A Randomized, Multi-center, Open-label, Controlled, In Vivo Study to Assess the Recovery and Survival of Radiolabeled Autologous INTERCEPT Apheresis Platelet Components Suspended in 100% Plasma Stored for up to 7 Days

Statistical Analysis Plan with Appendices
May 3, 2021

NCT04022889

STATISTICAL ANALYSIS PLAN

TITLE:	A Randomized, Multi-center, Multi-Stage, Controlled, *In Vivo* Study to Assess the Recovery and Survival of Radiolabeled Autologous INTERCEPT Apheresis Platelet Components Suspended in 100% Plasma Stored for up to 7 Days
CLINICAL PROTOCOL NO.:	CLI 00127, Version 5.0 September 16, 2020
IDE NO.:	BB-IDE 6200
PHASE:	Phase 2
INVESTIGATIONAL PRODUCT:	Device: INTERCEPT Blood System for Platelets Biologic: Apheresis platelet components collected in 100% plasma on the Trima Accel® Automated Blood Collection system
SPONSOR:	Cerus Corporation 1220 Concord Blvd. Concord, CA 94520
SAP PREPARED BY:	Ho-Lan Peng, PhD Biostatistician Yu-Ping Li, PhD Consulting Biostatistician Jamie Genthe, PhD Sr. Manager, Hematology and Early Clinical Development
DATE OF SAP:	May 3, 2021
SAP VERSION:	Version 1.0

STATISTICAL ANALYSIS PLAN APPROVAL SIGNATURES

Approval: Laurence Corash — 5/12/21

Name Laurence Corash, MD
Title Chief Scientific Officer, Cerus Corporation

Richard Benjamin — May 4th, 2021

Name Richard Benjamin, MD PhD
Title Chief Medical Officer, Cerus Corporation

5/3/21

Name Stanley Benlow, PhD
Title Vice President, Biostatistics and Data Management, Cerus Corporation

May 6th, 2021

Name Anna Erickson, PhD
Title Vice President, Hematology and Early Clinical Development, Cerus Corporation

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1. ABBREVIATIONS

Abbreviations list pertains to the SAP only.

AE	Adverse event
ATP	Adenosine 5'-Triphosphate
BEST	Biomedical Excellence for Safer Transfusion
BMI	Body mass index
CAS	Completer Analysis Set
CI	Confidence interval
CD62P	P-selectin expression on the surface of platelets
^{51}Cr	An isotope of chromium with a radioactive half-life of 27.7 days
CSR	Clinical study report
DPI	Days post infusion of autologous radiolabeled platelets
DS	Dual Storage (two storage containers)
EAS	Evaluable Analysis Set
eCRF	Electronic case report form
ESC	Extent of Shape Change
HSR	Hypotonic Shock Response
^{111}In	An isotope of indium with a radioactive half-life of 2.80 days
MedDRA	Medical dictionary for regulatory activities
MPV	Mean Platelet Volume
PC	Platelet Component
RBC	Red Blood Cell
SAE	Serious Adverse Event
SAP	Statistical analysis plan
SD	Standard deviation
SOC	System organ class
SOP	Standard operating procedure
WB	Whole blood
WBC	White Blood Cell

2. INTRODUCTION

This Statistical Analysis Plan (SAP) details the statistical methods that will be implemented to analyze data collected from clinical study "CLI 00127" [A Randomized, Multi-center, Open-label, Controlled, *In Vivo* Study to Assess the Recovery and Survival of Radiolabeled Autologous INTERCEPT Apheresis Platelet Components Suspended in 100% Plasma Stored for up to 7 Days]. First described is an introduction outlining the study objectives, design, and population. Next detailed is the data handling and statistical methods is detailed. Finally, the mock listings/tables follow in the appendices.

Any deviations from the planned data analysis will be detailed in the clinical study report (CSR).

3. STUDY BACKGROUND

3.1 Study Objectives

The principal objective of this study is to evaluate the hypothesis that INTERCEPT Platelets in 100% plasma stored for up to 7 days after apheresis collection retain sufficient viability for therapeutic transfusion efficacy. The post-infusion recovery and survival of autologous radiolabeled 7 day INTERCEPT platelets (Test) stored in 100% plasma will be measured in comparison to "fresh" autologous radiolabeled platelets (Control) according to FDA guidance for platelet testing (FDA 1999) in Stage 2 of this study protocol.

A secondary objective is to compare the recovery and survival results for Test platelets prepared for radiolabeling using the procedures outlined by the Biomedical Excellence for Safer Transfusion Collaboration (BEST, 2006) or a variation of the BEST procedure (referred to as Variant 1, Appendix C of the protocol) in Stage 1 of this study protocol. Cerus has demonstrated that the Variant 1 method, which does not incorporate an initial soft spin in the presence of ACD-A, results in improved *in vitro* platelet recovery and quality during preparation for radiolabeling compared to the BEST procedure. This comparison will evaluate the hypothesis that preparation methods prior to radiolabeling may influence *in vitro* quality of the radiolabeled platelets and post-infusion viability outcomes.

3.2 Study Design

This is a randomized, multi-center, open-label, controlled, *in vivo* study with two stages (Table 1). Stage 1 is a randomized, 2-period crossover design. Test platelets stored for 7 days will be radiolabeled based on either the BEST or Variant 1 methods (depending on the period and randomization scheme for the Test platelets) for 12 healthy subjects enrolled by two study centers. The recovery and survival for Test platelets prepared with the BEST and Variant 1 methods will be compared with each other and against the fresh Control platelets. With agreement from the FDA (BQ200481, July 8, 2020), completion of Stage 1 is not required.

Stage 2 is a single-arm, single-period design. Test platelets from 24 healthy subjects, stored for 7 days will be prepared for radiolabeling following the Variant 1 methodology. The recovery and survival for Test platelets will be compared against the fresh Control platelets for non-inferiority testing. Stage 1 subjects with evaluable Variant 1 method data will contribute to the requirement of the 24 subjects for Stage 2. With agreement from the FDA (BQ200481/1, April 8, 2021), 15 evaluable subjects from the BWNW site and at least 5 subjects from the HBC site are to be included for the Stage 2 analysis. At the end of study, there are a total of 23 evaluable subjects at Stage 2, including 15 from the BWNW and 8 from HBC.

For both stages, the study population will consist of healthy subjects who meet the FDA, AABB, and site-

specific research donor eligibility criteria for apheresis platelet donation. Apheresis platelets will be collected in 100% plasma on the Trima Accel® Automated Blood Collection system.

Each study apheresis collection will be processed using the INTERCEPT Blood System for Platelets. Platelet components containing 3.0 to 7.9 $x10^{11}$ platelets in 300 to 420 mL of plasma will be processed using the INTERCEPT Dual Storage (DS) set. The INTERCEPT process will begin on either the day of collection (Day 0) or the day following donation (Day 1); illumination must occur within 24 hours after the end of collection. Test platelets components will be stored for 7 days, from day of collection, in 100% plasma.

During each stage samples for *in vitro* platelet testing will be collected prior to INTERCEPT treatment (Day 0/1), post-INTERCEPT treatment and at the end of storage (Day 7) (see *In vitro platelet assessment* below).

At the end of storage, an aliquot of Test platelets will be aseptically removed from each subject's INTERCEPT platelet storage container for preparation of samples for radiolabeling using either the BEST or Variant 1 methodology. The *in vitro* quality of the Test platelet sample used for radiolabeling will be assessed prior to and following the pre-radiolabeling platelet sample preparations (Table 2 and Table 3). The pre-radiolabeling indices to be measured in Stage 1 are volume, $pH_{22°C}$, P-selection (CD62P), platelet count, red blood cell (RBC) count, and white blood cell (WBC) count. Assessments of these indices will enable the determination of platelet physical recovery for each sample preparation method and evaluation of RBC and WBC contamination in samples prior to radiolabeling. In Stage 2 platelet physical recovery during sample preparation will be calculated from volume and platelet count. In Stage 2 $pH_{22°C}$ will also be measured in the sample prior to radiolabeling.

Table 1 Description of Study Stages

		Period 1			Period 2		
		Test		Control	Test		Control
Stage	**Arm**	**Storage Duration (post collection)**	**Sample Prep**	**Sample Prep**	**Storage Duration (post collection)**	**Sample Prep**	**Sample Prep**
Stage 1[a]	Arm 1	7 days	Variant 1 (n=6)	BEST (n=6)	7 days	BEST (n=5)	BEST (n=5)
	Arm 2	7 days	BEST (n=7)	BEST (n=7)	7 days	Variant 1 (n=6)	BEST (n=6)
Stage 2	Single Arm (n=24)[b]	7days	Variant 1	BEST	Not Applicable, Single Arm		

[a] Based on correspondence with FDA (BQ200481, July 8, 2020), Stage 1 was not completed. The n represents the number of subjects which have completed the period.

[b] Stage 1 subjects with evaluable Variant 1 method data will contribute to the requirement of the 24 subjects for Stage 2.

Subjects will be randomized with equal probability to the radiolabeling sequences (Indium/Chromium $^{111}In/^{51}Cr$) vs. Chromium/Indium ($^{51}Cr/^{111}In$) for Test/Control. For subjects enrolled in Stage 1, there will be a minimum washout period of four weeks between the two study periods (e.g., four weeks after the last blood sample at 11±1 days post infusion (DPI), in Period 1). Subjects will be monitored for safety (adverse events) from the first apheresis procedure until 24 hours after the last day post infusion (DPI) blood sample is drawn.

4. SAMPLE SIZE

Up to a total of 36 subjects with evaluable (Test and Control) recovery and survival data may be obtained. In each study stage, subjects who do not have both paired (Test and Control) recovery and paired survival data may be replaced, and a sufficient number of subjects will be enrolled to provide 12 (Stage 1) and 24 (Stage 2) subjects with evaluable *in vivo* recovery and survival data. The sample sizes are not based on any power calculations. The sample size of 24 subjects for Stage 2 is chosen to provide reasonable estimates of the primary efficacy endpoints.

Based on correspondence with FDA (BQ200481, July 8, 2020), Stage 1 was not completed, and Stage 1 subjects with evaluable Variant 1 method data will contribute to the sample size of the 24 subjects for Stage 2. Furthermore, on April 8, 2021, FDA agreed that the application for a 7-day storage label will incorporate 15 subjects from the BWNW site and at least 5 subjects from the HBC site for the Stage 2 analysis. At the end of study, there are a total of 23 evaluable subjects at Stage 2, including 15 from BWNW and 8 from HBC.

5. ANALYSIS SETS

The analysis sets will be defined as follows:

Safety Analysis Set:

All randomized subjects who initiate an apheresis collection per the "Platelet Apheresis Collection and Storage" electronic case report form (eCRF).

Evaluable Analysis Set (EAS):

This is a subset of Safety Analysis Set. All randomized and infused subjects who have paired (referred to Test and Control) recovery and paired survival data in at least one treatment period for the relevant study stage and/or radiolabeling method and without any major protocol/procedure deviation impacting the primary efficacy outcome.

Completer Analysis Set (CAS):

This analysis set is for Stage 1 only and includes subjects in the EAS who completed both treatment periods and had both paired (referred to Test and Control) recovery and paired survival data available.

Summaries for the efficacy endpoints will be presented using EAS, which is the primary analysis population for efficacy endpoints. Selected efficacy data (e.g. recovery, survival, physical recovery, product parameters evaluation of platelet components, etc.) will also be summarized for CAS in Stage 1. All other summaries will be presented using the safety analysis set unless stated otherwise.

6. SUBJECT DISPOSITION AND DEVIATION

Data will be summarized by site, treatment (Test vs. Control), radiolabeling method (Variant 1 vs. BEST), and Stage as applicable.

The number and percentage of subjects who completed the study and the number and percentage of subjects who were withdrawn will be presented. Subjects who discontinued prematurely will be summarized by the primary reason for withdrawal as specified in the eCRFs. Any protocol and procedure deviations during the study will be documented in the eCRF and identified and detailed in the listings prior to database lock.

Subjects with major deviations may be excluded from the evaluable analysis set depending on the nature of the violation.

7. STUDY ENDPOINTS

7.1 Efficacy Endpoints

7.1.1 Primary Efficacy Endpoints

For each arm of Stage 1 and Stage 2:

- Post infusion recovery at end of storage (Day 7)
- Post infusion survival at end of storage (Day 7)

For Stage 1, recovery and survival of INTERCEPT (Test) components will be evaluated separately for platelets prepared for radiolabeling with the BEST and Variant 1 procedures. For Stage 2, all Test platelets will be prepared for radiolabeling using the Variant 1 method. See Section 8.1.4.2 and Appendix B for information and derivation details for recovery and survival.

7.1.2 Secondary Efficacy Endpoints

For each stage, the secondary efficacy endpoints will be summarized descriptively and are based on product parameters post-INTERCEPT treatment and at end of storage.

Product parameters at end of INTERCEPT treatment:

- Platelet dose ($\geq 3.0\times10^{11}$)
- Platelet yield retention ($\geq$ 80%)

Product parameters at end of storage:

- $pH_{22°C}$ ($\geq$6.2)

7.1.3 Additional Endpoints

Additional analyses will include the *in vitro* function parameters of the stored INTERCEPT platelet component (before radiolabeling preparation process) and the platelet samples (after radiolabeling preparation process) prior to radiolabeling. Appendix A contains derivation details for these endpoints.

Test platelet sample parameters prior to radiolabeling preparation process and again before radiolabeling (**Table 2**).

- Platelet count, component volume (Stages 1 and 2)
- Calculated % platelet yield (platelet physical recovery) during BEST or Variant 1 procedures (Stages 1 and 2)
- WBC count (WBC contamination) (Stage 1)
- RBC count (RBC contamination) (Stage 1)
- $pH_{22°C}$ (Stages 1 and 2)

- CD62P (Stages 1 and 2 assessed prior to radiolabeling preparation processing, and Stage 1 assessed again before radiolabeling)

Product parameters at Input (Day 0/1) (**Table 3**):

- Platelet count, platelet dose, component weight, and component volume
- Biochemical assessments: pH, supernatant LDH, total LDH, platelet lysis (unadjusted), ATP
- Functional assessments: CD62P (% P-selectin expression)

Product parameters at end of INTERCEPT treatment (Day 1/2) (**Table 3**):

- Platelet count, platelet dose, component weight, and component volume

Product parameters at end of storage (Day 7) (**Table 3**):

- Platelet count, platelet dose, component weight and component volume
- Biochemical assessments: glucose, lactate, pO_2, pCO_2, bicarbonate (HCO_3-), supernatant and total LDH, platelet lysis (unadjusted and baseline adjusted), and ATP. Normalized O_2 consumption, normalized CO_2 production, normalized HCO_3- production, normalized glucose consumption, normalized lactate production, and normalized ATP production values will be calculated per platelet
- Functional assessments: HSR, ESC, CD62P (% P-selectin expression) MPV, morphology score

RBC contamination in subject's radiolabeled whole blood (WB) sample

- Post infusion blood samples will be used to determine the level of RBC/WBC contamination in the radioactivity measurements. Formula and details are given in Appendix A.

In vivo elution at 1 hour post-infusion (for ^{51}Cr and ^{111}In)

- *In vivo* elution will be calculated by dividing the supernatant dose by the combined doses of supernatant and pellet from gamma counter at 1 hour post-infusion. Formula and details are given in Appendix A.

In vitro elution

- *In vitro* elution will be calculated by using the "Elution of Radioactivity from Labeled Platelets in Whole Blood" from the BEST method. Formula and details are given in Appendix A.

Radiolabeling efficiency (for Test and Control)

- The activity of supernatant and the labeled pellet will be determined in a dose calibrator. The radiolabeling efficiency will be calculated by dividing the activity of the pellet by the combined activities of the pellet and supernatant. Formula and details are given in Appendix A.

Dose recovery, and volume recovery

- Dose recovery will be determined at post-INTERCEPT (Day 1/2) and at end of storage (Day 7) compared to the Input dose by dividing the post-INTERCEPT or end of storage dose by the Input dose.

- Volume recovery will be determined at post-INTERCEPT (Day 1/2) and at end of storage (Day 7) compared to the Input volume by dividing the post-INTERCEPT or end of storage volume by the Input volume.

Formulas and details are given in Appendix A.

Physical platelet recovery

- The physical platelet recovery following the initial radiolabeling steps will be determined and assessed if meets ≥ 80% criteria. Formula and details are given in Appendix A.

7.1.4 Methods and Timing of Efficacy Endpoints

7.1.4.1 Assessment of Stored Platelet Samples Prior to Radiolabeling

A paired sample of stored (Day 7 or 0 DPI) Test platelets will be assessed prior to radiolabeling preparation process and immediately prior to radiolabeling step (resuspended hard spin pellet) to evaluate platelet yield (Stages 1 and 2), RBC (Stage 1), WBC content (Stage 1), pH (Stage 1 and Stage 2), and CD62P (Stage 1) (**Table 2**).

Characterization of residual RBCs will be performed either by manual counting or using an antibody to CD235a which is expressed on erythrocytes and erythrocyte precursors and is associated with the MNS blood group (Reid 2009; Gahmberg, et al. 1978). Characterization of residual WBCs will be performed using the Leucocount Kit (Becton Dickenson) which uses propidium iodide that stains the nucleic acids of the DNA contained within the WBCs and is analyzed using flow cytometry.

Table 2 Assessment of Test Platelet Sample Prior to Radiolabeling

Assay	Study Stage	Method	Stored Test Platelet Component Sample	Processed Platelet Sample for Radiolabeling Test
Sample volume	1 and 2	NA	X	X
Platelet Count	1 and 2	Automated counter	X[a]	X
RBC Count	1	Hemocytometer or Flow Cytometry	-	X
WBC Count	1	Leucocount	-	X
pH $_{22°C}$	1 and 2	Blood Gas Analyzer or ion selective electrode	X[a]	X
CD62P	1 and 2	Flow Cytometry	X[a]	X[b]

[a] Test platelet only will be analyzed as part of end of storage *in vitro* assessments outlined in **Table 3**.

[b] The processed platelet sample for radiolabeling Test is assessed for CD62P in Stage 1 only.

7.1.4.2 Radioactivity Measurements and Recovery and Survival Estimation

After radiolabeling ^{51}Cr or ^{111}In, blood samples will be drawn immediately before infusion and for radioactivity measurements at 1 hour ± 15 min and 2 hours ± 15 min post-infusion (0 DPI), and 6 more samples will be drawn at 1, 2, 3, 4 (or 5 or 6), 7 (or 8), and 11±1 DPI, at approximately the same time of day as the radiolabeled platelet infusion was administered (±4 hours). By measuring the volume infused, the total dose of radioactivity infused will be calculated. The radioactivity of the samples will be determined by use of a gamma counter. Sample dilutions for enumeration of radioactivity of the standards will be calibrated to ensure that measured values are at least 10-fold background values. Duplicates of the subject's WB will be measured for radioactivity while singletons of all other samples will be evaluated.

The post-infusion recovery and survival data from 7-day Test platelets will be assessed separately by the pre-radiolabeling platelet sample preparation (BEST vs. Variant 1), calculated based on the corrected radioactive counts observed from the six post-infusion sampling time points at 1, 2, 3, 4 (or 5 or 6), 7 (or 8) and 11 (±1) DPI, and compared with its paired Control descriptively. Post-infusion blood samples will be corrected for radioactive decay if the counts for each subject are taken on more than one day. Post-infusion blood samples will also be corrected for plasma associated radioisotope and the spontaneous *in vitro* dissociation (elution) of radiolabels using the method described in the BEST version 4.2.1. Moreover, the corrected count samples will be adjusted for cell-bound proportion and baseline. Then, the fully adjusted timed-sample counts for times greater than 20 hours are used for kinetic curve fitting and estimation of recovery and survival. A non-linear curve fitting model, with the multiple-hit algorithm, will be used to estimate platelet recovery and lifespan based on the processed (fully adjusted) ^{51}Cr and ^{111}In counts, respectively. Appendix B contains more detailed information about the quantitative formulas and calculations of recovery and survival.

7.1.4.3 RBC/WBC Contamination Assessments

Post infusion blood samples will be also used to determine the level of RBC/WBC contamination in the radioactivity measurements. Ficoll gradient centrifugation of the WB sample will allow for separation of the RBCs and some WBCs from the plasma, WBC, and platelets. The radioactivity associated with the RBC and non-RBC associated fractions will be measured. RBC/WBC contamination will be determined on 1, 4 (or 5 or 6) and 11±1 DPI in Stage 1 and only on 11±1 DPI in Stage 2.

7.1.4.4 *In Vitro* Platelet Assessments

Samples for analysis of pH need to be analyzed shortly after preparation. The remaining indices listed in **Table 3** should be tested or prepared for testing following site standard operating procedures (SOP). Samples for assessment of ATP will be prepared by the site and sent to a centralized lab for analysis. Samples for assessment of CD62P, LDH, glucose, morphology (if fixed), and lactate can be prepared and stored for analysis at a later date per site specific SOPs. Specific assays and equipment for the assessment of the *in vitro* parameters will be detailed in the study manual and the clinical study report.

Table 3 *In Vitro* Platelet Function Assays to Evaluate INTERCEPT Platelet Components

Assay	Pre INTERCEPT Day 0-1	Post INTERCEPT	End of Storage
Component weight (g)	X	X	X
Platelet count ($\times 10^3/\mu L$ or $10^6/mL$)	X	X	X
Platelet dose ($\times 10^{11}$ cells/unit) [a]	X	X	X

Mean platelet volume (MPV) (fL)	-	-	X
Morphology score (max 400)	-	-	X
$pH_{22°C}$	X	-	X
$pO_{2\ (37°C)}$ (mm Hg)[c]	-	-	X
$pCO_{2\ (37°C)}$ (mm Hg)[c]	-	-	X
$HCO_3^{-}{}_{(37°C)}$ (mmol/L)[c]	-	-	X
Supernatant glucose (mmol/L)[c]	-	-	X
Supernatant lactate (mmol/L)[c]	-	-	X
Supernatant LDH (U/L)[c]	X	-	X
Total LDH (U/L)	X	-	X
ATP (µmol/dL)[c]	X	-	X
Extent of Shape Change (%) (ESC)	-	-	X
Hypotonic Shock Response (%) (HSR)	-	-	X
CD62P (% P-selectin expression)	X	-	X
Platelet lysis (%)[b]	X	-	X
Bacterial culture	-	1-3 days before end of storage	-

[a] Platelet dose is calculated from the platelet count and volume.

[b] Calculated from ratio of LDH activity in 1 mL of platelet concentrate supernatant to the total LDH activity in 1 mL of Triton X-100 lysed platelet concentrate.

[c] The values for these parameters will also be normalized for platelet count.

7.2 Safety Endpoints

Safety will be assessed through monitoring of adverse events (AEs), physical examinations (including vital signs), and laboratory tests. Safety endpoints are listed below:

- Adverse events
- Vital signs
- Hematological profile
- Serum chemistry profile

8. STATISTICAL ANALYSIS AND CONSIDERATIONS

8.1 General Analysis Consideration

Unless stated otherwise, data will be summarized and tabulated for two sets: (1) Stage 1, and (2) Stage 2, for which will incorporate Stage 1 subjects with evaluable Variant 1 method data. In addition, summary will be presented by site (and with both sites combined). Summary by pre-radiolabeling platelet sample preparation method for Test platelets (BEST vs. Variant 1) will be presented for set (Stage 1). For primary efficacy endpoints, confidence intervals (CIs) for treatment differences between Test (INTERCEPT treated and stored) platelets to Control (fresh) platelets will be provided. The difference between BEST Test platelet components (PCs) and Variant 1 Test PCs will also be summarized for Stage 1 as applicable.

For categorical measurements, summaries will be presented using counts and proportions. For continuous measurements, summaries will be presented using descriptive statistics including the mean, SD, confidence interval (CI) for the mean, median, minimum, and maximum. Individual data points will be presented in data listings.

Data is read directly as input and rounding will occur at the final step of calculation for each summarized variable.

For the following assessment criteria, the comparison will be done after rounding the calculated value to the same precision as the threshold value.

- For platelet recovery, Test $\geq 0.66 \times$ Control (e.g., a ratio of 0.6551 for Test/Control will be rounded to 0.66 and considered as meeting this criterion)
- For platelet survival, Test $\geq 0.58 \times$ Control
- Platelet dose $\geq 3.0 \times 10^{11}$ (e.g., 2.951×10^{11} will be rounded to 3.0×10^{11})
- Platelet yield retention $\geq 80\%$ (e.g., 79.51% will be rounded to 80%)
- pH ≥ 6.2 (e.g., 6.151 will be rounded to 6.2)
- Platelet physical recovery $\geq 80\%$

All statistical analyses will be performed using SAS® version 9.4 (or higher).

8.1.1 Subject Disposition

Subject disposition will be summarized by site (and with both sites combined). Numbers of subjects terminating the study early and their reasons for early termination will be summarized.

8.1.2 Demographics, Baseline, and Clinical Measurements

The following demographic and clinical variables collected for the study will be summarized by site (and with both sites combined):

- Demographic variables: Age (at enrollment), Gender, Ethnicity, Race
- Baseline characteristics (Vital Signs at Screening): Weight, Height, BMI
- Clinical measurements: Blood Type, Rh Factor

8.1.3 Substance Use and Physical Examination

Substance use (including nicotine use or cannabis use) and physical examination will be summarized descriptively.

8.2 Efficacy Analyses

8.2.1 Analysis of Primary Endpoints

The primary endpoints are post-infusion recovery and survival at end of storage for both stages. Subjects who do not have both paired recovery and paired survival data may be replaced to ensure a sufficient number of evaluable subjects is reached for the primary analysis. Reasons for absence of primary endpoint measurement(s) for any subject will be listed in the CSR.

For both stages, the post-infusion recovery and survival data will be calculated based on the corrected radioactive counts observed from the six post-infusion sampling time points at 1, 2, 3, 4 (or 5 or 6), 7 (or 8)

and 11±1 DPI. The following acceptance criteria for recovery and survival will be used to demonstrate non-inferiority of Test (INTERCEPT treated and stored) platelets against Control (fresh) platelets for Stage 2:

(1) For recovery:

H_0: Test - 0.66×Control < 0 vs. H_1: Test - 0.66×Control ≥ 0

The null hypothesis will be rejected if the lower bound of a two-sided 95% CI for the mean treatment difference (Test - 0.66×Control) is greater than or equal to zero. For any platelet recovery values that are more than 100%, they will be capped at 100% for the data analysis.

(2) For survival:

H_0: Test - 0.58×Control < 0 vs. H_1: Test - 0.58×Control ≥ 0

The null hypothesis will be rejected if the lower bound a two-sided 95% CI for the mean treatment difference (Test - 0.58×Control) is greater than or equal to zero.

The primary analysis population for the primary efficacy endpoints will be analyzed on EAS. The two-sided 95% CIs will be computed using the variance estimated from a paired T-Test.

In the event that non-inferiority cannot be declared for the primary endpoints for Stage 2, additional exploratory analyses may be conducted to quantify the proportions of subjects whose recovery and survival data meet the 0.66 and 0.58 cutoff, respectively (e.g., platelet recovery from a Test PC greater than or equal to 66% of platelet recovery from its paired fresh Control PC).

8.2.2 Analysis of Secondary Endpoints

Data will be summarized descriptively for each stage. The proportions of

(1) Test PCs with platelet dose ≥ 3.0×10^{11} (end of INTERCEPT treatment),
(2) Test PCs with platelet yield retention ≥ 80% (end of INTERCEPT treatment), and
(3) Test PCs with pH at 22°C ≥ 6.2 (end of storage)

will be summarized, with the corresponding lower bound of a one-sided 95% CI for the proportion provided. Correlations between the primary and secondary efficacy endpoints may be explored using correlation matrix plots and multiple linear regression analysis.

8.2.3 Analysis of Additional Endpoints

Descriptive summary, including mean, standard deviation (SD), median, minimum, maximum, and 95% CI of mean will be provided for *in vitro* function parameters of the stored INTERCEPT PCs and the platelet samples prior to radiolabeling. In addition, assessment of the RBC/WBC contamination will be summarized descriptively by DPI and treatment group (BEST Test, Variant 1 Test, and BEST Control). In addition, the radiolabeling efficiency will be summarized descriptively.

8.2.4 Exploratory Analyses

To explore the carryover effect for Stage 1, the primary endpoints will be summarized separately by randomization sequence for the Test PCs (e.g., BEST from Period 1 vs Variant 1 from Period 1). Additionally, an ANOVA model may be considered for the primary efficacy endpoints with radiolabeling, site, treatment group (BEST Test and Variant 1 Test), period, and period-by-treatment as fixed effects.

8.3 Safety Analyses

Treatment-emergent AEs (TEAEs; defined as AEs with onset at or after the initiation of the first apheresis platelet collection) and serious adverse events (SAEs) will be summarized descriptively. For Stage 1, any TEAEs with onset before the start time of apheresis platelet collection at Period 2 will be counted as events during Period 1, otherwise, TEAEs with onset on or after the start time of apheresis platelet collection at Period 2 will be counted as events during Period 2. A TEAE that has onset during Period 1 and continues over both periods will be counted only once as a Period 1 event in summary tables. Other safety data including vital signs, hematological profile, and serum chemistry profile will be provided in the data listings. The observed results and change from pre-infusion for vital signs and hematology and chemistry parameters will be summarized descriptively by DPI for each stage.

Vital signs are collected for both stages at screening, and for each study period prior to apheresis collection (Day 0), on the day of infusion (pre-infusion, and approximately 1 and 2 hours post-infusion), and on 1, 2, 3, 4 (or 5 or 6), 7 (or 8), and 11 ± 1 DPI. Clinically significant changes in vital signs as assessed by the study investigator will be recorded as AEs. All verbatim AE terms detailed in the CRF will be mapped to their preferred terms and system organ class (SOC) using MedDRA Version 19.0.

Blood samples for hematology and chemistry panels will be obtained from each subject at screening, and for each study period, prior to apheresis platelet collection (Day 0), prior to platelet infusion, and at the end of the study period (11±1 DPI). Clinically significant laboratory findings will be recorded as AEs. The subject laboratory assessments are identified as following.

Hematology:	Hematocrit, Hemoglobin, RBC Count, Platelet Count, and WBC Count (with differential).
Serum Chemistry:	Blood Urea Nitrogen, Calcium, Carbon Dioxide, Chloride, Creatinine, Glucose, Potassium, and Sodium.

9. HANDLING MISSING DATA

Missing data will be noted as such and not be imputed, except for PCs with missing volume when calculating the total volume of PCs transfused and medications with partial start/stop date when determining if a medication is prior or concomitant. The missing volume will be imputed by the average volume per PC per treatment group. The partial medications start/stop date will be imputed as 1st if the day part is missing or as January if the month part is missing. If the whole date information is missing, the medication will be treated as concomitant.

10. CHANGES TO PROTOCOL SPECIFIED ANALYSES

The following changes to the data analysis pre-specified in the protocol are made after the study started.

1) In addition to the EAS summarizing data for the primary efficacy outcome, Completer Analysis Set (CAS) is added for Stage 1 only (Section 5), which includes subjects in the EAS who completed both treatment periods and had both paired (referred to Test and Control) recovery and paired survival data available.

2) For replicated data at a specific visit, only the one with a later collection or assessment date will be analyzed and summarized. This detailed information was not stated in the protocol.
3) In the process of Recovery and Survival calculation, the elution of radioactivity from labeled platelets in whole blood and the fully adjusted count at time *t* post infusion are derived using the average of the results from the dual blood samples (Steps 2 and 5, Appendix B). This detailed information was not stated in the protocol.
4) A few extreme values were observed for RBC/WBC contamination, in vivo elution, and in vitro elution data. They are included in the data listings but excluded from the table summary. This detailed information was not stated in the protocol.

11. REFERENCES

1. FDA Draft Guidance for Industry, Draft Guidance for Industry For Platelet Testing and Evaluation of Platelet Substitute Products. 1999
2. Gahmberg CG, Jokinen M, Andersson LC. Expression of the major sialoglycoprotein (glycophorin) on erythroid cells in human bone marrow. Blood. 1978;52:379-387.
3. Reid ME. MNS blood group system: a review. Immunohematology. 2009;25(3):95-101.
4. The Biomedical Excellence for Safer Transfusion (BEST) Collaborative. Platelet radiolabeling procedure. Transfusion 2006;46 Suppl:59S-66S.

12. APPENDICES

APPENDIX A: DERIVATION DETAILS

Adjusted and Unadjusted Lysis Calculation

On all collection days, the unadjusted and adjusted lysis will be calculated using the following formulas:

Unadjusted Lysis (%) = Supernatant LDH (U/L) ÷ Total LDH (U/L) $\times 10^2$

$$\text{Day } \mathbf{X}\text{'s Adjusted Lysis (\%)} = \frac{\text{Day } \mathbf{X}\text{'s Supernatant LDH (U/L)} - \text{Day 0's Supernatant LDH (U/L)}}{\text{Day } \mathbf{X}\text{'s Total LDH (U/L)}} \times 10^2$$

ATP Normalized for Platelet Count

ATP will be measured in µmol/dL.

Normalized ATP will be calculated using the following formula:

$$\text{ATP (nmol/}10^8\text{ platelets)} = \frac{\text{ATP (µmol/dL)}}{\text{Platelet Count (} \times 10^3/\mu\text{L)}} \times 10^3 ,$$

where Platelet Count units = $\times 10^3$ platelets/µL or $\times 10^6$ platelets/mL (interchangeable).

Body Mass Index (BMI)

$$\text{BMI} = \frac{\text{Weight (kg)}}{[\text{Height (cm)}/100]^2}$$

Component Volume and Platelet Dose

The component volume and platelet dose will be calculated using the following formulas:

$$\text{Component Volume (mL)} = \frac{\text{Component Gross Weight (g)} - \text{Tare Weight (g)}}{1.03 \text{ g/mL}}$$

$$\text{Platelet Dose } (\times 10^{11}) = \frac{\text{Component Volume (mL)} \times \text{Platelet Count } (\times 10^{6}/\text{mL})}{10^{5}},$$

where Component Gross Weight = Final Input Gross weight or Pre-sampling gross weight at the End of storage; Tare Weight = Empty container weight

Unless otherwise noted, the gross-weight (pre-sampling weight if available) and platelet count collected at each timepoint will be used to derive the timepoint specific volume and dose. The tare weights will be set to the following values:

Input (Day 0):

- HBC Tare Wt = 39g
- BWNW Tare Wt = 41.9g

Post-INTERCEPT (Day 1/2):

- Tare Wt = 43.5g for components stored in 1 bag (A or B)
- Tare Wt = 88.2g for components stored in 2 connected bags (A + B)
- Tare Wt = 83.9g for components stored in 2 separated bags (A and B)

Post-INTERCEPT Storage Volume (Day 1/2):

- Tare Wt = 40.4g for components stored in 1 bag (A or B)
- Tare Wt = 85.1g for components stored in 2 connected bags (A + B)
- Tare Wt = 80.8g for components stored in 2 separated bags (A and B)

End of Storage (Day 7):

- Tare Wt = 40.4g for components stored in 1 bag (A or B)
- Tare Wt = 85.1 for components stored in 2 connected bags (A + B)
- Tare Wt = 80.8g for components stored in 2 separated bags (A and B)

End of storage volume will be also corrected for sampling taken during the storage process including the sampling for the post-INTERCEPT sample, bacterial culture sample, and the sample removed for radiolabeling. The corrected volume will be used to calculate the platelet dose at end of storage. The corrected

weight will be used to calculate the corrected volume using the above equation. Sample weights will be calculated by the following formulas:

$$\text{End of storage volume Corrected (mL)} = \frac{\text{Component Gross Weight (g)} - \text{Tare Weight (g)}}{1.03\ \text{g/mL}} +$$

$$\frac{\text{Post INTERCEPT sample weight}}{1.03\ \text{g/mL}} + \frac{\text{BacT sample weight}}{1.03\ \text{g/mL}} + \frac{\text{Radiolabeled sample weight}}{1.03\ \text{g/mL}}$$

- Post-INTERCEPT sample weight (g) =
  Final Storage Container Gross Weight (g) – Final Storage Container Gross Weight after Sampling for Post-INTERCEPT Processing (g)
- BacT sample weight (g) =
  Gross weight of platelet unit pre-sampling (g) – Gross weight of platelet unit post-sampling (g)
- Radiolabeled sample weight (g) =
  Radiolabeling for Test Platelets Pre-Sample Gross Weight (g) – Radiolabeling for Test Platelets Post-Sample Gross Weight (g)

Day 10 Corrected CPM for Site 002 (Bloodworks Northwest)

CPM will be corrected when the radioactivity samples for Recovery and Survival calculations are not analyzed by the gamma counter on the same day.

For Chromium: Day 10 Corrected CPM = Day 10 CPM × exp (0.0250 × t)

where t = Duration in days = Day 10 date/time – Day 7 date/time start on gamma counter.

For Indium:

Day 10 Corrected CPM = Day 10 CPM × exp (0.24714 × t)

where t = Duration in days = Day 10 date/time – Day 7 date/time start on gamma counter.

Dose Recovery and Volume Recovery

The dose and volume recovery at post-INTERCEPT (Day 1/2) and end of storage (Day 7) will be calculated as follows:

- Dose Recovery at Post-INTERCEPT (%) = Post-INTERCEPT Dose / Input Dose × 10^2
- Dose Recovery at End of Storage (%) = End of Storage Dose / Input Dose × 10^2
- Volume Recovery at Post-INTERCEPT (%) = Post-INTERCEPT Volume / Input Volume × 10^2
- Volume Recovery at End of Storage (%) = Corrected End of Storage Volume / Input Volume × 10^2

Glucose Conversion

- If glucose is measured in mg/dL, then it will be converted to mmol/L using the following formula: Glucose (mmol/L) = Glucose (mg/dL) ÷ 18

Glucose and Lactate Normalized for Platelet Count

Glucose and lactate will be measured in mmol/L (or converted to mmol/L).

On all collection days, glucose and lactate will be normalized to platelet count by converting from mmol/L to mmol/10^{12} using the following formula:

$$\text{Glucose and Lactate (mmol/}10^{12}\text{ platelets)} = \frac{\text{Glucose and Lactate (mmol/L)}}{\text{Platelet Count (} \times 10^3/\mu\text{L)}} \times 10^3 ,$$

where Platelet Count units = $\times 10^3$ platelets/µL or $\times 10^6$ platelets/mL (interchangeable).

HCO_3- Normalized for Platelet Count

HCO_3- will be measured in mmol/L

On collection days, HCO_3- will be normalized to platelet count by converting from mmol/L to mmol/10^{12} platelets using the following formula:

$$HCO_3^- \text{ (mmol/}10^{12}\text{ platelets)} = \frac{HCO_3^- \text{ (mmol/L)}}{\text{Platelet Count (} \times 10^3/\mu\text{L)}} \times 10^3$$

***In Vivo* Elution at 1 hour Post-Infusion**

In vivo elution will be determined using the blood draw for radioactivity at 1 hr ± 15min. The *in vivo* elution will be calculated using the following formula:

$$In\ Vivo \text{ Elution (\%)} = \frac{\text{1hr plasma CMP/g}}{\text{(1hr plasma CPM/g} + \text{ 1hr Packed Cells CPM/g)}} \times 10^2$$

If the values at 1 hour post-infusion are missing, the values at 2 hour post-infusion will be used (and footnoted in the tables). Overall *in vivo* elution can be derived by the average of *in vivo* elution for all subjects.

***In Vitro* Elution**

In vitro elution will be determined using the "Elution of Radioactivity from Labeled Platelets in Whole Blood" from the BEST method where 10 µL of the mixed injectate will be mixed into a 5 or 7 mL EDTA tube of blood, incubated for 2 hours at 37ºC in a wet incubator, spun to separate the plasma and packed cells and counted on the gamma counter. The *in vitro* elution will be calculated using the following formula:

$$In\ Vitro \text{ Elution (\%)} = \frac{\text{Elution Plasma CMP/g}}{\text{(Elution Plasma CPM/g} + \text{ Elution Packed Cells CPM/g)}} \times 10^2$$

pH Temperature Conversion

Any pH measurement taken at a temperature outside of the range of 19°C to 25°C will be corrected to $pH_{22°C}$, calculated according to the CLSI (formerly NCCLS) Patient Temperature Correction, as follows:

$$pH_{22°C} = pH_{X°C} + (X-22) \times 0.015$$

where X is the degrees of temperature in Celsius.

Platelet Count Units

Depending on the cell counter, platelet counts will be measured in $\times 10^3$ platelets/µL or $\times 10^6$ platelets/mL. Platelet counts will be summarized in $\times 10^3$ platelets/µL (or, equivalently, $\times 10^6$ platelets/mL) in the tables.

Platelet counts at post-radiolabeling will be corrected for dilution used during analysis with the following formula:

Dilution corrected platelet count ($\times 10^3$ platelets/µL) = Platelet count at post-radiolabeling × 10

Platelet Physical Recovery Rate

The platelet physical recovery rate before radiolabeling will occur using the following formulas:

$$\text{Physical Recovery (\%)} = \frac{(\text{Weight of platelets radiolabeled} / 1.03) \times \text{Platelet count following hard spin}}{(\text{Weight of platelets to be radiolabeled} / 1.03) \times \text{End of storage platelet count}} \times 10^2$$

where if question "Sample stopped for *in vitro* analysis" is answered with Sample 2 or not answered:

Weight of platelets to be radiolabeled for Cr =

"Gross weight of the 2 or 4 filled 15 or 50mL conical tubes -3" – "Pre-weight of empty 15 or 50mL screw-cap conical centrifuge tubes-3" + "Gross weight of the 2 or 4 filled 15 or 50mL conical tubes -4" – "Pre-weight of empty 15 or 50mL screw-cap conical centrifuge tubes-4"

Weight of platelets to be radiolabeled for In =

"Gross weight of the 2 or 4 filled 15 or 50mL conical tubes -2" – "Pre-weight of empty 15 or 50mL screw-cap conical centrifuge tubes-2

Weight of platelets radiolabeled BEST =

"Gross weight of the filled 15 or 50mL conical tubes post resuspension after hard spin-2" – "Pre-weight of final 15 or 50mL conical tubes-2"

Weight of platelets radiolabeled Variant 1 =

"Gross weight of the filled 15 or 50mL conical tubes post resuspension after hard spin-2" – "Pre-weight of empty 15 or 50mL screw-cap conical centrifuge tubes-2"

Where if question "Sample stopped for *in vitro* analysis" is answered with Sample 1:

Weight of platelets to be radiolabeled for Cr =

"Gross weight of the 2 or 4 filled 15 or 50mL conical tubes -1" – "Pre-weight of empty 15 or 50mL screw-cap conical centrifuge tubes-1" + "Gross weight of the 2 or 4 filled 15 or 50mL conical tubes -2" – "Pre-weight of empty 15 or 50mL screw-cap conical centrifuge tubes-2"

Weight of platelets to be radiolabeled for In =

"Gross weight of the 2 or 4 filled 15 or 50mL conical tubes -1" – "Pre-weight of empty 15 or 50mL screw-cap conical centrifuge tubes-1

Weight of platelets radiolabeled BEST =

"Gross weight of the filled 15 or 50mL conical tubes post resuspension after hard spin-1" – "Pre-weight of final 15 or 50mL conical tubes-1"

Weight of platelets radiolabeled Variant 1 =

"Gross weight of the filled 15 or 50mL conical tubes post resuspension after hard spin-1" – "Pre-weight of empty 15 or 50mL screw-cap conical centrifuge tubes-1"

Platelet Yield Retention Post-INTERCEPT Treatment

Platelet Yield Retention will be determined for post-INTERCEPT (Day 1/2) using the following formula:

$$\text{Platelet Yield Retention (\%)} = \frac{\text{Post INTERCEPT Platelet Dose}}{\text{Input Platelet Dose}} \times 10^2$$

pO_2 and pCO_2 Normalized for Platelet Count

pO_2 and pCO_2 will be measured in mmHg.

On collection days, pO_2 and pCO_2 will be normalized to platelet count by converting from mmHg to µmol/hr/10^{12} by taking advantage of the ideal gas law where:

$$pO_2 \text{ and } pCO_2 \text{ (atm)} = \frac{\text{Moles (mol) x Gas Contstant } ([\text{L} \cdot \text{atm}]/[\text{mol} \cdot \text{K}]) \text{ x Temperature (K)}}{\text{Volume (L)}}$$

By reorganizing terms, pO_2 and pCO_2 values will be initially converted into molarity values (mol/L) prior to normalization. Thus:

$$\text{Molarity (mol/L)} = \frac{\text{Moles (mol)}}{\text{Volume (L)}} = \frac{pO_2 \text{ and } pCO_2\text{(atm)}}{\text{Gas Contstant } ([\text{L} \cdot \text{atm}]/[\text{mol} \cdot \text{K}]) \times \text{Temperature (K)}}$$

By using the following list of constants and conversions:

Gas Constant ([L·atm]/[mol·k]) = 0.08206 ([L·atm]/[mol·k])

Temperature (K) = 310.15

Moles (μmol) = Micromoles (mol) × 10^6

pO_2 and pCO_2 (atm) = pO_2 and pCO_2 (mmHg) ÷ 760,

the molarity can be re-written in terms of μmol/L, and furthermore, the pO_2 and pCO_2 values can also be expressed in mmHg units as collected in the study:

$$\text{Molarity (mol/L)} = \frac{[pO_2 \text{ and } pCO_2(\text{mmHg})] \div 760}{\text{Gas Contstant } ([\text{L} \cdot \text{atm}]/[\text{mol} \cdot \text{K}]) \times \text{Temperature (K)}} \times 10^6$$

$$= \frac{[pO_2 \text{ and } pCO_2(\text{mmHg})] \div 760}{0.08206 \times 310.15} \times 10^6$$

Once the molarity is calculated, the final portion of the normalization will be carried out as follows:

$$pO_2 \text{ and } pCO_2 \ (\mu\text{mol/hr}/10^{12}) = \frac{\text{Molarity } (\mu\text{mol})}{\text{Time (Hrs)} \times \text{Platelet Count } (\text{x}10^3/\mu L)} \times 10^3 ,$$

where Time (Hrs) will be set to 168 hrs (or 7 days) for Day 7 normalizations.

Radiolabeling Efficiency

Radiolabeling efficiency will be calculated using the dosimeter readings from the platelet pellet and the supernatant from the radiolabeling process for both the Test and the Control using the following equation:

$$\text{Radiolabeling Efficiency (\%)} = \frac{\text{Pellet Dose}}{(\text{Pellet Dose} + \text{Supernatant Dose})} \times 10^2$$

RBC/WBC Contamination

RBC/WBC contamination will be determined as a percentage of counts of whole blood on DPI 1. This will be determined using the measurements on Days post infusion (DPI) 1, 4 (or 5, or 6), and 11±1 using the following formulas:

$$\text{RBC/WBC Contamination at DPI X (\%)} = \frac{\text{DPI X RBC layer CPM / g}}{\text{DPI 1 WB CPM / g}} \times 10^2$$

Where:

$$\text{DPI X RBC layer (CPM/g)} = \frac{\text{DPI X RBC Layer CPM}}{(\text{Weight of Tube with aspirated fluid (g)} - \text{ Pre-weight of empty labeled tube (g))} \div 2}$$

And where

$$\text{DPI 1 WB CMP/g} = (\text{DPI 1 WB-A(CMP/g)} + \text{DPI 1 WB-B (CPM/g)})/2$$

$$\text{DPI 1 WB-A (CPM/g)} = \frac{\text{DPI 1 WB-A CPM}}{\text{DPI 1 WB-A post weight, filled tube (g)} - \text{DPI 1 WB-A pre-weight, empty tube (g)}}$$

$$\text{DPI 1 WB-B (CPM/g)} = \frac{\text{DPI 1 WB-B CPM}}{\text{DPI 1 WB-B post weight, filled tube (g)} - \text{DPI 1 WB-B pre-weight, empty tube (g)}}$$

For RBC/WBC contamination data analysis, when samples for radioactivity for one subject are not analyzed with the gamma counter on the same day, decay corrections are necessary. The CPMs will be corrected to Day 10 using the following decay calculation:

For Chromium:

Day X Corrected CPM = Day X CPM × exp (0.0250 × t)

where X = the nominal visit when the sample was taken

t = Duration in days = Day X date/time start on gamma counter - Day 10 date/time.

For Indium:

Day X Corrected CPM = Day X CPM × exp (0.24714 × t)

where X = the nominal visit when the sample was taken

t = Duration in days = Day X date/time start on gamma counter - Day 10 date/time.

This correction is applied to all subjects from site 02. 001-106's CPM for DPI 4 (or 5, or 6) is also corrected by applying the same decay calculation with t = 3.754861111 days.

Sample Volume

Sample volume will be measured at the end of storage, for radiolabeling and before radiolabeling (before addition of the radioisotopes).

$$\text{Sample volume at the End of Storage (mL)} = \frac{\text{Post-gross weight from radiolabel Test (g)} - \text{Post-gross weight at End of Storage (g)}}{1.03\ \text{g/mL}}$$

$$\text{Sample volume for Radiolabeling (mL)} = \frac{\text{Test Radiolabel Pre-sample gross weight (g)} - \text{Test Radiolabel Post-weight gross weight(g)}}{1.03\ \text{g/mL}}$$

$$\text{Sample volume for before radiolabeling (mL)} = \frac{\text{Gross weight Filled 15 or 50mL (post-resuspension after hard spin) (g)} - \text{Pre-weight (g)}}{1.03\ \text{g/mL}}$$

where, Pre-weight for BEST method = Pre-wt: Final 15 or 50mL Tube 1 or 2; Pre-weight for Variant 1 method = Pre-weight: Empty 15 or 50mL Tube 1 or 2. The "Sample stopped for in vitro analysis" will be the tube the sample volume is calculated for.

Sample Dose Prior to Addition of Radioisotope

Sample dose will be measured at before radiolabeling.

$$\text{Sample Dose Before Radiolabeling } (\times 10^9) = \frac{\text{Sample Volume (mL)} \times \text{Platelet Count } (\times 10^6/\text{mL})}{10^3},$$

Sample volume is the sample volume before radiolabeling; Platelet count is the platelet count before radiolabeling.

Supernatant LDH Normalized for Platelet Count

Supernatant LDH activity will be measured in U/L.

Supernatant LDH will be normalized to platelet count by converting from U/L to U/10^{12} platelets using the following formula:

$$\text{Supernatant LDH (U/}10^{12}\text{ platelets)} = \frac{\text{Supernatant LDH (U/L)}}{\text{Platelet Count } (\times 10^3/\mu\text{L})} \times 10^3,$$

where Platelet Count units = $\times 10^3$ platelets/µL or $\times 10^6$ platelets/mL (interchangeable).

Total LDH Dilution Correction

Total LDH will be measured in U/L and will be corrected for sample dilution by the following formula:

Total LDH Dilution (Actual Total LDH) = Total LDH Triton Lysate × 8

Total RBC and WBC counts

RBC counts will be measured in 10^4 cells/mL and WBC counts will be measured in cells/µL. To calculate the total number of RBC and WBC in each sample the following formulas will be followed:

Total RBC count (cells) = RBC Count (10^4 cells/mL) × Sample volume (mL)

Total WBC count (cells) = WBC Count (cells/µL) × Sample volume (mL) × 1000

Where, Sample volume (mL) = (Gross Wt. Filled 15 or 50mL (post-resuspension after hard spin) - Pre-Weight (g)) ÷ 1.03

Where, Pre-weight for BEST method = Pre-wt: Final 15 or 50mL Tube 1 or 2; Pre-weight for Variant 1 method = Pre-wt: Empty 15 or 50mL Tube 1 or 2. The sample tube that is stopped for in vitro analysis will be the tube the sample volume is calculated for.

APPENDIX B: CALCULATIONS AND DATA HANDLING RULES OF RECOVERY AND SURVIVAL

Please see the attached word file for details.

APPENDIX C: TABLE MOCK-UPS

Please see the attached word file for details.

APPENDIX D: LISTING MOCK-UPs

Please see the attached word file for details.

Appendix B
Calculations and Data Handling Rules of Recovery and Survival

Objective: To describe calculations for post infusion platelet recovery and survival at end of storage (Day 7, 6, or 5) for radioisotopic labeling and infusion of stored platelets with ^{111}In Oxine (^{111}Indium) and $Na_2{}^{51}CrO_4$ (^{51}Chromium).

Data Sources: Raw Data collected at Hoxworth Blood Center and Bloodworks Northwest Research Institute. After radiolabeling using ^{51}Cr (Chromium) or ^{111}In (Indium), blood samples will be drawn immediately before infusion and for radioactivity measurements at 1 hour ± 15 min and 2 hours ± 15 min post-infusion (Day 0), and 6 more samples will be drawn at 1, 2, 3, 4 (or 5 or 6), 7 (or 8), and 11±1 days post-infusion (DPI), at approximately the same time of day as the radiolabeled platelet infusion was administered (±4 hours). Duplicates of the subject's WB will be measured for radioactivity while singletons of all other samples will be evaluated. The following data information will be included in the calculation:

- Radiolabeling infusion date/time
- Elution of radioactivity from labeled platelets in whole blood
- Weight of syringe to be used for infusion including pre-infusion weight of filled syringe and post-infusion weight
- Weight of syringe in standard flasks (a total three flasks) including pre-infusion weight of filled syringe and post-infusion weight
- Mixed standard counted for weight and counts per minute (CPM) including pre-infusion values for empty tube and post-infusion values for filled tube
- Sample weights and CPMs with corresponding collection date/time for the radioactivity of the samples, determined by use of a gamma counter
- Individual sex and weight, height, and hematocrit value at Screening
- Standard solution volumes and densities

Methods: The post-infusion recovery and survival of INTERCEPT components will be assessed separately by the pre-radiolabeling platelet sample preparation (BEST vs. Variant 1), calculated based on the corrected radioactive counts observed from samples at 1, 2, 3, 4 (or 5 or 6), 7 (or 8) and 11 (±1) days post infusion (±4 hours). The post-infusion blood samples will be corrected for plasma associated radioisotope and the spontaneous in vitro and vivo dissociation (elution) of radiolabels using the Biomedical Excellence for Safer Transfusion (BEST) assessment method as described in the BEST version 4.2.1. A linear regression fitting model and a validated non-linear curve fitting model, the multiple-hit algorithm (from the COST program), will be used to estimate platelet recovery and lifespan based on the processed (fully adjusted) ^{51}Cr and ^{111}In counts, respectively.

Steps for calculations:

Step 1: Determine corrected CPM /g ($CPM_{corrected}$) of whole blood for each duplicate sample.
Formula:

$CPM_{corrected}$ (CPM/g) = CPM / WB Weight

Actual Derivation with respect to ^{51}Cr and ^{111}In:

Post-infusion $CPM_{corrected}$:
c_CPM_WBa = CPM_CrWBa/Wt_WBa;
c_CPM_WBb = CPM_CrWBb/Wt_WBb;

i_CPM_WBa = CPM_InWBa/Wt_WBa;
i_CPM_WBb = CPM_InWBb/Wt_WBb;

c_CPM_RBa = CPM_CrRBa/Wt_RBa;
c_CPM_RBb = CPM_CrRBb/Wt_RBb;
i_CPM_RBa = CPM_InRBa/Wt_RBa;
i_CPM_RBb = CPM_InRBb/Wt_RBb;

Due to collection of gamma counter data on two different days at Bloodworks Northwest Research Institute, the adjusted CPM at the last time point (Day 11 ± 1) will be used to determine the corrected CPM.

Adjusted CPM_CrWBa = exp(0.025*difft)* CPM_CrWBa
Adjusted CPM_CrWBb = exp(0.025*difft)* CPM_CrWBb
Adjusted CPM_InWBa = exp(0.24714*difft)* CPM_InWBa
Adjusted CPM_InWBb = exp(0.24714*difft)* CPM_InWBb
Adjusted CPM_CrRBa = exp(0.025*difft)* CPM_CrRBa
Adjusted CPM_CrRBb = exp(0.025*difft)* CPM_CrRBb
Adjusted CPM_InRBa = exp(0.24714*difft)* CPM_InRBa
Adjusted CPM_InRBb = exp(0.24714*difft)* CPM_InRBb

Where difft is the day difference (with decimal points accurate to minute) between Day 11 ± 1 and Day 7/8.

Pre-infusion $CPM_{corrected:}$
c_Pa = CPM_PreInfCra/(Wt_PreInf_WBaPos - Wt_PreInf_WBaPre) ;
i_Pa = CPM_PreInfIna/(Wt_PreInf_WBaPos - Wt_PreInf_WBaPre) ;
c_Pb = CPM_PreInfCrb/(Wt_PreInf_WBbPos - Wt_PreInf_WBbPre) ;
i_Pb = CPM_PreInfInb/(Wt_PreInf_WBbPos - Wt_PreInf_WBbPre) ;
if c_Pa < **0** then c_Pa = **0**;
if i_Pa < **0** then i_Pa = **0**;
if c_Pb < **0** then c_Pb = **0**;
if i_Pb < **0** then i_Pb = **0**;

Step 2: Determine Elution of Radioactivity from Labeled Platelets in Whole Blood

The activity found in the cells and supernatant plasma will be used to evaluate the in vivo cell-bound activity (elution) of the labeled platelets for each of the two radiolabels.

Formula:

Elution = $(CPM_{supernate})/[(CPM_{cells}) + (CPM_{supernate})]$

Actual Derivation with respect to ^{51}Cr and ^{111}In:

c_EA = (CPM_EluPLSCrA/abs(Wt_EluPLSPosA - Wt_EluPLSPreA))/(CPM_EluPLSCrA/abs(Wt_EluPLSPosA - Wt_EluPLSPreA) + CPM_EluRBCCrA/abs(Wt_EluRBCPosA - Wt_EluRBCPreA));

c_EB = (CPM_EluPLSCrB/abs(Wt_EluPLSPosB - Wt_EluPLSPreB))/(CPM_EluPLSCrB/abs(Wt_EluPLSPosB - Wt_EluPLSPreB) + CPM_EluRBCCrB/abs(Wt_EluRBCPosB - Wt_EluRBCPreB));

c_E = (c_EA + c_EB)/2;

i_EA = (CPM_EluPLSInA/abs(Wt_EluPLSPosA - Wt_EluPLSPreA))/(CPM_EluPLSInA/abs(Wt_EluPLSPosA - Wt_EluPLSPreA) + CPM_EluRBCInA/abs(Wt_EluRBCPosA - Wt_EluRBCPreA));

i_EB = (CPM_EluPLSInB/abs(Wt_EluPLSPosB - Wt_EluPLSPreB))/(CPM_EluPLSInB/abs(Wt_EluPLSPosB - Wt_EluPLSPreB) + CPM_EluRBCInB/abs(Wt_EluRBCPosB - Wt_EluRBCPreB));

i_E = (i_EA + i_EB)/2;

Note: Averaged activity found in the cells and supernatant plasma (elution) from two duplicate samples will be used.

Step 3: Determine Corrected Standard

All three standards are used and averaged to determine corrected Standard adjusted for injectate elution. Most gamma counters correct automatically for background activity and decay during counting as well as for "cross-up" and "cross-down". Corrected CPM values reported by the gamma counter ($CPM_{corrected}$), determine CPM/g for standards.

Formula:

Standard: STD = $CPM_{corrected}$ * dilution factor/mass counted, where dilution factor = mass of standard/mass of injectate added

Corrected standard: $STD_{corrected}$ = STD * (1-Elution)

Actual Derivation with respect to ^{51}Cr and ^{111}In:

c_S = ((CPM_StdCnt1Cr*StdSolnVol*Density/abs(Wt_SyrStd1Pos - Wt_SyrStd1Pre)/Wt_StdCnt1) + (CPM_StdCnt2Cr*StdSolnVol*Density/abs(Wt_SyrStd2Pos - Wt_SyrStd2Pre)/Wt_StdCnt2) + (CPM_StdCnt3Cr*StdSolnVol*Density/abs(Wt_SyrStd3Pos - Wt_SyrStd3Pre)/Wt_StdCnt3))/3 * (1- c_E);

i_S = ((CPM_StdCnt1In*StdSolnVol*Density/abs(Wt_SyrStd1Pos - Wt_SyrStd1Pre)/Wt_StdCnt1) + (CPM_StdCnt2In*StdSolnVol*Density/abs(Wt_SyrStd2Pos - Wt_SyrStd2Pre)/Wt_StdCnt2) + (CPM_StdCnt3In*StdSolnVol*Density/abs(Wt_SyrStd3Pos - Wt_SyrStd3Pre)/Wt_StdCnt3))/3 * (1- i_E);

Note: The density of the standard may be assumed to be **1.00**, and the final volume of the standard in mL may be taken as its mass in g. The averaged from three mixed standards will be used for the derivation of the corrected standard.

Step 4: Determine cell-bound proportion ($CBF_{Time\ t}$) for timed count adjustment, using timed split sample to calculate the proportion of the activity in each timed sample that can be associated with the cellular fraction.

Formula:

Cell Bound Fraction ($CBF_{Time\ t}$) = (Activity of cells)/(Activity of cells + Activity of plasma) = ($CPM_{cell\ bound}$)/[($CPM_{cell\ bound}$) + (CPM_{plasma})]

Actual Derivation with respect to ^{51}Cr and ^{111}In:

if CPM_CrRBC~=0 then c_CBF = (CPM_CrRBC/abs(Wt_RBCPos - Wt_RBCPre)) / (CPM_CrRBC/abs(Wt_RBCPos - Wt_RBCPre) + CPM_CrPLS/Wt_PLS);
if CPM_CrRBC=0 then c_CBF = 0;
if CPM_InRBC~=0 then i_CBF = (CPM_InRBC/abs(Wt_RBCPos - Wt_RBCPre)) / (CPM_InRBC/abs(Wt_RBCPos - Wt_RBCPre) + CPM_InPLS/Wt_PLS);
if CPM_InRBC=0 then i_CBF = 0;

Step 5: Determine adjusted CPM of Whole blood by Pre-infusion corrected CPM and Cell Bound Fraction.

Formula:

Adjusted $CPM_{corrected}$ at Time t = ($CPM_{corrected}$ at Time t - Pre-infusion $CPM_{corrected}$) × CBF.

Actual Derivation with respect to ^{51}Cr and ^{111}In:

```
c_CPM_WBaT = (c_CPM_WBa - c_Pa)*c_CBF;
c_CPM_WBbT = (c_CPM_WBb - c_Pb)*c_CBF;
i_CPM_WBaT = (i_CPM_WBa - i_Pa)*i_CBF;
i_CPM_WBbT = (i_CPM_WBb - i_Pb)*i_CBF;
```

Step 6: Calculate Fully Adjusted Count $_{Time\ t}$ at Time t post infusion with adjustment for cell-bound proportion (from Step 5) and non-platelet residual activity baseline

Formula:

Adjusted SAMPLE $_{Time\ t}$ (derived from Step 5) with further adjustment for non-platelet residual activity baseline

If last time point is on Day 10,

Fully adjusted count =adjusted SAMPLE $_{Time\ t}$ – [adjusted SAMPLE $_{Day\ 10}$ * (1.20-0.20 (Time t/Time of Day 10 sample)]

If last time point is on Day 11,

Fully adjusted count = adjusted SAMPLE $_{Time\ t}$ – [adjusted SAMPLE $_{Day\ 11}$ * (1.22-0.22 (Time t/Time of Day 11 sample)]

If last time point is on Day 12,

Fully adjusted count = adjusted SAMPLE $_{Time\ t}$ – [adjusted SAMPLE $_{Day\ 12}$ * (1.24-0.24 (Time t/Time of Day 12 sample)]

Actual Derivation with respect to ^{51}Cr and ^{111}In:

```
if 4<=Time_NominalL<=10 then do;
        c_CPM_WBaTr = c_CPM_WBaT - c_CPM_WBaTL*(1.20-0.20*Time/TimeL);
        c_CPM_WBbTr = c_CPM_WBbT - c_CPM_WBbTL*(1.20-0.20*Time/TimeL);
        i_CPM_WBaTr = i_CPM_WBaT - i_CPM_WBaTL*(1.20-0.20*Time/TimeL);
        i_CPM_WBbTr = i_CPM_WBbT - i_CPM_WBbTL*(1.20-0.20*Time/TimeL);
        end;
else if Time_NominalL=11 then do;
        c_CPM_WBaTr = c_CPM_WBaT - c_CPM_WBaTL*(1.22-0.22*Time/TimeL);
        c_CPM_WBbTr = c_CPM_WBbT - c_CPM_WBbTL*(1.22-0.22*Time/TimeL);
        i_CPM_WBaTr = i_CPM_WBaT - i_CPM_WBaTL*(1.22-0.22*Time/TimeL);
        i_CPM_WBbTr = i_CPM_WBbT - i_CPM_WBbTL*(1.22-0.22*Time/TimeL);
        end;
else do;
        c_CPM_WBaTr = c_CPM_WBaT - c_CPM_WBaTL*(1.24-0.24*Time/TimeL);
        c_CPM_WBbTr = c_CPM_WBbT - c_CPM_WBbTL*(1.24-0.24*Time/TimeL);
        i_CPM_WBaTr = i_CPM_WBaT - i_CPM_WBaTL*(1.24-0.24*Time/TimeL);
        i_CPM_WBbTr = i_CPM_WBbT - i_CPM_WBbTL*(1.24-0.24*Time/TimeL);
        end;

c_CPM = (c_CPM_WBaTr + c_CPM_WBbTr)/2;
i_CPM = (i_CPM_WBaTr + i_CPM_WBbTr)/2;
```

Note: Averaged fully adjusted Count $_{\text{Time t}}$ for each Time t post infusion from two sample will be used.

Step 7: Determination of expected Count $_{\text{Time 0}}$ at Time 0 following infusion

Formula:

Count $_{\text{Time 0}}$ = $STD_{corrected}$ * Infusate mass (g) / Blood mass (g)

Where

Blood mass (g) = specific gravity of 1.00 g/mL * BV (blood volume in ml)

and

Male : BV (mL) = ([0.3669*{height (m)}^{3}] + 0.03219*weight (kg) + 0.6041)*1000
Female: BV (mL) = ([0.3561*{height (m)}^{3}] + [0.03308*weight (kg)] + 0.1833)*1000

Actual Derivation with respect to ^{51}Cr and ^{111}In:

```
c_CPM0 = c_S*abs(Wt_SyrInfPre - Wt_SyrInfPos)/BM;
i_CPM0 = i_S*abs(Wt_SyrInfPre - Wt_SyrInfPos)/BM;
```

Where

if sex = "M" then BM = (**0.3669***(height***0.0254**)****3** + **0.03219***(weight***0.453592**) + **0.6041**)***1000** * (**1541**+Hct)/**1500**;
if sex = "F" then BM = (**0.3561***(height***0.0254**)****3** + **0.03308***(weight***0.453592**) + **0.1833**)***1000** * (**1541**+Hct)/**1500**;

Note: weight is collected in lb and height is collected in inch from raw datasets at sites. Hct refers to hematocrit lab result at screening.

Step 8: Determine observed recovery (%) for each fully adjusted timed sample

Formula:

Recovery $_{\text{Time t}}$ = Fully Adjusted Count $_{\text{Time t}}$ / Count $_{\text{Time 0}}$

Actual Derivation with respect to ^{51}Cr and ^{111}In:

```
c_SUR = c_CPM/c_CPM0 * 100;
i_SUR = i_CPM/i_CPM0 * 100;
```

Step 9: Estimate platelet recovery and lifespan based on the processed ^{51}Cr and ^{111}In counts by using a validated non-linear curve fitting routine, the multiple hit model, with the x-values (time after infusion in hours) and y-values (observed recovery (%) of fully adjusted timed sample count from Step 8) for each timed sample.

- If outliers are found, determine potential source of error and flag for review by medical director. Remove point from curve only if clearly a spurious result.

Sample Results

Data for Subject 001-103 Period 1 at Stage 1 are used.

subjid	Time_Nominal	Time	c_CPM0	c_CPM	c_SUR(%)	i_CPM0	i_CPM	i_SUR(%)	c_E	i_E
001-103	1	26.26667	299.9914	110.4417	36.81494	2820.502	1472.161	52.195	0.059866	0.020544
001-103	2	48.71667	299.9914	92.30779	30.77015	2820.502	1260.415	44.68763	0.059866	0.020544
001-103	3	73.38333	299.9914	71.39045	23.7975	2820.502	1169.268	41.45601	0.059866	0.020544
001-103	4	91.53333	299.9914	57.50313	19.16826	2820.502	894.9764	31.7311	0.059866	0.020544
001-103	7	171.55	299.9914	12.26417	4.088176	2820.502	322.8039	11.44491	0.059866	0.020544
001-103	10	243.75	299.9914	0	0	2820.502	0	0	0.059866	0.020544

Unit for CPM variables is counts/g; Elution is a ratio

Results of Recovery and Survival

Primary Analysis (as stated in the protocol) - Using Non-linear Curve Fitting Routine, the Multiple Hit Model:

Recovery_Cr_MultiHit	Survival_Cr_MultiHit	Recovery_In_MultiHit	Survival_In_MultiHit
44.14293	159.5706	59.84595	207.1509

Table of Contents

General notes for mock tables

Unless stated otherwise, data will be tabulated by stage in three sets:
(1) Stage 1 (i.e., Tables with a table number as x.x.x.a)
(2) Stage 2, which will include Stage 1 subjects with evaluable Variant 1 method data (i.e., Tables with a table number as x.x.x.b)
(2) New subjects from stage 2 (i.e., Tables with a table number as x.x.x.c)

The mock-up for Stage 1 tables are provided in the rest of document. Unless noted otherwise, tables for Stage 2 and Stage 3 will have the same variables summarized as shown in the corresponding Stage 1 tables but only with relevant columns presented.

Table 1.1.1.a. Eligibility and Radiolabeling Randomization (Stage 1, Consented Subjects)

	Hoxworth (N = xx)	Bloodworks (N = xx)	Total (N = xx)
Met All Eligibility Criteria for Both Periods [1]			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Criteria Not Met for Period 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Criteria Met for Period 1 But Not Met for Period 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subjects with Test Variant 1 in Period 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subjects with Test BEST in Period 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)
Randomized Radiolabeling Assignment for Test/Control [2]			
$^{111}In/^{51}Cr$	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
$^{51}Cr/^{111}In$	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)

[1] Stage 1 subjects without the Eligibility CRF for Period 2 are considered as criteria not met for Period 2.
[2] For a given subject, the radioisotope for Test PCs is the same for both BEST and Variant 1 methods in Stage 1.
Reference: Listing 1.1.

Table 1.1.1.b. Eligibility and Radiolabeling Randomization (Stage 2, Consented Subjects)

	Hoxworth (N = xx)	Bloodworks (N = xx)	Total (N = xx)
Met All Eligibility Criteria			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)
Randomized Radiolabeling Assignment for Test/Control			
$^{111}In/^{51}Cr$	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
$^{51}Cr/^{111}In$	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)

Reference: Listing 1.1.

Programming note:
Table 1.1.1.c. Eligibility and Radiolabeling Randomization (New Subjects from Stage 2, Consented Subjects)
Table 1.1.2.a. Eligibility and Radiolabeling Randomization (Stage 1, Safety Set)
Table 1.1.2.b. Eligibility and Radiolabeling Randomization (Stage 2, Safety Set)
Table 1.1.2.c. Eligibility and Radiolabeling Randomization (New Subjects from Stage 2, Safety Set)
Note: Safety Set includes subjects who initiated any apheresis collection per the “Platelet Apheresis Collection and Storage” CRF.

Table 1.1.3.a. Eligibility and Radiolabeling Randomization (Stage 1, EAS)
Table 1.1.3.b. Eligibility and Radiolabeling Randomization (Stage 2, EAS)
Table 1.1.3.c. Eligibility and Radiolabeling Randomization (New Subjects from Stage 2, EAS)
Note: Evaluable Analysis Set (EAS) includes infused subjects who had paired (referred to Test and Control) recovery and paired survival data from at least one treatment period and without any major protocol/procedure deviation impacting the primary efficacy outcome.

Table 1.2.1.a. Study Completion and Protocol/Procedural Deviation (Stage 1, Consented Subjects)

	Hoxworth (N = xx)	Bloodworks (N = xx)	Total (N = xx)
Analysis Set			
Randomized Subjects	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Safety Set [1]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Evaluable Analysis Set (EAS) [2]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Completer Analysis Set (CAS) [3]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Study Completion			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Adverse Events	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Significant Protocol Deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Screen Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Withdrew of Consent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost to Follow-up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Death	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Investigator Discretion	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Study Termination	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)
Withdrawal Related to COVID-19			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subject Acquired COVID-19	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subject Discretion	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Travel Restrictions	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Site Closed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)
Any Protocol/Procedural Deviations [4]			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Protocol Deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Procedural Deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)

Any Deviation Reportable to IRB			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)
Any Deviation Related to COVID-19 Impact			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)

[1] Safety Set includes subjects who initiated any apheresis collection per the "Platelet Apheresis Collection and Storage" CRF.
[2] Evaluable Analysis Set (EAS) includes infused subjects who had paired (referred to Test and Control) recovery and paired survival data from at least one treatment period and without any major protocol/procedure deviation impacting the primary efficacy outcome.
[3] Completer Analysis Set (CAS) is for Stage 1 only and includes subjects in the EAS who completed both treatment periods.
[4] The sum across subcategories may exceed the total subject count since some subjects had more than one type of deviations.
Reference: Listings 1.2 and 1.3.

Table 1.2.1.b. Study Completion and Protocol/Procedural Deviation (Stage 2, Consented Subjects)

	Hoxworth (N = xx)	Bloodworks (N = xx)	Total (N = xx)
Analysis Set			
Randomized Subjects	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Safety Set [1]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Evaluable Analysis Set (EAS) [2]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Study Completion			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Adverse Events	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Significant Protocol Deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Screen Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Withdrew of Consent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost to Follow-up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Death	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Investigator Discretion	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Study Termination	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)
Withdrawal Related to COVID-19			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subject Acquired COVID-19	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subject Discretion	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Travel Restrictions	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Site Closed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)
Any Protocol/Procedural Deviations [3]			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Protocol Deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Procedural Deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)

Any Deviation Reportable to IRB			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)
Any Deviation Related to COVID-19 Impact			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)

[1] Safety Set includes subjects who initiated any apheresis collection per the "Platelet Apheresis Collection and Storage" CRF.
[2] Evaluable Analysis Set (EAS) includes infused subjects who had paired (referred to Test and Control) recovery and paired survival data from at least one treatment period and without any major protocol/procedure deviation impacting the primary efficacy outcome.
[3] The sum across subcategories may exceed the total subject count since some subjects had more than one type of deviations.
Reference: Listings 1.2 and 1.3.

Programming note:
Table 1.2.1.c. Study Completion and Protocol/Procedural Deviation (New Subjects from Stage 2, Consented Subjects)
Table 1.2.2.a. Study Completion and Protocol/Procedural Deviation (Stage 1, Safety Set)
Table 1.2.2.b. Study Completion and Protocol/Procedural Deviation (Stage 2, Safety Set)
Table 1.2.2.c. Study Completion and Protocol/Procedural Deviation (New Subjects from Stage 2, Safety Set)
Table 1.2.3.a. Study Completion and Protocol/Procedural Deviation (Stage 1, EAS)
Table 1.2.3.b. Study Completion and Protocol/Procedural Deviation (Stage 2, EAS)
Table 1.2.3.c. Study Completion and Protocol/Procedural Deviation (New Subjects from Stage 2, EAS)

Table 2.1.1.a. Demographics and Baseline Characteristics (Stage 1, Safety Set)

	Hoxworth (N = xx)	Bloodworks (N = xx)	Total (N = xx)
Age (Year)			
N	xxx	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Gender			
Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)
Ethnicity			
Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Hispanic of Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)
Race			
White	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Non-White	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Black or African American	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
American Indian or Alaska Native	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Asian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Native Hawaiian or Pacific Islander	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)
Blood Type			
A	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
B	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
O	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
AB	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)
Rh Factor			
Negative	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Positive	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)
Height (cm) [2]			
N	xxx	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx	xx	xx

Min to Max	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Weight (kg) [2]			
N	xxx	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
BMI [2]			
N	xxx	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)

[1] The sum across subcategories may exceed the total subject count since some subjects may report multiple races.
[2] The Day 0 value will be used. If the values at Day 0 are missing, the values at Screening will be used. The Screening assessments (collected at period 1) will be shared in both periods. Body mass index (BMI) is calculated as weight in kilogram divided by height in meter squared.
Reference: Listings 2.1 and 3.3

Programming note:
Table 2.1.1.b. Demographics and Baseline Characteristics (Stage 2, Safety Set)
Table 2.1.1.c. Demographics and Baseline Characteristics (New Subjects from Stage 2, Safety Set)
Table 2.1.2.a. Demographics and Baseline Characteristics (Stage 1, EAS)
Table 2.1.2.b. Demographics and Baseline Characteristics (Stage 2, EAS)
Table 2.1.2.c. Demographics and Baseline Characteristics (New Subjects from Stage 2, EAS)

For table 2.1.x series, ‘b’ and ‘c’ sub-tables are following the same format as ‘a.’

Table 2.2.a. Substance Use (Stage 1, Safety Set)

	Hoxworth		Bloodworks		Total	
	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)
Screening [1]						
Nicotine Use						
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)
Cannabis Use						
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)
Day 0						
…						
Day 7						
…						
0 DPI (1hr±15mins)						
…						
0 DPI (2hr±15mins)						
…						
1 DPI						
…						
2 DPI						
…						
3 DPI						
…						
4, 5 or 6 DPI						
…						
7 or 8 DPI						
…						

11±1 DPI

…

Note: The following notes and abbreviations apply to all tables (as applicable).
For Stage 1, the columns "Test: Variant 1" and "Test: BEST" summarize the numbers of subjects randomized to Variant 1 and BEST sample preparation methods, respectively, for Test platelet components (PCs) in both periods.
Abbreviation: DPI = day post infusion.
Note: This table summarizes the use of nicotine or cannabis within the past 48 hours from each nominal visit.
[1] Data from Screening visit (collected at Period 1) are summarized under the randomized Test method for Period 1.
Reference: Listing 2.2.

Table 2.2.b. Substance Use (Stage 2, Safety Set)

	Hoxworth (N = xx)	Bloodworks (N = xx)	Total (N = xx)
Screening			
Nicotine Use			
Yes	xx (xx.x%)		
No	xx (xx.x%)		
Total	xx (100%)		
Cannabis Use			
Yes	xx (xx.x%)		
No	xx (xx.x%)		
Total	xx (100%)		
Day 0			
…			
Day 7			
…			
0 DPI (1hr±15mins)			
…			
0 DPI (2hr±15mins)			
…			
1 DPI			
…			
2 DPI			
…			
3 DPI			
…			
4, 5 or 6 DPI			
…			
7 or 8 DPI			
…			

11±1 DPI
…

Note: This table summarizes the use of nicotine or cannabis within the past 48 hours from each nominal visit.
Reference: Listing 2.2.

Programming note:
Table 2.2.c. Substance Use (New Subjects from Stage 2, Safety Set)
All the rest of tables with table format like Table 2.2.a will have their 'b' and 'c' tables using the same format as Table 2.2.b.

Table 2.3.a. Physical Examination (Stage 1, Safety Set)

	Hoxworth		Bloodworks		Total	
	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)
Screening [1]						
Physical Examination Performed						
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)
Skin Test						
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Done	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)
EENT Test						
. . .						
Head/Neck Test						
. . .						
Pulmonary Test						
. . .						
Chest Test						
. . .						
Cardiovascular Test						
. . .						
Abdominal and Liver/Spleen Test						
. . .						
Lymphatic Test						
. . .						

Musculoskeletal Test

. . .

Neurological Test

. . .

11±1 DPI

. . .

Change from Screening at 11±1 DPI

Skin Test

- From Normal to Abnormal
  - To CS
  - To Not CS
- From Abnormal to Normal
  - From CS
  - From Not CS
- No Change: Abnormal at Both Visits
  - Not CS to CS
  - CS to Not CS
  - CS to CS or Not CS to Not CS
- No Change: Normal at Both Visits
- Indeterminable
- Total

…

Note: Abbreviation: CS = Clinically Significant.
[1] Data from Screening visit (collected at Period 1) are summarized under the randomized Test method for Period 1.
Reference: Listings 2.3.1 and 2.3.2.

Programming note:
Table 2.3.b. Physical Examination (Stage 2, Safety Set)
Table 2.3.c. Physical Examination (New Subjects from Stage 2, Safety Set)

Table 3.1.1.a. Recovery and Survival Post Infusion (Stage 1, EAS)

	Comparison 1			Comparison 2			Comparison 3		
	Test Variant 1 (N = xx)	Control BEST (N = xx)	T-ΔC[1] (N = xx)	Test BEST (N = xx)	Control BEST (N = xx)	T-ΔC[1] (N = xx)	Test Variant 1 (N = xx)	Test BEST (N = xx)	V-B[1] (N = xx)
Overall									
Recovery (%)									
N	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min to Max	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
95% CI for Mean	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Test ≥ 0.66 × Control									
Yes	xx (xx.x%)			xx (xx.x%)					
No	xx (xx.x%)			xx (xx.x%)					
1-sided 95% CI for Yes	>= xx.x%			>= xx.x%					
Survival (Hour)									
N	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean (SD)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)
Median	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
Min to Max	xxx.x to xxx.x	xxx.x to xxx.x	xxx.x to xxx.x	xxx.x to xxx.x	xxx.x to xxx.x	xxx.x to xxx.x	xxx.x to xxx.x	xxx.x to xxx.x	xxx.x to xxx.x
95% CI for Mean	(xxx.x,xxx.x)	(xxx.x,xxx.x)	(xxx.x,xxx.x)	(xxx.x,xxx.x)	(xxx.x,xxx.x)	(xxx.x,xxx.x)	(xxx.x,xxx.x)	(xxx.x,xxx.x)	(xxx.x,xxx.x)
Test ≥ 0.58 × Control									
Yes	xx (xx.x%)			xx (xx.x%)					
No	xx (xx.x%)			xx (xx.x%)					
1-sided 95% CI for Yes	>= xx.x%			>= xx.x%					
Site 001 [Hoxworth]									
. . .									
Site 002 [Bloodworks]									
. . .									
Radiolabeling: Test=^{51}Cr									
. . .									
Radiolabeling: Test=^{111}In									
. . .									

Note: Only subjects with available pair values for Test BEST and TEST Variant 1 will be presented under Comparison 3.
[1] T - ΔC = Test - (Δ × Control), where Δ = 0.66 and 0.58 for recovery and survival, respectively. V – B = (Test Variant 1) – (Test BEST). Two-sided 95% confidence interval (CI) for the mean treatment difference is based on a paired T-Test.
Reference: Listing 4.3.

Programming Note: This mock table (or the mock table provided below for Table 3.1.1.b) will be repeated for the following sub-tables.

Table 3.1.1.b. Recovery and Survival Post Infusion (Stage 2, EAS)
Table 3.1.1.c. Recovery and Survival Post Infusion (New Subjects from Stage 2, EAS)
Table 3.1.2.a. Recovery and Survival Post Infusion (Stage 1, EAS, Subjects with BEST Test PCs for Period 1)
Table 3.1.3.a. Recovery and Survival Post Infusion (Stage 1, EAS, Subjects with Variant 1 Test PCs for Period 1)
Table 3.1.4.a. Recovery and Survival Post Infusion (Stage 1, CAS)
Table 3.1.5.a. Recovery and Survival Post Infusion (Stage 1, CAS, Subjects with BEST Test PCs for Period 1)
Table 3.1.6.a. Recovery and Survival Post Infusion (Stage 1, CAS, Subjects with Variant 1 Test PCs for Period 1)

Table 3.1.1.b. Recovery and Survival Post Infusion (Stage 2, EAS)

	Test Variant 1 (N = xx)	Control BEST (N = xx)	T-ΔC[1] (N = xx)
Overall			
Recovery (%)			
N	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x
Min to Max	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
95% CI for Mean	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Test ≥ 0.66 × Control			
Yes	xx (xx.x%)		
No	xx (xx.x%)		
1-sided 95% CI for Yes	>= xx.x%		
Survival (Hour)			
N	xx	xx	xx
Mean (SD)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)
Median	xxx.x	xxx.x	xxx.x
Min to Max	xxx.x to xxx.x	xxx.x to xxx.x	xxx.x to xxx.x
95% CI for Mean	(xxx.x,xxx.x)	(xxx.x,xxx.x)	(xxx.x,xxx.x)
Test ≥ 0.58 × Control			
Yes	xx (xx.x%)		
No	xx (xx.x%)		
1-sided 95% CI for Yes	>= xx.x%		
Site 001 [Hoxworth]			
. . .			
Site 002 [Bloodworks]			
. . .			
Radiolabeling: Test=^{51}Cr			
. . .			
Radiolabeling: Test=^{111}In			
. . .			

[1] T - ΔC = Test - (Δ × Control), where Δ = 0.66 and 0.58 for recovery and survival, respectively. Two-sided 95% confidence interval (CI) for the mean treatment difference is based on a paired T-Test.
Reference: Listing 4.3.

Table 3.2.1.1.a. Product Parameters Evaluation of Platelet Components (Stage 1, Safety Set)

	Hoxworth		Bloodworks		Total	
	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)
Platelet Dose at End of INTERCEPT ($\times 10^{11}$/unit)						
N	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)
$\geq 3.0 \times 10^{11}$						
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1-sided 95% CI for Yes	>= xx.x%	>= xx.x%	>= xx.x%	>= xx.x%	>= xx.x%	>= xx.x%
Platelet Yield Retention at End of INTERCEPT (%)						
N	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)
≥ 80%	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	>= xx.x%	xx (xx.x%)	>= xx.x%	xx (xx.x%)	>= xx.x%
1-sided 95% CI for Yes	>= xx.x%	>= xx.x%	>= xx.x%	>= xx.x%	>= xx.x%	>= xx.x%
pH 22° C at End of Storage						
N	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)
≥ 6.2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1-sided 95% CI for Yes	>= xx.x%	>= xx.x%	>= xx.x%	>= xx.x%	>= xx.x%	>= xx.x%

Reference: Listings 3.9 and 3.13.3.

Programming note: This mock table (or the mock table provided below for Table 3.2.1.1.d) will be repeated for the following sub-tables.

Table 3.2.1.1.b. Product Parameters Evaluation of Platelet Components (Stage 2, Safety Set)
Table 3.2.1.1.c. Product Parameters Evaluation of Platelet Components (New Subjects from Stage 2, Safety Set)
Table 3.2.1.1.d. Product Parameters Evaluation of Platelet Components (Per-Component Analysis by Stage, Safety Set)
Table 3.2.1.2.a. Product Parameters Evaluation of Platelet Components (Stage 1, EAS)
Table 3.2.1.2.b. Product Parameters Evaluation of Platelet Components (Stage 2, EAS)
Table 3.2.1.2.c. Product Parameters Evaluation of Platelet Components (New Subjects from Stage 2, EAS)
Table 3.2.1.2.d. Product Parameters Evaluation of Platelet Components (Per-Component Analysis by Stage, EAS)
Table 3.2.2.a. Product Parameters Evaluation of Platelet Components (Stage 1, EAS, Subjects with BEST Test PCs for Period 1)
Table 3.2.3.a. Product Parameters Evaluation of Platelet Components (Stage 1, EAS, Subjects with Variant 1 Test PCs for Period 1)
Table 3.2.4.a. Product Parameters Evaluation of Platelet Components (Stage 1, CAS)
Table 3.2.5.a. Product Parameters Evaluation of Platelet Components (Stage 1, CAS, Subjects with BEST Test PCs for Period 1)
Table 3.2.6.a. Product Parameters Evaluation of Platelet Components (Stage 1, CAS, Subjects with Variant 1 Test PCs for Period 1)

Table 3.2.1.1.d. Product Parameters Evaluation of Platelet Components (Per-Component Analysis by Stage, Safety Set)

	Stage 1 (N = xx)	Stage 2 (N = xx)	Overall (N = xx)
Platelet Dose at End of INTERCEPT ($\times 10^{11}$/unit)			
N	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)
$\geq 3.0 \times 10^{11}$			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1-sided 95% CI for Yes	>= xx.x%	>= xx.x%	>= xx.x%
Platelet Yield Retention at End of INTERCEPT (%)			
N	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)
≥ 80%	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1-sided 95% CI for Yes	>= xx.x%	>= xx.x%	>= xx.x%
pH 22˚C at End of Storage			
N	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)
≥ 6.2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1-sided 95% CI for Yes	>= xx.x%	>= xx.x%	>= xx.x%

Note: Stage 1 column includes data from both periods in Stage 1. A subject at Stage 1 can be counted twice if he/she has evaluable Variant 1 and BEST data from both periods. Stage 2 column includes evaluable Variant 1 data from Stage 1 and new subjects collected in Stage 2. Overall column includes data from both periods in Stage 1 and data for new subjects enrolled in Stage 2.
Reference: Listings 3.9 and 3.13.3.

Table 3.3.1.1.1.a. In Vitro Platelet Function: Platelet Count ($\times 10^3/\mu L$) (Stage 1, Safety Set)

	Hoxworth			Bloodworks			Total		
	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)
Input Day 0-1									
N	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx	xx	xx	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)
Input Day 0-1 (Normalized)									
…									
Post-INTERCEPT									
…									
Post-INTERCEPT (Normalized)									
…									
Change from Input at Post-INTERCEPT									
…									
Change from Input at Post-INTERCEPT (Normalized)									
…									
End of Storage									
…									
End of Storage (Normalized)									
…									
Change from Input at End of Storage									
…									
Change from Input at End of Storage (Normalized)									
…									
Change from Post-INTERCEPT at End of Storage									
…									

Change from Post-INTERCEPT at End of Storage (Normalized)	
…	
Before Radiolabeling	
…	
Change from End of Storage at Before Radiolabeling	
…	
Before Radiolabeling – ^{51}Cr only	(Only for Platelet Count)
…	
Before Radiolabeling – ^{111}In only	(Only for Platelet Count)
…	

[1] V – B = (Test Variant 1) – (Test BEST).
Reference: Listings 3.13.1, 3.13.2, and 3.13.3.
(IV_INP, INT_FIN, IV_END,IV_PLT)

Table 3.3.1.1.1.b. In Vitro Platelet Function: Platelet Count ($\times 10^3/\mu L$) (Stage 2, Safety Set)

	Hoxworth (N = xx)	Bloodworks (N = xx)	Total (N = xx)
Input Day 0-1			
N	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x
Median	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)
Input Day 0-1 (Normalized)			
…			
Post-INTERCEPT			
…			
Post-INTERCEPT (Normalized)			
…			
Change from Input at Post-INTERCEPT			
…			
Change from Input at Post-INTERCEPT (Normalized)			
…			
End of Storage			
…			
End of Storage (Normalized)			
…			
Change from Input at End of Storage			
…			
Change from Input at End of Storage (Normalized)			
…			
Change from Post-INTERCEPT at End of Storage			
…			
Change from Post-INTERCEPT at End of Storage (Normalized)			
…			
Before Radiolabeling			
…			

Change from End of Storage at Before Radiolabeling

…

Before Radiolabeling – ^{51}Cr only	(Only for 3.3.1.1.2.x, 3.3.1.1.21.x, and 3.3.1.1.22.x)

…

Before Radiolabeling – ^{111}In only	(Only for 3.3.1.1.2.x, 3.3.1.1.21.x, and 3.3.1.1.22.x)

…

Reference: Listings 3.13.1, 3.13.2, and 3.13.3.

Programming note:
Only show rows with available time points. The "Change from A at B" is only shown when A is the previous time point of B for the specific assays. For tables with any exceptions, the complete list of "Change from" are provided below.

All the rest of tables with table format like Table 3.3.1.1.a will have their 'b' and 'c' tables using the same format as Table 3.3.1.1.b and 3.3.1.1.c.

Table 3.3.1.1.1.a. In Vitro Platelet Function: Platelet Count ($\times 10^3/\mu L$) (Stage 1, Safety Set)
(IV_INP, INT_FIN, IV_END,IV_PLT)
Table 3.3.1.1.1.b. In Vitro Platelet Function: Platelet Count ($\times 10^3/\mu L$) (Stage 2, Safety Set)
Table 3.3.1.1.1.c. In Vitro Platelet Function: Platelet Count ($\times 10^3/\mu L$) (New Subjects from Stage 2, Safety Set)
Table 3.3.1.1.1.d. In Vitro Platelet Function: Platelet Count ($\times 10^3/\mu L$) (Per-Component Analysis by Stage, Safety Set)

Table 3.3.1.1.2.a. In Vitro Platelet Function: Platelet Count ($\times 10^3/\mu L$) (Stage 1, EAS)
Table 3.3.1.1.2.b. In Vitro Platelet Function: Platelet Count ($\times 10^3/\mu L$) (Stage 2, EAS)
Table 3.3.1.1.2.c. In Vitro Platelet Function: Platelet Count ($\times 10^3/\mu L$) (New Subjects from Stage 2, EAS)
Table 3.3.1.1.2.d. In Vitro Platelet Function: Platelet Count ($\times 10^3/\mu L$) (Per-Component Analysis by Stage, EAS)
(Change from Input at Post-INTERCEPT, Change from Post-INTERCEPT at End of Storage, Change from Input at Before Radiolabeling)

Table 3.3.1.2.1.a. In Vitro Platelet Function: Component Volume (mL) (Stage 1, Safety Set)
(IV_INP, INT_FIN, IV_END)
Table 3.3.1.2.1.b. In Vitro Platelet Function: Component Volume (mL) (Stage 2, Safety Set)
Table 3.3.1.2.1.c. In Vitro Platelet Function: Component Volume (mL) (New Subjects from Stage 2, Safety Set)
Table 3.3.1.2.1.d. In Vitro Platelet Function: Component Volume (mL) (Per-Component Analysis by Stage, Safety Set)

Table 3.3.1.2.2.a. In Vitro Platelet Function: Component Volume (mL) (Stage 1, EAS)
Table 3.3.1.2.2.b. In Vitro Platelet Function: Component Volume (mL) (Stage 2, EAS)
Table 3.3.1.2.2.c. In Vitro Platelet Function: Component Volume (mL) (New Subjects from Stage 2, EAS)
Table 3.3.1.2.2.d. In Vitro Platelet Function: Component Volume (mL) (Per-Component Analysis by Stage, EAS)

(Change from Input at Post-INTERCEPT, Change from Input at End of Storage)
For End of Storage volume, please present Corrected and Uncorrected ones.

End of Storage (Uncorrected)
…

End of Storage (Corrected) [1]
…

Change from Input at End of Storage (Uncorrected)
…

Change from Input at End of Storage (Corrected)

Add footnote: End of storage volume will be corrected for sampling taken during the storage process including the sampling for the post-INTERCEPT sample, bacterial culture sample, and the sample removed for radiolabeling.

Table 3.3.1.3.1.a. In Vitro Platelet Function: Platelet Dose (×10^{11}/unit) (Stage 1, Safety Set)
(IV_INP, INT_FIN, IV_END)
Table 3.3.1.3.1.b. In Vitro Platelet Function: Platelet Dose (×10^{11}/unit) (Stage 2, Safety Set)
Table 3.3.1.3.1.c. In Vitro Platelet Function: Platelet Dose (×10^{11}/unit) (New Subjects from Stage 2, Safety Set)
Table 3.3.1.3.1.d. In Vitro Platelet Function: Platelet Dose (×10^{11}/unit) (Per-Component Analysis by Stage, Safety Set)

Table 3.3.1.3.2.a. In Vitro Platelet Function: Platelet Dose (×10^{11}/unit) (Stage 1, EAS)
Table 3.3.1.3.2.b. In Vitro Platelet Function: Platelet Dose (×10^{11}/unit) (Stage 2, EAS)
Table 3.3.1.3.2.c. In Vitro Platelet Function: Platelet Dose (×10^{11}/unit) (New Subjects from Stage 2, EAS)
Table 3.3.1.3.2.d. In Vitro Platelet Function: Platelet Dose (×10^{11}/unit) (Per-Component Analysis by Stage, EAS)

(Change from Input at Post-INTERCEPT, Change from Input at End of Storage)
For End of Storage dose, please present Corrected and Uncorrected ones based on corrected/uncorrected volume.

End of Storage (Uncorrected)
…

End of Storage (Corrected) [1]
…

Change from Input at End of Storage (Uncorrected)
…

Add footnote: End of storage dose will be corrected by corrected volume.

Table 3.3.1.4.1.a. In Vitro Platelet Function: Glucose (mmol/L) and Normalized Glucose (mmol/10^{12}) (Stage 1, Safety Set)
(x,x,IV_END,x)
Table 3.3.1.4.1.b. In Vitro Platelet Function: Glucose (mmol/L) and Normalized Glucose (mmol/10^{12}) (Stage 2, Safety Set)
Table 3.3.1.4.1.c. In Vitro Platelet Function: Glucose (mmol/L) and Normalized Glucose (mmol/10^{12}) (New Subjects from Stage 2, Safety Set)
Table 3.3.1.4.1.d. In Vitro Platelet Function: Glucose (mmol/L) and Normalized Glucose (mmol/10^{12}) (Per-Component Analysis by Stage, Safety Set)

Table 3.3.1.4.2.a. In Vitro Platelet Function: Glucose (mmol/L) and Normalized Glucose (mmol/10^{12}) (Stage 1, EAS)
Table 3.3.1.4.2.b. In Vitro Platelet Function: Glucose (mmol/L) and Normalized Glucose (mmol/10^{12}) (Stage 2, EAS)
Table 3.3.1.4.2.c. In Vitro Platelet Function: Glucose (mmol/L) and Normalized Glucose (mmol/10^{12}) (New Subjects from Stage 2, EAS)
Table 3.3.1.4.2.d. In Vitro Platelet Function: Glucose (mmol/L) and Normalized Glucose (mmol/10^{12}) (Per-Component Analysis by Stage, EAS)

Table 3.3.1.5.1.a. In Vitro Platelet Function: Lactate (mmol/L) and Normalized Lactate (mmol/10^{12}) (Stage 1, Safety Set)
(x,x,IV_END,x)
Table 3.3.1.5.1.b. In Vitro Platelet Function: Lactate (mmol/L) and Normalized Lactate (mmol/10^{12}) (Stage 2, Safety Set)
Table 3.3.1.5.1.c. In Vitro Platelet Function: Lactate (mmol/L) and Normalized Lactate (mmol/10^{12}) (New Subjects from Stage 2, Safety Set)
Table 3.3.1.5.1.d. In Vitro Platelet Function: Lactate (mmol/L) and Normalized Lactate (mmol/10^{12}) (Per-Component Analysis by Stage, Safety Set)

Table 3.3.1.5.2.a. In Vitro Platelet Function: Lactate (mmol/L) and Normalized Lactate (mmol/10^{12}) (Stage 1, EAS)
Table 3.3.1.5.2.b. In Vitro Platelet Function: Lactate (mmol/L) and Normalized Lactate (mmol/10^{12}) (Stage 2, EAS)
Table 3.3.1.5.2.c. In Vitro Platelet Function: Lactate (mmol/L) and Normalized Lactate (mmol/10^{12}) (New Subjects from Stage 2, EAS)
Table 3.3.1.5.2.d. In Vitro Platelet Function: Lactate (mmol/L) and Normalized Lactate (mmol/10^{12}) (Per-Component Analysis by Stage, EAS)

Table 3.3.1.6.1.a. In Vitro Platelet Function: pO_2 (mm Hg) and Normalized pO_2 @ 37°C (µmol/hour/10^{12}) (Stage 1, Safety Set)
(x,x,IV_END,x)
Table 3.3.1.6.1.b. In Vitro Platelet Function: pO_2 (mm Hg) and Normalized pO_2 @ 37°C (µmol/hour/10^{12}) (Stage 2, Safety Set)
Table 3.3.1.6.1.c. In Vitro Platelet Function: pO_2 (mm Hg) and Normalized pO_2 @ 37°C (µmol/hour/10^{12}) (New Subjects from Stage 2, Safety Set)
Table 3.3.1.6.1.d. In Vitro Platelet Function: pO_2 (mm Hg) and Normalized pO_2 @ 37°C (µmol/hour/10^{12}) (Per-Component Analysis by Stage, Safety Set)

Table 3.3.1.6.2.a. In Vitro Platelet Function: pO_2 (mm Hg) and Normalized pO_2 @ 37°C (µmol/hour/10^{12}) (Stage 1, EAS)
Table 3.3.1.6.2.b. In Vitro Platelet Function: pO_2 (mm Hg) and Normalized pO_2 @ 37°C (µmol/hour/10^{12}) (Stage 2, EAS)
Table 3.3.1.6.2.c. In Vitro Platelet Function: pO_2 (mm Hg) and Normalized pO_2 @ 37°C (µmol/hour/10^{12}) (New Subjects from Stage 2, EAS)
Table 3.3.1.6.2.d. In Vitro Platelet Function: pO_2 (mm Hg) and Normalized pO_2 @ 37°C (µmol/hour/10^{12}) (Per-Component Analysis by Stage, EAS)

Table 3.3.1.7.1.a. In Vitro Platelet Function: pCO_2 (mm Hg) and Normalized pCO_2 @ 37°C (µmol/hour/10^{12}) (Stage 1, Safety Set)
(x,x,IV_END,x)
Table 3.3.1.7.1.b. In Vitro Platelet Function: pCO_2 (mm Hg) and Normalized pCO_2 @ 37°C (µmol/hour/10^{12}) (Stage 2, Safety Set)
Table 3.3.1.7.1.c. In Vitro Platelet Function: pCO_2 (mm Hg) and Normalized pCO_2 @ 37°C (µmol/hour/10^{12}) (New Subjects from Stage 2, Safety Set)
Table 3.3.1.7.1.d. In Vitro Platelet Function: pCO_2 (mm Hg) and Normalized pCO_2 @ 37°C (µmol/hour/10^{12}) (Per-Component Analysis by Stage, Safety Set)

Table 3.3.1.7.2.a. In Vitro Platelet Function: pCO_2 (mm Hg) and Normalized pCO_2 @ 37°C (µmol/hour/10^{12}) (Stage 1, EAS)
Table 3.3.1.7.2.b. In Vitro Platelet Function: pCO_2 (mm Hg) and Normalized pCO_2 @ 37°C (µmol/hour/10^{12}) (Stage 2, EAS)
Table 3.3.1.7.2.c. In Vitro Platelet Function: pCO_2 (mm Hg) and Normalized pCO_2 @ 37°C (µmol/hour/10^{12}) (New Subjects from Stage 2, EAS)
Table 3.3.1.7.2.d. In Vitro Platelet Function: pCO_2 (mm Hg) and Normalized pCO_2 @ 37°C (µmol/hour/10^{12}) (Per-Component Analysis by Stage, EAS)

Table 3.3.1.8.1.a. In Vitro Platelet Function: HCO_3^- and Normalized HCO_3^- @ 37°C (mmol/L) (Stage 1, Safety Set)
(x,x,IV_END,x)
Table 3.3.1.8.1.b. In Vitro Platelet Function: HCO_3^- and Normalized HCO_3^- @ 37°C (mmol/L) (Stage 2, Safety Set)
Table 3.3.1.8.1.c. In Vitro Platelet Function: HCO_3^- and Normalized HCO_3^- @ 37°C (mmol/L) (New Subjects from Stage 2, Safety Set)
Table 3.3.1.8.1.d. In Vitro Platelet Function: HCO_3^- and Normalized HCO_3^- @ 37°C (mmol/L) (Per-Component Analysis by Stage, Safety Set)

Table 3.3.1.8.2.a. In Vitro Platelet Function: HCO_3^- and Normalized HCO_3^- @ 37°C (mmol/L) (Stage 1, EAS)
Table 3.3.1.8.2.b. In Vitro Platelet Function: HCO_3^- and Normalized HCO_3^- @ 37°C (mmol/L) (Stage 2, EAS)
Table 3.3.1.8.2.c. In Vitro Platelet Function: HCO_3^- and Normalized HCO_3^- @ 37°C (mmol/L) (New Subjects from Stage 2, EAS)
Table 3.3.1.8.2.d. In Vitro Platelet Function: HCO_3^- and Normalized HCO_3^- @ 37°C (mmol/L) (Per-Component Analysis by Stage, EAS)

Table 3.3.1.9.1.a. In Vitro Platelet Function: Supernatant LDH (U/L) and Normalized Supernatant LDH (U/10^{12}) (Stage 1, Safety Set)
(IV_INP,x, IV_END,x)

Table 3.3.1.9.1.b. In Vitro Platelet Function: Supernatant LDH (U/L) and Normalized Supernatant LDH ($U/10^{12}$) (Stage 2, Safety Set)
Table 3.3.1.9.1.c. In Vitro Platelet Function: Supernatant LDH (U/L) and Normalized Supernatant LDH ($U/10^{12}$) (New Subjects from Stage 2, Safety Set)
Table 3.3.1.9.1.d. In Vitro Platelet Function: Supernatant LDH (U/L) and Normalized Supernatant LDH ($U/10^{12}$) (Per-Component Analysis by Stage, Safety Set)

Table 3.3.1.9.2.a. In Vitro Platelet Function: Supernatant LDH (U/L) and Normalized Supernatant LDH ($U/10^{12}$) (Stage 1, EAS)
Table 3.3.1.9.2.b. In Vitro Platelet Function: Supernatant LDH (U/L) and Normalized Supernatant LDH ($U/10^{12}$) (Stage 2, EAS)
Table 3.3.1.9.2.c. In Vitro Platelet Function: Supernatant LDH (U/L) and Normalized Supernatant LDH ($U/10^{12}$) (New Subjects from Stage 2, EAS)
Table 3.3.1.9.2.d. In Vitro Platelet Function: Supernatant LDH (U/L) and Normalized Supernatant LDH ($U/10^{12}$) (Per-Component Analysis by Stage, EAS)

Table 3.3.1.10.1.a. In Vitro Platelet Function: Total LDH (U/L) (Stage 1, Safety Set)
(IV_INP,x, IV_END,x)
Table 3.3.1.10.1.b. In Vitro Platelet Function: Total LDH (U/L) (Stage 2, Safety Set)
Table 3.3.1.10.1.c. In Vitro Platelet Function: Total LDH (U/L) (New Subjects from Stage 2, Safety Set)
Table 3.3.1.10.1.d. In Vitro Platelet Function: Total LDH (U/L) (Per-Component Analysis by Stage, Safety Set)

Table 3.3.1.10.2.a. In Vitro Platelet Function: Total LDH (U/L) (Stage 1, EAS)
Table 3.3.1.10.2.b. In Vitro Platelet Function: Total LDH (U/L) (Stage 2, EAS)
Table 3.3.1.10.2.c. In Vitro Platelet Function: Total LDH (U/L) (New Subjects from Stage 2, EAS)
Table 3.3.1.10.2.d. In Vitro Platelet Function: Total LDH (U/L) (Per-Component Analysis by Stage, EAS)

Table 3.3.1.11.1.a. In Vitro Platelet Function: ATP (µmol/dL) and Normalized ATP ($nmol/10^{8}$) (Stage 1, Safety Set)
(IV_INP,x, IV_END,x)
Table 3.3.1.11.1.b. In Vitro Platelet Function: ATP (µmol/dL) and Normalized ATP ($nmol/10^{8}$) (Stage 2, Safety Set)
Table 3.3.1.11.1.c. In Vitro Platelet Function: ATP (µmol/dL) and Normalized ATP ($nmol/10^{8}$) (New Subjects from Stage 2, Safety Set)
Table 3.3.1.11.1.d. In Vitro Platelet Function: ATP (µmol/dL) and Normalized ATP ($nmol/10^{8}$) (Per-Component Analysis by Stage, Safety Set)

Table 3.3.1.11.2.a. In Vitro Platelet Function: ATP (µmol/dL) and Normalized ATP ($nmol/10^{8}$) (Stage 1, EAS)
Table 3.3.1.11.2.b. In Vitro Platelet Function: ATP (µmol/dL) and Normalized ATP ($nmol/10^{8}$) (Stage 2, EAS)
Table 3.3.1.11.2.c. In Vitro Platelet Function: ATP (µmol/dL) and Normalized ATP ($nmol/10^{8}$) (New Subjects from Stage 2, EAS)
Table 3.3.1.11.2.d. In Vitro Platelet Function: ATP (µmol/dL) and Normalized ATP ($nmol/10^{8}$) (Per-Component Analysis by Stage, EAS)

Table 3.3.1.12.1.a. In Vitro Platelet Function: Lysis (%) and Adjusted Lysis (%) (Stage 1, Safety Set)
(IV_INP,x, IV_END,x)
Table 3.3.1.12.1.b. In Vitro Platelet Function: Lysis (%) and Adjusted Lysis (%) (Stage 2, Safety Set)
Table 3.3.1.12.1.c. In Vitro Platelet Function: Lysis (%) and Adjusted Lysis (%) (New Subjects from Stage 2, Safety Set)
Table 3.3.1.12.1.d. In Vitro Platelet Function: Lysis (%) and Adjusted Lysis (%) (Per-Component Analysis by Stage, Safety Set)

Table 3.3.1.12.2.a. In Vitro Platelet Function: Lysis (%) and Adjusted Lysis (%) (Stage 1, EAS)
Table 3.3.1.12.2.b. In Vitro Platelet Function: Lysis (%) and Adjusted Lysis (%) (Stage 2, EAS)
Table 3.3.1.12.2.c. In Vitro Platelet Function: Lysis (%) and Adjusted Lysis (%) (New Subjects from Stage 2, EAS)
Table 3.3.1.12.2.d. In Vitro Platelet Function: Lysis (%) and Adjusted Lysis (%) (Per-Component Analysis by Stage, EAS)

Table 3.3.1.13.1.a. In Vitro Platelet Function: Hypotonic Shock Response (%) (Stage 1, Safety Set)
(x,x, IV_END,x)
Table 3.3.1.13.1.b. In Vitro Platelet Function: Hypotonic Shock Response (%) (Stage 2, Safety Set)
Table 3.3.1.13.1.c. In Vitro Platelet Function: Hypotonic Shock Response (%) (New Subjects from Stage 2, Safety Set)
Table 3.3.1.13.1.d. In Vitro Platelet Function: Hypotonic Shock Response (%) (Per-Component Analysis by Stage, Safety Set)

Table 3.3.1.13.2.a. In Vitro Platelet Function: Hypotonic Shock Response (%) (Stage 1, EAS)
Table 3.3.1.13.2.b. In Vitro Platelet Function: Hypotonic Shock Response (%) (Stage 2, EAS)
Table 3.3.1.13.2.c. In Vitro Platelet Function: Hypotonic Shock Response (%) (New Subjects from Stage 2, EAS)
Table 3.3.1.13.2.d. In Vitro Platelet Function: Hypotonic Shock Response (%) (Per-Component Analysis by Stage, EAS)

Table 3.3.1.14.1.a. In Vitro Platelet Function: Extend of Shape Change (%) (Stage 1, Safety Set)
(x,x, IV_END,x)
Table 3.3.1.14.1.b. In Vitro Platelet Function: Extend of Shape Change (%) (Stage 2, Safety Set)
Table 3.3.1.14.1.c. In Vitro Platelet Function: Extend of Shape Change (%) (New Subjects from Stage 2, Safety Set)
Table 3.3.1.14.1.d. In Vitro Platelet Function: Extend of Shape Change (%) (Per-Component Analysis by Stage, Safety Set)

Table 3.3.1.14.2.a. In Vitro Platelet Function: Extend of Shape Change (%) (Stage 1, EAS)
Table 3.3.1.14.2.b. In Vitro Platelet Function: Extend of Shape Change (%) (Stage 2, EAS)
Table 3.3.1.14.2.c. In Vitro Platelet Function: Extend of Shape Change (%) (New Subjects from Stage 2, EAS)
Table 3.3.1.14.2.d. In Vitro Platelet Function: Extend of Shape Change (%) (Per-Component Analysis by Stage, EAS)

Table 3.3.1.15.1.a. In Vitro Platelet Function: CD62P (%) (Stage 1, Safety Set)
(IV_INP,x, IV_END,IV_PLT)
Table 3.3.1.15.1.b. In Vitro Platelet Function: CD62P (%) (Stage 2, Safety Set)
Table 3.3.1.15.1.c. In Vitro Platelet Function: CD62P (%) (New Subjects from Stage 2, Safety Set)
Table 3.3.1.15.1.d. In Vitro Platelet Function: CD62P (%) (Per-Component Analysis by Stage, Safety Set)

Table 3.3.1.15.2.a. In Vitro Platelet Function: CD62P (%) (Stage 1, EAS)
Table 3.3.1.15.2.b. In Vitro Platelet Function: CD62P (%) (Stage 2, EAS)
Table 3.3.1.15.2.c. In Vitro Platelet Function: CD62P (%) (New Subjects from Stage 2, EAS)
Table 3.3.1.15.2.d. In Vitro Platelet Function: CD62P (%) (Per-Component Analysis by Stage, EAS)
(IV_INP,x, IV_END,x)
(For 3.3.1.15.2.a. only: Change from Input at End of Storage, Change from Input at Before Radiolabeling. For 3.3.1.15.b. only: Change from Input at End of Storage.)

Table 3.3.1.16.1.a. In Vitro Platelet Function: Morphology Score (Stage 1, Safety Set)
(x,x, IV_END,x)
Table 3.3.1.16.1.b. In Vitro Platelet Function: Morphology Score (Stage 2, Safety Set)
Table 3.3.1.16.1.c. In Vitro Platelet Function: Morphology Score (New Subjects from Stage 2, Safety Set)
Table 3.3.1.16.1.d. In Vitro Platelet Function: Morphology Score (Per-Component Analysis by Stage, Safety Set)

Table 3.3.1.16.2.a. In Vitro Platelet Function: Morphology Score (Stage 1, EAS)
Table 3.3.1.16.2.b. In Vitro Platelet Function: Morphology Score (Stage 2, EAS)
Table 3.3.1.16.2.c. In Vitro Platelet Function: Morphology Score (New Subjects from Stage 2, EAS)
Table 3.3.1.16.2.d. In Vitro Platelet Function: Morphology Score (Per-Component Analysis by Stage, EAS)

Table 3.3.1.17.1.a. In Vitro Platelet Function: Mean Platelet Volume (fL) (Stage 1, Safety Set)
(x,x, IV_END,x)
Table 3.3.1.17.1.b. In Vitro Platelet Function: Mean Platelet Volume (fL) (Stage 2, Safety Set)
Table 3.3.1.17.1.c. In Vitro Platelet Function: Mean Platelet Volume (fL) (New Subjects from Stage 2, Safety Set)
Table 3.3.1.17.1.d. In Vitro Platelet Function: Mean Platelet Volume (fL) (Per-Component Analysis by Stage, Safety Set)

Table 3.3.1.17.2.a. In Vitro Platelet Function: Mean Platelet Volume (fL) (Stage 1, EAS)
Table 3.3.1.17.2.b. In Vitro Platelet Function: Mean Platelet Volume (fL) (Stage 2, EAS)
Table 3.3.1.17.2.c. In Vitro Platelet Function: Mean Platelet Volume (fL) (New Subjects from Stage 2, EAS)
Table 3.3.1.17.2.d. In Vitro Platelet Function: Mean Platelet Volume (fL) (Per-Component Analysis by Stage, EAS)

Table 3.3.1.18.1.a. In Vitro Platelet Function: pH @ 22°C (Stage 1, Safety Set)
(IV_INP,x, IV_END,IV_PLT)
Table 3.3.1.18.1.b. In Vitro Platelet Function: pH @ 22°C (Stage 2, Safety Set)
Table 3.3.1.18.1.c. In Vitro Platelet Function: pH @ 22°C (New Subjects from Stage 2, Safety Set)
Table 3.3.1.18.1.d. In Vitro Platelet Function: pH @ 22°C (Per-Component Analysis by Stage, Safety Set)

Table 3.3.1.18.2.a. In Vitro Platelet Function: pH @ 22°C (Stage 1, EAS)
Table 3.3.1.18.2.b. In Vitro Platelet Function: pH @ 22°C (Stage 2, EAS)
Table 3.3.1.18.2.c. In Vitro Platelet Function: pH @ 22°C (New Subjects from Stage 2, EAS)
Table 3.3.1.18.2.d. In Vitro Platelet Function: pH @ 22°C (Per-Component Analysis by Stage, EAS)
(Change from Input at End of Storage, Change from Input at Before Radiolabeling)

Please add the following for pH before radiolabeling.
- ≥ 6.2
  - Yes
  - No
  - 1-sided 95% CI for Yes

Table 3.3.1.19.1.a. In Vitro Platelet Function: RBC Count ($\times 10^4$/mL) and Total RBC Count (cells) (Stage 1, Safety Set)
Table 3.3.1.19.1.d. In Vitro Platelet Function: RBC Count ($\times 10^4$/mL) and Total RBC Count (cells) (Per-Component Analysis by Stage, Safety Set)
(x,x,x,IV_PLT)
Table 3.3.1.19.2.a. In Vitro Platelet Function: RBC Count ($\times 10^4$/mL) and Total RBC Count (cells) (Stage 1, EAS)
Table 3.3.1.19.2.d. In Vitro Platelet Function: RBC Count ($\times 10^4$/mL) and Total RBC Count (cells) (Per-Component Analysis by Stage, EAS)
(x,x,x,IV_PLT)

Table 3.3.1.20.1.a. In Vitro Platelet Function: WBC Count (cells/µL) and Total WBC Count (cells) (Stage 1, Safety Set)
Table 3.3.1.20.1.d. In Vitro Platelet Function: WBC Count (cells/µL) and Total WBC Count (cells) (Per-Component Analysis by Stage, Safety Set)
(x,x,x,IV_PLT)
Table 3.3.1.20.2.a. In Vitro Platelet Function: WBC Count (cells/µL) and Total WBC Count (cells) (Stage 1, EAS)
Table 3.3.1.20.2.d. In Vitro Platelet Function: WBC Count (cells/µL) and Total WBC Count (cells) (Per-Component Analysis by Stage, EAS)
(x,x,x,IV_PLT)

Table 3.3.1.21.1.a. In Vitro Platelet Function: Sample Volume (mL) (Stage 1, Safety Set)
(x,x, IV_END, IV_PLT,RL_TES)
Table 3.3.1.21.1.b. In Vitro Platelet Function: Sample Volume (mL) (Stage 2, Safety Set)
Table 3.3.1.21.1.c. In Vitro Platelet Function: Sample Volume (mL) (New Subjects from Stage 2, Safety Set)
Table 3.3.1.21.1.d. In Vitro Platelet Function: Sample Volume (mL) (Per-Component Analysis by Stage, Safety Set)

Table 3.3.1.21.2.a. In Vitro Platelet Function: Sample Volume (mL) (Stage 1, EAS)
Table 3.3.1.21.2.b. In Vitro Platelet Function: Sample Volume (mL) (Stage 2, EAS)
Table 3.3.1.21.2.c. In Vitro Platelet Function: Sample Volume (mL) (New Subjects from Stage 2, EAS)
Table 3.3.1.21.2.d. In Vitro Platelet Function: Sample Volume (mL) (Per-Component Analysis by Stage, EAS)

(DELETE Change from End of Storage at Before Radiolabeling, i.e. no “change from” variable in this table.)

Table 3.3.1.22.1.a. In Vitro Platelet Function: Sample Dose ($\times 10^9$) (Stage 1, Safety Set)
(IV_PLT)
Table 3.3.1.22.1.b. In Vitro Platelet Function: Sample Dose ($\times 10^9$) (Stage 2, Safety Set)
Table 3.3.1.22.1.c. In Vitro Platelet Function: Sample Dose ($\times 10^9$) (New Subjects from Stage 2, Safety Set)
Table 3.3.1.22.1.d. In Vitro Platelet Function: Sample Dose ($\times 10^9$) (Per-Component Analysis by Stage, Safety Set)

Table 3.3.1.22.2.a. In Vitro Platelet Function: Sample Dose ($\times 10^9$) (Stage 1, EAS)
Table 3.3.1.22.2.b. In Vitro Platelet Function: Sample Dose ($\times 10^9$) (Stage 2, EAS)
Table 3.3.1.22.2.c. In Vitro Platelet Function: Sample Dose ($\times 10^9$) (New Subjects from Stage 2, EAS)
Table 3.3.1.22.2.d. In Vitro Platelet Function: Sample Dose ($\times 10^9$) (Per-Component Analysis by Stage, EAS)

Table 3.3.2.1.a. RBC/WBC Contamination (%) (Stage 1, Safety Set)

	Comparison 1			Comparison 2			Comparison 3		
	Test Variant 1 (N = xx)	Control BEST (N = xx)	T-C[1] (N = xx)	Test BEST (N = xx)	Control BEST (N = xx)	T-C[1] (N = xx)	Test Variant 1 (N = xx)	Test BEST (N = xx)	V-B[1] (N = xx)
Overall									
Contamination at 1 DPI									
N	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min to Max	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
95% CI for Mean	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Contamination at 4/5/6 DPI									
…									
Contamination at 11±1 DPI									
…									
Site 001 [Hoxworth]									
. . .									
Site 002 [Bloodworks]									
. . .									
Radiolabeling: Test=^{51}Cr									
. . .									
Radiolabeling: Test=^{111}In									
. . .									

Note: Only subjects with available pair values for Test BEST and TEST Variant 1 will be presented under Comparison 3.
Note: Contaminations larger or equal to 40 are not included in the analysis.
[1] T – C = Test – Control; V – B = (Test Variant 1) – (Test BEST).
Reference: Listing 3.11.

Programming Note:
Table 3.3.2.1.b. RBC/WBC contamination (%) (Stage 2, Safety Set)
Table 3.3.2.1.c. RBC/WBC contamination (%) (New Subjects from Stage 2, Safety Set)
Table 3.3.2.2.a. RBC/WBC contamination (%) (Stage 1, EAS)
Table 3.3.2.2.b. RBC/WBC contamination (%) (Stage 2, EAS)
Table 3.3.2.2.c. RBC/WBC contamination (%) (New Subjects from Stage 2, EAS)
Table 3.3.2.3.a. RBC/WBC contamination (%) (Stage 1, CAS)

Only Contamination at 11±1 DPI will be presented for Stage 2 and New Subjects from Stage 2

Table 3.3.3.1.a. Radiolabeling Efficiency (%) (Stage 1, Safety Set)

	Comparison 1			Comparison 2			Comparison 3		
	Test Variant 1 (N = xx)	Control BEST (N = xx)	T-C[1] (N = xx)	Test BEST (N = xx)	Control BEST (N = xx)	T-C[1] (N = xx)	Test Variant 1 (N = xx)	Test BEST (N = xx)	V-B[1] (N = xx)
Overall									
N	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min to Max	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
95% CI for Mean	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Site 001 [Hoxworth]									
. . .									
Site 002 [Bloodworks]									
. . .									
Radiolabeling: Test=^{51}Cr									
. . .									
Radiolabeling: Test=^{111}In									
. . .									

Note: Only subjects with available pair values for Test BEST and TEST Variant 1 will be presented under Comparison 3.
Note: Radiolabeling Efficiency = (Pellet Dose) / (Pellet Dose + Supernatant Dose).
[1] T – C = Test – Control; V – B = (Test Variant 1) – (Test BEST).

Reference: Listing 3.15.

Programming note:
Table 3.3.3.1.b. Radiolabeling Efficiency (%) (Stage 2, Safety Set)
Table 3.3.3.1.c. Radiolabeling Efficiency (%) (New Subjects from Stage 2, Safety Set)
Table 3.3.3.2.a. Radiolabeling Efficiency (%) (Stage 1, EAS)
Table 3.3.3.2.b. Radiolabeling Efficiency (%) (Stage 2, EAS)
Table 3.3.3.2.c. Radiolabeling Efficiency (%) (New Subjects from Stage 2, EAS)
Table 3.3.3.3.a. Radiolabeling Efficiency (%) (Stage 1, CAS)

Table 3.3.4.1.a. In Vivo Elution (%) (Stage 1, Safety Set)

	Comparison 1			Comparison 2			Comparison 3		
	Test Variant 1 (N = xx)	Control BEST (N = xx)	T-C[1] (N = xx)	Test BEST (N = xx)	Control BEST (N = xx)	T-C[1] (N = xx)	Test Variant 1 (N = xx)	Test BEST (N = xx)	V-B[1] (N = xx)
Overall									
N	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min to Max	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
95% CI for Mean	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Site 001 [Hoxworth]									
. . .									
Site 002 [Bloodworks]									
. . .									
Radiolabeling: Test=^{51}Cr									
. . .									
Radiolabeling: Test=^{111}In									
. . .									

Note: Only subjects with available pair values for Test BEST and TEST Variant 1 will be presented under Comparison 3.
Note: In Vivo Elution = (1-hour Plasma CPM per g) / (1-hour Plasma CPM per g + 1-hour RBC CPM per g). The averaged value from the two samples is used. If the values at 1-hour post-infusion are missing, the values at 2-hour post-infusion are used.
[1] T – C = Test – Control; V – B = (Test Variant 1) – (Test BEST).
Reference: Listing 4.2.

Programming note:
Table 3.3.4.1.b. In Vivo Elution (%) (Stage 2, Safety Set)
Table 3.3.4.1.c. In Vivo Elution (%) (New Subjects from Stage 2, Safety Set)
Table 3.3.4.2.a. In Vivo Elution (%) (Stage 1, EAS)
Table 3.3.4.2.b. In Vivo Elution (%) (Stage 2, EAS)
Table 3.3.4.2.c. In Vivo Elution (%) (New Subjects from Stage 2, EAS)
Table 3.3.4.3.a. In Vivo Elution (%) (Stage 1, CAS)

Table 3.3.5.1.a. In Vitro Elution (%) (Stage 1, Safety Set)

	Comparison 1			Comparison 2			Comparison 3		
	Test Variant 1 (N = xx)	Control BEST (N = xx)	T-C[1] (N = xx)	Test BEST (N = xx)	Control BEST (N = xx)	T-C[1] (N = xx)	Test Variant 1 (N = xx)	Test BEST (N = xx)	V-B[1] (N = xx)
Overall									
N	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min to Max	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
95% CI for Mean	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Site 001 [Hoxworth]									
. . .									
Site 002 [Bloodworks]									
. . .									
Radiolabeling: Test=^{51}Cr									
. . .									
Radiolabeling: Test=^{111}In									
. . .									

Note: Only subjects with available pair values for Test BEST and TEST Variant 1 will be presented under Comparison 3.
Note: In vitro elution (%) = (Elution Plasma CPM per g)/ (Elution Plasma CPM per g + Elution Packed Cells CPM per g)×100.
[1] T – C = Test – Control; V – B = (Test Variant 1) – (Test BEST).
Reference: Listing 4.2.

Programming note:
Table 3.3.5.1.b. In Vitro Elution (%) (Stage 2, Safety Set)
Table 3.3.5.1.c. In Vitro Elution (%) (New Subjects from Stage 2, Safety Set)
Table 3.3.5.2.a. In Vitro Elution (%) (Stage 1, EAS)
Table 3.3.5.2.b. In Vitro Elution (%) (Stage 2, EAS)
Table 3.3.5.2.c. In Vitro Elution (%) (New Subjects from Stage 2, EAS)
Table 3.3.5.3.a. In Vitro Elution (%) (Stage 1, CAS)

Table 3.3.6.1.a. Platelet Physical Recovery Before Radiolabeling (%) (Stage 1, Safety Set)

	Hoxworth			Bloodworks			Total		
	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)
Overall									
N	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx	xx	xx	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)
≥ 80%									
Yes	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
No	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
1-sided 95% CI for Yes	>= xx.x%	>= xx.x%		>= xx.x%	>= xx.x%		>= xx.x%	>= xx.x%	
Site 001 [Hoxworth]									
. . .									
Site 002 [Bloodworks]									
. . .									
Radiolabeling: Test=^{51}Cr									
. . .									
Radiolabeling: Test=^{111}In									
. . .									

Note: Physical recovery (%) = [(Weight of platelets radiolabeled / 1.03) × (Platelet count following hard spin)] / [(Weight of platelets to be radiolabeled / 1.03) × (End of storage platelet count)] × 100.
[1] V – B = (Test Variant 1) – (Test BEST).
Reference: Listing 4.3.

Programming note:
Table 3.3.6.1.b. Platelet Physical Recovery Before Radiolabeling (%) (Stage 2, Safety Set)
Table 3.3.6.1.c. Platelet Physical Recovery Before Radiolabeling (%) (New Subjects from Stage 2, Safety Set)
Table 3.3.6.2.a. Platelet Physical Recovery Before Radiolabeling (%) (Stage 1, EAS)
Table 3.3.6.2.b. Platelet Physical Recovery Before Radiolabeling (%) (Stage 2, EAS)
Table 3.3.6.2.c. Platelet Physical Recovery Before Radiolabeling (%) (New Subjects from Stage 2, EAS)
Table 3.3.6.3.a. Platelet Physical Recovery Before Radiolabeling (%) (Stage 1, CAS)

Table 3.3.7.1.a. Dose and Volume Recovery (%) (Stage 1, Safety Set)

	Hoxworth			Bloodworks			Total		
	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)
Dose Recovery at Day 7									
N	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx	xx	xx	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)
≥ 80%									
Yes	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
No	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
1-sided 95% CI for Yes	>= xx.x%	>= xx.x%		>= xx.x%	>= xx.x%		>= xx.x%	>= xx.x%	
Volume Recovery at Post-INTERCEPT									
N	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx	xx	xx	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)
≥ 80%									
Yes	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
No	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
1-sided 95% CI for Yes	>= xx.x%	>= xx.x%		>= xx.x%	>= xx.x%		>= xx.x%	>= xx.x%	
Volume Recovery at Day 7									
N	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx	xx	xx	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)
≥ 80%									
Yes	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
No	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
1-sided 95% CI for Yes	>= xx.x%	>= xx.x%		>= xx.x%	>= xx.x%		>= xx.x%	>= xx.x%	

Note: Dose recovery = (dose at a given visit) / (dose at input). Volume recovery = (volume at a given visit) / (volume at input). The corrected volumes are applied to calculate volume and dose recoveries at end of storage (Day 7).
[1] V – B = (Test Variant 1) – (Test BEST).
Reference: Listing 4.3.

Programming note:
Table 3.3.7.1.b Dose and Volume Recovery (%) (Stage 2, Safety Set)
Table 3.3.7.1.c. Dose and Volume Recovery (%) (New Subjects from Stage 2, Safety Set)
Table 3.3.7.2.a. Dose and Volume Recovery (%) (Stage 1, EAS)
Table 3.3.7.2.b. Dose and Volume Recovery (%) (Stage 2, EAS)
Table 3.3.7.2.c. Dose and Volume Recovery (%) (New Subjects from Stage 2, EAS)
Table 3.3.7.3.a. Dose and Volume Recovery (%) (Stage 1, CAS)

Table 3.4.1.a. Platelet Apheresis Collection and Storage (Stage 1, Safety Set)

	Hoxworth			Bloodworks			Total		
	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)
Pre-donation Subject Platelet Count and Target Collection Size									
Subject Platelet Count (×10^3/µL)									
N	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx	xx	xx	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)
Target Collection									
Single dose collection	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
Double dose collection	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
Total	xx (100%)	xx (100%)		xx (100%)	xx (100%)		xx (100%)	xx (100%)	
Apheresis Platelet Collection									
Collection Duration (hr)									
N	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx	xx	xx	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)
Apheresis Set Kit Type									
Single needle	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
Double needle	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
Total	xx (100%)	xx (100%)		xx (100%)	xx (100%)		xx (100%)	xx (100%)	
Machine Messages or Alarms									
Yes	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
No	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
Total	xx (100%)	xx (100%)		xx (100%)	xx (100%)		xx (100%)	xx (100%)	
Collection Completed									
Yes	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
No	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
Total	xx (100%)	xx (100%)		xx (100%)	xx (100%)		xx (100%)	xx (100%)	

[1] V – B = (Test Variant 1) – (Test BEST).
Reference: Listing 3.4.

Programming note:
Table 3.4.1.b. Platelet Apheresis Collection and Storage (Stage 2, Safety Set)
Table 3.4.1.c. Platelet Apheresis Collection and Storage (New Subjects from Stage 2, Safety Set)
Table 3.4.2.a. Platelet Apheresis Collection and Storage (Stage 1, EAS)
Table 3.4.2.b. Platelet Apheresis Collection and Storage (Stage 2, EAS)
Table 3.4.2.c. Platelet Apheresis Collection and Storage (New Subjects from Stage 2, EAS)

Table 3.5.1.a. Input Component Form (Stage 1, Safety Set)

	Hoxworth			Bloodworks			Total		
	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)
Acceptability Criteria Met									
Yes	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
No	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
RBCs ≥ 4×10^6/mL	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
Visible aggregates	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
Other	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
Total	xx (100%)	xx (100%)		xx (100%)	xx (100%)		xx (100%)	xx (100%)	
Collection Container(s)									
One	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
Two	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
Total	xx (100%)	xx (100%)		xx (100%)	xx (100%)		xx (100%)	xx (100%)	
Platelet Count (10^3/µL)									
N	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx	xx	xx	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)

[1] V – B = (Test Variant 1) – (Test BEST).

Reference: Listing 3.5.

Programming note:
Table 3.5.1.b. Input Component Form (Stage 2, Safety Set)
Table 3.5.1.c. Input Component Form (New Subjects from Stage 2, Safety Set)
Table 3.5.2.a. Input Component Form (Stage 1, EAS)
Table 3.5.2.b. Input Component Form (Stage 2, EAS)
Table 3.5.2.c. Input Component Form (New Subjects from Stage 2, EAS)

Table 3.6.1.a. Test Input (Stage 1, Safety Set)

	Hoxworth			Bloodworks			Total		
	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)
Final Input Volume (mL)									
N	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx	xx	xx	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)
Final Input Count ($\times 10^3/\mu L$)									
N	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx	xx	xx	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)
Final Input Platelet Dose ($\times 10^{11}$)									
N	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx	xx	xx	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)
Input Platelet Characteristics [2]									
DS	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
DS 2	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
Criteria Not Met	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
Total	xx (100%)	xx (100%)		xx (100%)	xx (100%)		xx (100%)	xx (100%)	

[1] V – B = (Test Variant 1) – (Test BEST).
[2] DS (Input Dose 3.0 - 5.2 × 10^{11}, Volume 300 - 390 mL); DS 2 (Input Dose 5.3 - 7.9 × 10^{11}, Volume 375 - 420 mL).
Reference: Listing 3.6.

Programming note:
Table 3.6.1.b. Test Input (Stage 2, Safety Set)
Table 3.6.1.c. Test Input (New Subjects from Stage 2, Safety Set)
Table 3.6.2.a. Test Input (Stage 1, EAS)
Table 3.6.2.b. Test Input (Stage 2, EAS)
Table 3.6.2.c. Test Input (New Subjects from Stage 2, EAS)

Table 3.7.1.a. INTERCEPT Treatment: Illumination (Stage 1, Safety Set)

	Hoxworth			Bloodworks			Total		
	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)
Duration from Donation to Illumination (Hour)									
N	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx	xx	xx	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)
UV Dose (J/cm^2)									
N	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx	xx	xx	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)
Container Illumination Status									
Complete	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
Incomplete	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
Total	xx (100%)	xx (100%)		xx (100%)	xx (100%)		xx (100%)	xx (100%)	

[1] V – B = (Test Variant 1) – (Test BEST).
Reference: Listing 3.7.

Programming note:
Table 3.7.1.b. INTERCEPT Treatment: Illumination (Stage 2, Safety Set)
Table 3.7.1.c. INTERCEPT Treatment: Illumination (New Subjects from Stage 2, Safety Set)
Table 3.7.2.a. INTERCEPT Treatment: Illumination (Stage 1, EAS)
Table 3.7.2.b. INTERCEPT Treatment: Illumination (Stage 2, EAS)
Table 3.7.2.c. INTERCEPT Treatment: Illumination (New Subjects from Stage 2, EAS)

Table 3.8.1.a. INTERCEPT Treatment: CAD (Stage 1, Safety Set)

	Hoxworth			Bloodworks			Total		
	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)
CAD Duration (hr)									
N	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx	xx	xx	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)
CAD Duration within 12 to 24 Hours									
Yes	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
No	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
Total	xx (100%)	xx (100%)		xx (100%)	xx (100%)		xx (100%)	xx (100%)	

[1] V – B = (Test Variant 1) – (Test BEST).
Reference: Listing 3.8.

Programming note:
Table 3.8.1.b. INTERCEPT Treatment: CAD (Stage 2, Safety Set)
Table 3.8.1.c. INTERCEPT Treatment: CAD (New Subjects from Stage 2, Safety Set)
Table 3.8.2.a. INTERCEPT Treatment: CAD (Stage 1, EAS)
Table 3.8.2.b. INTERCEPT Treatment: CAD (Stage 2, EAS)
Table 3.8.2.c. INTERCEPT Treatment: CAD (New Subjects from Stage 2, EAS)

Table 3.9.1.a. INTERCEPT Treatment: Transfer to Final Storage (Stage 1, Safety Set)

	Hoxworth			Bloodworks			Total		
	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)
Storage Container(s)									
One	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
Two - Connected	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
Two - Separated	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
Total	xx (100%)	xx (100%)		xx (100%)	xx (100%)		xx (100%)	xx (100%)	
Container Sampled									
A	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
A+B	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
B	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
Total	xx (100%)	xx (100%)		xx (100%)	xx (100%)		xx (100%)	xx (100%)	
INTERCEPT Component A Sample Volume (mL) [2]									
N	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx	xx	xx	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)
INTERCEPT Component A+B Sample Volume (mL) [2]									
…									
INTERCEPT Component B Sample Volume (mL) [3]									
…									
INTERCEPT Component A Sample Dose ($\times 10^{11}$) [3]									
…									
INTERCEPT Component A+B Sample Dose ($\times 10^{11}$) [3]									
…									
INTERCEPT Component B Sample Dose ($\times 10^{11}$) [2]									
…									

Platelet Count ($\times 10^3/\mu L$)

…

[1] V – B = (Test Variant 1) – (Test BEST).
[2] Volume = [(Final Storage Container Gross Weight) – (Tare weight)] / 1.03. The tare weight is depended on the storage conditions (see details given in the text section of Statistical Analysis Plan).
[3] Dose = Volume × (Post-INTERCEPT platelet count) / 10^5.
Reference: Listing 3.9.

Programming note: Delete rows if no data
Table 3.9.1.b. INTERCEPT Treatment: Transfer to Final Storage (Stage 2, Safety Set)
Table 3.9.1.c. INTERCEPT Treatment: Transfer to Final Storage (New Subjects from Stage 2, Safety Set)
Table 3.9.2.a. INTERCEPT Treatment: Transfer to Final Storage (Stage 1, EAS)
Table 3.9.2.b. INTERCEPT Treatment: Transfer to Final Storage (Stage 2, EAS)
Table 3.9.2.c. INTERCEPT Treatment: Transfer to Final Storage (New Subjects from Stage 2, EAS)

Table 3.10.1.a. Bacteria Culture (Stage 1, Safety Set)

	Hoxworth		Bloodworks		Total	
	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)
Container Sampled						
A	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
A + B	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
B	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)
Pre-Infusion Result						
Positive	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)
Final Result						
Positive	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)

Reference: Listing 3.10.

Programming note:
Table 3.10.1.b. Bacteria Culture (Stage 2, Safety Set)
Table 3.10.1.c. Bacteria Culture (New Subjects from Stage 2, Safety Set)
Table 3.10.2.a. Bacteria Culture (Stage 1, EAS)
Table 3.10.2.b. Bacteria Culture (Stage 2, EAS)
Table 3.10.2.c. Bacteria Culture (New Subjects from Stage 2, EAS)

Table 3.11.1.a. RBC Contamination Assessment (Stage 1, Safety Set)

	Hoxworth			Bloodworks			Total		
	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)
1 DPI									
Plasma/Leukocyte Layers									
Weight of Aspirated Fluid (g) [2]									
N	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx	xx	xx	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)
RBC Layers									
Weight of Aspirated Fluid (g) [1]									
…									
Counts per Minute (CPM)									
Plasma/Leukocyte Layers for Test									
…									
Plasma/Leukocyte Layers for Control									
…									
RBC Layer for Test									
…									
RBC Layer for Control									
…									
4, 5, or 6 DPI									
…									
11±1 DPI									
…									

[1] V – B = (Test Variant 1) – (Test BEST).
[2] Weight of aspirated fluid = (weight of tube with aspirated fluid) – (pre-weight of empty labeled tube).
Reference: Listing 3.11.

Programming note:

Table 3.12.1.a. Storage Bag Sampling at End of Storage (Stage 1, Safety Set)

	Hoxworth		Bloodworks		Total	
	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)
One Storage Bag Sampling						
Container Sampled						
A	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
A + B	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
B	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Two Storage Bag Sampling – pH Sample						
Container Sampled						
A	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
A + B	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
B	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Two Storage Bag Sampling – Other In Vitro Tests Sample						
Container Sampled						
A	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
A + B	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
B	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Reference: Listing 3.12.

Programming note:
Table 3.12.1.b. Storage Bag Sampling at End of Storage (Stage 2, Safety Set)
Table 3.12.1.c. Storage Bag Sampling at End of Storage (New Subjects from Stage 2, Safety Set)
Table 3.12.2.a. Storage Bag Sampling at End of Storage (Stage 1, EAS)
Table 3.12.2.b. Storage Bag Sampling at End of Storage (Stage 2, EAS)
Table 3.12.2.c. Storage Bag Sampling at End of Storage (New Subjects from Stage 2, EAS)

Table 3.13.1.a. Ethylenediaminetetraacetic Acid (EDTA) Sample Collection (Stage 1, Safety Set)

	Hoxworth		Bloodworks		Total	
	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)
Sample Collected						
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)
Sample Collected at Scheduled Time Point						
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)

Reference: Listing 3.14.

Programming note:
Table 3.13.2.b. Ethylenediaminetetraacetic Acid (EDTA) Sample Collection (Stage 2, Safety Set)
Table 3.13.2.c. Ethylenediaminetetraacetic Acid (EDTA) Sample Collection (New Subjects from Stage 2, Safety Set)
Table 3.13.2.a. Ethylenediaminetetraacetic Acid (EDTA) Sample Collection (Stage 1, EAS)
Table 3.13.2.b. Ethylenediaminetetraacetic Acid (EDTA) Sample Collection (Stage 2, EAS)
Table 3.13.2.c. Ethylenediaminetetraacetic Acid (EDTA) Sample Collection (New Subjects from Stage 2, EAS)

Table 3.14.1.a. Radiolabeling for Test Platelets (Stage 1, Safety Set)

	Hoxworth		Bloodworks		Total	
	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)
Release Criterion Met						
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)
Container Sampled						
A	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
A+B	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
B	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)

Reference: Listing 3.16.

Programming note:
Table 3.14.1.b. Radiolabeling for Test Platelets (Stage 2, Safety Set)
Table 3.14.1.c. Radiolabeling for Test Platelets (New Subjects from Stage 2, Safety Set)
Table 3.14.2.a. Radiolabeling for Test Platelets (Stage 1, EAS)
Table 3.14.2.b. Radiolabeling for Test Platelets (Stage 2, EAS)
Table 3.14.2.c. Radiolabeling for Test Platelets (New Subjects from Stage 2, EAS)

Table 3.15.1.a. Radiolabeling for Test and Control Platelets (Stage 1, Safety Set)

	Comparison 1			Comparison 2			Comparison 3		
	Test Variant 1 (N = xx)	Control BEST (N = xx)	T-C[1] (N = xx)	Test BEST (N = xx)	Control BEST (N = xx)	T-C[1] (N = xx)	Test Variant 1 (N = xx)	Test BEST (N = xx)	V-B[1] (N = xx)
Radiolabeled With									
^{111}In	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
^{51}Cr	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
Total	xx (100%)	xx (100%)		xx (100%)	xx (100%)		xx (100%)	xx (100%)	
Radiolabel Incubation Time (min)									
N	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min to Max	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
95% CI for Mean	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Problems During Process									
Yes	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
No	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	
Total	xx (100%)	xx (100%)		xx (100%)	xx (100%)		xx (100%)	xx (100%)	
Supernatant Dose (µCi)									
N	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min to Max	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
95% CI for Mean	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Pellet Dose (µCi)									
N	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min to Max	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x	xx.x to xx.x
95% CI for Mean	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)

Note: Only subjects with available pair values for Test BEST and TEST Variant 1 will be presented under Comparison 3.
[1] T – C = Test – Control; V – B = (Test Variant 1) – (Test BEST).

Reference: Listing 3.15.

Programming note:
Table 3.15.1.b. Radiolabeling for Test and Control Platelets (Stage 2, Safety Set)
Table 3.15.1.c. Radiolabeling for Test and Control Platelets (New Subjects from Stage 2, Safety Set)
Table 3.15.2.a. Radiolabeling for Test and Control Platelets (Stage 1, EAS)
Table 3.15.2.b. Radiolabeling for Test and Control Platelets (Stage 2, EAS)
Table 3.15.2.c. Radiolabeling for Test and Control Platelets (New Subjects from Stage 2, EAS)

Table 3.16.1.a. Injectate Infusion (Stage 1, Safety Set)

	Hoxworth		Bloodworks		Total	
	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)
Infusion Performed						
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)
Problems During Infusion						
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)

Reference: Listing 3.17.

Programming note:
Table 3.16.1.b. Injectate Infusion (Stage 2, Safety Set)
Table 3.16.1.c. Injectate Infusion (New Subjects from Stage 2, Safety Set)
Table 3.16.2.a. Injectate Infusion (Stage 1, EAS)
Table 3.16.2.b. Injectate Infusion (Stage 2, EAS)
Table 3.16.2.c. Injectate Infusion (New Subjects from Stage 2, EAS)

Table 3.17.1.a. Blood Sample Drawn for Radioactivity Measurement (Stage 1, Safety Set)

	Hoxworth		Bloodworks		Total	
	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)
Day 7						
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
From Contralateral Arm	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not from Contralateral Arm	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)
0 DPI (1hr±15mins)						
...						
0 DPI (2hr±15mins)						
...						
1 DPI						
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)
2 DPI						
...						
3 DPI						
...						
4, 5, or 6 DPI						
...						
7 or 8 DPI						
...						
11±1 DPI						
...						

Reference: Listing 3.18.

Table 3.17.1.b. Blood Sample Drawn for Radioactivity Measurement (Stage 2, Safety Set)

	Hoxworth		Bloodworks		Total	
	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)
Day 7						
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)
0 DPI (1hr±15mins)						
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
From Contralateral Arm	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not from Contralateral Arm	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)
0 DPI (2hr±15mins)						
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
From Contralateral Arm	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not from Contralateral Arm	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)
1 DPI						
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)
2 DPI						
...						
3 DPI						
...						
4, 5, or 6 DPI						
...						
7 or 8 DPI						
...						
11±1 DPI						
...						

Reference: Listing 3.18.

Programming note:
Table 3.17.1.c. Blood Sample Drawn for Radioactivity Measurement (New Subjects from Stage 2, Safety Set)
Table 3.17.2.a. Blood Sample Drawn for Radioactivity Measurement (Stage 1, EAS)
Table 3.17.2.b. Blood Sample Drawn for Radioactivity Measurement (Stage 2, EAS)
Table 3.17.2.c. Blood Sample Drawn for Radioactivity Measurement (New Subjects from Stage 2, EAS)

In Stage 1, only Day 7, 0 DPI (1hr±15mins) and 0 DPI (2hr±15mins) have Contralateral information (BSRCONYN).
In Stage 2, only 0 DPI (1hr±15mins) and 0 DPI (2hr±15mins) have Contralateral information (BSRCONYN).

Table 4.1.1.a. Laboratory Test: Chemistry – Blood Urea Nitrogen (mg/dL) (Stage 1, Safety Set)

	Hoxworth			Bloodworks			Total		
	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)
Baseline [2]									
N	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx	xx	xx	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)
0 DPI									
N	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx	xx	xx	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)
11±1 DPI									
N	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx	xx	xx	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)
Change from 0 DPI at 11±1 DPI									
N	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx	xx	xx	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)

[1] V – B = (Test Variant 1) – (Test BEST).
[2] The Day 0 value is used. If the value at Day 0 is missing, the value at Screening is used. The Screening assessment (collected at Period 1) is used for both Periods.
Reference: Listing 3.1. for Chemistry
Reference: Listing 3.2. for Hematology

Programming note:
Table 4.1.1.b. Laboratory Test: Chemistry – Blood Urea Nitrogen (mg/dL) (Stage 2, Safety Set)
Table 4.1.1.c. Laboratory Test: Chemistry – Blood Urea Nitrogen (mg/dL) (New Subjects from Stage 2, Safety Set)

Table 4.1.2.a. Laboratory Test: Chemistry – Calcium (mg/dL) (Stage 1, Safety Set)
Table 4.1.2.b. Laboratory Test: Chemistry – Calcium (mg/dL) (Stage 2, Safety Set)
Table 4.1.2.c. Laboratory Test: Chemistry – Calcium (mg/dL) (New Subjects from Stage 2, Safety Set)

Table 4.1.3.a. Laboratory Test: Chemistry – Carbon Dioxide (mmol/L) (Stage 1, Safety Set)
Table 4.1.3.b. Laboratory Test: Chemistry – Carbon Dioxide (mmol/L) (Stage 2, Safety Set)
Table 4.1.3.c. Laboratory Test: Chemistry – Carbon Dioxide (mmol/L) (New Subjects from Stage 2, Safety Set)

Table 4.1.4.a. Laboratory Test: Chemistry – Chloride (mmol/L) (Stage 1, Safety Set)
Table 4.1.4.b. Laboratory Test: Chemistry – Chloride (mmol/L) (Stage 2, Safety Set)
Table 4.1.4.c. Laboratory Test: Chemistry – Chloride (mmol/L) (New Subjects from Stage 2, Safety Set)

Table 4.1.5.a. Laboratory Test: Chemistry – Creatinine (mg/dL) (Stage 1, Safety Set)
Table 4.1.5.b. Laboratory Test: Chemistry – Creatinine (mg/dL) (Stage 2, Safety Set)
Table 4.1.5.c. Laboratory Test: Chemistry – Creatinine (mg/dL) (New Subjects from Stage 2, Safety Set)

Table 4.1.6.a. Laboratory Test: Chemistry – Glucose (mg/dL) (Stage 1, Safety Set)
Table 4.1.6.b. Laboratory Test: Chemistry – Glucose (mg/dL) (Stage 2, Safety Set)
Table 4.1.6.c. Laboratory Test: Chemistry – Glucose (mg/dL) (New Subjects from Stage 2, Safety Set)

Table 4.1.7.a. Laboratory Test: Chemistry – Potassium (mmol/L) (Stage 1, Safety Set)
Table 4.1.7.b. Laboratory Test: Chemistry – Potassium (mmol/L) (Stage 2, Safety Set)
Table 4.1.7.c. Laboratory Test: Chemistry – Potassium (mmol/L) (New Subjects from Stage 2, Safety Set)

Table 4.1.8.a. Laboratory Test: Chemistry – Sodium (mmol/L) (Stage 1, Safety Set)
Table 4.1.8.b. Laboratory Test: Chemistry – Sodium (mmol/L) (Stage 2, Safety Set)
Table 4.1.8.c. Laboratory Test: Chemistry – Sodium (mmol/L) (New Subjects from Stage 2, Safety Set)

Table 4.2.1.a. Laboratory Test: Hematology – Hematocrit (%) (Stage 1, Safety Set)
Table 4.2.1.b. Laboratory Test: Hematology – Hematocrit (%) (Stage 2, Safety Set)
Table 4.2.1.c. Laboratory Test: Hematology – Hematocrit (%) (New Subjects from Stage 2, Safety Set)

Table 4.2.2.a. Laboratory Test: Hematology – Hemoglobin (g/dL) (Stage 1, Safety Set)
Table 4.2.2.b. Laboratory Test: Hematology – Hemoglobin (g/dL) (Stage 2, Safety Set)
Table 4.2.2.c. Laboratory Test: Hematology – Hemoglobin (g/dL) (New Subjects from Stage 2, Safety Set)

Table 4.2.3.a. Laboratory Test: Hematology – RBC Count (10^6/µL) (Stage 1, Safety Set)
Table 4.2.3.b. Laboratory Test: Hematology – RBC Count (10^6/µL) (Stage 2, Safety Set)
Table 4.2.3.c. Laboratory Test: Hematology – RBC Count (10^6/µL) (New Subjects from Stage 2, Safety Set)

Table 4.2.4.a. Laboratory Test: Hematology – Platelet Count (10^3/µL) (Stage 1, Safety Set)
Table 4.2.4.b. Laboratory Test: Hematology – Platelet Count (10^3/µL) (Stage 2, Safety Set)
Table 4.2.4.c. Laboratory Test: Hematology – Platelet Count (10^3/µL) (New Subjects from Stage 2, Safety Set)

Table 4.2.5.a. Laboratory Test: Hematology – WBC Count (10^3/µL) (Stage 1, Safety Set)
Table 4.2.5.b. Laboratory Test: Hematology – WBC Count (10^3/µL) (Stage 2, Safety Set)
Table 4.2.5.c. Laboratory Test: Hematology – WBC Count (10^3/µL) (New Subjects from Stage 2, Safety Set)

Table 4.2.6.a. Laboratory Test: Hematology – Neutrophils (cells/µL) (Stage 1, Safety Set)
Table 4.2.6.b. Laboratory Test: Hematology – Neutrophils (cells/µL) (Stage 2, Safety Set)
Table 4.2.6.c. Laboratory Test: Hematology – Neutrophils (cells/µL) (New Subjects from Stage 2, Safety Set)

Table 4.2.7.a. Laboratory Test: Hematology – Monocytes (cells/µL) (Stage 1, Safety Set)
Table 4.2.7.b. Laboratory Test: Hematology – Monocytes (cells/µL) (Stage 2, Safety Set)
Table 4.2.7.c. Laboratory Test: Hematology – Monocytes (cells/µL) (New Subjects from Stage 2, Safety Set)

Table 4.2.8.a. Laboratory Test: Hematology – Lymphocytes (cells/µL) (Stage 1, Safety Set)
Table 4.2.8.b. Laboratory Test: Hematology – Lymphocytes (cells/µL) (Stage 2, Safety Set)
Table 4.2.8.c. Laboratory Test: Hematology – Lymphocytes (cells/µL) (New Subjects from Stage 2, Safety Set)

Table 4.2.9.a. Laboratory Test: Hematology – Basophils (cells/µL) (Stage 1, Safety Set)
Table 4.2.9.b. Laboratory Test: Hematology – Basophils (cells/µL) (Stage 2, Safety Set)
Table 4.2.9.c. Laboratory Test: Hematology – Basophils (cells/µL) (New Subjects from Stage 2, Safety Set)

Table 4.2.10.a. Laboratory Test: Hematology – Eosinophils (cells/µL) (Stage 1, Safety Set)
Table 4.2.10.b. Laboratory Test: Hematology – Eosinophils (cells/µL) (Stage 2, Safety Set)
Table 4.2.10.c. Laboratory Test: Hematology – Eosinophils (cells/µL) (New Subjects from Stage 2, Safety Set)

Table 4.3.1.a. Vital Sign: Body Weight (kg) (Stage 1, Safety Set)

	Hoxworth			Bloodworks			Total		
	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	V-B[1] (N = xx)
Baseline [2]									
N	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Mean (SD)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx	xx	xx	xx	xx	xx	xx	xx	xx
Min to Max	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
95% CI for Mean	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)	(xx,xx)
Day 7 (Pre-Infusion)									
…									
11±1 DPI									
…									
Change from Pre-Infusion at 11±1 DPI									
…									

[1] V – B = (Test Variant 1) – (Test BEST).
[2] The Day 0 value is used. If the value at Day 0 is missing, the value at Screening is used. The Screening assessment (collected at Period 1) is used for both Periods.
Reference: Listing 3.3.

Programming note:
Table 4.3.1.b. Vital Sign: Body Weight (kg) (Stage 2, Safety Set)
Table 4.3.1.c. Vital Sign: Body Weight (kg) (New Subjects from Stage 2, Safety Set)
Table 4.3.2.a. Vital Sign: Oral Temperature (°C) (Stage 1, Safety Set)
Table 4.3.2.b. Vital Sign: Oral Temperature (°C) (Stage 2, Safety Set)
Table 4.3.2.c. Vital Sign: Oral Temperature (°C) (New Subjects from Stage 2, Safety Set)
Table 4.3.3.a. Vital Sign: Pulse (bpm) (Stage 1, Safety Set)
Table 4.3.3.b. Vital Sign: Pulse (bpm) (Stage 2, Safety Set)
Table 4.3.3.c. Vital Sign: Pulse (bpm) (New Subjects from Stage 2, Safety Set)
Table 4.3.4.a. Vital Sign: Sitting Systolic Blood Pressure (mmHg) (Stage 1, Safety Set)
Table 4.3.4.b. Vital Sign: Sitting Systolic Blood Pressure (mmHg) (Stage 2, Safety Set)
Table 4.3.4.c. Vital Sign: Sitting Systolic Blood Pressure (mmHg) (New Subjects from Stage 2, Safety Set)

Table 4.3.5.a. Vital Sign: Sitting Diastolic Blood Pressure (mmHg) (Stage 1, Safety Set)
Table 4.3.5.b. Vital Sign: Sitting Diastolic Blood Pressure (mmHg) (Stage 2, Safety Set)
Table 4.3.5.c. Vital Sign: Sitting Diastolic Blood Pressure (mmHg) (New Subjects from Stage 2, Safety Set)

Table 5.1.1.a. Overall Summary of Treatment Emergent Adverse Events (Stage 1, Safety Set)

	Hoxworth			Bloodworks			Total		
	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	Total[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	Total[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	Total[1] (N = xx)
Any AEs									
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)
Any Related AEs for Apheresis Collection [2]									
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Definite/certain	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Probable/likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Possible	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Excluded	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)
Any Related AEs for Study Infusion [2]									
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Definite/certain	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Probable/likely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Possible	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unlikely	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Excluded	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)
Any Grade 3 to 5 AEs [2]									
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Death (Grade 5)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Life threatening (Grade 4)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe (Grade 3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Moderate (Grade 2)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild (Grade 1)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)
Any SAEs									
Yes [3,4]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Fatal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Life threatening	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Hospitalization	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Significant disability	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Congenital anomaly/defect	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Medically important	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)
Any Related Grade 3 to 5 AEs [2]									
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Death (Grade 5)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Life threatening (Grade 4)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe (Grade 3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)
Any Related SAEs									
Yes [3,4]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Fatal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Life threatening	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Hospitalization	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Significant disability	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Congenital anomaly/defect	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Medically important	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)

Any AEs Leading to Death or Discontinuation of Study Treatment [3, 5]									
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Death	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Discontinuation of study treatment	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)
AE Outcome [3]									
Fatal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not recovered/not resolved	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Recovered/resolved with sequelae	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Recovering/resolving	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Recovered/resolved	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unknown or not determined	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
AE Action Taken [3]									
No change/continued	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Interrupted/interrupted but resumed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Discontinued	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not applicable	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Medical History Associated									
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)
Treatment Provided									
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)	xx (100%)

Note: Treatment-emergent AEs are defined as AEs with onset at or after the initiation of apheresis platelet collection for each Period. TEAEs with onset on or after the start time of the initial apheresis platelet collection (i.e., 1st) at Period 2 will be counted as events during Period 2.
[1] Due to the cross-over design, the Total column (representing the number of unique subjects with a given event) may not equal to the sum of the corresponding sub-columns.

[2] Events with missing relationship/severity/seriousness of AEs are counted as Yes. Sub-categories are based on the worst-case scenarios. For example, a subject who experienced "possibly" and "definitely" related AEs is summarized under the "definitely"-related category.
[3] The sum across subcategories may exceed the total subject count since some subjects experienced multiple AEs.
[4] "Hospitalization" includes initial hospitalization or prolonged hospitalization. "Significant disability" includes significant disability / incapacity. "Medically important" includes other medical important events / intervention required.
[5] Death records are based on the AE Outcome. Discontinuation of study treatments are from AE Action Taken.
Reference: Listing 5.1.

Programming note:
Table 5.1.1.b. Overall Summary of Treatment Emergent Adverse Events (Stage 2, Safety Set)
Table 5.1.1.c. Overall Summary of Treatment Emergent Adverse Events (New Subjects from Stage 2, Safety Set)
Table 5.1.2.a. Overall Summary of Treatment Emergent Adverse Events – From Collection to Before Infusion (Stage 1, Safety Set)
Table 5.1.2.b. Overall Summary of Treatment Emergent Adverse Events – From Collection to Before Infusion (Stage 2, Safety Set)
Table 5.1.2.c. Overall Summary of Treatment Emergent Adverse Events – From Collection to Before Infusion (New Subjects from Stage 2, Safety Set)
Table 5.1.3.a. Overall Summary of Treatment Emergent Adverse Events – On or After Infusion (Stage 1, Safety Set)
Table 5.1.3.b. Overall Summary of Treatment Emergent Adverse Events – On or After Infusion (Stage 2, Safety Set)
Table 5.1.3.c. Overall Summary of Treatment Emergent Adverse Events – On or After Infusion (New Subjects from Stage 2, Safety Set)

Table 5.2.1.a. AEs by SOC and Preferred Term (Stage 1, Safety Set)

	Hoxworth			Bloodworks			Total		
	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	Total[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	Total[1] (N = xx)	Test: Variant 1 (N = xx)	Test: BEST (N = xx)	Total[1] (N = xx)
Any Adverse Events	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
SOC 1: xxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT1: xxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT2: xxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT3: xxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT4: xxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
SOC 2: xxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT5: xxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT6: xxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT7: xxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[1] Due to the cross-over design, the Total column (representing the number of unique subjects with a given event) may not equal to the sum of the corresponding sub-columns.
Reference: Listing 5.1.

Programming note:
Table 5.2.1.b. AEs by SOC and Preferred Term (Stage 2, Safety Set)
Table 5.2.1.c. AEs by SOC and Preferred Term (New Subjects from Stage 2, Safety Set)
Table 5.2.2.a. AEs by SOC and Preferred Term – From Collection to Before Infusion (Stage 1, Safety Set)
Table 5.2.2.b. AEs by SOC and Preferred Term – From Collection to Before Infusion (Stage 2, Safety Set)
Table 5.2.2.c. AEs by SOC and Preferred Term – From Collection to Before Infusion (New Subjects from Stage 2, Safety Set)
Table 5.2.3.a. AEs by SOC and Preferred Term – On and After Infusion (Stage 1, Safety Set)
Table 5.2.3.b. AEs by SOC and Preferred Term – On and After Infusion (Stage 2, Safety Set)
Table 5.2.3.c. AEs by SOC and Preferred Term – On and After Infusion (New Subjects from Stage 2, Safety Set)

To add sub-tables, like AE related to apheresis collection, AE related to study infusion, SAEs, etc., as needed.

Table 6.a. Device Malfunction (Stage 1, Consented Subjects)

	Hoxworth (N = xx)	Bloodworks (N = xx)	Total (N = xx)
Any Device Malfunction			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (100%)	xx (100%)	xx (100%)
Detection Occurring			
Before Use	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
During Processing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
After Processing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Processing Step			
Transfer of Component through Amotosalen Container	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
During Illumination	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
During CAD treatment	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
During Final Storage	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
During QC Sampling	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Detection Location			
Carton Box	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Packaging	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Processing Set	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Label and Labeling	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Loss of Disposable Set			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Loss of Components			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Reference: Listing 6.1.

Programming note:
Table 6.b. Device Malfunction (Stage 2, Consented Subjects)
Table 6.c. Device Malfunction (New Subjects from Stage 2, Consented Subjects)

'b' and 'c' table using the same format as Table 6.a.

TABLE OF CONTENTS FOR LISTINGS

Listing 1.1. Eligibility

Subject ID [1]	Arm – Radiolabeling [2]	Visit	Age (Yr) (Sex)	Consent Date (Day)	Met All Eligibility	Inclusion or Exclusion Criterion Not Met
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	S1P1	xx (M)	ddMMMyyyy (-x)	Yes	Inclusion: xxxxxxx xxxxxxxx xxxxxxxxxx xxxxxxxxxx Exclusion: xxxxxx xxxxx xxxx xxxxxxx x xxxxxx xxx
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$	S1P2	xx (F)		No	
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$	S2				Inclusion: xxxxxx xx x xxx xxxxx xxxx xxxxxxxxxxxxx xxxxxxxxxx
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$					Exclusion: xxxxxxxxxxx xxxxxxx xxxx x xxxxxx xxxxxxx xxxxxxxxx
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$					…
xxx-xxx@	Variant 1 – $^{111}In/^{51}Cr$					

Note: The following notes and abbreviations apply to all data listings.
For Stage 1, subject IDs starting from #101 to #199 (#161 to #199 for replacements) and #201 to #299 (#261 to #299 for replacements) for Sites 001 and 002, respectively.
For Stage 2, subject IDs starting from #301 to #399 (#361 to #399 for replacements) and #401 to #499 (#461 to #499 for replacements) for Sites 001 and 002, respectively.
Unless otherwise specified, Study Day (Day) is calculated relative to the day of apheresis collection in Period 1 (Day 0), and the day before Day 0 is Day -1.
Abbreviation: Tx = treatment; T = Test; C = Control; B = BEST; V = Variant 1; ^{51}Cr = Chromium-51; ^{111}In = Indium-111; Plt = platelet; Wt = Weight; ND = Not Done; S1P1 = Stage 1, Period 1; S1P2 = Stage 1, Period 2; S2 = Stage 2; Sc = Screening; Dx = Day x; xDPI = x days post infusion.
[1] For both Stages, subjects flagged by an at sign (@) are excluded from Safety Set; subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
Source: [CLI 00127: analysis-adsl; adie]

Programming notes for all data listings:

- Unless specified otherwise, please list all data from the database (e.g., subjects who had more than one collections within a given period will have all collections listed).
- Within each data listing, please sort the data by subject ID first, nominal visit (if applicable), and then the date/time of collection (e.g., vital signs) or onset (e.g., AE). In general, to have data sorted within a subject in a chronological order.

Listing 1.2. Study Completion and Disposition

Subject ID [1]	Arm – Radiolabeling [2]	Study Completion	Completion or Withdrawal Date (Day)	Primary Withdrawal Reason	Withdrawal Related to COVID-19	Comments
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	Yes	ddMMMyyyy (xx)	Death	Yes (Subject acquired COVID-19)	xxxxxxxxxxxx xxxxxxxxxxxxx xx xxxxxxx xxxxxxxxxxxxxxxxx xxx
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$	No		Adverse Event (AE #)	Yes (xxxxx xxxxxx xxxxxxxxxxx xx xxxxx)	
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$			Significant Protocol Deviation (PD #)	No	
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$			Withdrew of Consent (Withdrawn Date)	…	
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$			Study Termination		
xxx-xxx@	Variant 1 – $^{111}In/^{51}Cr$			Other (xxxxx xxxxxx)		
				…		

[1] For both Stages, subjects flagged by an at sign (@) are excluded from Safety Set; subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
Source: [CLI 00112: analysis-adsl]

Listing 1.3. Protocol and Procedural Deviations

Subject ID [1]	Arm – Radiolabeling [2]	Deviation (Period) [3]	Deviation Date (Day)	Date Known to Site (Day)	Reportable to IRB	Date Reported to Sponsor (Day)	Deviation Type	COVID-19 Impact	Description	Corrective Action
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	Yes (S1P1)	xxFEB2016 (xx)	xxFEB2016 (xx)	Yes	xxFEB2016 (xx)	Protocol (xxxxxxx xxxx)	Yes	xxxxxxxxxxxx xxxxxxx xxx xxxxx xxxxxxxx	xxx xx xxx xxxxxx xx xxxxx xx xxxxx
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$	Yes (S1P2)								
					No		Procedural (xx xxx xxxx x xxx)	No		
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$	No								
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$									
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$									
	Variant 1 – $^{111}In/^{51}Cr$									

Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period (Day 0), and the day before Day 0 is Day -1.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
[3] The stage and study period when the protocol deviation was occurred is shown in parentheses.
Source: [CLI 00127: analysis-adsl, addv]

Listing 2.1. Demography

Subject ID [1]	Arm – Radiolabeling [2]	Age (Yr) (Sex)	Birth Date	Race // Ethnicity	Blood Type // Rh Factor
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	xx (M)	ddMMMyyyy	White // Hispanic or Latino	A // Positive
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$	xx (F)		White // Not Hispanic or Latino	B // Positive
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$			Black or African American // Not Hispanic or Latino	AB // Negative
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$			Other (xxxxxxxxxx xxxxxxxxxx) // Hispanic or Latino	O // Positive
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$			Unknown // Unknown	
	Variant 1 – $^{111}In/^{51}Cr$				

[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign($).
Source: [CLI 00127: analysis-adsl]

Listing 2.2. Substance Use

Subject ID [1]	Arm – Radiolabeling [2]	Visit	Substance Use Collection Date (Day)	Use of Nicotine within Past 48 Hrs	Use of Cannabis within Past 48 Hrs
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	S1P1 Sc	ddMMMyyyy (xx)	Yes	Yes
				No	No
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$	S1Px D0			
		S1Px D7			
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$	S1Px 0DPI (1hr±15min)			
		S1Px 0DPI (2hr±15min)			
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$	S1Px 1DPI			
		S1Px 2DPI			
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$	S1Px 3DPI			
		S1Px 4,5,6DPI			
	Variant 1 – $^{111}In/^{51}Cr$	S1Px 7,8DPI			
		S1Px 11±1DPI			
		S2 Sc			
		...			

Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
Source: [CLI 00127: analysis-adsu]

Programming notes:
- Please show "--" (i.e., 2 dashes) for any study day that cannot be calculated (e.g., without collection/infusion date).
- Please show all data from a given subject (e.g., subject 002-204 who had multiple collections for Period 2).

Listing 2.3.1. Physical Examination (Part 1 of 2)

Subject ID [1]	Arm – Radiolabeling [2]	Visit	PE Done	PE Date (Day)	Skin	EENT	Head/Neck	Pulmonary	Chest	Cardiovascular
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	S1P1 Sc	Yes	ddMMMyyy (xx)	ND	ND	ND	ND	ND	ND
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$	S1P1 11±1DPI	No		Normal	Normal	Normal	Normal	Normal	Normal
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$	S1P2 11±1DPI			Ab (NCS)	Ab (NCS)	Ab (NCS)	Ab (NCS)	Ab (NCS)	Ab (NCS)
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$				Ab (CS)	Ab (CS)	Ab (CS)	Ab (CS; xxx x xxxxxx xxxxxxxxx xxx)	Ab (CS)	Ab (CS)
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$ Variant 1 – $^{111}In/^{51}Cr$	S2 Sc S2 11±1DPI								

Note: Abbreviation: PE= Physical Examination; ND = Not Done; Ab = Abnormal; CS = Clinical Significant; NCS = Non-Clinical Significant.
Note: If abnormal, physical exam finding(s) are provided in paranthesis as applicable.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
Source: [CLI 00127: analysis-adpe]

Listing 2.3.2. Physical Examination (Part 2 of 2)

Subject ID [1]	Arm – Radiolabeling [2]	Visit	PE Done	PE Date (Day)	Abdominal & Liver/Spleen	Lymphatic	Musculoskeletal	Neurological	Other
xxx-xxx	BEST/Variant 1 – ^{51}Cr/^{111}In	S1P1 Sc	Yes	ddMMMyyy (xx)	ND	ND	ND	ND	
xxx-xxx^	Variant 1/BEST – ^{51}Cr/^{111}In	S1P1 11±1DPI	No		Normal	Normal	Normal	Normal	xxxxxx xxxx: Normal
xxx-xxx*	BEST/Variant 1 – ^{11}^{1}In/^{51}Cr	S1P2 11±1DPI			Ab (NCS)	Ab (NCS)	Ab (NCS)	Ab (NCS)	xxxxxx xxxx: Ab (NCS)
xxx-xxx^#	Variant 1/BEST – ^{111}In/^{51}Cr				Ab (CS)	Ab (CS; xxx x xxxxxx xxxxxxxxx xxx)	Ab (CS)	Ab (CS)	xxxxxx xxxx: Ab (CS)
xxx-xxx*#	Variant 1 – ^{51}Cr/^{111}In	S2 Sc							
	Variant 1 – ^{111}In/^{51}Cr	S2 11±1DPI							

Note: Abbreviation: PE= Physical Examination; ND = Not Done; Ab = Abnormal; CS = Clinical Significant; NCS = Non-Clinical Significant.
Note: If abnormal, physical exam finding(s) are provided in paranthesis as applicable.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
Source: [CLI 00127: analysis-adpe]

Listing 2.4. Medical History

Subject ID [1]	Arm – Radiolabeling [2]	Visit	Any Relevant Med. History	Onset // Resolution Date (Day)	Body System Category	Diagnosis and/or Procedure
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	S1P1 Sc	Yes	ddMMMyyy (xx) // ddMMMyyy (xx)	01: Skin	Allergy to clindamycin and almonds
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$	S2 Sc	No	ddMMMyyy (xx) // Ongoing	02: EENT	xxx x xxxxxx xxxxxxxxx xxx
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$				03: Breasts	
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$				04: Respiratory	
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$				xx: Lymphatic/Hematologic	
	Variant 1 – $^{111}In/^{51}Cr$				xx: xxxx xxxxxxxxxxxxx	
					...	

[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
Source: [CLI 00127: analysis-adsl; admh]

Listing 2.5. Prior or Concomitant Medication

Subject ID [1]	Arm – Radiolabeling [2]	Med. [3]	Prior or Concomitant	Stage Period [4]	Start // Stop Date (Day)	Medication Name (AE) // Indication [5]	Dose (Unit)	Frequency // Route
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	Yes	Prior		2014 // Ongoing	Emergen-C // Vitamin/supplement	200 (mg)	PRN // TOP
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$	No	Concomitant	S1P1	02MAR2020 (0) // 02MAR2020 (0)	Ciprofloxacin (Urinary Tract Infection; Kidney infection) // Urinary tract and kidney infection	xxx (xxxxx)	x5 doses during aplt // PO
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$			S1P2				Other (xx xxxxxx) // Other (xxxxxx xxxxx xxx)
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$			S2				
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$ Variant 1 – $^{111}In/^{51}Cr$					...		...

[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
[3] Has the subject taken any medications within 4 weeks prior to the first donation and/or during the study?
[4] Study period of the start date, if applicable.
[5] AE verbatim(s) are provided in parentheses, if applicable.
Source: [CLI 00127: analysis-adsl; adcm]

Listing 2.6. Pregnancy Test

Subject ID [1]	Arm – Radiolabeling [2]	Age (Yr) (Sex)	Visit	Childbearing Potential (Reason)	Pregnancy Test Performed	Pregnancy Test Date (Day)	Pregnancy Test Type // Result
		xx (M)					
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	xx (F)	S1P1 Sc	Yes	Yes	ddMMMyyyy (xx)	Blood // Negative
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$		S1Px D7				Urine // Positive
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$		S1Px 11±1DPI	No (Postmenopausal)	No (xxxxxxxxxxx)		
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$						...
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$		S2 Sc	No (Surgically sterile)			
	Variant 1 – $^{111}In/^{51}Cr$		S2 D7				
			S2 11±1DPI	No (Other: xxxx xxx xx xx)			

Note: Only female subjects are included in this data listing.
Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period (Day 0), and the day before Day 0 is Day -1.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
Source: [CLI 00127: analysis-adrp]

Listing 3.1. Local Laboratory Tests - Chemistry

Subject ID [1]	Arm – Radiolabeling [2]	Visit	Lab Performed (Lab Name)	Sampling Date Time (Day)	Test Item: Evaluation of Result // Result // Lab Ranges	Comments
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	S1P1 Sc	Yes (xxxxxx xxxxxxxx)	ddMMMyyyy hh:mm (xx)	1.BUN: Normal // 15 mmol/L // 10-20	xxxxxxxxxxxxx xx xxxx
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$	S1Px D0			2.Ca: Not Done	
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$	S1Px D7	No		3.CO_2: Abnormal, not CS // 20 mg/dL // 12-18	
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$	S1Px 11±1DPI			4.Cl: xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$				5.Cr: Abnormal, CS // xxxxxx // xxxxxx	
	Variant 1 – $^{111}In/^{51}Cr$				6.Glu: xxxxxxxxxxxxxxxxxxx	
		S2 Sc			7.K: xxxxxxxxxxxxxxxxx	
		S2 D0			8.Na: xxxxxxxxxxxxxxxxxxxxxxxxxx	
		S2 D7				
		S2 11±1DPI				

Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period (Day 0), and the day before Day 0 is Day -1.
Note: Abbreviation for test items: BUN = Blood Urea Nitrogen; Ca = Calcium; CO_2 = Carbon Dioxide; Cl = Chloride; Cr = Creatinine; Glu= Glucose; K = Potassium; Na = Sodium.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
Source: [CLI 00127: analysis-adlb]

Listing 3.2. Local Laboratory Test - Hematology

Subject ID [1]	Arm – Radiolabeling [2]	Visit	Lab Performed (Lab Name)	Sampling Date Time (Day)	Test Item: Evaluation of Result // Result // Lab Ranges	Comments
xxx-xxx	BEST/Variant 1 – ^{51}Cr/^{111}In	S1P1 Sc	Yes (xxxxxx xxxxxxxx)	ddMMMyyyy hh:mm (xx)	1.HCT: Normal // 45.7 % // 38.5-50	xxxxxxxxxxxxx xx xxxx
xxx-xxx^	Variant 1/BEST – ^{51}Cr/^{111}In	S1Px D0			2.HGB: Normal // 15.2 g/dL // 13.2-17.1	
xxx-xxx*	BEST/Variant 1 – ^{111}In/^{51}Cr	S1Px D7	No		3.RBC: Not Done	
xxx-xxx^#	Variant 1/BEST – ^{111}In/^{51}Cr	S1Px 11±1DPI			4.PLT: Abnormal, CS // xxxxxxx // xxxxxxxxxx	
xxx-xxx*#	Variant 1 – ^{51}Cr/^{111}In Variant 1 – ^{111}In/^{51}Cr				5.WBC: Abnormal, CS // xxxxxxx // xxxxxxxxxx 6.ANC: Normal // 3764 cells/µL // 1500-7800	
		S2 Sc			7.AMC: Normal // 787 cells/µL // 200-950	
		S2 D0			8.ALC: Normal // 3321 cells/µL // 850-3900	
		S2 D7			9.BAS: Normal // 33 cells/µL // 0-200	
		S2 11±1DPI			10.EOS: Normal // 295 cells/µL // 15-500	

Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period (Day 0), and the day before Day 0 is Day -1.
Note: Abbreviation for test items: HCT = Hematocrit; HGB = Hemoglobin; RBC = Red Blood Cell Count; PLT = Platelet Count; WBC = Total White Blood Cell Count; ANC = Neutrophil (Absolute); AMC = Monocyte (Absolute); ALC = Lymphocyte (Absolute); BAS = Basophils (Absolute); EOS = Eosinophils (Absolute).
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
Source: [CLI 00127: analysis-adlb]

Listing 3.3. Vital Signs

Subject ID [1]	Arm – Radiolabeling [2]	Visit	Vital Sign Performed	Assessment Date Time (Days)	Height (cm)	Weight (kg)	BMI	Temp. (°C)	Pulse (bpm)	SBP (mmHg)	DBP (mmHg)
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	S1P1 Sc	Yes	ddMMMyyy hh:mm (xx, xx)	xxx.x	xxx.x	xx.x	xx.x	xx	xxx	xxx
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$		No								
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$	S1Px D0		ddMMMyyy hh:mm (xx, --)							
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$	S1Px D7									
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$ Variant 1 – $^{111}In/^{51}Cr$	S1Px 0DPI (1hr±15min) S1Px 0DPI (2hr±15 min) S1Px 1DPI S1Px 2DPI S1Px 3DPI S1Px 4,5,6DPI S1Px 7,8DPI S1Px 11±1DPI									
		S2 Sc ...									

Note: For this listing, Study Days (Days) are calculated relative to the day of apheresis collection as well as the day of infusion within each period. The day of collection/infusion is Day 0, and the day before Day 0 is Day -1.
Note: Height is collected at the screening visit only. Body mass index (BMI) is calculated as weight in kilograms divided by height (from Screening) in meters squared.
Note: Abbreviation: Temp = Oral Temperature; SBP = Sitting Systolic Blood Pressure; DBP = Sitting Diastolic Blood Pressure.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
Source: [CLI 00127: analysis-advs]

Programming notes:
- Please calculate the BMI, instead of using the BMI value entered by the sites.

Listing 3.4. Platelet Apheresis Collection and Storage

Subject ID [1]	Arm – Radiolabeling [2]	Stage Period	Collection Date (Day)	Plt Count (Target) [3]	Start // End Time	Component or Donation ID // MID [4]	Lot # (Kit) // Expiry Date [5]	ACD Lot // Expiry Date (Day)	Alarms // Completed [6]	Comments
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	S1P1	ddMMMyyyy (0)	xxx (S)	08:36 // 09:39	W037719028718 // T-25	191011130 (S) // 01OCT2021	19BC3058C // 01APR2021 (443)	No // Yes	xxxx xxx xxxx
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$	S1P2		xxx (D)					Yes (xxx x) // No (xxx xxxx)	
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$					BWNW 127-111 // APL-158	1809135151 (S) // 01SEP2020			
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$	S2								
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$ Variant 1 – $^{111}In/^{51}Cr$									

Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period (Day 0), and the day before Day 0 is Day -1.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
[3] Pre-donation subject platelet count ($\times 10^3$ /µL), with target dose collection (S = single dose; D = double dose) presented in parentheses.
[4] MID = Apheresis machine ID number.
[5] Apheresis collection set lot number, Apheresis set kit type (S = single needle; D = double needle) presented in parentheses, and Apheresis set expiration date.
[6] Were there any machine messages or alarms during the collection? Was the collection successfully completed? Any details specified are presented in parentheses.
Source: [CLI 00127: analysis-adcoll]

Listing 3.5. In-Vitro Study Assessment: Input Component Form

Subject ID [1]	Arm – Radiolabeling [2]	Stage Period	Acceptability Criteria Met	Sampling Date Time (Day)	Pre // Post Gross Wt (g)	Vol. (mL)	Dose ($\times 10^{11}$)	Plt. Count (10^3/µl)	pH (22°C)	CD62P (%)	Sup. [3] // Total LDH (U/L)	ATP (µmol/ dL)	Comments
xxx-xxx	BEST/Variant 1 – ^{51}Cr/^{111}In	S1P1	Yes	ddMMMyyyy hh:mm (xx)	xxx.x // xxx.x	xxx.x	x.x	xxxx	x.xxx	xx.x	xxx // xxx	xx	xxxx xxx xxxx
xxx-xxx^	Variant 1/BEST – ^{51}Cr/^{111}In	S1P2	No (xx xxxxx xx)										
xxx-xxx*	BEST/Variant 1 – ^{111}In/^{51}Cr												
xxx-xxx^#	Variant 1/BEST – ^{111}In/^{51}Cr	S2											
xxx-xxx*#	Variant 1 – ^{51}Cr/^{111}In Variant 1 – ^{111}In/^{51}Cr												

Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period (Day 0), and the day before Day 0 is Day -1.
Note: Normalized numbers for Sup LDH, ATP, and Lysis are on Listing 3.13.2.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
[3] Sup = Supernatant.
Source: [CLI 00127: analysis-adinv]

Listing 3.6. Test Input

Subject ID [1]	Arm – Radiolabeling [2]	Stage Period	Preparation Start Date (Day)	Final Input Weight (g)	Final Input Volume (mL)	Final Input Dose (x10^{11})	Input Platelet Characteristics	Comments
xxx-xxx	BEST/Variant 1 – ^{51}Cr/^{111}In	S1P1	ddMMMyyyy (xx)	xxx.x	xxx.x	x.x	DS (Input Dose 3.0 5.2 ×10^{11}, Volume 300 - 390 mL)	xxxxxxxxxxxxxxxx
xxx-xxx^	Variant 1/BEST – ^{51}Cr/^{111}In	S1P2						
xxx-xxx*	BEST/Variant 1 – ^{111}In/^{51}Cr						DS 2 (Input Dose 5.3 7.9 ×10^{11}, Volume 375 - 420 mL)	
xxx-xxx^#	Variant 1/BEST – ^{111}In/^{51}Cr	S2						
xxx-xxx*#	Variant 1 – ^{51}Cr/^{111}In						Input Platelet Characteristics Criteria Not Met	
	Variant 1 – ^{111}In/^{51}Cr							

Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period (Day 0), and the day before Day 0 is Day -1.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
Source: [CLI 00127: analysis-adcoll]

Listing 3.7. INTERCEPT Treatment: Illumination

Subject ID [1]	Arm – Radiolabeling [2]	Stage Period	Cannulas Broken Time	Input Gross Weight (g)	Treatment Set Lot No.	Illumination Start Date Time (Day)	Duration from Donation (hr)	UV Dose (J/cm^2)	Tx Duration (min)	Container Status	Comments
xxx-xxx	BEST/Variant 1 – ^{51}Cr/^{111}In	S1P1	hh:mm	xxx.x	CE19B08L72	ddMMMyyyy	x.xx	x.xx	xx.x	Complete	xxxxx
xxx-xxx^	Variant 1/BEST – ^{51}Cr/^{111}In	S1P2				hh:mm (xx)				Incomplete	xxxxxxxx
xxx-xxx*	BEST/Variant 1 – ^{111}In/^{51}Cr										
xxx-xxx^#	Variant 1/BEST – ^{111}In/^{51}Cr	S2				Not Done					
xxx-xxx*#	Variant 1 – ^{51}Cr/^{111}In Variant 1 – ^{111}In/^{51}Cr										

Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period (Day 0), and the day before Day 0 is Day -1.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
Source: [CLI 00127: analysis-adibs]

Programming notes:

- If Not Done was checked for the “INTERCEPT Treatment: Illumination” CRF, please show “Not Done” under the column noted above.

Listing 3.8. INTERCEPT Treatment: CAD

Subject ID [1]	Arm – Radiolabeling [2]	Stage Period	Container Gross Weight (g)	Transfer to CAD Container Date Time (Day)	CAD Start Date Time (Day)	CAD Stop Date Time (Day)	CAD Duration (hr)	Post-CAD Weight (g)	Comments
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	S1P1	xxx.x	ddMMMyyyy hh:mm (xx)	ddMMMyyyy hh:mm (xx)	ddMMMyyyy hh:mm (xx)	xx.x	xxx.x	xxxxxxxxxx
xxx-xxx ^	Variant 1/BEST – $^{51}Cr/^{111}In$	S1P2							
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$				Not Done				
xxx-xxx ^#	Variant 1/BEST – $^{111}In/^{51}Cr$	S2							
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$								
	Variant 1 – $^{111}In/^{51}Cr$								

Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period (Day 0), and the day before Day 0 is Day -1.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
Source: [CLI 00127: analysis-adibs]

Programming notes:

- If Not Done was checked for the “INTERCEPT Treatment: CAD” CRF, please show “Not Done” under the column noted above.

Listing 3.9. INTERCEPT Treatment: Transfer to Final Storage

			CAD to Storage Container		Post-INTERCEPT Pre-Sampling						Post-INTERCEPT Post-Sampling			
Subject ID [1]	Arm – Radiolabeling [2]	Stage Period	Transfer Date Time (Day)	Container Stored [3]	Container Sampled [4]	Weight (g) [4]	Vol. (mL)	Plt Cnt ($x10^3/\mu L$)	Dose ($x10^{11}$)	Plt Yield Ret. (%)	Weight (g)	Vol. (mL)	Transfer Date Time (Day)	Comments
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	S1P1	ddMMMyyyy hh:mm (xx)	One	A	xxx.x	xxx.x	xxxx	x.x	xx.x	xxx.x	xxx.x	ddMMMyyyy hh:mm (xx)	xxxxxxxxxx
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$	S1P2		Two-Conn.	B									
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$													
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$	S2		Two-Sep.	A+B									
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$													
	Variant 1 – $^{111}In/^{51}Cr$													
			Not Done											

Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period (Day 0), and the day before Day 0 is Day -1.
Note: Abbreviation: Vol = volume; Plt Cnt = platelet count; Ret = Retention.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
[3] Component stored in 1 container or 2 containers (connected or separated).
[4] Container sampled and the gross weight of the component in final storage container.
Source: [CLI 00127: analysis-adibs, adeff3]

Programming notes:
- If Not Done was checked for the “INTERCEPT Treatment: Transfer to Final Storage” CRF, please show “Not Done” under the column noted above.

Listing 3.10. Bacteria Culture

Subject ID [1]	Arm – Radiolabeling [2]	Stage Period	Gross Weight of Plt Unit Pre // Post Sampling (g) [3]	Sampling // Loading Date Time (Day)	Result Before Infusion Date Time (Day) // Result	Final Result Date Time (Day) // Result	Comments
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	S1P1	(A) xxx.x // xxx.x	ddMMMyyyy xx:xx (xx) // ddMMMyyyy xx:xx (xx)	ddMMMyyyy xx:xx (xx) // Positive	ddMMMyyyy xx:xx (xx) // Positive	xxxxxxxxx
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$						
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$	S1P2	(A+B) xxx.x // xxx.x		ddMMMyyyy xx:xx (xx) // Negative	ddMMMyyyy xx:xx (xx) // Negative	
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$						
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$		(B) xxx.x // xxx.x				
	Variant 1 – $^{111}In/^{51}Cr$	S2					
				Not Done			

Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period (Day 0), and the day before Day 0 is Day -1.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
[3] Container sampled is provided in parentheses.
Source: [CLI 00127: analysis-adoth]

Programming notes:

- If Not Done was checked for the “Bacteria Culture” CRF, please show “Not Done” under the column noted above.

Listing 3.11. RBC Contamination Assessment (Ficoll Gradient)

Subject ID [1]	Arm – Radiolabeling [2]	Visit	Start Date Time (Day)	P/L Layers Wt Pre//Post (g) [3]	RBC Layers Wt Pre//Post (g) [3]	P/L Layer CPM		RBC Layer CPM		Contamination (%)		Comments
						^{51}Cr	^{111}In	^{51}Cr	^{111}In	Test	Control	
xxx-xxx	BEST/Variant 1 – ^{51}Cr/^{111}In	S1Px 1DPI	ddMMMyyyy hh:mm (xx)	0 // 0.xxxx	0 // 0.xxxx	xxx	xxx	xxx	xxx	xx.x	xx.x	xxxxx xxxxxxxx
xxx-xxx^	Variant 1/BEST – ^{51}Cr/^{111}In			x.xxxx // x.xxxx	x.xxxx // x.xxxx	xxx.x	xxx.x	xxx.x	xxx.x			
xxx-xxx*	BEST/Variant 1 – ^{111}In/^{51}Cr	S1Px 4,5,6DPI										
xxx-xxx^#	Variant 1/BEST – ^{111}In/^{51}Cr											
xxx-xxx*#	Variant 1 – ^{51}Cr/^{111}In Variant 1 – ^{111}In/^{51}Cr	S1Px 11±1 DPI										
		S2 11±1 DPI	Not Done									

Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period (Day 0), and the day before Day 0 is Day -1.
Note: Abbreviation: P/L = plasma/leukocyte; CPM = counts per minute.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
[3] Pre = pre-weight of empty labeled tube; Post = weight of tube with aspirated fluid.
Source: [CLI 00127: analysis-adoth, adeff4]

Programming notes:

- If Not Done was checked for the “RBC Contamination Assessment (Ficoll Gradient)” CRF, please show “Not Done” under the column noted above.
- In terms of data precision, please ensure the weights and counts shown above are exactly the same as the data entered in the database.

Listing 3.12. In-Vitro Study Assessment: End of Storage (Day 7)

Subject ID [1]	Arm – Radiolabeling [2]	Stage Period	Storage Bag	pH Sample		Pre // Post Gross Wt (g)	Plt Vol (mL) [3]	Plt Dose ($\times 10^{11}$)	Plt Count ($\times 10^3$ /µL)
				Sampling Container	Sampling Date Time (Day)				
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	S1P1	One	A	ddMMMyyyy hh:mm (xx)	xxx.x // xxx.x	xxx.x	x.x	xxxx
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$	S1P2	Two	B					
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$			A+B					
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$	S2							
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$								
	Variant 1 – $^{111}In/^{51}Cr$								

Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period (Day 0), and the day before Day 0 is Day -1.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
[3] Corrected volume.
Source: [CLI 00127: analysis-adinv, adeff3]

Listing 3.13.1. In-Vitro Study Assessment: Additional Efficacy Endpoints – Part 1 of 3

Subject ID [1]	Arm – Radiolabeling [2]	Visit	Sampling Date Time (Day)	Plt Count ($\times 10^3$ /µL)	Comp Vol (Cor) (mL) [3]	Plt Dose (Cor) ($\times 10^{11}$) [3]	Glucose // Norm. [4]	Lactate // Norm. [4]	pO_2 // Norm. [4]	pCO_2 // Norm. [4]
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	S1Px D0-1 (PreI)	ddMMMyyyy hh:mm (xx)	xxxx	xxx	x.x	xx.x // xx.x	xx.x // xx.x	xxx.x // xxx.x	xx.x // xx.x
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$				or	or				
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$	S1Px D0-1 (PosI)			xxx (xxx)	x.x (x.x)				
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$									
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$	S1Px D7 (ES)								
	Variant 1 – $^{111}In/^{51}Cr$	S1Px D7 (BR)								
		S2 D0 1 (PreI)								
		...								

Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period (Day 0), and the day before Day 0 is Day -1.
Note: Abbreviation for Visit: PreI = Pre INTERCEPT; PosI = Post INTERCEPT; ES = End of storage; BR = Before Radiolabeling.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
[3] Comp = Component; Cor = Corrected. Data presented inside the parentheses is the corrected version, applicable only to the end of storage visit; see SAP for details about this correction handling.
[4] Units of assessments: Glucose (mmol/L), Normalized Glucose (mmol/10^{12}), Lactate (mmol/L), Normalized Lactate (mmol/10^{12}), pO_2 at 37°C (mmHg), Normalized pO_2 at 37°C (µmol/hrs/10^{12}), pCO_2 at 37°C (mmHg), Normalized pCO_2 37°C (µmol/hrs/10^{12}).
Source: [CLI 00127: analysis-adeff3]

Listing 3.13.2. In-Vitro Study Assessment: Additional Efficacy Endpoints – Part 2 of 3

Subject ID [1]	Arm – Radiolabeling [2]	Visit	Sampling Date Time (Day)	HCO_3- // Norm. [3]	Sup. LDH // Norm. [3]	Total LDH [3]	ATP // Norm. [3]	Lysis // Adj Lysis [3]	Sample Vol (mL)	Sample Dose (10^9)
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	S1Px D0-1 (PreI)	ddMMMyyyy hh:mm (xx)	x.x // x.x	xxx // xxx	xxx	xx.x // xx.x	xx.x // xx.x	xx.x	xx
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$									
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$									
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$									
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$	S1Px D7 (ES)								
	Variant 1 – $^{111}In/^{51}Cr$									
		S2 D0 1 (PreI)								
		...								

Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period (Day 0), and the day before Day 0 is Day -1.
Note: Abbreviation for Visit: PreI = Pre INTERCEPT; PosI = Post INTERCEPT; ES = End of storage; BR = Before Radiolabeling; FR = For Radiolabeling.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
[3] Units of assessments: HCO_3- at 37°C (mmol/L), Normalized HCO_3- at 37°C(mmol/10^{12}), Supernatant LDH (U/L), Normalized Supernatant LDH (mmol/10^{12}), Total LDH (U/L), ATP (µmol/dL), Normalized ATP (nmol/10^8), Lysis (%), Adjusted Lysis (%).
Source: [CLI 00127: analysis-adeff3]

Listing 3.13.3. In-Vitro Study Assessment: Additional Efficacy Endpoints – Part 3 of 3

Subject ID [1]	Arm – Radiolabeling [2]	Visit	Sampling Date Time (Day)	Morphology Score	HSR (%)	ESC (%)	CD62P (%)	MPV (fL)	pH @ 22°C	RBC Count (10^4/mL)	Total RBC Count (cells)	WBC Count (cells/µL)	Total WBC Count (cells)	Comments
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	S1Px D0-1 (PreI)	ddMMMyyyy hh:mm (xx)	xxx	xx.x	xx.x	xx.x	xx.x	xx.x	xx	xx	xx.x	xx	xxxxx
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$													xxxxxx
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$													
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$													
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$	S1Px D7 (ES)												
	Variant 1 – $^{111}In/^{51}Cr$	S1Px D7 (BR)												
		S2 D0 1 (PreI)												
		...												

Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period (Day 0), and the day before Day 0 is Day -1.
Note: Abbreviation for Visit: PreI = Pre INTERCEPT; PosI = Post INTERCEPT; ES = End of storage; BR = Before Radiolabeling.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
Source: [CLI 00127: analysis-adeff3, adinv]

Listing 3.14. EDTA Sample Collection

Subject ID [1]	Arm – Radiolabeling [2]	Stage Period	Sample Collected	Sampling Date Time (Day)	Sampled as Scheduled
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	S1P1	Yes	ddMMMyyyy hh:mm (xx)	Yes
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$				
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$	S1P2	No (xxxxxxx xxxxxxx xxxxxxxxxx)		No (xx xxxxxxxxxx xxxxxxxx xxxxxxx)
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$				
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$	S2			
	Variant 1 – $^{111}In/^{51}Cr$				

Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period (Day 0), and the day before Day 0 is Day -1.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
Source: [CLI 00127: analysis-adsmp]

Listing 3.15. Radiolabeling for Control and Test Platelets

Subject ID [1]	Arm – Radiolabeling [2]	Stage Period	WB Collection Date Time (hh:mm) (Day) [3]	WB Vol (mL) [3]	Platelet Type	Radiolabel Incubation Start // End Time (hh:mm)	Pellet Dose // Supernate Dose (µCi)	Radiolabel Efficiency (%) [4]	Problems during Radiolabeling (Comments)
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	S1P1							
			ddMMMyyyy hh:mm (xx)	xx	Control	hh:mm // hh:mm	xx.x // xx.x	xx.x	No
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$				Test	hh:mm // hh:mm	xx.x // xx.x	xx.x	No
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$								
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$	S1P2							
			ddMMMyyyy hh:mm (xx)	xx	Control	hh:mm // hh:mm	xx.x // xx.x	xx.x	No
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$				Test	hh:mm // hh:mm	xx.x // xx.x	xx.x	Yes (xxxxx xx xxxxxx)
	Variant 1 – $^{111}In/^{51}Cr$	S2							

Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period (Day 0), and the day before Day 0 is Day -1.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
[3] Whole blood (WB) collection date/time and volume are collected for Control platelets only.
[4] Radiolabeling Efficiency = pellet dose / (pellet dose + supernatant dose).
Source: [CLI 00127: analysis-adrd, adeff4]

Programming notes:

- For this listing, within each period and each patient, please present the result for Control platelet first, and then for Test platelet (instead of chronological order).

Listing 3.16. Radiolabeling for Test Platelets

Subject ID [1]	Arm – Radiolabeling [2]	Stage Period	Cri. Met [3]	(Container) Sampling Date Time (Day) [4]	Pre // Post Gross Wt (g)	Pre-Wt of Empty Tubes 1 // 2 // 3 // 4 (g) [5]	Gross Wt of Filled Tubes 1 // 2 // 3 // 4 (g) [5]	Pre-Wt of Final Tubes 1 // 2 (g) [6]	Gross Wt Post Hard Spin 1 // 2 (g)	Sample Stopped [7]
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	S1P1	Yes	(A) ddMMMyyyy hh:mm (xx)	xxx.x // xxx.x	xx.x // xx.x // xx.x // xx.x	xx.x // xx.x // xx.x // xx.x	xx.x // xx.x	xx.x // xx.x	Sample 1
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$	S1P2								
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$		No (xxx)	(B) ddMMMyyyy hh:mm (xx)		xx.x // xx.x // NA // NA	xx.x // xx.x // NA // NA	NA // NA		Sample 2
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$	S2								
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$ Variant 1 – $^{111}In/^{51}Cr$			(A+B) ddMMMyyyy hh:mm (xx)		xx.x // -- // -- // NA	-- // -- // -- // --	-- // --		

Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period (Day 0), and the day before Day 0 is Day -1.
Missing weights are shown as "--" (double dashes).
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
[3] Did the platelets meet the release criterion?
[4] Container sampled is shown in parentheses.
[5] Tubes #3 and #4 are only needed for ^{51}Cr radiolabeling.
[6] Pre-weight of final tubes only needed for BEST method labeling
[7] Sample stopped for *in vitro* analysis.
Source: [CLI 00127: analysis-adrd]

Programming notes:

- For this listings, please show "--" (double dashes) if a given tube's weight is missing to avoid possible confusion caused by misalignment. If "NA" was checked for a tube's weight, please show is as "NA".

Listing 3.17. Injectate Infusion

Subject ID [1]	Arm – Radiolabeling [2]	Stage Period	Infusion Performed	Infusion Date (Day)	Time 1/2 Injectate Infused	Problems during Infusion (Comments)
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	S1P1	Yes	ddMMMyyyy (xx)	hh:mm	Yes (xxxxxxxxxxxxxx xxxxx)
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$		or			or
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$	S1P2	No			No
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$					
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$	S2				
	Variant 1 – $^{111}In/^{51}Cr$					

Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period (Day 0), and the day before Day 0 is Day -1.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
Source: [CLI 00127: analysis-adoth]

Listing 3.18. Blood Sample for Radioactivity Measurement

Subject ID [1]	Arm – Radiolabeling [2]	Visit	Sample Drawn (Contralateral Arm)	Sampling Date Time (Day)	Comments
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	S1Px D7	Yes (Yes)	ddMMMyyyy hh:mm (xx, xx)	xxxx xxxxx xxxxxx xxxxxxx xxxxxx
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$	S1Px 0DPI (1hr±15mins)			
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$	S1Px 0DPI (2hr±15min)	Yes (No)		
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$	S1Px 1DPI			
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$	S1Px 2DPI	No		
	Variant 1 – $^{111}In/^{51}Cr$	S1Px 3DPI			
		S1Px 4,5,6DPI			
		S1Px 7or8DPI			
		S1Px 11±1DPI			
		S2 D7			
		...			

Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period, and the second number inside the parentheses is the number of days post infusion.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
Source: [CLI 00127: analysis-adsmp]

Listing 4.1. Sample Weights

			Pre // Post (g)								
								Sampled Weight			
Subject ID [1]	**Arm – Radiolabeling [2]**	**Stage Period**	**Wt of Syringe for Infusion [3]**	**Wt of Syringe in Flasks [4]**	**Mixed Standard Counted [5]**	**Elution [5]**	**Visit: Date Time (Day)**	**WBa [5]**	**WBb [5]**	**Packed Cells [5]**	**PLS [5]**
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	S1P1	xx.xxx // xx.xxx	Wt 1: x.xxxx // x.xxx	Wt 1: x.xxxx // x.xxx	RBC-A: x.xxx // x.xxx	D7: ddMMMyyyy hh:mm (xx)	x.xxxx // x.xxxx	x.xxxx // x.xxxx	x.xxxx // x.xxxx	x.xxxx // x.xxxx
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$	S1P2		Wt 2: x.xxxx // x.xxx	Wt 2: x.xxxx // x.xxx	RBC-B: x.xxx // x.xxx	0DPI (1hr±15min): ddMMMyyyy hh:mm (xx)				
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$			Wt 3: x.xxxx // x.xxx	Wt 3: x.xxxx // x.xxx	PLS-A: x.xxx // x.xxx	0DP I(2hr±15min): ddMMMyyyy hh:mm (xx)				
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$	S2				PLS-B: x.xxx // x.xxx	1DPI: ddMMMyyyy hh:mm (xx)				
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$						2DPI: ddMMMyyyy hh:mm (xx)				
	Variant 1 – $^{111}In/^{51}Cr$						3DPI: ddMMMyyyy hh:mm (xx)				
							4,5,6DPI: ddMMMyyyy hh:mm (xx)				
							7or8DPI: ddMMMyyyy hh:mm (xx)				
							11±1DPI: ddMMMyyyy hh:mm (xx)				
							11±1DPI: ...	ND // ND	ND // ND	ND // ND	ND // ND

Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period (Day 0), and the day before Day 0 is Day -1.
Note: Abbreviation: WBa = whole blood sample a; WBb = whole blood sample b; PLS = plasma.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
[3] Pre-Weight, Filled Syringe // Post-Weight, Post-Infusion.
[4] Pre-Weight, Filled Syringe // Post-Weight, Post-Syringe.
[5] For mixed standard counted, elution of radioactivity from labeled platelets in whole blood, and sample weights: Pre-Weight, Empty Tube // Post-Weight, Filled Tube.
Source: [CLI 00127: analysis-adscw]
Programming notes:

- If “Not Done” was checked for Sample Weights at any visit, please show “ND” for the given visit. And, please page break by Period and show subject ID in each page.

Listing 4.2. Sample Counts Per Minute (CPM)

Subject ID [1]	Arm – Radiolabeling [2]	Stage Period	(Cr // In) Mixed Standard Count (CPM) STD 1	STD 2	STD 3	Elution (CPM) [3] PC-A	PC-B	PLS-A	PLS-B	In Vitro Elution (%) [4]	Blood Sampling for Radioactivity (CPM) Visit	WBa	WBb	PC	PLS	In Vivo Elution (%) [5]
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	S1P1	xx//xx	xx//xx	xx//xx	xx//xx	xx//xx	xx//xx	xx//xx	xx.x // xx.x	D7	xxxx // xxxx	xxxx // xxxx	xxxx // xxxx	xxxx // xxxx	
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$										0DPI (1hr±15min)	xxxx // xxxx	xxxx // xxxx	xxxx // xxxx	xxxx // xxxx	xx.x // xx.x
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$										0DPI (2hr±15min)	xxxx // xxxx	xxxx // xxxx	xxxx // xxxx	xxxx // xxxx	
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$										1DPI	xxxx // xxxx	xxxx // xxxx	xxxx // xxxx	xxxx // xxxx	
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$										2DPI	xxxx // xxxx	xxxx // xxxx	xxxx // xxxx	xxxx // xxxx	
	Variant 1 – $^{111}In/^{51}Cr$										3DPI	xxxx // xxxx	xxxx // xxxx	xxxx // xxxx	xxxx // xxxx	
											4,5,6DPI	xxxx // xxxx	xxxx // xxxx	xxxx // xxxx	xxxx // xxxx	
											7or8DPI	xxxx // xxxx	xxxx // xxxx	xxxx // xxxx	xxxx // xxxx	
											11±1DPI	xxxx // xxxx	xxxx // xxxx	xxxx // xxxx	xxxx // xxxx	
		S1P2									0DPI (1hr±15min)	ND // ND	ND // ND	ND // ND	ND // ND	xx.x // xx.x
		S2														

Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period (Day 0), and the day before Day 0 is Day -1.
Note: Abbreviation: WBa = whole blood sample a; WBb = whole blood sample b; PLS = plasma; PLS-A = plasma sample a; PLS-B = plasma sample B; PC = packed cells. STD = Standard.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
[3] In vitro elution of radioactivity from labeled platelets in whole blood.
[4] In vitro elution (%) = (Elution Plasma CPM per g)/ (Elution Plasma CPM per g + Elution Packed Cells CPM per g)×100.
[5] In vivo Elution = (1-hour Plasma CPM per g) / (1-hour Plasma CPM per g + 1-hour RBC CPM per g). The averaged value from the two samples is used. If the values at 1-hour post-infusion are missing, the values at 2-hour post-infusion are used.
Source: [CLI 00127: analysis-adscw, adeff4]

Data Date: @DataDate **Run Date:** @RunDate @Author

Programming notes:

- If “Not Done” was checked for Sample CPM at any visit, please show “ND” for the given visit.
- The calculated “In Vivo Elution” will only appear for the row of “0DPI (1hr±15min)” visit.

Listing 4.3. Recovery, Lifespan, and Platelet Physical Recovery Rate

Subject ID [1]	Arm – Radiolabeling [2]	Stage Period	Recovery(%) Test // Control	Survival (Hr) Test // Control	Plt Physical Recovery (%)	Dose Recovery (%)		Volume Recovery (%)	
						Post-INTERCEPT	Day 7 [3]	Post-INTERCEPT	Day 7 [3]
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	S1P1	xx.x // xx.x	xxx.x // xxx.x	xx	xx	xx	xx	xx
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$	S1P2							
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$								
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$	S2							
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$ Variant 1 – $^{111}In/^{51}Cr$								

[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
[3] Day 7 volume used for Volume/Dose recovery calculations was corrected for sampling.
Source: [CLI 00127: analysis-adeff2, adeff4]

Listing 5.1. Adverse Events (AEs)

Subject ID [1]	Arm – Radiolabeling [2]	Any AE	Actual Tx at Onset	Onset Date Time (Day) // Stop Date Time (Day)	System Organ Class // Preferred Term // Verbatim Term [3]	Sev. // Cau. [4]	Out. // Act. [5]	MH Assoc.[6] // Tx Provided	SAE
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	Yes		ddMMMyyyy hh:mm (xx) // ddMMMyyyy hh:mm (xx)	xxxxxx xxxxxxxxxxxxx // xxxxxxxxxxxxxxxxxx xxxx// xx x xxxxxxxxxxxxxxxxx (non-TE)	G1 // (CE, EX)	RR2 // IR	Yes (xxxxxxxxx) // No	Yes
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$		BEST	ddMMMyyyy UNK (xx) // ddMMMyyyy UNK (xx)		...	...	Yes (Patellar tendon repair - Right Knee) // Yes (Acetaminophen)	No
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$				xxxxxx xxxxxxx // xxxxxxxxxxxxx xxxx// xx x xxxxxxxxxx (TE)				
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$		Variant 1	ddMMMyyyy UNK (xx, xx) // Ongoing				No // No	
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$								
	Variant 1 – $^{111}In/^{51}Cr$							…..	
		No							

Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period. TEAEs with onset on or after the start time of the initial apheresis platelet collection (i.e., 1st) at Period 2 will be counted as events during Period 2.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
[3] AEs are coded using MedDRA Version 18.1. Treatment-emergent (TE) AEs are AEs with an onset date/time that is on or after the apheresis collection start date/time or missing.
[4] For severity (Sev): G1 = Grade 1 (Mild); G2 = Grade 2 (Moderate); G3 = Grade 3 (Severe); G4 = Grade 4 (Life-Threatening); G5 = Grade 5 (Death). For causality (Cau): EX=Excluded; UN=Unlikely; PO=Possible; LI=Likely/Probable; CE=Certain. The causality due to apheresis and infusion are given in parentheses separated out by a comma.
[5] For outcome (Out): RR1 = Recovered/Resolved; RR2 = Recovering/Resolving; RS = Recovered/Resolved with Sequelae; NR= Not Recovered/Not Resolved; DE = Death; UNK=Unknown. For action taken (Act): C = Continued; D = Discontinued; IR = Interrupted but Resumed; NA = Not Applicable.
[6] Is there a Medical History (MH) finding associated with this AE? Was treatment (Tx) provided? If Yes, the associated MH and/or concomitant medication are given in parentheses.
Source: [CLI 00127: analysis-adsl; adae]

Listing 5.2. Serious Adverse Event (SAE) Narrative

Subject ID [1]	Arm – Radiolabeling [2]	Actual Tx at Onset	Onset Date Time (Day) // Stop Date Time (Day)	SAE Criterion [3]	Verbatim Term [4] // SAE Narrative
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	BEST	ddMMMyyyy hh:mm (xx) // ddMMMyyyy hh:mm (xx)	HP (ddMMMyyyy – ddMMMyyyy)	xx x xxxxxxxxxxxxxxxxx (non-TE) // xxxxxxxxxx xxxxx xxxxx xxx xxxxx xxxxxxxxx xxxxxx xxxxxx xxx xxxxxxx xxxxxxxxxxxx xxxxxxxxx xxxxxx xxx xxxxxx xxx xxxxxx
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$				
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$	Variant 1	ddMMMyyyy UNK (xx) // ddMMMyyyy UNK (xx)	DE (ddMMMyyyy)	xx x xxxxxxxxxxxxxxxxx (TE) // xxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxx xxxxxxxxxxxx
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$			LT	
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$		ddMMMyyyy UNK (xx) // Ongoing		
	Variant 1 – $^{111}In/^{51}Cr$			...	

Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period. TEAEs with onset on or after the start time of the initial apheresis platelet collection (i.e., 1st) at Period 2 will be counted as events during Period 2.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
[3] HP = Hospitalization (Admission date – Discharge date); LT = Life Threatening; PS = Persistent or Significant Disability/Incapacity; CB = Congenital Anomaly or Birth Defect; OM = Other Medically Important Condition; DE = Death (Death date).
[4] Treatment-emergent (TE) AEs are AEs with an onset date/time that is on or after the apheresis collection start date/time or missing.
Source: [CLI 00112: analysis-adsl; adae]

Listing 6.1. Device Malfunction

Subject ID [1]	Arm – Radiolabeling [2]	Mal-function (Period) [3]	Malfunction Date (Day) // Report Date to Sponsor (Day)	# Units Affected: Product Code // Lot Number	Problem Detected (Location)	Which Processing Step	Problem Description	Loss of Disposable Set // Components	Other
xxx-xxx	BEST/Variant 1 – $^{51}Cr/^{111}In$	Yes (S1P1)	ddMMMyyyy (xx) // ddMMMyyyy (xx)	x: INT2530B // CE19B08L72	Before Use		Approx 1/2 thru plt unit transfer x xxxx xx xxx xx xxx xxxxx	Yes // Yes	Yes (xxxx xxxxxx)
xxx-xxx^	Variant 1/BEST – $^{51}Cr/^{111}In$	No			During Processing (Processing Set)	During Illumination (Illuminat Serial # xxxxxx, Alarm Code ID xxxxxx)		No // Yes	No
xxx-xxx*	BEST/Variant 1 – $^{111}In/^{51}Cr$	No							
xxx-xxx^#	Variant 1/BEST – $^{111}In/^{51}Cr$				After Processing (Label & Labeling)				
xxx-xxx*#	Variant 1 – $^{51}Cr/^{111}In$ Variant 1 – $^{111}In/^{51}Cr$								

Note: For this listing, Study Day (Day) is calculated relative to the day of apheresis collection within each period (Day 0), and the day before Day 0 is Day -1.
[1] For both Stages, subjects flagged by an asterisk (*) are excluded from Evaluable Analysis Set (EAS). For Stage 1 only, subjects flagged by a caret (^) are included in EAS but excluded from Completer Analysis Set (CAS), and subjects flagged by a pound (#) are excluded from Stage 2 combined analysis.
[2] If not performed as randomized, the actual treatment arm (method for Test in each period) and radiolabeling sequence (for Test/Control) are shown and flagged by a dollar sign ($).
[3] Any Device Malfunctions occurred? The stage and study period when the malfunction occurred is shown in parentheses.
Source: [CLI 00127: analysis-adsl, adcoll]