

STATISTICAL ANALYSIS PLAN

Study Title: In Vivo 24-Hour Recovery Study of Leukoreduced RBCs
Collected on the Trima Accel System Using Non-DEHP
Disposable Sets and Stored for 42 Days

Study Number: CTS-5091

Study Device: Trima Accel System

Sponsor: Terumo BCT, Inc.
10811 West Collins Avenue; Lakewood, CO 80215; USA
Phone: +1 (877) 339-4228

Sponsor Contact: Alexis James
Director, Global Clinical Affairs
Phone: +1 (720) 229-4606
Email: Alexis.James @terumobct.com



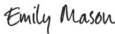

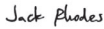

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Revision A

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STATISTICAL ANALYSIS PLAN APPROVAL

Name:	Rebecca Sedjo, PhD, MSPH		
Title:	Clinical Development Manager, Global Clinical Affairs		
	<div><div>Signed by:</div><div></div><div><div>Signer Name: Rebecca Sedjo Signing Reason: I approve this document Signing Time: 3/25/2025 2:59:13 PM MDT 692492C189904E0FBD63616DBC3FC2B4</div></div></div>		
Signature:		Date:	3/25/2025
Name:	Emily Mason, MSCS		
Title:	Senior Clinical Scientist, Global Clinical Affairs		
	<div><div>Signed by:</div><div></div><div><div>Signer Name: Emily Mason Signing Reason: I am the author of this document Signing Time: 3/25/2025 1:56:56 PM PDT 434FFEEA2CEA460BAE90BD7044932C24</div></div></div>		
Signature:		Date:	3/25/2025
Name:	Jack Rhodes, BS		
Title:	Senior Manager, Global Clinical Affairs		
	<div><div>Signed by:</div><div></div><div><div>Signer Name: Jack Rhodes Signing Reason: I approve this document Signing Time: 3/26/2025 8:42:34 AM MDT 3BC40A2306EC41428DB19E059837B6D9</div></div></div>		
Signature:		Date:	3/26/2025

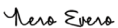





Name:	Nero Evero, MS		
Title:	Clinical Trial Manager, Global Clinical Affairs		
	<div><div>Signed by:</div><div></div></div>		
	<div><div></div><div>Signer Name: Nero Evero Signing Reason: I approve this document Signing Time: 3/25/2025 4:39:39 PM MDT B968B87D731E423AA4292C7BDF81FD2B</div></div>		
Signature:		Date:	3/25/2025
<hr/>			
Name:	Christopher Dzura, MS		
Title:	Consultant Sr. Manager Biostatistics and Data Analysis, Prosoft Clinical		
	<div><div>Signed by:</div><div></div></div>		
	<div><div></div><div>Signer Name: Chris Dzura Signing Reason: I approve this document Signing Time: 3/26/2025 8:14:23 AM EDT D5BE1ABB694B4DF79A8F141B118D3B03</div></div>		
Signature:		Date:	3/26/2025
<hr/>			
Name:	Richard Cook, PhD		
Title:	Consultant Statistician, Lifetime Scientific, Inc.		
	<div><div>Signed by:</div><div></div></div>		
	<div><div></div><div>Signer Name: Richard Cook Signing Reason: I approve this document Signing Time: 3/26/2025 12:56:11 PM PDT E996A47EF631418D9528260AC5040B58</div></div>		
Signature:		Date:	3/26/2025
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TABLE OF CONTENTS

1	INTRODUCTION.....	7
1.1	Background.....	7
1.2	Study Design.....	7
1.3	Objectives	8
1.3.1	Primary Objective	8
1.4	Endpoints	8
1.4.1	Efficacy Endpoints.....	8
1.4.2	Safety Endpoints	9
2	STATISTICAL METHODOLOGY.....	9
2.1	General Principles.....	9
2.2	Sample Size Determination.....	10
2.3	Analysis Sets.....	11
2.3.1	Enrolled Set.....	11
2.3.2	Safety Set	11
2.3.3	Evaluable Analysis Set	11
2.4	Participant Accounting and Baseline Characteristics	13
2.4.1	Participant Disposition.....	13
2.4.2	Participant Characteristics	13
2.4.3	Protocol Deviations.....	13
2.4.4	Device Deficiencies	13
2.5	Efficacy Analyses	13
2.6	Safety Analyses.....	14
3	DATA HANDLING	15
3.1	Baseline and Study Visits	15
3.2	Interim Analyses	15
3.3	Missing or Incomplete Data.....	15
3.3.1	Missing or Incomplete Adverse Event Dates or Times	15
3.3.2	Missing or Incomplete Concomitant Medication Dates or Times	15
4	CHANGES FROM THE CLINICAL INVESTIGATION PLAN	15
5	REFERENCES.....	15

LIST OF TABLES

Table 2-1:	Sample Sizes and Numbers of Successes and Failures along with Lower 95% Confidence Intervals for Assessing Evidence for the First of the US FDA RBC Recovery Criteria	11
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LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

⁵¹ Cr	chromium-51
^{99m} Tc	technetium-99m
AC	anticoagulant
ADE	adverse device effect
AE	adverse event
AS-3	Additive Solution Formula 3
CFR	US Code of Federal Regulations
CIP	Clinical Investigation Plan
cpm	counts per minute
DD	device deficiency
DEHP	di(2-ethylhexyl) phthalate
EAS	Evaluable Analysis Set
ES	Enrolled Set
FDA	Food and Drug Administration
IFU	Instructions for Use
LR	leukoreduced
MedDRA	Medical Dictionary for Regulatory Activities
MOP	Manual of Procedures
n	number or count
PD	protocol deviation
PEAE	procedure-emergent adverse event
PVC	polyvinyl chloride
RBC	red blood cell
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SAE	serious adverse event
SD	standard deviation
SOP	Standard Operating Procedures
SS	Safety Set
UADE	unanticipated adverse device effect
US	United States
WHO	World Health Organization
w/w	weight for weight

1 INTRODUCTION

1.1 Background

The Trima Accel system, manufactured by Terumo BCT, Inc., (hereafter referred to as the Sponsor), is an automated blood component collection system that uses continuous-flow centrifugal force to separate whole blood into red blood cells (RBCs), platelets, and plasma. During the collection procedure, anticoagulant (AC) and whole blood are mixed at a manifold near the needle site. The inlet pump draws the blood and AC mixture into the Trima Accel system, where the mixture enters the channel. As the whole blood is separated within the channel, pumps remove the platelets and plasma. The pressure created from the blood being continuously pumped into the centrifuge pushes RBCs out of the channel. Depending on the selected procedure, RBCs, plasma, and platelets are either collected in the product bags or routed to the return reservoir to be returned to the donor.

The Trima Accel system received United States (US) Food and Drug Administration (FDA) clearance in 2002 (BK010046) and has been Conformité Européenne (CE) marked in Europe since 2001. The Trima Accel software Version 7 (BK170157) received FDA clearance on 04 April 2018. The Trima Accel Software Version 7.0.4. was assessed in accordance with the FDA regulations and guidance documents for when to file a 510(k) for a product change and it was deemed that a new 510(k) submission was not required; therefore, a letter to file was written and entered into file on 18 April 2022.

The current approved disposables are manufactured with materials containing di(2-ethylhexyl) phthalate (DEHP). Recently the Annex XIV of Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), also called the REACH authorization list, was amended to include DEHP on the list of substances that cannot be placed on the market or used after a given 'sunset date.' As the existing Trima Accel disposables contain DEHP, the Sponsor has developed investigational non-DEHP plastics to replace all DEHP plasticized polyvinyl chloride (PVC) in the existing Trima Accel disposables to comply with the REACH regulation (ie, < 0.1% weight for weight [w/w] DEHP).

The primary objective of this study is to demonstrate that leukoreduced (LR) RBCs collected on the Trima Accel system using investigational non-DEHP disposable tubing sets with Additive Solution Formula 3 (AS-3) meet the US FDA criteria for 24-hour recovery after refrigerated storage in non-DEHP storage bags for 42 days.¹ NOTE: blood products will not be transfused to recipient patients in this study but will be autologously reinfused to healthy adult volunteers.

1.2 Study Design

This is a prospective, open-label, multicenter study designed to demonstrate that LR-RBCs collected on the Trima Accel system with the investigational non-DEHP disposable tubing sets

with integrated AS-3 delivery meet the FDA criteria for 24-hour recovery after refrigerated storage for 42 days.¹

1.3 Objectives

1.3.1 Primary Objective

The primary objective of this study is to demonstrate that LR-RBCs collected on the Trima Accel system using non-DEHP disposable tubing sets with AS-3 meet the FDA criteria for 24-hour recovery after 42 days of refrigerated storage in non-DEHP storage bags.¹ NOTE: blood products will not be transfused to recipient patients in this study but will be autologously reinfused to healthy adult volunteers.

The performance criteria are based on FDA criteria for in vivo RBC quality:

1. A one-sided lower confidence limit for the proportion of RBC components with 24-hour RBC in vivo recovery $>75\%$ is $70\%^*$,

*Allows for low recoveries ($< 75\%$) in up to 3 out of 24 to 26 participants

2. A sample mean of in vivo 24-hour RBC percent recovery $\geq 75\%$, and
3. A sample standard deviation of in vivo 24-hour percent RBC recovery $\leq 9\%$.

If all 3 criteria are met, the Trima Accel system with the investigational non-DEHP disposable tubing sets will be deemed to have met the pre-established criteria for 24-hour in vivo RBC recovery. This performance criteria will be evaluated in healthy adult participants who receive radiolabeled, autologous reinfusions of LR-RBC components after 42 days of refrigerated storage.

1.4 Endpoints

1.4.1 Efficacy Endpoints

1.4.1.1 Primary Endpoint

The primary endpoint is the 24-hour in vivo RBC recovery after 42 days of refrigerated storage, determined using the single-label (using chromium-51 [^{51}Cr] only) and dual-label (using ^{51}Cr and technetium-99m [$^{99\text{m}}\text{Tc}$], if possible, dependent upon availability of $^{99\text{m}}\text{Tc}$ labeling kits at both study sites) radiolabeling methods. The single label method for 24-hour RBC recovery uses Nadler's method² to estimate a participant's blood volume by accounting for their gender, height, and weight. The dual-label method uses a direct determination of the blood volume of the participant through the co-infusion of autologous, freshly collected $^{99\text{m}}\text{Tc}$ -labeled RBCs.³⁻⁸

1.4.2 Safety Endpoints

Safety will be monitored through collection of adverse events (AEs), serious AEs (SAEs), and unanticipated adverse device effects (UADEs).

2 STATISTICAL METHODOLOGY

2.1 General Principles

All analyses will be performed using SAS software version 9.4 or later. Concomitant medications used to treat AEs will be coded using World Health Organization (WHO) Drug Dictionary Enhanced September 2023 or later. Medical history and AEs will be coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.1 or later.

Inferential statistical tests and confidence intervals will either be one- or two-sided. Exact one-sided confidence intervals will be computed for the probability of success and used to guide the decision regarding the outcome of the study as described in Section 1.4. Continuous demographic parameters, such as the participant's age at the time of enrollment, will be summarized using descriptive statistics (number, mean, median, standard deviation [SD], minimum and maximum value).

In addition to examining the demographic and baseline parameters, adherence to the sampling preparation and reinfusion procedure will also be examined and presented as evidence of compliance. The examination for compliance to the study protocol will be performed on the participant-level. Failing to follow the sample handling and preparation procedures could have a demonstrative effect on the results. Including information from reinfusions where the sample was not properly prepared could impact the results by increasing variability and challenging the normality of the distribution of values used for calculating the average recovery values.

The following general conventions will be applied to all data presentations and analyses.

- Summary statistics will consist of the number and percentage of responses in each level for categorical variables, and the sample size (n), mean, median, SD, and range.
 - All mean and median values will be formatted to one or more decimal place(s) than the measured value. Standard deviation values will be formatted to two or more decimal places than the measured value. Minimum and maximum values will be presented with the same number of decimal places as the measured value.
- The number and percentage of responses will be presented in the form XX (XX %) where the percentage is in parentheses.
 - All summary tables will include the analysis population sample size (ie, Enrolled Set, Safety Set, or Evaluable Analysis Set).

2.2 Sample Size Determination

The sample size is based on the first of the US FDA's 3-part RBC recovery criteria.¹

1. The one-sided 95% lower confidence limit for the probability of success is greater than 70% where success is defined as the in vivo 24-hour RBC percent recovery $> 75\%$,
2. The sample mean of percent in vivo 24-hour RBC recovery $\geq 75\%$
3. The sample standard deviation of the percent in vivo 24-hour RBC recovery $\leq 9\%$.

Specifically, the sample size was chosen to ensure sufficient precision in the probability of success so that the lower 95% confidence limit is above 0.70 for acceptable scenarios. Sample size was based on the first criterion with at least 24 participants, examining the one-sided confidence interval for the proportion of successes using the Clopper-Pearson exact method for a 95% confidence interval. Table 2-1 shows the lower 95% confidence intervals for sample sizes of 24 and 26 units and different numbers of successes. With a sample size of 24 and if the observed proportion of successes is 21/24 (87.50%) or higher, the one-sided lower 95% binomial confidence interval will exceed 70% (lower confidence limit = 70.77%) and the study will be deemed to have met its primary outcome. If a participant does not return for reinfusion of radiolabeled RBCs and/or 24-hour recovery sampling, an additional participant must be enrolled to replace the missing sample. This additional participant will then require sample storage for 42 days. To avoid this type of potential delay, up to 2 additional participants will be enrolled so the final sample size will be at least 24 and up to 26 participants. As shown in Table 2-1, 3 or fewer failures will meet the 1st FDA criterion with 24 to 26 participants. Comparison of the statistical scenarios between sample sizes of $n=24$ and $n=26$ demonstrates that the planned statistical method will not be impacted across this sample size range (ie, 3 failures would result in the one-sided lower 95% binomial confidence interval exceeding 70% [lower confidence limit = 70.77% for $n=24$ and 72.81% for $n=26$]).

Table 2-1: Sample Sizes and Numbers of Successes and Failures along with Lower 95% Confidence Intervals for Assessing Evidence for the First of the US FDA RBC Recovery Criteria

Failures	4	3	2	1
Sample Size n=24				
Number of Treatment Successes	20/24	21/24	22/24	23/24
Percentage of Treatment Success	83.33	87.50	91.67	95.83
One-Sided Lower 95% Confidence Limit	65.82	70.77	76.02	81.71
Sample Size n=26				
Number of Treatment Successes	22/26	23/26	24/26	25/26
Percentage of Treatment Success	84.61	88.46	92.31	96.15
One-Sided Lower 95% Confidence Limit	68.18	72.81	77.71	83.02

In order to reach the total target number of evaluable participants, additional participants will be enrolled to replace those for whom the primary endpoints are not evaluable (as determined using study protocol analysis exclusion criteria, Section 2.3.3.1). It is anticipated that up to 50 healthy adult volunteers may need to be enrolled to accrue at least 24 and up to 26 evaluable participants for the primary endpoint analysis. Participants, regardless of the availability of their endpoint data, will be included in evaluations of in vitro data (where samples are available) and in evaluations of AEs.

2.3 Analysis Sets

2.3.1 Enrolled Set

The Enrolled Set (ES) will include all participants enrolled in the study (ie, who have signed informed consent). Efforts will be made to obtain complete in vivo recovery data from all participants.

2.3.2 Safety Set

The Safety Set (SS) will include all participants enrolled (ie, not unique individuals) in the study who meet all eligibility criteria and who are exposed to the investigational non-DEHP disposable (defined as venipuncture for LR-RBC collection). It is possible for a participant to be included in the SS more than once if they did not have an evaluable recovery endpoint.

2.3.3 Evaluable Analysis Set

The Evaluable Analysis Set (EAS) will consist of the first 24 to 26 evaluable participants in the SS. An evaluable participant is defined as a participant who completes all study visits per the Clinical Investigation Plan (CIP) with valid 24-hour recovery endpoint(s) for the single-label and dual-label (if available) methods without having met any of the protocol analysis exclusion

criteria described in Section 2.3.3.1. Participants will only be included in the EAS once. The EAS is used in the analysis of the primary endpoint. The analysis of the primary endpoint in the EAS will be based on all recorded data. While the criteria outlined in the CIP allow for up to 26 participants, the final analysis will be based on all participants meeting the EAS.

Within the EAS, all attempts will be made to obtain complete recovery data from all participants for the analysis of the primary endpoint.

2.3.3.1 Protocol Analysis Exclusions

There may be situations wherein the data will be considered non-evaluable and will not be included in the EAS.

Data will be excluded from the EAS in the following situations:

1. Inability to complete the procedure and/or study due to:
 - a. Participant issues (eg, inadequate access, reaction, needle abort)
 - b. Participant lost to follow-up or withdrawn from study
 - c. Equipment failure or malfunction (eg, filter plugs)
 - d. Compromised product sterility (eg, open weld, bag puncture)
 - e. Unanticipated processing failure
 - f. Decision to stop procedure by participant, Investigator, site staff or operator
2. Incomplete post-collection processing
 - a. Equipment failure or malfunction (eg, unrecoverable system failure)
 - b. Product damaged during storage
3. Protocol deviations (PDs) that affect the primary endpoint due to:
 - a. Failure to follow collection procedures outlined in the device Operator's Manual, Instructions for Use (IFU; Package Insert), CIP, Manual(s) of Procedures (MOPs), and site Standard Operating Procedures (SOPs)
4. Product non-reinfusable due to:
 - a. Product not available
 - b. Product does not pass quality check for reinfusion (eg, positive viral screen, visual inspection, hemolysis, bacterial growth, radiolabeling procedure issues to include aseptic preparation of research-grade ⁵¹Cr per site SOPs [if applicable] or failed endotoxin testing [if applicable])

2.4 Participant Accounting and Baseline Characteristics

2.4.1 Participant Disposition

Enrollment and extent of participation in the study will be summarized for the ES. The number and percent of participants in each analysis set, and the number and percent of participants who were screen failures or who otherwise discontinued the study early (including the primary reason for discontinuation) will be presented.

Participant disposition data will be provided in a listing. Separate listings describing each participant's eligibility for study participation as well as inclusion in or exclusion from each of the analysis sets will also be provided (including enrollment and procedure initiation, completion, and/or evaluability).

2.4.2 Participant Characteristics

Demographics and baseline characteristics (eg, vital signs, laboratory results) will be provided in listings for the ES and summarized for the SS and EAS.

2.4.3 Protocol Deviations

The Sponsor will compile a listing of all PDs (major and minor, as defined in CIP Section 19.6.1) for the ES, and a summary of major PDs will be prepared.

2.4.4 Device Deficiencies

Initial reports of DDs will be provided in a listing for the SS. The Sponsor will separately provide disposition information for each suspected DD as well as a summary of confirmed DDs for the SS.

2.5 Efficacy Analyses

The analysis of the primary endpoint will be conducted using the EAS, defined in Section 2.3.3.

In vivo RBC viability has been assessed for decades using radiolabeled autologous RBCs to assess the proportion of RBCs remaining in the circulation 24 hours after autologous reinfusion (24-hr RBC recovery). Radiolabeling methods and reporting of recovery have been standardized, allowing comparison of data between studies. Calculation of the proportion of RBCs surviving at 24-hr post reinfusion requires that RBC mass be accurately estimated. This can be performed by extrapolating the early disappearance of cells to the midpoint of the reinfusion.

Calculation of the primary endpoint may be done using both the single-label and dual-label (if possible) method, dependent upon the availability of ^{99m}Tc labeling kits at both study sites. The dual-label method will only be conducted with data reported if ^{99m}Tc labeling kits are expected to

be available at both sites for all participants in time for reinfusion start (Day 42). In the event ^{99m}Tc labeling kits are expected to be unavailable, the dual-label method will not be pursued and only the single-label method will be conducted with data reported. If complete data are collected for both the single-label and dual-label methods, analysis will be conducted to evaluate the 24-hour RBC recovery primary endpoint and reported for each method. If there is discordance in the results between the two methods, the dual-label method will take precedence.

RBC recovery 24 hours after reinfusion will be reported using the method recommended by Moroff et al.⁴ The ^{51}Cr value at time = 0 (T zero, T0) is obtained by doing a regression analysis of the values obtained for ^{51}Cr labeled samples drawn at different timepoints post reinfusion. The T0 is used to calculate the percent recovery at 24 hours. The calculated T0 may be falsely low if the labeled RBCs are removed by the reticulo-endothelial system in large numbers prior to the first blood being drawn at 5 minutes post injection. This would result in a falsely higher 24-hour recovery. Recovery at 24 hours will be calculated using the following equation:⁴

$$\% \text{ recovery} = (\text{Adjusted RBC counts per minute [cpm] at 24 hours} / \text{Adjusted RBC cpm at time 0}) \times 100$$

Radiolabeled samples will be drawn at different timepoints post reinfusion. The counts will be adjusted for background counts and corrected for loss of label (elution) over time.³

The primary endpoint of RBC percent recovery at 24 hours post reinfusion will be assessed against the three FDA-specified criteria.¹ To evaluate the criterion related to the percentage of samples with at least a 75% recovery, each observed value will be categorized as a success (recovery $\geq 75\%$) or failure (recovery $< 75\%$). A one-sided 95% confidence interval for the proportion of successes will be calculated using the Clopper-Pearson exact method. The study will meet this primary endpoint criterion if the lower confidence limit exceeds 70% (equivalent to no more than 3 failures).

Summary statistics and one-sided confidence intervals will be presented to assess the actual RBC recovery values and to evaluate the remaining criteria specified by FDA.

2.6 Safety Analyses

Adverse events (AEs) will be provided in a listing for the ES by MedDRA system organ class and preferred term. Adverse event (AE) summaries for the purposes of device safety assessments will be limited to PEAEs, defined as any AE that occurs upon or after the start of the study procedure and until participant study completion. Procedure-emergent AE (PEAE) summaries will be provided for the SS.

Tables will describe the frequency and percentage of all PEAEs, serious PEAEs, ADEs, and UADEs. Additional presentations will summarize PEAEs by maximum reported severity;

maximum relatedness to device(s), procedure(s), and medical history (related, not related); and those leading to discontinuation/termination. Concomitant medications used to treat PEAEs will also be summarized.

3 DATA HANDLING

3.1 Baseline and Study Visits

Study participation will consist of up to 4 visits: Visit 1 (Days -14 to 0) for screening, Visit 2 (Day 0) for LR-RBC collection, Visit 3 (Day 42) for reinfusion, and Visit 4 (Day 43) for assessing 24-hour in vivo RBC recovery.

3.2 Interim Analyses

No interim analyses will be performed.

3.3 Missing or Incomplete Data

No imputation for missing data will be performed.

3.3.1 Missing or Incomplete Adverse Event Dates or Times

If an AE has an incomplete start date and/or time, the AE will be assumed to be a PEA unless the provided dates/times or partial dates/times, if any, are enough to conclude that the AE could not have started on or after the start of the procedure.

3.3.2 Missing or Incomplete Concomitant Medication Dates or Times

In accordance with the CIP, reporting of concomitant medications is limited to those used to treat AEs. If a reported medication used to treat an AE has an incomplete start or stop date, the medication will be assumed to have been taken upon or after procedure initiation (ie, concomitant medication used to treat a PEA) unless the provided dates or partial dates, if any, are enough to conclude that the medication could not have been taken upon or after procedure initiation.

4 CHANGES FROM THE CLINICAL INVESTIGATION PLAN

No changes were made from the CIP.

5 REFERENCES

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