potential

Table 6 Substudy 1 Schedule of Activities – PK, Immunogenicity, and Biomarkers (Interventional Phase)

	Sample Type	Baseline	Lymphodepletion				T-cell infusion					Post T-cell infusion							
Month (1 month = 4 weeks)		-1					1								2			3-6	Q3M from month 9 until confirmed PD[1]
Week		-3 to -2	-1				1					2	3	4	5	6	8	(10) [2], 12, 18, 24 or until confirmed PD, whichever is sooner[1,2]	
Day		-17 to -8	-7	-6	-5	-4	1[3]	2	3	4	6	8	15	22	29	36	50	(64) [2], 78, 120, 162	
Visit Window		N/A								±1 day					±3 days			±7 days	±3 months
Cell phenotype and Functional Assays	PBMC	X								X		X	X	X		X	X	X	X
Transgene Copies (Persistence)	PBMC	X					X	X		X		X	X	X		X	X	X	X
Cytokine Analyses[4]	Serum	X					X	X	X	X	X	X	X	X		X	X	X	X
TGF-β analyses	Plasma	X					X					X	X	X		X		X	X
Anti-lete-cel Antibodies	Serum						X						X			X	X	Week 12, 24	Month 9, 12, 18, 24, 30, 36
Liquid biopsy (blood)[5]	Plasma	X										X		X		X		X	X
Tumor Biopsy[6]	Biopsy	X[7]												X[8]				X[9]	

1. All assessments need to be performed at all visits specified in the Table, up to the visit establishing confirmed PD or study withdrawal or discontinuation.
2. Assessments should match imaging (Body CT/MRI) visits; consequently PK, immunogenicity and Biomarker samples will not be collected at Week 10.
3. All assessments to be performed prior to T-cell infusions
4. If CRS is suspected, serum for cytokine analysis should be collected for research every day for the first week and approximately every other day thereafter until symptoms are improving or an alternative diagnosis is confirmed.

Notes:
- For scheduled visits where a cytokine sample collection is already requested, there is no need to collect an additional sample from the CRS collection kit that day.
- Chemistry, hematology, ferritin, coagulation, and CRP tests should also be performed locally following same schedule (as per SOA).

5. Blood sample from which circulating cell-free DNA (cfDNA), circulating tumor DNA (ctDNA), and exosomes may be extracted.
6. Biopsies for research are at Baseline, at Week 4, and at disease progression with the exception of participants for whom there is no safely accessible tumor tissue. In addition to the indicated collection times, tumor biopsies can be obtained at any time during the study execution.
7. The Baseline biopsy should be collected anytime within 90 days prior to the start of lymphodepleting chemotherapy An archived FFPE block from a biopsy preferably taken after completion of the participant's last line of therapy, preferably within 90 days prior to initiating lymphodepleting chemotherapy, may be accepted at the discretion of the Medical Monitor (or designee).
8. Week 4 biopsy must be taken preferably from D21 if medically feasible, but window for collection is extended until Week 6 visit (D39).
9. Must be taken once at disease progression if medically feasible.

PBMC=peripheral blood mononuclear cell; PD=progressive disease; Q3M = every 3 months

14.3. Appendix 3: Assessment Windows

No assessment windows 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 Disposition

Study Phase	Definition
Pre-Lymphodepletion Phase	First Day of Leukapheresis ≤ Date < First Day of Lymphodepletion
Interventional Phase - (Lymphodepletion)	First Day of Lymphodepletion Date ≤ Date < T-cell Infusion
Interventional Phase - (Post T-cell Infusion)	T-cell Infusion ≤ Date ≤ End of Interventional Phase Date (Completion or Withdrawal)
Follow-up Phase	End of Interventional Phase Date (Completion or Withdrawal) < Date

14.4.1.2. Study Phases for Concomitant Medications and Blood Products

Study Phase	Definition
Prior	End date of medication or blood product is not missing and End Date < Lymphodepletion Start Date or lymphodepletion start date is missing
Concomitant	Any medication or blood product that is not a prior

14.4.1.3. Phases of COVID-19 Pandemic Measures

Pandemic measures began in different countries at different times. A dataset containing the date when pandemic measures began, as determined by the GSK country Issue Management Teams (IMT), and available within the HARP reporting environment (arcomn folder), will be used to determine the start date of pandemic measures within each country. A copy of this dataset will be taken at the time of database lock (DBL).

Adverse events will be summarized according to whether the onset date was before or after the start of the COVID-19 pandemic measures.

Pandemic Measures Phase	Definition
Before	• AE onset date < pandemic measures start date
After	• Pandemic measures start date ≤ AE onset date

14.4.2. Treatment Emergent Flag for Adverse Events

Flag	Definition
Treatment Emergent (T-cell Phase)	• If the AE onset date is on or after T-cell infusion start date (T-cell Infusion Start Date ≤ AE Start Date) OR if the AE onset date is before T-cell infusion start date, but the AE increases in grade after T-cell infusion (with respect to the maximum grade of the AE before T-cell infusion) • If the AE onset date is missing and the AE end date is before the T-cell start date, then the AE *will not* be classified as treatment emergent. If the AE onset date is missing and the AE end date is either missing or is on or after T-cell start date, then the AE will be classified as treatment emergent. ○ If the T-cell infusion date is missing, the AE will not be classified as treatment emergent
Lymphodepletion Emergent (Lymphodepletion Phase)	• If the AE onset date is on or after the lymphodepletion start date and before the T-cell infusion start date ([Lymphodepletion Start Date ≤ AE Start Date < T-cell Infusion Start Date] or [Lymphodepletion Start Date ≤ AE Start Date and T-cell Infusion Start Date is missing]) OR if the AE onset date is before the lymphodepletion start date, but the AE increases in grade in the lymphodepletion phase (with respect to the maximum grade of the AE before lymphodepletion) • If the AE onset date is missing and the AE end date is before the lymphodepletion start date, then the AE *will not* be classified as lymphodepletion emergent. If the AE onset date is missing and the AE end date is either missing or after the lymphodepletion start date, then the AE will be classified as lymphodepletion emergent ○ If the lymphodepletion date is missing, the AE cannot be classified as lymphodepletion emergent
Pre-Lymphodepletion Emergent (Pre-Lymphodepletion Phase)	• If the AE onset date is before the lymphodepletion start date (AE Start Date ≤ Lymphodepletion Start Date or Lymphodepletion Start Date is missing) • If the AE onset date is missing the AE will be classified as pre-lymphodepletion emergent.

NOTES:

- The time of study treatment dosing and start[/stop] time of AEs should be considered, if collected.
- Incomplete AE start dates will be imputed following rules in Section 14.7.2.1 for determining treatment-emergent AEs.

14.5. Appendix 5: Data Display Standards & Handling Conventions

14.5.1. Reporting Process

Software	
• The currently supported versions of SAS software SAS will be used.	
Reporting Area	
HARP Server	: US1SALX00259
HARP Compound	: arprod\GSK3377794\mid208467
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 SAC upon request.	

14.5.2. Reporting Standards

General
The "Combined Statistical Display Principles v2" will be applied for reporting, unless otherwise stated (IDSL Standards Location: IDSL Library - Home (gsk.com)): • 4.3 to 4.24: Principles for all displays • 5.1 to 5.9: Principles for Data Listings • 6.1 to 6.11: Principles for Summary Tables • 7.1 to 7.13: Principles for 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
• **Formats**
• GSK Combined Statistical Display Principles v2 (4.24 & 6.9) 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: o Planned time relative to dosing will be used in figures, summaries, statistical analyses, and calculation of any derived parameters, unless otherwise stated. o 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: o Planned and actual time relative to study drug dosing will be shown in listings (Refer to Combined Statistical Display Principles v2 5.5). o 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 and/or best-case post-baseline is calculated.

• All unscheduled visits will be included in listings.	
Descriptive Summary Statistics	
Continuous Data	Refer to Combined Statistical Display Principles v2 6.6.1
Categorical Data	N, n, frequency, %
Graphical Displays	
• Refer to IDSL Statistical Principals 7.1 to 7.13.	

14.5.3. Reporting Standards for Pharmacokinetic

Pharmacokinetic Concentration Data	
PC Windows Non-Linear (WNL) File	PC WNL file (CSV format) for the non-compartmental analysis by Clinical Pharmacology Modelling and Simulation function will be created according to SOP 00000314000: Non-Compartmental Analysis of Clinical Pharmacokinetic Data Note: Concentration values will be imputed as per GUI_51487
Descriptive Summary Statistics, Graphical Displays, and Listings	Refer to IDSL PK Display Standards. Graphical displays: Refer to Combined Statistical Displays Principles Section 7. Listings: Refer to Combined Statistical Displays Principles Section 5. Note: Concentration values will be imputed as per GUI_51487 for descriptive summary statistics/analysis and summarized graphical displays only.
NONMEM/Pop PK File	See separate pop PK RAP
NONMEM/PK/PD File	See separate pop PK RAP
Pharmacokinetic Parameter Derivation	
PK Parameter to be Derived by Programmer	None
Pharmacokinetic Parameter Data	
Is NQ impacted PK Parameters Rule Being Followed	Yes, refer to Standards for Handling NQ Impacted PK Parameters
Untransformed PK parameter	Tmax
PK parameter listed only	None
Descriptive Summary Statistics, Graphical Displays and Listings	Refer to IDSL PK Display Standards.

14.6. Appendix 6: Derived and Transformed Data

14.6.1. General

Multiple Measurements at One Analysis Time Point
• Mean of the measurements will be calculated and used in any derivation of summary statistics but if listed, all data will be presented. • 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 T-cell Infusion Date: o Ref Date = Missing → Study Day = Missing o Ref Date < T-cell Infusion Date → Study Day = Ref Date – T -cell infusion Date o Ref Date ≥ T-cell Infusion Date → Study Day = Ref Date – 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 scan date; for other response categories (SD [or Non-CR/Non-PD], NE, PD), the date of response is assigned to the earliest scan date.
Date of New Anti-Cancer Therapy
• Derived as the earliest date of new 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 14.7.2.1.

14.6.2. Study Population

Age
• For participants with a T-cell infusion date, age is derived using T-cell infusion date as the reference date. For ITT participants without a T-cell Infusion date, date of eligibility for leukapheresis is used as the reference date.
BMI
• (Weight in kg) / (Height in meters)^2
Body Surface Area (BSA) (m^2) DuBois & DuBois Formula
• 0.007184 x Height(cm)$^{0.725}$ x Weight(kg)$^{0.425}$
Time since Initial Diagnosis
• Calculated as the number of Months from the Date of Initial Diagnosis: ○ Leukapheresis Eligibility Screening Visit Date = Missing → Elapse Time = Missing ○ Date of Initial Diagnosis = Completely/partially Missing → Elapse Time = Missing ○ Otherwise → Elapse Time = (Leukapheresis Eligibility Screening Visit Date – Date of Initial Diagnosis + 1) /30.4375

14.6.3. Safety

Adverse Events
AEs of Special Interest
• Cytokine release syndrome (CRS) • Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) Grade 1 persisting beyond 24 hrs or associated with concurrent CRS or Grade 2 or higher • Hematopoietic cytopenias including Pancytopenia/ Aplastic anemia • Graft vs host disease (GvHD) • Guillain Barre syndrome (GBS) including acute inflammatory demyelinating polyneuropathy (AIDP) • Treatment-related inflammatory response at tumor site(s) • G4 Neutropenia Lasting ≥ 28 Days
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 calculate AE duration
QTcF Formula (Fridericia Corrected QT Interval)
• QT / RR$^{1/3}$

List of Preferred Terms (PTs) to Be Combined	
The following synonyms will be combined under the PT as shown below. The combined term will be used when reporting AE data in tables by PT. Synonymous terms will be combined regardless of body system. This is an instream list of combined preferred terms and is subject to change.	
Synonym (Combined Term)	**MedDRA Preferred Term Version 25.0 [1]**
Anemia/Red blood cell count decreased	Anemia Red blood cell count decreased
Cytokine Release Syndrome (CRS)	Cytokine release syndrome Cytokine storm
Acute GVHD - Skin	Acute graft versus host disease in skin
Acute GVHD - Gut (Liver and Intestine)	Acute graft versus host disease in liver Acute graft versus host disease in intestine
Acute GVHD - Other (Lung, Bone Marrow, not specified)	Acute graft versus host disease Acute graft versus host disease oral
Chronic GVHD - Skin	Chronic graft versus host disease in skin
Chronic GVHD - Gut (Liver and Intestine)	Chronic graft versus host disease in liver Chronic graft versus host disease in intestine
Chronic GVHD Other - (Lung, Bone Marrow, not specified)	Chronic graft versus host disease Chronic graft versus host disease in eye Chronic graft versus host disease oral Chronic graft versus host disease in lung
Unspecified GVHD - Skin	Graft versus host disease in skin
Unspecified GVHD - Gut (Liver and Intestine)	Graft versus host disease in liver Graft versus host disease in gastrointestinal tract
Unspecified GVHD - Other (Lung, Bone Marrow, not specified)	Graft versus host disease Graft versus host disease in eye Graft versus host disease in lung Prophylaxis against graft versus host disease Transfusion associated graft versus host disease Engraftment syndrome
Leukopenia/White blood cell decreased	White blood cell count decreased Leukopenia
Lymphopenia/Lymphocyte count decreased	Lymphocyte count decreased CD4 lymphocytes decreased CD8 lymphocytes decreased Lymphopenia
Neutropenia/Neutrophil count decreased	Neutrophil count decreased Neutropenia
Rash/Rash maculo-papular	Rash maculo-papular Rash Rash erythematous
Thrombocytopenia/Platelet count decreased	Platelet count decreased Thrombocytopenia
Immune effector cell-associated neurotoxicity syndrome (ICANS)	Immune effector cell-associated neurotoxicity syndrome Encephalopathy

[1] MedDRA Version at the time of Database Lock will be used for reporting. MedDRA terms consistent with Version 25.0 are shown in the table and are subject to change if a different MedDRA version is used.

14.6.4. Efficacy

Overall Survival
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 RS.RSDTC where RSEVAL='INDEPENDENT ASSESSOR' will be excluded • Partial and missing dates will not be imputed for the purpose of deriving date of last contact

14.6.5. Health Outcomes Analysis

CCI

CCI

[redacted]

CCI

[redacted]

14.7. Appendix 7: Reporting Standards for Missing Data

14.7.1. Premature Withdrawals

Element	Reporting Detail
General	• Participant study completion occurs at time of death or transfer to the long-term follow-up study • Withdrawn participants will not be replaced in the study. • All available data from participants who were withdrawn from the study will be listed and all available planned data will be included in summary tables and figures, unless otherwise specified.

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

14.7.2.1. Handling of Missing and Partial Dates

Imputed dates will not be displayed in listings. However, where necessary, display macros may impute dates as temporary variables for the purpose of sorting data in listings only. In addition, partial dates may be imputed for 'slotting' data to study time periods 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

XYZDTFL - flag variable

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

Element	Reporting Detail
General	• Partial dates will be displayed as captured in participant listing displays. However, where necessary, display macros may impute dates as temporary variables for sorting data in listings only. 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. • Imputed partial dates will not be used to derive study day, duration (e.g., duration of adverse events), or elapsed time variables (e.g., time since diagnosis). In addition, imputed dates are not used for deriving the last contact date in overall survival analysis dataset. • With the exception of new anti-cancer therapy start date in the time to event analysis dataset and exposure end date in the exposure analysis dataset, imputed dates will not be stored on datasets.
Age	• Age is only imputed for non-missing birth year and is imputed to the 30th of June • Month and day of birth is never captured.
Adverse Events	• Imputations in the adverse events dataset are used for slotting events to the appropriate study time periods and for sorting in data listings. ○ This includes identifying an AESI as first or last occurrence. • Partial dates for AE recorded in the CRF will be imputed using the following conventions:

Missing start day	• 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 and T-cell infusion date is missing (i.e., participant did not have T-cell infusion)
	  ○ 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.
	  ○ Else set start date =1st of the month
	• Else if lymphodepletion start date is not missing and T-cell infusion date is not missing
	  ○ If month and year of start date = month and year of both T-cell infusion start date and lymphodepletion start date, then

Element	Reporting Detail	
		▪ If stop date contains a full date and stop date is earlier than lymphodepletion start date, then set start date=1st of the month ▪ Else if stop date contains a full date and stop date is earlier than T-cell start date but later than lymphodepletion start date, then set start date=Lymphodepletion start date ▪ Else set start date=T-cell infusion start date o If month and year of start date = month of only T-cell infusion start date, then ▪ If stop date contains a full date and stop date is earlier than T-cell infusion, then set start date=1st of the month ▪ Else set start date=T-cell infusion start date o If month and year of start date = month and year of only lymphodepletion start date, then ▪ If stop date contains a full date and stop date is earlier than lymphodepletion, then set start date=1st of the month ▪ Else set start date=lymphodepletion start date o Else set start date =1st of the month
	Missing start day and month	• 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 and T-cell infusion date is missing (i.e., participant did not have T-cell infusion) 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 • Else if lymphodepletion start date is not missing and T-cell infusion date is not missing o If year of start date = year of both T-cell infusion start date and 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 if stop date contains a full date and stop date is earlier than T-cell start date but later than lymphodepletion start date, then set start date=Lymphodepletion start date ▪ Else set start date=T-cell infusion start date o If year of start date = year of only T-cell infusion start date, then ▪ If stop date contains a full date and stop date is earlier than T-cell infusion, then set start date=January 1st ▪ Else set start date=T-cell infusion start date o If year of start date = year of only lymphodepletion start date, then

<table>
<tr><th>Element</th><th>Reporting Detail</th></tr>
<tr><td></td><td>
<table>
<tr><td></td><td>▪ If stop date contains a full date and stop date is earlier lymphodepletion, 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. Consequently, time to onset and duration of such events will be missing.</td></tr>
</table>
</td></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 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 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>Earliest of (Dec 31st, date of last contact) will be used</td></tr>
<tr><td>Completely missing start/end date</td><td>No imputation</td></tr>
</table>
</td></tr>
<tr><td>Surgical Procedures/Radiotherapy</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>
<tr><td>New Anti-Cancer Therapy/ Radiotherapy/ Surgical Procedures for Efficacy Evaluation</td><td>
Start dates for on-study anti-cancer therapy, radiotherapy (where applicable), and surgical procedures (where applicable) will be 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 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.
</td></tr>
</table>

Element	Reporting Detail

	• Partial start dates will be imputed using the following convention:
	  • If both month and day are missing, no imputation will be applied.
	  • If only day is missing:
	  o If the month of partial date is the same as the month of T-cell infusion, minimum of (T-cell infusion date + 1, last day of the month) will be used for the day.
	  o If the month of partial date is the same as the month of last disease assessment and the last disease assessment is PD, minimum of (last date of disease assessment + 1, last day of the month) will be used for the day.
	  o If both conditions above are met, the later date will be used for the day.
	  o Otherwise, a '01' will be used for the day.
	• Completely or partial missing end dates will remain missing, with no imputation applied;

14.8. Appendix 8: Values of Potential Clinical Importance

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). Note: a high abnormal or low abnormal laboratory value is not necessarily of clinical concern. 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 v5.0) will be used to assign grades to the relevant laboratory parameters. NCI-CTCAE v5.0 can be found at http://ctep.cancer.gov/reporting/ctc.html.

For laboratory data which are not listed in the NCI CTCAE v5.0, a summary of values outside the normal range will be provided.

14.8.2. Vital Signs

To identify values of potential clinical importance (PCI), NCI-CTCAE v5.0 will be used to assign categories that align with the grades for 'Hypothermia', 'Fever', 'Hypoxia' and 'Sinus bradycardia'/ 'Sinus Tachycardia'.

Vital Sign Parameter (Absolute)	Units	Potential Clinical Importance (PCI) Range	
		Lower (L)	Upper (H)
Heart Rate	bpm	Decrease to <60	Increase to >100
Temperature	Degrees C	Decrease to ≤ 35	Increase to ≥38
Pulse Oximetry	%	Decrease to <88	N/A

Values of potential clinical importance for hypotension will be presented as defined below:

Vital Sign Parameter (Absolute)	Units	Potential Clinical Importance (PCI) Range
Decrease from baseline Systolic Blood Pressure	mmHg	≥80 to <100 (Low) <80 (Very low)
Decrease from baseline Diastolic Blood Pressure	mmHg	≥60 to <70 (Low) <60 (Very low)

An increase from baseline for diastolic blood pressure/systolic blood pressure will be presented by grade, using NCI-CTCAE v5.0 grades for 'Hypertension'. A change from baseline to Grade 1, 2, or 3 will be presented. Systolic and diastolic blood pressures Grade ≥ 1 will be flagged as High (H) in the listing.

Vital Sign Parameter	Unit	Potential Clinical Importance (PCI) Range
Increase from baseline Systolic Blood Pressure	mmHg	≥120 to <140 (Grade 1) ≥140 to <160 (Grade 2) ≥160 (Grade 3)
Increase from baseline Diastolic Blood Pressure	mmHg	≥80 to <90 (Grade 1) ≥90 to <100 (Grade 2) ≥100 (Grade 3)

14.8.3. ECG Parameters

To identify QTc (Bazett's or Fridericia's) values of potential clinical importance, NCI-CTCAE v5.0 will be used to assign grades (see adverse event 'Electrocardiogram QT corrected interval prolonged'). The clinical concern range for QRS interval is approximately based on the limits determined by Ramirez et al (Ramirez, 2011).

By default, the definition of PCI is defined based on QTc value (e.g., QTcF Interval, Aggregate) where a participant has a QTc value ≥450 or a QTc increase of >30 msec.

PCI Flag	Potential Clinical Importance (PCI) Range
High (H)	Grade 1 or Higher (QTc ≥450 ms) or QTc increase from baseline of >30 ms or QRS duration >105 msec
Low (L)	QRS duration < 70 msec

14.9. Appendix 9: Population Pharmacokinetic (PopPK) Analyses

Not applicable.

14.10. Appendix 10: Exploratory Pharmacokinetic / Pharmacodynamic Analyses

Not applicable.

14.11. Appendix 11: Abbreviations & Trademarks

14.11.1. Abbreviations

Abbreviation	Description
ADaM	Analysis Data Model
AE	Adverse Event
A&R	Analysis and Reporting
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
CPMS	Clinical Pharmacology Modelling and Simulation
CRS	Cytokine Release Syndrome
CS	Clinical Statistics
CSR	Clinical Study Report
CTCAE	Common Toxicity Criteria for Adverse Events
CTR	Clinical Trial Register
CV_b / CV_w	Coefficient of Variation (Between) / Coefficient of Variation (Within)
DBF	Database Freeze
DBR	Database Release
DOB	Date of Birth
DP	Decimal Places
ECOG	Eastern Cooperative Oncology Group
eCRF	Electronic Case Record Form
EMA	European Medicines Agency
EudraCT	European Clinical Trials Database
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Clinical Results Disclosure Requirements
GSK	GlaxoSmithKline
IA	Interim Analysis
ICH	International Conference on Harmonization
IDMC	Independent Data Monitoring Committee
IDSL	Integrated Data Standards Library
IMMS	International Modules Management System
IP	Investigational Product
ITT	Intent-To-Treat
LVEF	Left Ventricular Ejection Fraction
MedDRA	Medical Dictionary for Regulatory Affairs
ORR	Overall Response Rate
OS	Overall Survival
PFS	Progression Free Survival
PP	Per Protocol
PT	Preferred Term
PCI	Potential Clinical Importance
PD	Pharmacodynamic
PDMP	Protocol Deviation Management Plan
PK	Pharmacokinetic
PopPK	Population PK
QC	Quality Control
QTcF	Frederica's QT Interval Corrected for Heart Rate
QTcB	Bazett's QT Interval Corrected for Heart Rate

Abbreviation	Description
RAP	Reporting & Analysis Plan
RAMOS	Randomization & Medication Ordering System
SAC	Statistical Analysis Complete
SDSP	Study Data Standardization Plan
SDTM	Study Data Tabulation Model
SOP	Standard Operation Procedure
TA	Therapeutic Area
TFL	Tables, Figures & Listings
TTR	Time to response
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	1.010 to 1.370	1.380
Efficacy	2.150 to 2.350	2.380 to 2.510
Safety	3.010 to 3.810	3.905 to 3.950
Pharmacokinetic	4.010 to 4.020	4.030
Section	**Listings**	
ICH Listings	1 to 1.42	
Other Listings	1.50 to 2.2	

14.12.2. Mock Example Shell Referencing

Non-IDSL specifications will be referenced as indicated and if required example mock-up displays will be provided upon request.

Section	Figure	Table	Listing
Study Population	POP_Fn	POP_Tn	POP_Ln
Efficacy	EFF_Fn	EFF_Tn	EFF_Ln
Safety	SAFE_Fn	SAFE_Tn	SAFE_Ln
Pharmacokinetic	PK_Fn	PK_Tn	PK_Ln
PRO	PRO_Fn	PRO_Tn	PRO_Ln

NOTES:

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

14.12.3. Deliverables

Programming notes should be utilized to determine if the display is in scope for the deliverable. If the programming note reads "Not required- do not produce", the display was originally planned for the CSR, but will not be produced for the abbreviated CSR. Programming notes will detail the conditional nature of the display, based on how many participants are dosed or have an event in the population.

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

NOTES:

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

14.12.4. Study Population Tables

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Disposition					
1.010.	ITT	ES8	Summary of Subject Status and Subject Disposition for the Study Conclusion Record	ICH E3, FDAAA, EudraCT Participant status will be displayed with the categories Completed (Death, Transferred to LTFU), Ongoing (IN PRE-LYMPHODEPLETION PHASE, IN INTERVENTIONAL PHASE, IN FOLLOW-UP PHASE), and Withdrawn (Primary reasons as captured in the CRF) Required display if ≥2 participants have an event	Primary Final SAC
1.020.	mITT	ES8	Summary of Subject Status and Subject Disposition for the Study Conclusion Record	ICH E3, FDAAA, EudraCT Participant status will be displayed with the categories Completed (Death, Transferred to LTFU), Ongoing (IN PRE-LYMPHODEPLETION PHASE, IN INTERVENTIONAL PHASE, IN FOLLOW-UP PHASE), and Withdrawn (Primary reasons as captured in the CRF) Required display if ≥2 participants have an event	Primary Final SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.045	LYMPH	SD1	Summary of Interventional Phase Status	ICH E3, FDAAA, EudraCT Reasons for withdrawal from interventional phase as captured in the CRF will be summarized. Required display if ≥2 participants have an event	Primary Final SAC
1.060	SCR	ES6	Summary of Screening Status and Reasons for Screen Failure	Journal Requirements Subjects who were rescreened will appear once in these displays according to their final status. Categories include Entered Into Trial and Failed. Reasons for failure as captured in the CRF will be summarized. Required display if ≥2 participants have an event	Primary Final SAC
1.070	ITT	ES10	Summary of Subject T-cell Infusion Status and Reason for Failure to Receive T-cell Infusion	Participant status will be displayed with the categories Completed and Failed. Reasons for failure as captured in the CRF will be summarized. Required display if ≥2 participants have an event	Primary Final SAC
1.080	ENRL	NS1	Summary of Number of Participants by Country and Site ID	EudraCT/Clinical Operations Required display if ≥2 participants have an event	Primary Final SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.090	mITT	NS1	Summary of Number of Participants by Country and Site ID	EudraCT/Clinical Operations Required display if ≥2 participants have an event	Primary Final SAC
1.100	ITT	PAN4	Summary of Visits Impacted by COVID-19 Pandemic	Required display if ≥4 participants have an event	Primary Final SAC
Protocol Deviation					
1.110	ITT	DV1	Summary of Important Protocol Deviations	ICH E3 Required display if ≥4 participants have an event	Primary Final SAC
1.120	ITT	DV1	Summary of Important COVID-19 Related Protocol Deviations	Required display if ≥4 participants have an event	Primary Final SAC
1.130	ITT	DV1	Summary of Important Non COVID-19 Related Protocol Deviations	Not required- do not produce	
1.140	SCR	IE1	Summary of Inclusion/Exclusion Criteria Deviations	Not required- do not produce	
Population Analyzed					
1.150	ENR	SP1	Summary of Study Populations	IDSL Only analysis population used for each analysis deliverable will be summarized. Required display	Primary Final SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Demographic and Baseline Characteristics					
1.160	ITT	DM1	Summary of Demographic Characteristics	ICH E3, FDAAA, EudraCT Report sex, age [years] summary, age [years] categories [<=18, 19-64, >=65], ethnicity, race, race detail, baseline height [cm], baseline weight [kg], baseline Body Mass Index [kg/m2] & baseline Body Surface Area [m2]. Required display if ≥2 participants have an event	Primary Final SAC
1.180	mITT	DM1	Summary of Demographic Characteristics	ICH E3, FDAAA, EudraCT Report sex, age [years] summary, age [years] categories [<=18, 19-64, >=65], ethnicity, race, race detail, baseline height [cm], baseline weight [kg], baseline Body Mass Index [kg/m2] & baseline Body Surface Area [m2]. Required display if ≥2 participants have an event	Primary Final SAC
1.190	ENRL	DM11	Summary of Age Ranges	EudraCT Required display if ≥2 participants have an event	Primary Final SAC
Disease Characteristics					
1.210	mITT	DC1	Summary of Disease Characteristics at Initial Diagnosis	ICHE3 Required display if ≥4 participants have an event	Primary Final SAC

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.230	mITT	DC2	Summary of Disease Characteristics at Screening	ICH3 Prior systemic therapy comes from a different form and does not include radiotherapy and surgeries. Required display if ≥6 participants have an event	Primary Final SAC
1.240	mITT	LA1	Summary of Disease Burden at Baseline	Not required- do not produce	
1.250	mITT	MD1	Summary of Metastatic Disease at Screening	Not required- do not produce	
Anti-Cancer Therapy					
1.260	mITT	CM1	Summary of Dictionary Coded Anti-Cancer Bridging Therapy	Not required- do not produce	
1.270	mITT	FAC1	Summary of On-Study Anti-Cancer Therapy	Not required- do not produce	
1.310	mITT	CM8	Summary of On-Study Dictionary Coded Anti-Cancer Therapy	Not required- do not produce	
Prior and Concomitant Medications and Medical Conditions					
1.320	mITT	CM8	Summary of Concomitant Medications	ICH E3 Use GSK Drug Dictionary Required display if ≥4 participants have an event	Primary Final SAC
1.321	mITT	BP1A	Summary of Blood Products	Required display if ≥4 participants have an event	Primary Final SAC
1.330	ITT	MH1	Summary of Past Medical Conditions	Not required- do not produce	
1.340	mITT	MH1	Summary of Past Medical Conditions	Not required- do not produce	
1.350	ITT	MH1	Summary of Current Medical Conditions	Not required- do not produce	
1.360	mITT	MH1	Summary of Current Medical Conditions	Not required- do not produce	

Study Population Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Exposure					
1.370	LYMPH	EX1	Summary of Exposure on Study Treatment	ICH E3 Vein to vein time, total cyclophosphamide and fludarabine doses, and total number of Transduced T-cells will be summarized using mean, standard deviation, median, minimum, and maximum. Cyclophosphamide, fludarabine, and total number of Transduced T-cells will also be categorized as follows. Total number of transduced T-cell: <1 x 10^9, >=1 x 10^9 to <=8 x 10^9, >8 x 10^9 to <=15 x 10^9 and >15 x 10^9. Total cyclophosphamide dose: <=1800, >1800 to <=2400, >2400 to <=2700, >2700 to <=3600 and >3600. Total fludarabine dose: <=60, >60 to <=80, >80 to <=90, >90 to <=120, >120. Required display if ≥4 participants have an event	Primary Final SAC

14.12.5. Study Population Figures

Study Population Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Disposition					
1.400	ITT	PAN8	Proportion of Subject Visits impacted by COVID-19 Pandemic	Not required- do not produce	

14.12.6. Efficacy Tables

Efficacy Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Response					
2.149	ITT	RE1a	Summary of Investigator-Assessed Best Response with Confirmation (RECIST 1.1 Criteria)	Not required- do not produce	
2.152	mITT	RE1a	Summary of Investigator-Assessed Overall Response Rate and Best Response with Confirmation (RECIST 1.1 Criteria)	Required display if ≥2 participants in mITT population	Primary Final SAC
2.180	ITT	RE1a	Summary of Investigator-Assessed Overall Response Rate with Confirmation (iRECIST 1.1 Criteria)	Not required- do not produce	
2.190	mITT	RE1a	Summary of Investigator-Assessed Overall Response Rate with Confirmation (iRECIST 1.1 Criteria)	Not required- do not produce	

Efficacy Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.220	ITT	RE1c	Summary of Investigator-Assessed Disease Control Rate with Confirmation (RECIST 1.1 Criteria)	Not required- do not produce	
2.225	mITT	RE1c	Summary of Investigator-Assessed Disease Control Rate with Confirmation (RECIST 1.1 Criteria)	Required display if ≥2 participants in mITT population	Primary Final SAC
Time-to-Event					
2.231	mITT	TTE1	Summary of Overall Survival	Do not include Probability of OS at 6-month intervals (6, 12, 18, etc.) Required display if ≥4 participants in mITT population	Final SAC
2.241	mITT	TTE1	Summary of Reverse Kaplan-Meier Estimates for Overall Survival Follow-up	Do not include Probability of OS at 6-month intervals (6, 12, 18, etc.) Required display if ≥4 participants in mITT	Final SAC
2.280	mITT	TTE1	Summary of Investigator-Assessed Progression-Free Survival (RECIST 1.1 Criteria)	Do not include Probability of PFS at 3-month intervals (3, 6, 9, 12, etc.) Required display if ≥2 participants in mITT population	Primary Final SAC
2.282	mITT	TTE1	Summary of Investigator-Assessed Reverse Kaplan-Meier Estimates for Progression Free Survival Follow-up (RECIST 1.1 Criteria)	Do not include Probability of PFS at 3-month intervals (3, 6, 9, 12, etc.) Required display if ≥2 participants in mITT population	Primary Final SAC
2.290	mITT	TTE1	Summary of Investigator-Assessed Progression-Free Survival (iRECIST 1.1 Criteria)	Not required- do not produce	
2.320	mITT	TTE1a	Summary of Investigator-Assessed Duration of Response (RECIST 1.1 Criteria)	Required display if ≥2 participants have an event	Primary Final SAC

Efficacy Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2..322	mITT	TTE1a	Summary of Investigator-Assessed Reverse Kaplan-Meier Estimates for Duration of Response (RECIST 1.1 Criteria)	Required display if ≥2 participants have an event	Primary Final SAC
2.330	mITT	TTE1a	Summary of Investigator-Assessed Duration of Response (iRECIST 1.1 Criteria)	Not required- do not produce	
2.350	mITT	EFF_T1	Summary of Investigator-Assessed Time to Response (RECIST 1.1 Criteria)	Required display if ≥2 participants have an event	Primary Final SAC

14.12.7. Efficacy Figures

Efficacy Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Time-to-Event					
2.380	mITT	EFF_F3	Plot of Duration on Interventional Phase	Include bridging therapy Required display if ≥4 participants have an event	Primary Final SAC
2.400	mITT	RE8b	Investigator-Assessed Maximum Percent Reduction from Baseline in Tumor Measurement (RECIST 1.1 Criteria)	Not required- do not produce	
2.420	mITT	EFF_F1	Spider Plot of Investigator-Assessed Percent Change from Baseline in Target Lesion Diameter (RECIST 1.1 Criteria)	Required display if ≥2 participants have an event	Primary Final SAC
2.440	mITT	TTE10	Graph of Kaplan Meier Survival Curves of Investigator-Assessed Duration of Response with 95% Confidence Bands (RECIST 1.1 Criteria)	Required display if ≥2 participants have event	Primary Final SAC

Efficacy Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.451	mITT	TTE10	Graph of Kaplan Meier Survival Curves of Overall Survival	Required display if ≥4 participants in mITT population	Final SAC
2.470	mITT	TTE10	Graph of Kaplan Meier Survival Curves of Investigator-Assessed Progression-Free Survival with 95% Confidence Bands (RECIST 1.1 Criteria)	Required display if ≥2 participants in mITT population	Primary Final SAC
2.490	mITT	TTE10	Graph of Kaplan Meier Survival Curves of Investigator-Assessed Progression-Free Survival with 95% Confidence Bands (iRECIST 1.1 Criteria)	Not required- do not produce	
2.510	mITT	TTE10	Graph of Kaplan Meier Survival Curves of Investigator-Assessed Duration of Response with 95% Confidence Bands (iRECIST 1.1 Criteria)	Not required- do not produce	

14.12.8. Safety Tables

Safety Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events					
3.010	ITT	AE1	Summary of All Adverse Events Grouped by Similarity of Preferred Terms	Only include Combined PT Term AEs Required display if ≥2 participants have an event	Primary Final SAC
3.020	ITT	AE1	Summary of Adverse Events in the Pre-Lymphodepletion Phase by System Organ Class and Preferred Term	Not required – do not produce	
3.030	ITT	AE5B	Summary of Adverse Events in the Pre-Lymphodepletion Phase by Maximum Grade	Include Combined PT Term AEs Required display if ≥2 participants have an event	Primary Final SAC

Safety Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.040	LYMPH	AE1	Summary of Adverse Events in the Lymphodepletion Phase by System Organ Class and Preferred Term	Not required – do not produce	
3.050	LYMPH	AE5B	Summary of Adverse Events in the Lymphodepletion Phase by Maximum Grade	Include Combined PT Term AEs Required display if ≥2 participants have an event	Primary Final SAC
3.060	LYMPH	AE5B	Summary of Lymphodepletion Related Adverse Events in the Lymphodepletion Phase by Maximum Grade	Not required – do not produce	
3.070	SAF	AE1	Summary of Treatment Emergent Adverse Events by System Organ Class and Preferred Term	ICH3 Required display if ≥2 participants have an event	Primary Final SAC
3.080	SAF	AE5B	Summary of Treatment Emergent Adverse Events by Maximum Grade	Include Combined PT Term AEs Required display if ≥2 participants have an event	Primary Final SAC
3.090	SAF	AE5B	Summary of Treatment Emergent T-cell Related Adverse Events by Maximum Grade	Include Combined PT Term AEs Required display if ≥2 participants have an event	Primary Final SAC
3.100	SAF	AE5B	Summary of Treatment Emergent Lymphodepletion Related Adverse Events by Maximum Grade	Include Combined PT Term AEs Required display if ≥4 participants have an event	Primary Final SAC
3.110	SAF	AE1	Summary of Treatment Emergent T-cell Related Adverse Events by System Organ Class and Preferred Term	Not required – do not produce	
3.190	SAF90	AE5B	Summary of Delayed Adverse Events by Delayed Category and Maximum Grade	Not required – do not produce	
3.200	SAF	AE3	Summary of Treatment Emergent T-cell Related Non-Serious Adverse Events by Overall Frequency	Plain Language Summaries Required display if ≥2 participants have an event	Primary Final SAC

Safety Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.210	SAF	AE15	Summary of Common (≥5%) Treatment Emergent Non-Serious Adverse Events by System Organ Class and Preferred Term (Number of Subjects and Occurrences)	FDAAA, EudraCT Required display if ≥2 participants have an event	Primary Final SAC
Adverse Events of Special Interest					
3.300	SAF	AE5B	Summary of Treatment Emergent Adverse Events of Special Interest by Maximum Grade (Comprehensive List)	Not required – do not produce	
3.310	SAF	AE5B	Summary of Treatment Emergent Adverse Events of Special Interest by Maximum Grade (Focused List)	Use combined PTs Use variable for the 3 segments for Hematopoietic Cytopenias similar to how comprehensive AESI tables create multiple sections for preferred terms that are part of more than 1 AESI The Hematopoietic Cytopenias section of the AESI tables will have 4 parts. The Hematopoietic Cytopenias section preferred terms is a super set of all the preferred terms in the 3 cell line sections Keep these 4 sections together in table: Hematopoietic Cytopenias: All Hematopoietic Cytopenias Anemia all the Anemia preferred terms Neutropenia all the Neutropenia preferred terms Thrombocytopenia all the Thrombocytopenia preferred term	Primary Final SAC

Safety Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Refer to Table 3.010 "Summary of All Adverse Events Grouped by Similarity of Preferred Terms" Required display if ≥2 participants have an event	
3.320	SAF	AE5B	Summary of AEs Linked to AESIs Identified by the Investigator by Maximum Grade	Not required – do not produce	
3.330	SAF	CM8	Summary of the Concomitant Medications Linked to AESIs	Not required – do not produce	
3.340	SAF	ESI1	Summary of Characteristics of Treatment Emergent Cytokine Release Syndrome (CRS)	Use combined PTs Use Focused List Adverse events with different preferred terms are counted as different occurrences, no matter when they occurred. Required display if ≥4 participants have an event	Primary Final SAC
3.350	SAF	ESI2b	Summary of Time to Onset and Duration of the First Occurrence of Treatment Emergent Cytokine Release Syndrome (CRS)	Use combined PTs Use Focused List Duration (days) (1-30, 31-60,61-90,>90, Ongoing) Required display if ≥4 participants have an event	Primary Final SAC
3.360	SAF	ESI2b	Summary of Onset and Duration of the First Occurrence of Treatment Emergent Serious Cytokine Release Syndrome (CRS)	Not required – do not produce	
3.370	SAF	EX1	Summary of Number of Doses per Patient that Received Tocilizumab for CRS	Not required – do not produce	
3.380	SAF	PR1	Summary of Procedures Associated with Cytokine Release Syndrome (CRS)	Not required – do not produce	

Safety Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.400	SAF	ESI1	Summary of Characteristics of Treatment Emergent Hematopoietic Cytopenias (Focused List)	Use combined PTs Use Focused List Adverse events with different preferred terms are counted as different occurrences, no matter when they occurred. Required display if ≥4 participants have an event	Primary Final SAC
3.410	SAF	ESI2b	Summary of Time to Onset and Duration of the First Occurrence of Treatment Emergent Febrile Neutropenia	ADAE.ADECOD=FEBRILE NEUTROPENIA Required display if ≥4 participants have an event	Primary Final SAC
3.420	SAF	ESI1	Summary of Characteristics of Treatment Emergent Graft vs Host Disease (GvHD)	Use combined PTs Use Focused List. Adverse events with different preferred terms are counted as different occurrences, no matter when they occurred. Required display if ≥4 participants have an event	Primary Final SAC
3.430	SAF	ESI2b	Summary of Time to Onset and Duration of the First Occurrence of Treatment Emergent Graft vs Host Disease (GvHD)	Use combined PTs Use Focused List. Required display if ≥4 participants have an event	Primary Final SAC
3.440	SAF	ESI1	Summary of Characteristics of Treatment Emergent Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)	Use combined PTs Use Focused List. Adverse events with different preferred terms are counted as different occurrences, no matter when they occurred. Required display if ≥4 participants have an event	Primary Final SAC

Safety Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
3.450	SAF	ESI2b	Summary of Time to Onset and Duration of the First Occurrence of Treatment Emergent Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)	Use combined PTs Use Focused List. Required display if ≥4 participants have an event	Primary Final SAC
Serious and Other Significant Adverse Events					
3.480	ITT	AE5B	Summary of Serious Adverse Events in the Pre-Lymphodepletion Phase by Maximum Grade	Not required – do not produce	
3.490	LYMPH	AE5B	Summary of Serious Adverse Events in the Lymphodepletion Phase by Maximum Grade	Include Combined PT Term AEs Required display if ≥4 participants have an event	Primary Final SAC
3.500	SAF	AE1	Summary of Treatment Emergent Serious Adverse Events by System Organ Class and Preferred Term	Not required – do not produce	
3.510	SAF	AE16	Summary of Treatment Emergent Serious Adverse Events by System Organ Class and Preferred Term (Number of Participants and Occurrences)	Do not use combined PT Required display if ≥2 participants have an event	Primary Final SAC
3.520	SAF	AE5B	Summary of Treatment Emergent Serious Adverse Events by Maximum Grade	Include Combined PT Term AEs Required display if ≥2 participants have an event	Primary Final SAC
3.530	SAF	AE5B	Summary of Treatment Emergent Lymphodepletion Related Serious Adverse Events by Maximum Grade	Not required – do not produce	
3.540	SAF	AE5B	Summary of Treatment Emergent T-cell Related Serious Adverse Events by Maximum Grade	Include Combined PT Term AEs Not required- do not produce	
3.550	SAF	AE20	Summary of Treatment Emergent T-cell Related Serious Fatal and Non-Fatal AEs by Overall Frequency	Plain Language Summaries Required display if ≥2 participants have an event	Primary Final SAC

Safety Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Death					
3.580	SAF	DD1	Summary of Deaths	IDSL Required display if ≥2 participants have an event	Primary Final SAC
ECG					
3.590	SAF	EG10	Summary of Maximum QTc Values Post-Baseline Relative to Baseline by Category	Not required – do not produce	
3.600	SAF	EG11	Summary of Maximum Increase in QTc Values Post-Baseline Relative to Baseline by Category	Not required – do not produce	
Vital Signs					
3.630	SAF	VS7	Summary of Vital Sign Results Relative to Potential Clinical Importance (PCI) Criteria Post-Baseline Relative to Baseline	Not required – do not produce	
3.640	SAF	VS6	Summary of Worst-Case Increase in Blood Pressure by Maximum Grade Increase Post-Baseline Relative to Baseline	Not required – do not produce	
Performance Status					
3.650	SAF	PS1A	Summary of ECOG Performance Status	Not required – do not produce	
Laboratory: Hematology					
3.670	SAF	LB1	Summary of Post-Baseline Change of Hematology Values by Visit	Not required – do not produce	
3.680	SAF	LB15A	Summary of Worst-Case Hematology Results Relative to Normal Range Post-Baseline Relative to Baseline	Not required – do not produce	
3.690	SAF	LB16A	Summary of Hematology Results by Maximum Grade Increase Post-Baseline Relative to Baseline	Not required – do not produce	

Safety Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Laboratory: Chemistry					
3.700	SAF	LB1	Summary of Post-Baseline Change of Chemistry Values by Visit	Not required – do not produce	
3.710	SAF	LB15A	Summary of Worst-Case Chemistry Results Relative to Normal Range Post-Baseline Relative to Baseline	Not required – do not produce	
3.720	SAF	LB16A	Summary of Chemistry Results by Maximum Grade Increase Post-Baseline Relative to Baseline	Not required – do not produce	
Laboratory					
3.730	SAF	SAFE_T1	Summary of Time to Resolution of Persistent Clinically Significant Thrombocytopenia	Not required – do not produce	
3.740	SAF	SAFE_T1	Summary of Time to Resolution of Persistent Clinically Significant Neutropenia	Not required – do not produce	
3.750	SAF	SAFE_T1	Summary of Time to Resolution of Persistent Clinically Significant Anemia	Not required – do not produce	
Laboratory: Hepatobiliary (Liver)					
3.760	SAF	LIVER1	Summary of Liver Monitoring/Stopping Event Reporting	Not required – do not produce	
3.770	SAF	LIVER10	Summary of Hepatobiliary Laboratory Abnormalities	Not required – do not produce	
Laboratory: Urinalysis					
3.780	SAF	UR1	Summary of Worst-Case Urinalysis Results (Discrete or Character Values) Post-Baseline Relative to Baseline	Not required – do not produce	
Biomarker					
3.790	SAF	SAFE_T4	Summary of Subjects Showing >1% Gene Marked PBMCs 1 Year Post-Treatment	Not required – do not produce	
3.800	SAF	SAFE_T4	Summary of Replication Competent Lentivirus Positive	Required display if ≥2 participants have an event	Primary Final SAC
3.810	SAF	SAFE_T5	Summary of Anti-GSK3377794 Antibodies (ATA)	Not required – do not produce	

14.12.9. Safety Figures

Safety Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Laboratory: Hematology					
3.905	SAF	SAFE_F3	Hematology Values Over Time – Neutrophils	Not required- do not produce	
3.915	SAF	SAFE_F3	Hematology Values Over Time –Hemoglobin	Not required- do not produce	
3.925	SAF	SAFE_F3	Hematology Values Over Time – Platelets	Not required- do not produce	
3.932	SAF	SAFE_F6	Plot of Hemoglobin, Neutrophils, and Platelets Over Time	Required display if ≥1 participant have an event	Primary Final SAC
3.935	SAF	SAFE_F3	Hematology Values Over Time – Lymphocytes	Not required- do not produce	
Laboratory: Hepatobiliary (Liver)					
3.940	SAF	LIVER14	Scatter Plot of Maximum vs. Baseline for ALT	Not required- do not produce	
3.950	SAF	LIVER9	Scatter Plot of Maximum ALT vs. Maximum Total Bilirubin – eDISH	Not required- do not produce	

14.12.10. Pharmacokinetic Tables

Pharmacokinetic: Tables					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
4.010	PK	PK03	Summary of Derived GSK3377794 Pharmacokinetic Parameters	Include Cmax, AUC and Tmax parameters. Calculate n, min, arithmetic mean, 95% CI, max, median and SD Required display if ≥2 participants have an event	Primary Final SAC
4.020	PK	PK05	Summary of Derived Log-Transformed GSK3377794 Pharmacokinetic Parameters	Include Cmax and AUC, Exclude Tmax parameter. Calculate n, geometric mean , 95% CI, %CVb and SD (Logs) Required display if ≥2 participants have an event	Primary Final SAC

14.12.11. Pharmacokinetic Figures

PK Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
4.030	PK	PK_F1	GSK3377794 Pharmacokinetic Concentration–Time Plot	Y-axis is log transformed (not the values). Label x-axis=0 as "Pre T-cell". Plot each subject using a different colored line and list all subjects in x-axis legend. Values <1 are set to 1. Required display if ≥2 participants have an event	Primary Final SAC

14.12.12. Patient Reported Outcome (PRO) Tables

CCI

14.12.13. Patient Reported Outcome (PRO) Figures

Patient Reported Outcome: Figures					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
CCI					

14.12.14. ICH Listings

ICH Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Disposition					
1.01	ITT	ES2	Listing of Reasons for Study Withdrawal	Add a flag variable to indicate withdrawal due to COVID Required display	Primary Final SAC
1.02	SCR	ES7	Listing of Reasons for Screen Failure	Required display	Primary Final SAC
Protocol Deviations					
1.03	ITT	DV2	Listing of Important Protocol Deviations	Required display	Primary Final SAC
1.04	ITT	DV2	Listing of Non-Important Protocol Deviations due to COVID-19 Pandemic	Required display	Primary Final SAC
1.05	ITT	IE3	Listing of Participants with Inclusion/Exclusion Criteria Deviations	Required display	Primary Final SAC
Population Analyzed					

ICH Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.06	SCR	SP3	Listing of Participants Excluded from Any Population	Required display	Primary Final SAC
Demographic and Baseline Characteristics					
1.07	ITT	DM2	Listing of Demographic Characteristics	Required display	Primary Final SAC
1.08	ITT	DM9	Listing of Race	Required display	Primary Final SAC
Prior and Concomitant Medications					
1.09	ITT	CM3	Listing of Concomitant Medications using Ingredient	Required display	Primary Final SAC
1.10	ITT	BP4	Listing of Blood Products	Required display	Primary Final SAC
Exposure					
1.11	SAF	POP_L1	Listing of Lete-cel Dosing Status	Required display	Primary Final SAC
1.12	ITT	EX3	Listing of Exposure Data	Required display	Primary Final SAC
Adverse Events					
1.21	ITT	SAFE_L11	Listing of All Adverse Events	ICH E3 Overall record line will contain all phases where event started or worsened in phase(pre-lymphodepletion, lymphodepletion, and T-cell infusion) concatenated in the Overall Phase(s) column An event can have multiple phases and will be determined whether the AE started or worsened in a given phase. For	Primary Final SAC

ICH Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				example, an AE started in Pre-lymphodepletion phase, continued into but did not worsen in the lymphodepletion phase and continued in and worsened in the T-cell infusion, will have two phases assigned: Pre-lymphodepletion & T-cell Infusion . Segment lines list just start/end date tox grade and phase, if event does not start or worsen in phase, phase can be missing on a segment line Required display	
1.22	ITT	AE7	Listing of Subject Numbers for Individual Adverse Events	ICH E3 Required display	Primary Final SAC
Adverse Events of Special Interest					
1.23	ITT	SAFE_L12	Listing of Cytokine Release Syndrome (CRS) Subject Profile	Required display	Primary Final SAC
1.24	ITT	SAFE_L16	Listing of Pancytopenia / Aplastic Anemia Subject Profile	Required display	Primary Final SAC
1.25	ITT	SAFE_L14	Listing of Graft vs Host Disease (GvHD) Subject Profile	Required display	Primary Final SAC
1.26	ITT	SAFE_L15	Listing of Immune Effector Cell-Associated Neurotoxicity syndrome (ICANS) Subject Profile	Required display	Primary Final SAC
1.27	ITT	SAFE_L13	Listing of Guillain-Barre Syndrome (GBS) Subject Profile	Required display	Primary Final SAC
Serious and Other Significant Adverse Events					
1.28	ITT	AE14	Listing of Reasons for Considering as a Serious Adverse Event	ICH E3 Required display	Primary Final SAC
1.29	ITT	SAFE_L11	Listing of Non-Fatal Serious Adverse Events	ICH E3	Primary

ICH Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Overall record line will contain all phases where event started or worsened in phase("pre-lymphodepletion, lymphodepletion, and T-cell infusion) concatenated in the Overall Phase(s) column An event can have multiple phases and will be determined whether the AE started or worsened in a given phase. For example, an AE started in Pre-lymphodepletion phase, continued into but did not worsen in the lymphodepletion phase and continued in and worsened in the T-cell infusion, will have two phases assigned: Pre-lymphodepletion phase & T-cell Infusion . Segment lines list just start/end date tox grade and phase, if event does not start or worsen in phase, phase can be missing on a segment line Required display	Final SAC
1.30	SAF	SAFE_L11	Listing of Delayed Adverse Events by Delayed Category (GSK Adjudicated)	ICH E3 Delayed AE categories are provided in the RAP. Overall record line will contain all phases where event started or worsened in phase ("pre-lymphodepletion, lymphodepletion, and t-cell infusion) concatenated in the Overall Phase(s) column An event can have multiple phases and will be determined whether the AE started or worsened in a given phase. For example, an AE started in Pre-lymphodepletion, continued into but did not worsen in the lymphodepletion phase and continued in and worsened in the T-cell infusion, will have two phases assigned: pre-lymphodepletion, & T-cell Infusion . Segment lines list just start/end date toxicity grade and phase, if event does not start or worsen in phase, phase can be missing on a segment line	Primary Final SAC

ICH Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Required display	
Deaths					
1.31	ITT	DD3	Listing of Death Subject Profile	ICH E3 Last treatment prior to death is derived based on actual treatment Required display	Primary Final SAC
1.32	ITT	EG3	Listing of All ECG Values	ICH E3 Required display	Primary Final SAC
1.33	ITT	EG5	Listing of All ECG Findings	ICH E3 Required display	Primary Final SAC
1.34	ITT	VS4	Listing of All Vital Signs	ICH E3 Required display	Primary Final SAC
Performance Status					
1.35	ITT	PS5A	Listing of ECOG Performance Status	ICH E3 100 = Fully active, normal. 90 = Minor restrictions in physically strenuous activity. 80 = Active, but tries more quickly. 70 = Both greater restriction of, and less time spent in, active play. 60 = Up and around, but minimal active play; keeps busy with quieter activities. 50 = Gets dressed, but lies around much of the day; no active play; able to participate in quiet play and activities.. 40 = Mostly in bed; participates in quiet activities. 30 = In bed; needs assistance even for quiet play. 20 = Often sleeping; play entirely limited to very passive activities. 10 = No play; does not get out of bed. 0 = Unresponsive; Dead.	Primary Final SAC

ICH Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				Required display	
1.36	ITT	PS5A	Listing of Lansky Performance Status	ICH E3 100 = Fully active, normal. 90 = Minor restrictions in physically strenuous activity. 80 = Active, but tries more quickly. 70 = Both greater restriction of, and less time spent in, active play. 60 = Up and around, but minimal active play; keeps busy with quieter activities. 50 = Gets dressed, but lies around much of the day; no active play; able to participate in quiet play and activities.. 40 = Mostly in bed; participates in quiet activities. 30 = In bed; needs assistance even for quiet play. 20 = Often sleeping; play entirely limited to very passive activities. 10 = No play; does not get out of bed. 0 = Unresponsive; Dead. Required display	Primary Final SAC
1.37	ITT	PS5A	Listing of Karnofsky Performance Status	ICH E3 100 = Normal; no complaints; no evidence of disease. 90 = Able to carry on normal activity; minor signs or symptoms of disease. 80 = Normal activity with effort; some signs or symptoms of disease. 70 = Cares for self; unable to carry on normal activity or to do active work. 60 = Requires occasional assistance, but able to care for most of his/her needs. 50 = Requires considerable assistance and frequent medical care.	Primary Final SAC

ICH Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
				40 = Disabled; requires special care and assistance. 30 = Severely disabled; hospitalization is indicated although death not imminent. 20 = Very sick; hospitalization necessary; active supportive treatment is necessary. 10 = Moribund; fatal processes progressing rapidly. 0 = Dead. Required display	
Laboratory					
1.38	ITT	LB5A	Listing of All Laboratory Data	ICH E3 Chemistry, hematology, coagulation, immunology, virology Required display	Primary Final SAC
Laboratory: Hepatobiliary (Liver)					
1.39	ITT	LIVER13	Listing of Subjects Meeting Hepatobiliary Laboratory Criteria Post-Baseline	Required display	Primary Final SAC
1.40	ITT	LIVER15	Liver Stopping Event Profile	GSK Hepatic Safety Panel Only required if liver stopping event form is filled for any number of subjects. Required display	Primary Final SAC
1.41	ITT	LIVER5	Listing of Liver Monitoring/Stopping Event Reporting	GSK Hepatic Safety Panel Required display	Primary Final SAC
Laboratory: Urinalysis					
1.42	ITT	UR2	Listing of Urinalysis Data	ICH E3 Required display	Primary Final SAC

14.12.15. Non-ICH Listings

Non-ICH Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Disposition					
1.50	ITT	PAN5	Country Level Listing of Start Dates of COVID-19 Pandemic Measures	Required display	Primary Final SAC
1.51	ITT	PAN7	Listing of Visits Impacted by COVID-19 Pandemic	Required display	Primary Final SAC
Disease Characteristics					
1.52	ITT	DC3	Listing of Disease Characteristics at Initial Diagnosis	Required display	Primary Final SAC
1.53	ITT	DC4	Listing of Disease Characteristics at Screening	Required display	Primary Final SAC
1.54	ITT	MD2	Listing of Metastatic Disease at Screening	Required display	Primary Final SAC
Anti-Cancer Therapy					
1.55	ITT	AC6	Listing of Systemic Anti-Cancer Therapy	Required display	Primary Final SAC
1.56	ITT	AC7	Listing of Anti-Cancer Radiotherapies	Required display	Primary Final SAC
1.57	ITT	PR2	Listing of Cancer-Related Surgical Procedures	Required display	Primary Final SAC
Medical Conditions					
1.58	ITT	MH2	Listing of Past and Current Medical Conditions	Required display	Primary Final SAC
Exposure					
1.59	ITT	ODMOD12A	Listing of Lymphodepletion Chemotherapy Dose Delays	Required display	Primary Final SAC

Non-ICH Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.60	ITT	ODMOD10A	Listing of Lymphodepletion Chemotherapy Dose Reductions	Required display	Primary Final SAC
Response					
1.63	mITT	LA5	Listing of Investigator-Assessed Lesion Assessments (RECIST 1.1 Criteria)	Required display	Primary Final SAC
1.65	mITT	RE5	Listing of Investigator-Assessed Responses at Each Visit with Confirmation (RECIST 1.1 Criteria)	Required display	Primary Final SAC
1.67	mITT	RE5	Listing of Investigator-Assessed Responses at Each Visit with Confirmation (iRECIST Criteria)	Not required- do not produce	
Time-to-Event					
1.71	mITT	TTE9	Listing of Investigator-Assessed Duration of Response (RECIST 1.1 Criteria)	Required display	Primary Final SAC
1.73	mITT	TTE9	Listing of Investigator-Assessed Duration of Response (iRECIST Criteria)	Not required- do not produce	
1.75	mITT	TTE9	Listing of Overall Survival	Required display	Primary Final SAC
1.77	mITT	TTE9	Listing of Investigator-Assessed Progression-Free Survival (RECIST 1.1 Criteria)	Required display	Primary Final SAC
1.78	mITT	TTE9	Listing of Investigator-Assessed Progression-Free Survival (iRECIST Criteria)	Not required- do not produce	
1.80	mITT	TTE9	Listing of Investigator-Assessed Time to Response (RECIST 1.1 Criteria)	Required display	Primary Final SAC
ECG					
1.81	ITT	LVEF2	Listing of Left Ventricular Ejection Fractions	Not required- do not produce	
Biomarker					
1.82	SAF	SAFE_L9	Listing of Replication Competent Lentivirus Data	Required display	Primary Final SAC
1.83	SAF	SAFE_L7	Listing of Anti-GSK3377794 Antibodies (ATA)	Required display	Final SAC

Non-ICH Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
1.84	SAF	SAFE_L8	Listing of Subjects with Integration Site Analysis Data	Produce a null report if there is no data. Required display	Primary Final SAC
Cardiovascular Events					
1.85	ITT	ARR1	Arrythmias Subject Profile	Conditional if at least one event happens Do not produce a null report if no data.	Primary Final SAC
1.86	ITT	CHF1	Congestive Heart Failure Subject Profile	Conditional if at least one event happens Do not produce a null report if no data.	Primary Final SAC
1.87	ITT	DVT1	Deep Vein Thrombosis / Pulmonary Embolism Subject Profile	Conditional if at least one event happens Do not produce a null report if no data.	Primary Final SAC
1.88	ITT	PUL1	Pulmonary Hypertension Subject Profile	Conditional if at least one event happens Do not produce a null report if no data.	Primary Final SAC
1.89	ITT	CVATIA1	Cerebrovascular Events Subject Profile	Conditional if at least one event happens Do not produce a null report if no data.	Primary Final SAC
1.90	ITT	MI1	Unstable Angina / Myocardial Infarction Subject Profile	Conditional if at least one event happens Do not produce a null report if no data.	Primary Final SAC
1.91	ITT	PATE1	Patient Profile for Peripheral Arterial Thromboembolism	Conditional if at least one event happens Do not produce a null report if no data.	Primary Final SAC
1.92	ITT	REV1	Coronary Revascularisation Subject Profile	Conditional if at least one event happens Do not produce a null report if no data.	Primary Final SAC
1.93	ITT	VAL1	Valvulopathy Subject Profile	Conditional if at least one event happens Do not produce a null report if no data.	Primary Final SAC
Other Safety					
1.94	ITT	PREG1	Listing of Subjects or Partners of Subjects Who Became Pregnant During the Study	Required display	Primary Final SAC
COVID-19					
1.95	ITT	PAN12	Listing of COVID-19 Assessments and Symptom Assessments for Subjects with COVID-19 Adverse Events	Required display	Primary Final SAC

Non-ICH Listings					
No.	**Population**	**IDSL / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Pharmacokinetics					
2.1	PK	PK07	Listing of GSK3377794 Pharmacokinetic Concentration–Time Data	Required display	Primary Final SAC
2.2	PK	PK13	Listing of Derived GSK3377794 Pharmacokinetic Parameters	Required display	Primary Final SAC

14.13. Appendix 13: Custom Mock-up for Data Displays

14.13.1. Study Population

14.13.1.1. Tables

N/A

14.13.1.2. Figures

N/A

14.13.2. Efficacy

14.13.2.1. Tables

EFF_T1: Summary of Investigator-Assessed Time to Response (RECIST 1.1 Criteria)

Protocol: ABC123456
Population: study specific

(Data as of: DDMMMYYYY)

	GSK794 (N=xxx)
Number of responders	xx (yy%)
Time to Response (months)	
Min	x
1st Quartile	x.x
Median	x.x
3rd Quartile	x.xx
Max.	x

/Directory/program.sas DDMMMYYYY HH:MM

14.13.2.2. Figures

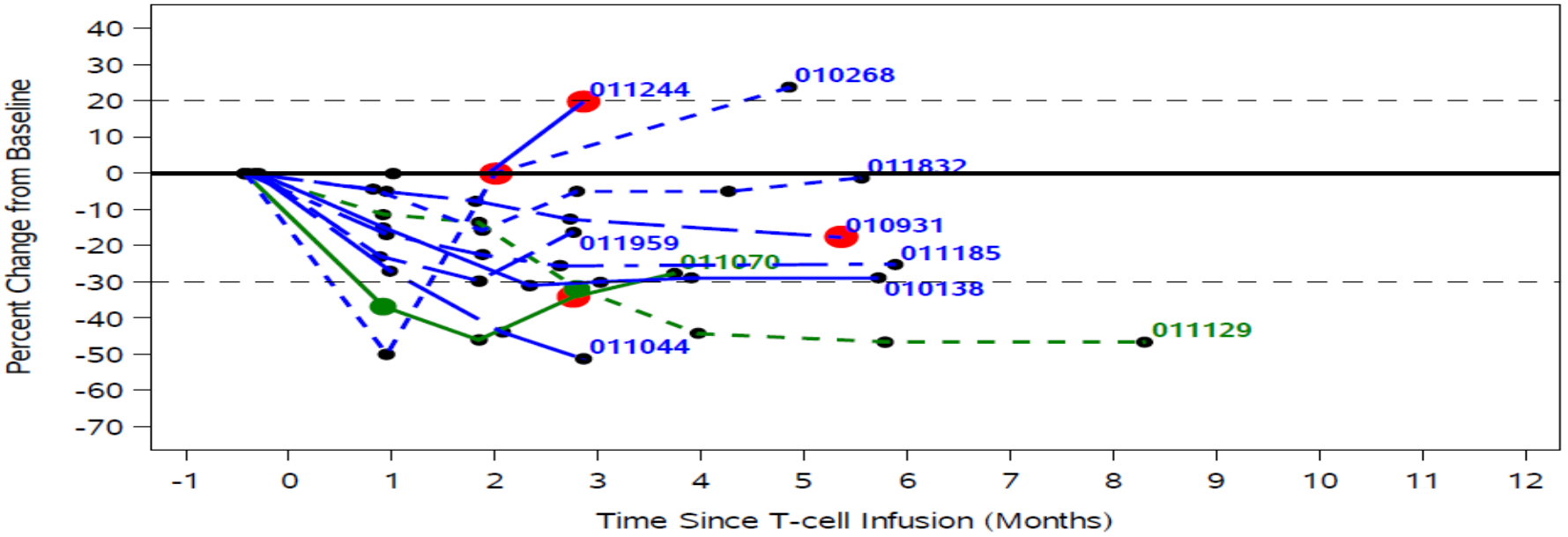
EFF_F1: Spider Plot of Investigator-Assessed Percent Change from Baseline in Target Lesion Diameter (RECIST 1.1 Criteria)

G B

Protocol: 208467 Page 1 of x

Population: Study specific (Data as of: DDMMMYYYY)

Figure X.XXX



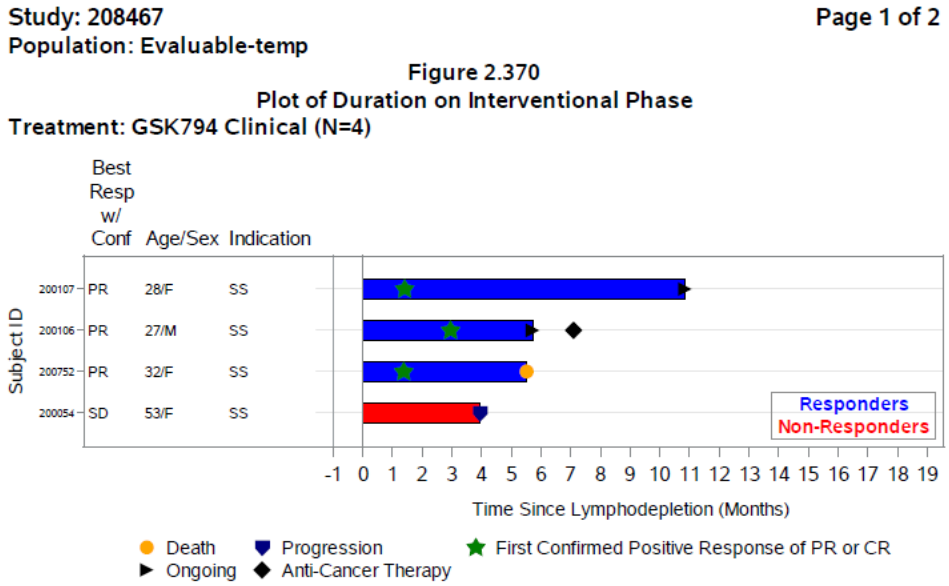
/Directory/program.sas DDMMMYYYY HH:MM

EFF_F3: Plot of Duration on Interventional Phase

Protocol: 208467 Page 1 of x
Population: Study Specific (Data as of: DDMMMYYYY)

Figure X

Treatment: GSK794 (N=xx)



/Directory/program.sas DDMMMYYYY HH:MM

14.13.3. Safety

14.13.3.1. Tables

SAFE_T4: Summary of Replication Competent Lentivirus Positive

Protocol: ABC123456			Page 1 of 1
Population: Intent-to-Treat/ Study specified			(Data as of: 24APR2018)
Table x.xx			
Summary of Replication Competent Lentivirus Positive			
	GSK794		
	(N=10)		
<Replication Competent Lentivirus Positive> <>1% Gene Marked PBMCs 1 Year Post-treatment>			
n	xx		
Count	xx (yy%)		
<footnotes as defined in the programming document> /Directory/program.sas 01JAN2002 12:01			

14.13.3.2. Figures

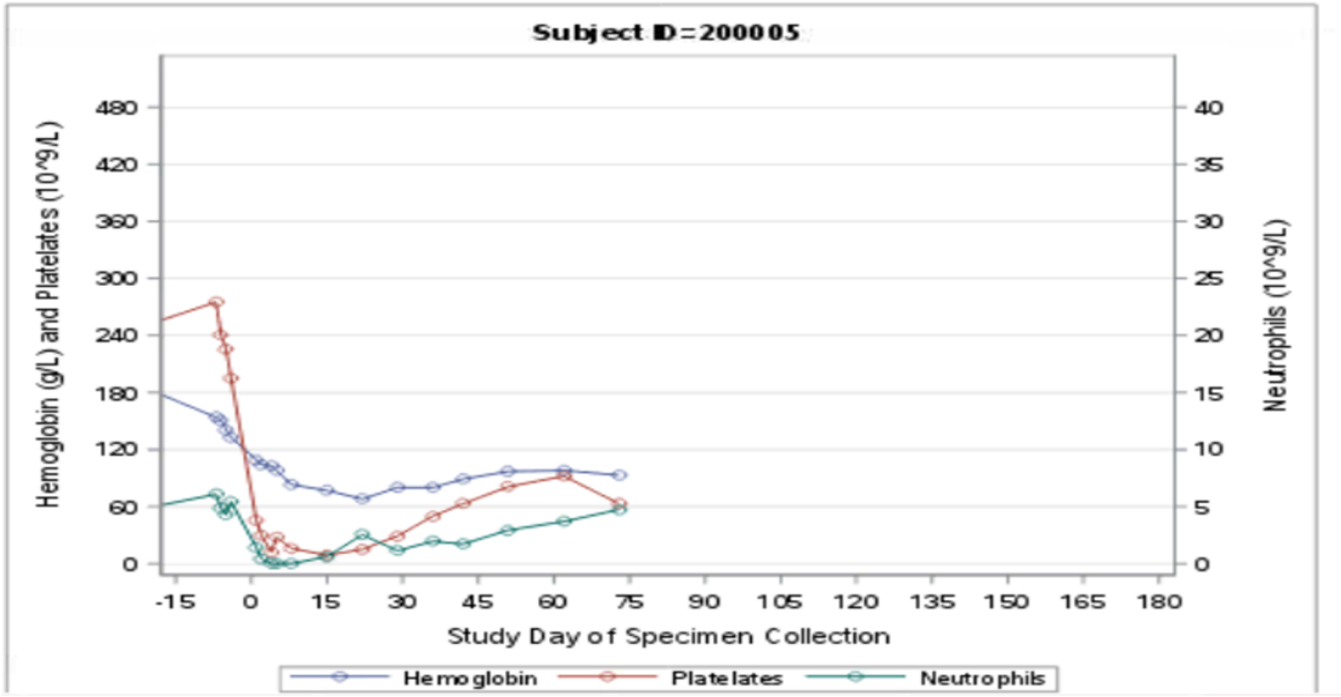
SAFE_F6: Plot of Hemoglobin, Neutrophils and Platelets Over Time

Protocol: ABC123456
Population: Intent-to-Treat/Safety/Other study specific

(Data as of: 30MAY2011)

Figure X

Plot of Hemoglobin, Neutrophils and Platelets Over Time for Subjects with Grade 5 Cytopenia Adverse Events (Focused List)



14.13.4. Pharmacokinetics (PK)

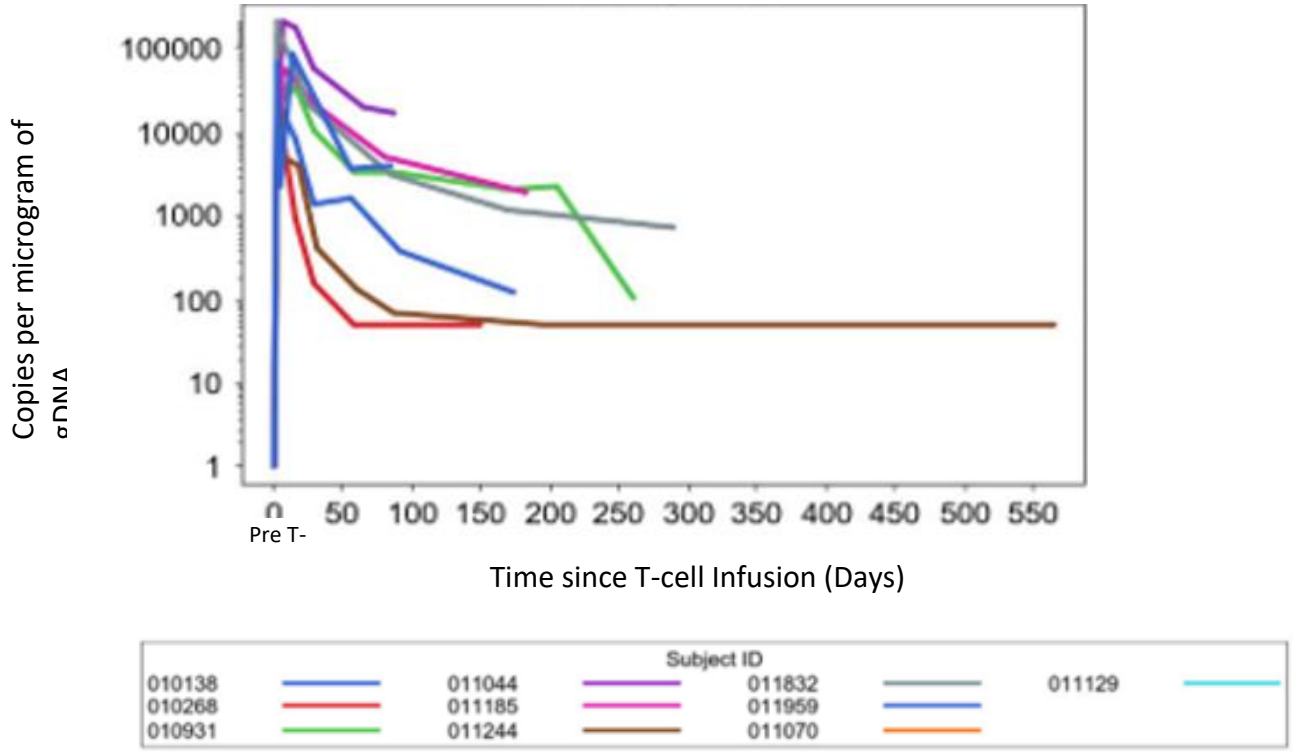
14.13.4.1. Tables

Not applicable

14.13.4.2. Figures

PK_F1: GSK3377794 Pharmacokinetic Concentration-Time Plot

Protocol: ABC123456			Page 1 of 1
Population: As defined in the RAP			(Data as of: 30MAY2011)
Figure x.xx			
GSK3377794 Pharmacokinetic Concentration-Time Plot			
Treatment: GSK794			



<footnotes as defined in the programming document>
/Directory/program.sas 01JAN2002 12:01

The image is used as the mock example for this figure. All content must be updated based on 208467 needs (e.g. change treatments used in the x-axis label to GSK794

<footnotes as defined in the programming document>
/Directory/program.sas 01JAN2002 12:01

The image is used as the mock example for this figure. All content must be updated based on 208467 needs (e.g. change treatments used in the x-axis label to GSK794.

14.13.5. ICH Listings

POP_L1: Listing of Lete-cel Dosing Status

Protocol: 208467							Page 1 of x	
Population:							(Data as of: DDMMMYYYY)	
Listing X.XX								
Listing of Lete-cel Dosing Status								
Site Id./ Unique Subj. ID/ Subject/ Analysis Pop.	Start Date/ Start Time/ Study Day/	End Date/ End Time/ Study Day/	Total Cell Dose (10^9 cells)	Total Number of Transduced Cells (10^9 cells)	Percentage of Cells Transduced (%)	Whole Bag Infused	Estimated % of Cells Infused/ Reason for Reduced Infusion	Product Status
001474/ 208467.100001/ 100001/ SCR, ENRL, ITT, mITT, SAF, PEAP	23OCT2008/ 14:30/ 1	23OCT2008/ 15:30/ 1	3.42	1.21	35.4	Yes		Conforming
001474/ 208467.100001/ 100001/ SCR, ENRL, ITT, mITT, SAF	23OCT2008/ 14:30/ 1	23OCT2008/ 15:30/ 1	8.91	2.52	28.3	No	80%/ <text>	non-conforming
<footnotes as defined in the programming document>								
/Directory/program.sas 01JAN2002 12:01								

SAFE_L11: Listing of All Adverse Events; Listing of Non-Fatal Serious Adverse Events; Listing of Delayed Adverse Events by Delayed Category (GSK Adjudicated)

Protocol:
ABC123456

Population: study specific

(Data as of: DDMMMYYYY)

Listing X

<Title>

<By Delayed AE Category (only for GSK adjudicated listing)>

Site Id.: 111111

Treatment: TRT A / TRT B

Unique Subject Id./ Subject Id./ Analysis Pop.	Age (YEARS)/ Sex/ Race Detail/ Weight (kg)	Preferred Term/ Verbatim Text	Onset Date/ Date of Resolution/ Duration (Days)	Time Since T-Cell Infusion	Maximum Grade/ Overall Phase(s)/ Serious/	Segment Grade/ Segment Phase	Action(s) Taken/ Outcome/ Relation to Study Treatment	Investigator Assessed Delayed AE [1]
GSK123456.000001/ 000001/ SCR, ITT, mITT	65/ F/ WHITE - WHITE/CAUSASIAN/EUROPEAN HERITAGE/ 62	Nasal congestion and blockage/ NASAL CONGESTION	YYYY-MM-DD/ YYYY-MM-DD/ xx	19d	1/ T-cell/ Y		DOSE REDUCED/ RECOVERED/RESOLVED/ N	Yes: <Delayed AE Category>
GSK123456.000044/ 000002/ SCR, ITT, mITT, EVAL	75/ M/ MIXED ASIAN RACE/ 57	Candidiasis mouth and throat/ ORAL CANDIDIASIS	1999-05-04/ /	36d	4/ PRE-LYMPH, Lymph, T-cell/ Y		DRUG WITHDRAWN, DOSE REDUCED/ NOT RECOVERED/NOT RESOLVED/ N/ Y: TRT A, TRT B, TRT C	No
			YYYY-MM-DD/ YYYY-MM-DD/ xx			2/ Leuk		
			YYYY-MM-DD/ YYYY-MM-DD/ xx			3/ Lymph		
			YYYY-MM-DD/ YYYY-MM-DD/ xx			3/ T-cell		

	YYYY-MM-DD/	4/
	YYYY-MM-DD/	T-cell
	xx	Infusion

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SAFE_L12: Cytokine Release Syndrome (CRS) Subject Profile

Protocol: ABC123456 Page 1 of x
Population: <study specified> (Data as of: DDMMMYYYY)

Listing X
Cytokine Release Syndrome (CRS) Subject Profile

Treatment: GSK Treatment
Site Id.: 456789
Unique Subject Id: XYZ000.000044

Subject Id: 000044	Age (YEARS): 50
Analysis Population: SCR, ITT, SAF, mITT	Sex: M
Start Date/[Time] of Treatment: YYYY-MM-DD	Race Details: WHITE - WHITE/CAUSASIAN/EUROPEAN
End Date/[Time] of Treatment: YYYY-MM-DD	Weight (kg) : xx

Adverse Event Information

Reference ID	xxx
Preferred term	<text>
Verbatim term	<text>
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (DAYS)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)/ Serious	4/ Leuk, Lymph, T-cell/ Y
Seriousness Criteria	Y: Results in Death, Is Life Threatening
Outcome	NOT RECOVERED/RESOLVED
Action taken: <lymphodepletion drug>	DOSE INTERRUPTED/DELAYED

Action taken: <lymphodepletion drug>	NOT APPLICABLE
Action taken: <study treatment>	INFUSION INTERRUPTED BUT COMPLETED
Related to study treatment(s)	Yes: Cyclophosphamide; GSK3377794
Signs and symptoms experienced by the subject	Rash; Decreased Cardiac Output; Dyspnea
Tests performed	C-reactive Protein; Aspartate Amino Transferase
Indication of Procedure/ Start Date/ Stop Date	Supplemental Oxygen/ YYYY-MM-DD/ YYYY-MM-DD

All Adverse Events Suspected to be Linked to CRS

Preferred term	<text>
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (DAYS)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)/ Serious	1/ T-cell/ N
Outcome	NOT RECOVERED/RESOLVED
Related to study treatment(s)	Yes: Cyclophosphamide; GSK3377794

Concomitant Medication Information

Ingredient	<text>
Verbatim text	<text>
Start date[/time]/ Study day	YYYY-MM-DD/ xxx
End date[/time]/ Study day	YYYY-MM-DD/ xxx
Dose/ Dose unit/ Frequency/ Route	240/ mg/ Q12H/ ORAL
Indication of Medication	Vasopressin; Intravenous fluids; Other Medication

<Footnote 1>
<Footnote …>
<Footnote 9>
/Directory/program.sas DDMMMYYYY HH:MM

SAFE_L13: Guillain-Barre Syndrome (GBS) Subject Profile

Protocol: ABC123456 Page 1 of x
Population: <study specified> (Data as of: DDMMMYYYY)

Listing X
Guillain Barre Syndrome (GBS) Subject Profile

Treatment: GSK Treatment
Site Id.: 456789
Unique Subject Id: XYZ000.000044

Subject Id: 000044	Age (YEARS): 50
Analysis Population: SCR, ITT, SAF, mITT	Sex: M
Start Date/[Time] of Treatment: YYY-MM-DD	Race Details: WHITE - WHITE/CAUSASIAN/EUROPEAN
End Date/[Time] of Treatment: YYY-MM-DD	Weight (kg) : xx

Adverse Event Information	
Reference ID	xxx
Preferred term	<text>
Verbatim term	<text>
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (Days)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)/ Serious	4/ Leuk, Lymph, T-cell/ Y
Outcome	NOT RECOVERED/RESOLVED
Action taken: Cyclophosphamide	DOSE INTERRUPTED/DELAYED
Action taken: Fludarabine	NOT APPLICABLE
Action taken: GSK3377794	INFUSION INTERRUPTED BUT COMPLETED
Related to study treatment(s)	Yes: Cyclophosphamide; GSK3377794
Any vaccination received within 4 weeks prior to onset of symptoms	Yes: <treatment name> No
Was Brighton Criteria Assessed at hospital admission?	Yes: <treatment name> No
Brighton Criteria Score at GBS hospital admission	Grade 1 or 2 or 3 or 4

Brighton Criteria Score 7 days after GBS hospital admission	Grade 1 or 2 or 3 or 4
Symptoms Experienced	Preceding symptoms of respiratory or gastrointestinal tract, Pain, Cranial Nerve….
Did the patient experience Hypokalaemia, Phosphataemia, Magnesaemia, Hypoglycaemia?	Yes: Magnesaemia, Hypoglycaemia
Was Patient Diabetic?	Yes No
Did Patient develop CNS metastasis?	Yes No
Early initiation of intravenous or plasma exchange	Yes No
Did Patient receive Supplemental Oxygen or Mechanical Ventilation assistance?	Supplemental Oxygen (Start Date/End Date) Mechanical Ventilation assistance (Start Date/End Date)
Was Patient admitted to ICU?	Yes No
MRC score at hospital admission	31-40
MRC score at 7 days from hospital admission	51-60
EGRS score at hospital admission	High Risk (EGRIS 5-7)
EGRS score at 7 days from hospital admission	Low Risk (EGRIS 0-2)
mEGOS score at hospital admission	Value from drop down menu
mEGOS score at 7 days from hospital admission	Value from drop down menu
Test performed	CSF , Electrophysiological & Pathological studies, Other (Specify)
All Adverse Events Suspected to be Linked to GBS	
Preferred term	<text>
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (DAYS)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)/ Serious	1/ T-cell/ N
Outcome	NOT RECOVERED/RESOLVED
Related to study treatment(s)	Yes: Cyclophosphamide; GSK3377794
Concomitant Medication Information	
Ingredient	<text>

Verbatim text	<text>
Start date[/time]/ Study day	YYYY-MM-DD/ xxx
End date[/time]/ Study day	YYYY-MM-DD/ xxx
Dose/ Dose unit/ Frequency/ Route	240/ mg/ Q12H/ ORAL

<Footnote 1>
<Footnote …>
<Footnote 9>
/Directory/program.sas DDMMMYYYY HH:MM

SAFE_L14: Graft-versus-Host Disease (GVHD) Subject Profile

Protocol: ABC123456 Page 1 of x
Population: <study specified> (Data as of: DDMMMYYYY)

Listing X
Graft-Versus-Host Disease (GVHD) Subject Profile

Treatment: GSK Treatment
Site Id.: 456789
Unique Subject Id: XYZ000.000044

Subject Id: 000044	Age (YEARS): 50
Analysis Population: SCR, ITT, SAF, mITT	Sex: M
Start Date/[Time] of Treatment: YYYY-MM-DD	Race Details: WHITE - WHITE/CAUSASIAN/EUROPEAN
End Date/[Time] of Treatment: YYYY-MM-DD	Weight (kg) : xx

Adverse Event Information

Reference ID	xxx
Preferred term	Confusional state
Verbatim term	MILD INTERMITTENT CONFUSION (THOUGHT TO BE RELATED TO CHRONIC ATIVAN/MORPHINE USE)
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (DAYS)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)	4/ Leuk, Lymph, T-cell
Serious[: Criteria for determining seriousness]	Y: Results in Death, Is life threatening, …
Outcome	NOT RECOVERED/RESOLVED
Action taken: Cyclophosphamide	DOSE INTERRUPTED/DELAYED
Action taken: Fludarabine	NOT APPLICABLE
Action taken: GSK3377794	INFUSION INTERRUPTED BUT COMPLETED
Related to study treatment(s)	Yes: Cyclophosphamide; GSK3377794
Symptoms Experienced	Fever, Rash, Nausea, …
Tests Performed	Alanine Amino Transferase, Bilirubin, …
Biopsy Site	<site>
Medication Administered	Corticosteroids - Prophylactic, Sirolimus, …

```
All Adverse Events Suspected to be Linked to GVHD
     Preferred term                                          <text>
     Onset Date/ Date of resolution                          YYYY-MM-DD/ YYYY-MM-DD
     Duration (DAYS)                                         xxx
     Time Since T-Cell Infusion (DAYS)                       xxx
     Maximum Grade/ Overall Phase(s)                         1/ T-cell
     Serious[: Criteria for determining seriousness]         Y: Results in Death, Is life threatening, …
     Outcome                                                 NOT RECOVERED/RESOLVED
     Related to study treatment(s)                           Yes: Cyclophosphamide; GSK3377794

Concomitant Medication Information
     Ingredient                                              <text>
     Verbatim text                                           <text>
     Start date[/time]/ Study day                            YYYY-MM-DD/ xxx
     End date[/time]/ Study day                              YYYY-MM-DD/ xxx
     Dose/ Dose unit/ Frequency/ Route                       240/ mg/ Q12H/ ORAL

<Footnote 1>
<Footnote …>
<Footnote 9>
/Directory/program.sas  DDMMMYYYY HH:MM
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SAFE_L15: Immune Effector-Cell Associated Neurotoxicity Syndrome (ICANS) Subject Profile

```
Protocol: ABC123456                                                                    Page 1 of x
Population: <study specified>                                              (Data as of: DDMMMYYYY)
                                          Listing X
               Immune Effector-Cell Associated Neurotoxicity Syndrome (ICANS) Subject Profile

Treatment: GSK Treatment
Site Id.: 456789
Unique Subject Id: XYZ000.000044
```

Subject Id: 000044	Age (YEARS): 50
Analysis Population: SCR, ITT, SAF, mITT	Sex: M
Start Date/[Time] of Treatment: YYYY-MM-DD	Race Details: WHITE - WHITE/CAUSASIAN/EUROPEAN
End Date/[Time] of Treatment: YYYY-MM-DD	Weight (kg) : xx

Adverse Event Information	
Reference ID	xxx
Preferred term	Confusional state
Verbatim term	MILD INTERMITTENT CONFUSION (THOUGHT TO BE RELATED TO CHRONIC ATIVAN/MORPHINE USE)
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (DAYS)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)/ Serious	4/ Leuk, Lymph, T-cell/ Y
Outcome	NOT RECOVERED/RESOLVED
Action taken: Cyclophosphamide	DOSE INTERRUPTED/DELAYED
Action taken: Fludarabine	NOT APPLICABLE
Action taken: GSK3377794	INFUSION INTERRUPTED BUT COMPLETED
Related to study treatment(s)	Yes: Cyclophosphamide; GSK3377794
Participant received anti-seizure prophylaxis	Yes: <treatment name> No
ICANS panel completed for the participant	Yes: <value from predefined drop down options> No: <reason>
All Adverse Events Suspected to be Linked to ICANS	
Preferred term	<text>
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (DAYS)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)/ Serious	1/ T-cell/ N
Outcome	NOT RECOVERED/RESOLVED
Related to study treatment(s)	Yes: Cyclophosphamide; GSK3377794
Concomitant Medication Information	

Ingredient	<text>
Verbatim text	<text>
Start date[/time]/ Study day	YYYY-MM-DD/ xxx
End date[/time]/ Study day	YYYY-MM-DD/ xxx
Dose/ Dose unit/ Frequency/ Route	240/ mg/ Q12H/ ORAL

<Footnote 1>
<Footnote …>
<Footnote 9>
/Directory/program.sas DDMMMYYYY HH:MM

SAFE_L16: Pancytopenia/Aplastic Anemia Subject Profile

Protocol: ABC123456 Page 1 of x
Population: <study specified> (Data as of: DDMMMYYYY)

Listing X
Pancytopenia / Aplastic Anemia Subject Profile

Treatment: GSK Treatment
Site Id.: 456789
Unique Subject Id: XYZ000.000044

Subject Id: 000044	Age (YEARS): 50
Analysis Population: SCR, ITT, SAF, mITT	Sex: M
Start Date/[Time] of Treatment: YYYY-MM-DD	Race Details: WHITE - WHITE/CAUSASIAN/EUROPEAN
End Date/[Time] of Treatment: YYYY-MM-DD	Weight (kg) : xx

Adverse Event Information

Reference ID	xxx
Preferred term	Confusional state
Verbatim term	MILD INTERMITTENT CONFUSION (THOUGHT TO BE RELATED TO CHRONIC ATIVAN/MORPHINE USE)
Onset Date/ Date of resolution	YYYY-MM-DD/ YYYY-MM-DD
Duration (DAYS)	xxx
Time Since T-Cell Infusion (DAYS)	xxx
Maximum Grade/ Overall Phase(s)/ Serious	4/ Leuk, Lymph, T-cell/ Y
Outcome	NOT RECOVERED/RESOLVED
Action taken: Cyclophosphamide	DOSE INTERRUPTED/DELAYED
Action taken: Fludarabine	NOT APPLICABLE
Action taken: GSK3377794	INFUSION INTERRUPTED BUT COMPLETED
Related to study treatment(s)	Yes: Cyclophosphamide; GSK3377794
Was treatment with G-CSF initiated?	Yes or No
Was immunosuppresive agent given?	Yes or No
Other Immunosuppression methods provided	aggressive regimens

All Adverse Events Suspected to be Linked to P-AA

```
     Preferred term                                  <text>
     Onset Date/ Date of resolution                  YYYY-MM-DD/ YYYY-MM-DD
     Duration (DAYS)                                 xxx
     Time Since T-Cell Infusion (DAYS)               xxx
     Maximum Grade/ Overall Phase(s)/ Serious        1/ T-cell/ N
     Outcome                                         NOT RECOVERED/RESOLVED
     Related to study treatment(s)                   Yes: Cyclophosphamide; GSK3377794

Concomitant Medication Information
     Ingredient                                      <text>
     Verbatim text                                   <text>
     Start date[time]/ Study day                     YYYY-MM-DD/ xxx
     End date[time]/ Study day                       YYYY-MM-DD/ xxx
     Dose/ Dose unit/ Frequency/ Route               240/ mg/ Q12H/ ORAL

<Footnote 1>
<Footnote …>
<Footnote 9>
/Directory/program.sas  DDMMMYYYY HH:MM
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14.13.6. Non-ICH Listings

SAFE_L7: Listing of Anti-GSK3377794 Antibodies (ATA)

Protocol: ABC123456						Page 1 of 1
Population: Study specific						(Data as of: DDMMMYYYY)
Listing X						
Listing of Anti-<Antigen> Antibodies						
Treatment: GSK794 Clinical / GSK794 Commercial						
Site Id./ Unique Subject Id./ Subject Id./ Analysis Pop.	Age (Years)/ Sex/ Race Detail	Visit	Date/ Study Day	Screening Assay	Confirming Assay	Titer

11101/ 208467.059867/ 059867/ SCR, ENRL, ITT	65/ Male/ WHITE	DAY x	YYYY-MM-DD/ 15	NEGATIVE	NOT APPLICABLE	NOT APPLICABLE
		WEEK x	YYYY-MM-DD/ 44	NEGATIVE	NOT APPLICABLE	NOT APPLICABLE
		MONTH x	YYYY-MM-DD/ 180	NEGATIVE	NOT APPLICABLE	NOT APPLICABLE
21101/ 208467.021867/ 021867/ SCR, ENRL, ITT	65/ Female/ WHITE	DAY x	YYYY-MM-DD/ 15	NEGATIVE	NOT APPLICABLE	NOT APPLICABLE
		WEEK x	YYYY-MM-DD/ 44	NEGATIVE	NOT APPLICABLE	NOT APPLICABLE
		MONTH x	YYYY-MM-DD/ 180	NEGATIVE	NOT APPLICABLE	NOT APPLICABLE
/Directory/program.sas 01JAN2002 12:01						

SAFE_L8: Listing of Subjects with Integration Site Analysis Data

Protocol: ABC123456						Page 1 of 1
Population: Study specific						
Treatment: GSK794 Clinical / GSK794 Commercial						
Site Id./ Unique Subject Id./ Subject Id./ Analysis Pop.	Age (YEARS)/ Sex/ Race Detail	[Visit] or [Planned Time]	Date/ Study Day	Shannon Index	Gini Index	Number of Clones (>20% abundance)
11101/ 208467.059867/ 059867/ SCR, ENRL, ITT	65/ Male/ WHITE	XXXX	YYYY-MM-DD/ 15	xx (xx.x-xx.x)	x.x	x
21101/ 208467.021867/ 021867/ SCR, ENRL, ITT	65/ Female/ WHITE	XXXX	YYYY-MM-DD/ 15	xx (xx.x-xx.x)	x.x	x

SAFE_L9: Listing of Replication Competent Lentivirus Data

Protocol: ABC123456				Page 1 of 1
Population: Study specific				(Data as of: DDMMMYYYY)
Listing X				
Listing of Replication Competent Lentivirus Data				
Treatment: GSK794 Clinical / GSK794 Commercial				
Site Id./ Unique Subject Id./ Subject Id./ Analysis Pop.	Age (YEARS)/ Sex/ Race Detail	Visit	Date/ Study Day	RCL Interpretive Result
11101/ 123456.059867/ 059867/ SCR, ENRL, ITT	65/ Male/ WHITE	Baseline_Pre_Lympho	YYYY-MM-DD/ 15	NEGATIVE
		DAY x	YYYY-MM-DD/ 15	NEGATIVE
		WEEK x	YYYY-MM-DD/ 44	NEGATIVE
		MONTH x	YYYY-MM-DD/ 180	NEGATIVE
		COMPLETION / WITHDRAWN	YYYY-MM-DD/ 180	NEGATIVE
/Directory/program.sas 01JAN2002 12:01				

Signature Page for 208467 TMF-11907991 v2.0

Reason for signing: Approved	Name: PPD Role: A r Date of signature: 07-Dec-2022 14:17:02 GMT+0000

Reason for signing: Approved	Name: PPD Role: A Date of signature: 07-Dec-2022 17:44:05 GMT+0000

Signature Page for TMF-11907991 v2.0