FDP-1

A Phase 1, Single-Center, Partial Double-Blind, Randomized, Controlled (versus Fresh Frozen Plasma [FFP] in Cohort 3 only) Clinical Study of the Safety of Ascending Doses of Autologous Freeze Dried Plasma (FDP) in Healthy Volunteers

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STATISTICAL ANALYSIS PLAN
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Version 2.0

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1. STUDY OVERVIEW

1.1 Design

This single-site, partial double blind study in healthy volunteers is to assess the safety of infusing ascending doses of reconstituted autologous freeze dried plasma (FDP) in three fixed-dose cohorts. In the lowest dose cohort, Cohort 1, subjects will receive a single infusion dose of one unit (approximately 270 mL) of autologous investigational product. Subjects in Cohort 2 will receive a higher single infusion dose of two autologous FDP units (approximately 540 mL). Subject enrollment will be sequentially activated in each cohort, beginning with Cohort 1, and remain open until the target completion numbers are met for the specific cohort.

For subjects in Cohorts 1 and 2, assignment to one of two treatment arms will occur upon study enrollment. These treatment arms indicate the type of FDP product the subject will receive when infused at the cohort-defined dose. The FDP product type corresponds to the collection method used for collecting the plasma used in FDP manufacturing. The two investigational FDP product types are:

- FDP-CPD: FDP manufactured from fresh frozen plasma (FFP) derived from autologous whole blood (WB) collection(s) that use citrate phosphate dextrose (CPD) as the anticoagulant; and
- FDP-ACD: FDP manufactured from FFP units from autologous plasmapheresis where acid citrate dextrose (ACD) is used as the anticoagulant.

The design of Cohort 3 differs from Cohorts 1 and 2. As a randomized, controlled, crossover study, Cohort 3 subjects will undergo two separate study infusions where they will receive the study's highest planned single infusion dose, three units (approximately 810 mL), of autologous FDP during one infusion and the same single infusion dose of FFP during the other infusion. Cohort 3 subjects will only be infused with FDP and FFP products sourced from autologous plasmapheresis. Because of this, the investigational product defined as FDP-ACD is what Cohort 3 subjects will receive.

Just prior to first infusion, subjects will be randomized to a treatment sequence, or schedule, that determines which product, FDP or FFP, is to be administered at the first visit. The blinded subjects will receive the alternate product during the second infusion. Product treatment crossover at this higher fixed dose allows for comparison of safety between the two products within the same subject and it allows for the comparison of recovery of select coagulation factors and proteins post-infusion with each product. A two-week interval between each Cohort 3 subject's infusion visits is required regardless of the product treatment sequence.

If any of the stopping rules (SRs) occur throughout the trial, the study will be paused to assess continuation of the study:

1. A serious adverse event (SAE) that is determined to be possibly, probably, or definitely related to the study product;
2. An adverse event (AE) related to the study product that the Principal Investigator (PI), Research Monitor (RM), and/or the sponsor's Pharmacovigilance Physician (PVG MD) agree jeopardizes the subject's health or safety;
3. An AE related to the study product that requires medical or surgical intervention to prevent occurrence of an SAE;
4. A post-infusion, abnormal coagulation function assay which is also a greater than 20% change from baseline for prothrombin time and international normalized ratio (PT/INR) and/or activated

partial thromboplastin time (aPTT) values (e.g., a subject who has a baseline INR of 1.0 with a post-infusion INR of 1.3 will activate a SR, because this is an abnormal coagulation function assay result that is also a greater than 20% change from the pre-infusion assay result); and/or

5. Post-infusion development of hemolysis or deep vein thrombosis (DVT), cardiac ischemia, or pulmonary embolism. DVT will be determined following the Institute for Clinical Systems Improvement Health Care Guideline: Venous Thromboembolism Diagnosis and Treatment (includes assessment of D-Dimer results and Wells criteria ≥ 2). (Dupras et al-2013).

A Data and Safety Monitoring Board (DSMB) will formally review study safety reports at the completion of each cohort. Cohort safety data reported to the DSMB will minimally include complete subject data through the 7-day post-infusion follow-up visit. Following each meeting, the DSMB will provide the sponsor with a recommendation about proceeding with infusions in the subsequent cohort or, at the conclusion of Cohort 3, about proceeding with the next planned FDP trial. After reviewing and considering the recommendation, the sponsor is responsible for making the final determination about whether to proceed.

1.2 Aims

1.2.1 Primary Objectives

The primary objective of this study is to assess the safety of single infusions with the RePlas™ FDP product at increasing fixed doses of either one unit (approximately 270 mL), two units (approximately 540 mL), or three units (approximately 810 mL) in normal healthy subjects.

1.2.2 Secondary Objectives (Cohort 3 Only)

The secondary objectives are to:

- Assess the safety of fixed-dose infusion with three autologous FDP units (approximately 810 mL) in comparison to fixed-dose infusion with the same dose of autologous FFP collected during plasmapheresis; and
- Determine if the changes in specific coagulation factors, hematology, and chemistry values are similar within clinically meaningful levels after infusion of three units of either autologous FDP or FFP.

2. SAFETY

The safety of infusion with the experimental product will be determined by observation of treatment emergent adverse events (TEAEs), defined as only AEs that occur after starting the trial infusion administration. In addition to TEAEs, safety will be evaluated based on the occurrence of SAEs, suspected unexpected serious adverse reactions (SUSARs), and deaths. Safety assessment in Cohorts 1 and 2 subjects will examine the cohort-specific product infusion dose and the specific FDP product type infused (e.g., FDP-CPD or FDP-ACD). The safety assessment performed in Cohort 3 subjects will assess treatment with FDP at the highest fixed infusion dose (approximately 810 mL) and compare, within the same subject, the treatment safety of FDP versus FFP at the equivalent dose.

2.1 Treatments

Each subject's infusion dose and treatment product(s) are summarized in Table 1 and discussed in this section of the statistical analysis plan (SAP). Study arm assignments are based on donor type for Cohorts

1 and 2 subjects where WB donors will be assigned to Arm 1 or Arm 3 depending on which cohort is active and plasmapheresis donors will be assigned to Arm 2 or Arm 4 depending on which cohort is active. Enrolled subjects of Arm 1 and Arm 3 will receive one or two units, respectively, of autologous FDP-CPD at a single infusion visit and those in Arm 2 and Arm 4 will receive the corresponding dose of FDP-ACD at the single infusion visit. Subjects enrolled in the Cohort 3 crossover will have two study infusion visits where they will receive separate treatments of autologous FFP at one visit and autologous FDP-ACD at the other. Randomization to one of two treatment arms just prior to the first infusion visit will indicate the specific product treatment sequence where they will be administered one of the products at the first infusion visit followed by the alternative product at the second infusion visit. See Section 3.2 for additional information regarding subject assignment and randomization.

2.1.1 Cohorts 1 and 2

All Cohort 1 subjects will receive a single infusion dose of 1 experimental product unit (approximately 270 mL) and those in Cohort 2 will receive a single infusion dose of 2 experimental FDP product units (approximately 540 mL). Subjects in Arm 1 and Arm 3 will receive the same experimental product type, FDP-CPD, but at single infusion doses of one unit and two units, respectively. Subjects in Arm 2 and Arm 4 will receive FDP-ACD instead at single infusion doses of one and two units, respectively.

2.1.2 Cohort 3

For the crossover, Cohort 3 subjects in Arm 5 and Arm 6 will receive single infusion doses of 3 autologous plasma units (approximately 810 mL) at each of their 2 infusion visits. Depending on their treatment arm, subjects will receive either the autologous experimental product (FDP-ACD) or the autologous control product (FFP) with the opposite product administered at the second scheduled infusion. Table 1 exhibits the three dose cohorts, their corresponding treatment arms, and the number of subjects needed to complete the trial.

Table 1. Dose Cohorts and Treatments

Cohort	Single Infusion Dose	Treatment	# of Subjects
1	1 unit (~270 mL)	Arm 1: FDP-CPD	4
		Arm 2: FDP-ACD	4
2	2 units (~540 mL)	Arm 3: FDP-CPD	4
		Arm 4: FDP-ACD	4
3 crossover	3 units (~810 mL/ infusion)	Arm 5: FDP-ACD x FFP	4
		Arm 6: FFP x FDP-ACD	4
		Total # of Subjects	24

2.2 General Schedule for Plasma Collection, Infusion and Follow-up

There are distinct study schedules associated with subject participation. The schedules are cohort- and arm- dependent given the different plasma collection requirements of each, and for Cohort 3 the crossover design necessitating two infusion visits rather than the one infusion visit in Cohorts 1 and 2. Table 2 summarizes the number and types of study visits (e.g., collection, infusion, and follow-up) associated with the three study schedules. All of the visits are to be conducted in-person with the exception of 3 post-infusion follow-up visits that are conducted by telephone (e.g., 48-hour, 72-hour, and 14-day follow-up visits).

Table 2. Number of Study Visits by Visit Type and Treatment Arm

Study Arm	Screening Visit	Donation Type*	Collection Visit	Infusion Visit	Post-Infusion Follow-up Visits				Total # Visits
					24-hour	48 hrs, 72 hrs, and 14-day	7-day	28-day	
1	1	WB	1	1	1	3	1	1	9
2		PP	1	1	1	3	1	1	9
3		WB	2	1	1	3	1	1	10
4		PP	1	1	1	3	1	1	9
5		PP	2-3	2	2	5	2	1	15-16
6		PP	3-4	2	2	5	2	1	15-16

*WB=Whole Blood, PP=Plasmapheresis

2.2.1 Screening Visit

Individuals interested in participating must sign the study's informed consent. Subjects who consent are not enrolled, however, until eligibility is confirmed at the Screening Visit by physical examination and laboratory testing performed on the subject's collected biospecimens.

2.2.2 Collection Visit(s)

Enrolled subjects must make either autologous WB or plasmapheresis donation(s) to provide the cohort-defined volume of source plasma. A minimum interval of 7 days is required between all individual subject's plasmapheresis donations and a minimum interval of 28 days between all individual subject's WB donations.

- **Arms 1 and 3.** Subjects in Arms 1 and 3 will make autologous WB donations for the manufacture of FDP-CPD. One WB collection is required of subjects in Arm 1 and two WB collections are required from subjects in Arm 3. As approved by the clinical site's Institutional Review Board (IRB), subjects, such as those in Arm 3, making more than 1 WB donation must maintain a minimum 28-day interval between donations. Subjects with a low volume donation (< 450 mL) will generally be withdrawn from the study and the collection discarded per blood center standard operating procedures (SOPs). Low volume donations in the study are never combined with other potential donations made by the study subject.

  At the discretion of the PI, there may be cases where subjects making a low volume donation are allowed to make a second WB collection attempt. In such cases, however, the minimum 28-day interval between WB donations is still required.

- **Arms 2, 4, 5, and 6.** Autologous plasmapheresis is the plasma collection method used for subjects in the remaining study arms. One plasmapheresis collection is adequate for the manufacture of up to two units of FDP-ACD so subjects in Arms 2 and 4 will only require a single successful collection visit. Subjects in Arms 5 and 6, however, will need to make 3 to 4 successful plasmapheresis donations to provide the minimum total plasma volume needed (approximately 1620 mL) for 3 FFP units and 3 FDP units. Approximately 10% of plasma units that are supplied for manufacturing FDP are damaged during the process and must be discarded. In those instances, the autologous plasma unit corresponding to the individual subject must be replaced, which requires the subject to return to the clinic for additional plasmapheresis to meet the required volumes for the plasma infusion visit(s).

A minimum donation interval of 7 days is required for subjects making multiple plasmapheresis donations. Subjects with a low volume donation (< 500 mL) will generally be withdrawn from the study and all low volume donations discarded per blood center SOPs; low volume donations are never

combined with other potential donations made by a subject during the study. At the discretion of the PI, there may be cases where subjects making a low volume donation are allowed a second attempt by plasmapheresis. In these cases, however, the minimum 7-day interval between donations is still required.

2.2.3 Infusion Visit(s)

The infusion visit for the first subject in each cohort is to occur approximately five weeks following his or her last collection visit. Unlike Cohorts 1 and 2 subjects, Cohort 3 subjects require two infusion visits. These are to occur with no less than a two-week interval in between infusions. Subjects will undergo autologous infusion at each of these visits according to the corresponding treatment specifications of the arm to which they belong.

2.2.4 Follow-up Visits

Post-infusion, subject assessments are to occur at scheduled in-person and telephone follow-up visits. For Cohorts 1 and 2, in-person post-infusion visits will occur on Study Days 2, 8, and 29, which corresponds to conducting assessments 24 hours, 7 days, and 28 days post-infusion. These visits will take one to two hours. Telephone follow-up visits of a 15 to 20 minute duration are to occur on Study Days 3, 4 and 15, or 48 hours, 72 hours, and 14 days post-infusion.

Follow-up visits for Cohort 3 subjects subsequent to the first infusion visit are the same as those scheduled for Cohorts 1 and 2. However, on Study Day 15, Cohort 3 subjects will undergo the second infusion and accompanying follow-up visits for this infusion are spaced in time to occur as those performed for Cohorts 1 and 2. Cohort 3 in-person follow-up visits will be scheduled for Study Days 2, 8, 16, 22, and 43 and take 1 to 2 hours to complete. The telephone follow-up visits, each taking approximately 15 to 20 minutes to complete, will be conducted on Study Days 3, 4, 17, 18, and 29.

3. PROCEDURES

3.1 Subject Identification

All consenting subjects are assigned a unique numeric subject identifier (SID). If later enrolled in the study, the SID can be used to identify individual subject's electronic Case Report Forms (CRFs). Name and date of birth will be used to identify subjects on site source documents. No personal identifiers will be used in any study associated communications or publications resulting from the research. The unique SID is to be used to identify data specific to a single subject. Representatives of the United States Army Medical Research and Materiel Command (USAMRMC), the Sponsor's Representative, the local IRB, the USAMRMC Office of Research Protections (ORP), and the Food and Drug Administration (FDA) are eligible to review medical and research records related to this study as a part of their responsibility to protect human subjects in clinical research. For such review, medical and research records will be photocopied and all personal identifiers redacted. Subjects will not receive individual study results. Aggregate findings will be published in the open literature and available by way of public record.

3.2 Randomization

Subject recruitment at Hoxworth Blood Center (HBC) will depend on accessing lists of WB and plasmapheresis donors who previously indicated an interest in participating in research. These lists of WB and plasmapheresis donors will be sorted by donation type and the center will work through the lists using a systematic scheme that represents a diverse subset of the population without bias based on race, ethnicity, gender, or age (as determined by the protocol) until the target numbers have been reached.

Research recruitment flyers are also posted at the blood center. These flyers include a telephone number for donors to call if they are interested in learning about research participation.

Depending on the activation status of recruitment for the lower dose cohorts and the version of the informed consent document that is signed, WB donors who are enrolled in the study will automatically be assigned to the FDP-CPD study arms of Cohort 1 or 2. Similarly, plasmapheresis donors who are enrolled will automatically be assigned to the FDP-ACD study arms of Cohorts 1 or 2.

For Cohort 3, which includes product crossover of FDP-ACD and FFP, only plasmapheresis donors who consent to the study are potentially eligible for study enrollment. Once enrolled, Cohort 3 subjects are randomized no more than 48 hours prior to their first infusion in a 1:1 ratio to 1 of 2 treatment arms that will determine the order in which the two plasma treatment products, FFP and FDP-ACD, are to be infused across the two study infusion visits. Based on this, some subjects will receive FFP at the first infusion visit while others will receive FDP-ACD at the first infusion visit. Cohort 3 subjects who leave the study without completing both infusion visits will be replaced; the replacement subject, assigned a unique SID, will be assigned to the same treatment arm as the discontinued subject.

The randomization list allows for over-enrollments and additional randomization slots to compensate for subjects who discontinue early. The Westat Statistician is responsible for the randomization assignments performed via the study website [https://www.fdpcollaboration.org]. Randomization is addressed in Section 6.6.1 of the protocol and detailed in the FDP-1 Randomization, Masking and Unmasking Plan.

3.3 Blinding/Unblinding

3.3.1 Blinding

This is a partial double-blind study. Blinding is not necessary for Cohorts 1 and 2 because they will only receive a single infusion of FDP. Cohort 3 subjects are to receive FDP at one infusion and the control product, FFP, at another. Cohort 3 subjects randomized to a treatment sequence are to remain blinded to the product they receive at each visit. The HBC Clinical Research Coordinator and 5th Floor HBC FDP research staff preparing the plasma product will be unblinded. All other HBC staff including but not limited to, the HBC PI, study subjects, RM, and 3rd Floor HBC FDP research staff involved in subject treatment will be blinded.

At Westat, the FDP-1 Clinical Operations Manager, Site Monitor, Unblinded Statistician, and Unblinded Programmers will be unblinded. All other Westat staff including but not limited to, the Project Manager (PM), Protocol Specialist, Data Manager, Data Research Associate, Project Statistician, and Project Programmers will be blinded. The Clinical Site Monitor for the Sponsor will be unblinded. All other Sponsor staff including but not limited to, the Product Manager and PVG MD will be blinded. Blinding is addressed in Section 6.6.2 of the protocol and detailed in the FDP-1 Randomization, Masking and Unmasking Plan.

3.3.2 Unblinding

Unblinding of a subject's individual randomization code is only performed for the following approved reasons:

- Medical emergency, or in the event of a serious medical condition, when knowledge of the investigational study product is essential for the clinical management or welfare of the subject;
- DSMB requests to be unmasked for subject safety review; and
- Unblinding for all reported pregnancies occurring during the study by the HBC PI.

Reasons and justification for the unblinding are to be clearly specified in the source documentation. Otherwise, unblinding is not to occur until study data are entered and cleaned, and the database is locked. Unblinding is addressed in Section 6.6.3 of the protocol and detailed in the FDP-1 Randomization, Masking and Unmasking Plan.

3.4 Subject Replacement and Completion

A total of 24 subjects (8 in each cohort) are to fully complete the trial. Depending on the cohort, study completion is defined as:

- Cohorts 1 and 2: infused with autologous FDP and completion of the 7-day post-infusion follow-up visit; and
- Cohort 3: infused with both the autologous experimental and control products per the assigned treatment sequence and completion of the 7-day post-infusion follow-up visit subsequent to the second infusion.

In cases where subjects discontinue participation prior to study completion, a replacement subject will be enrolled in the study. The replacement, assigned a new and unique SID, will be assigned to the same treatment arm as the discontinued subject. This is necessary to maintain the 1:1 ratio between study arms.

3.5 Data and Safety Monitoring

An independent DSMB will be convened to review clinical trial safety data and provide recommendations to the USAMMDA Office of Regulated Activities Product Safety Surveillance Branch (USAMMDA ORA PSSB) about proceeding with the trial at the next cohort dose or, following Cohort 3, a recommendation about proceeding with additional planned FDP protocols. The PSSB will deliver the DSMB recommendations to the Sponsor's Representative for final decision. The USAMRMC USAMMDA ORA will communicate the final decision to the PI, who will notify the IRB. USAMRMC USAMMDA ORA will communicate the final decision to the FDA, as appropriate. A further description of the DSMB roles and responsibilities, functions, and reporting requirements is included in the DSMB charter.

4. STATISTICAL ANALYSIS CONSIDERATIONS

4.1 Sample Size and Power

The sample size for this single-site study is 24 subjects. Safety will be measured using the following primary safety endpoints: AEs, TEAEs, SAEs, SUSARs, and deaths. The selection of the sample size was based on reasonably balancing the ability to address the study's primary objective and to minimize the number of subjects potentially at risk. Different safety outcome incidence rates and sample sizes were used to calculate the precision estimates calculated and presented in Table 3; the accompanying confidence intervals are based on Clopper-Pearson and were calculated using PASS software Version 13.0.3.

As shown, a safety outcome occurring at a rate of 10% incidence in 24 subjects would have a 95% confidence interval from 1.6-29.2% and a corresponding width=27.6 at a 2-sided alpha of 0.05. To account for subject attrition and for comparison purposes, a sample size of 20 and 28, respectively, are included in the table.

Table 3. 95% Confidence Intervals and Precision (δ) for Incidence

Sample Size	Incidence		
	10%	25%	50%
20	(1.2-31.7) δ=30.5	(8.7-49.1) δ=40.4	(27.2-72.8) δ=45.6
24	(1.6-29.2) δ=27.6	(9.8-46.7) δ=36.9	(29.1-70.9) δ=41.8
28	(2.0-27.3) δ=25.4	(10.7-44.9) δ=34.2	(30.6-69.4) δ=38.7

Concurrent infusions will not take place across cohorts to ensure infusions at the next higher dose do not begin until all subject infusions at the previous dose are completed. Based on the study schedule, the estimated duration for which each cohort will remain active is approximately 6 months for Cohorts 1 and 2, and for Cohort 3 approximately 7 months.

4.2 Analysis Populations

Healthy male and female volunteers determined to be acceptable WB or plasmapheresis donors based on FDA regulations and responses to the AABB Full-Length Donor History Questionnaire (Appendix B of the protocol) are eligible to provide study consent. In addition, the study considers those deferred from donating due only to travel, as outlined by the AABB Full-Length Donor History Questionnaire, as eligible to consent for potential study enrollment. All subjects subsequently enrolled must meet the study inclusion and exclusion criteria, detailed in sections 7.4 and 7.5 of the protocol.

There will be five analysis populations for this study, two full analysis populations and three safety populations.

4.2.1 Full Analysis Populations

The two full analysis populations are defined as:

- All enrolled subjects including subjects who were prematurely withdrawn from the study prior to the Infusion Visit and were never infused **(F1)**; and
- Enrolled and presented for treatment at the Infusion Visit **(F2).** (F2 includes infused and not infused).

4.2.2 Safety Populations

The three subject populations for assessing safety are defined as those who:

- Receive any volume of infused product; (i.e., In Cohort 3 subjects this includes those who received a partial dose at either Infusion Visit) (S1);
- Receive the full infusion dose and have at least one outcome measure (S2); and
- Receive the full infusion dose and can be fully evaluated because in: (S3, or the per protocol population).
  - Cohorts 1 and 2 the subjects also minimally completed the 7-day follow-up visit; and

- Cohort 3 the subjects had both complete infusion doses and minimally completed the 7-day follow-up visit after the second infusion.

The demographic tables (Table 1.1- Table 1.20) will include all five analysis populations listed in Section 4.2 unless it is found that both full populations include the same subjects, in which case only one table for the F1 and F2 population will be produced with the title indicating that it represents the F1, F2 populations, unless otherwise specified. Likewise, if all three safety populations are found to include the same subjects, only one table will be produced with the title indicating that it represents all safety populations, the S1, S2 and S3, unless otherwise specified. This pattern of table reduction will be repeated for the remaining tables unless otherwise indicated. Subject disposition tables will include all five populations. AE tables that display overall AE incidence will include all five populations. Tables that are restricted to TEAEs will include the safety populations only. Study drug exposure will be presented in the first safety population (S1). All other analyses will be performed in the third safety population only (S3).

4.3 Study Duration

The duration of individual subject participation ranges from 12 to 16 weeks depending on the subject's cohort and arm assignments. Table 4 presents the estimated duration of subject participation accounting for time needed to complete eligibility screening, autologous plasma collection(s), FDP manufacturing, and the infusion and follow-up visits.

Table 4. Duration of Subject Participation by Cohort and Treatment Arm

Cohort, Treatment Arm	Screening Period	WB/Plasma Collection Time	FDP Manufacturing Time	Planned Study Follow-up Period	Total Expected Duration
Cohort 1, Arm 1	~2 Weeks	1 Week	~5 Weeks	4 Weeks	~12 Weeks
Cohort 1, Arm 2		1 Week			~12 Weeks
Cohort 2, Arm 3		~5 Weeks			~16 Weeks
Cohort 2, Arm 4		1 Week			~12 Weeks
Cohort 3, Arm 5		~3 Weeks		6 Weeks	~16 Weeks
Cohort 3, Arm 6		~3 Weeks			~16 Weeks

4.4 Data Handling Conventions

4.4.1 Non-Analyzable Data

Non-analyzable data will include inconclusive, invalid laboratory values, and data resulting from deviations in performing study procedures (i.e. data sent to the wrong laboratory or resulting from errors in procedure or processing). The protocol's Study Events Schedule indicates the specific time window in which each of the visits is to occur post-infusion. Results outside of these visit windows will be included in the analysis. Both non-analyzable data and results outside of visit windows will be treated as deviations and documented in the final clinical study report.

4.4.2 Baseline Values

Baseline demographic variables are those captured at the Screening Visit. Safety endpoint values, vital signs and laboratory test results, taken at the Infusion Visit just prior to subject infusion, are the baseline values.

4.4.3 Repeated Data

In cases where measurements taken at specific time-points must be repeated for any reason (e.g., the result of the initial laboratory test clinically or procedurally requires that it be repeated), only the initial or original value will be considered. However, all data, original or repeat, will be presented in the data listings.

4.4.4 Missing Data

Counts of missing data will be included with the summary descriptive statistics.

4.5 Statistical Methods and Analysis

4.5.1 Overview and General Plans

This section describes the analytic approach for addressing each of the study's objectives by the defined primary and secondary endpoints. The analysis will be descriptive and consist of frequencies and percentages for categorical measures and the number of subjects, mean, standard deviation, median, minimum, maximum, 25^{th} and 75^{th} percentile for continuous measures as appropriate. Descriptive statistics will be summarized for each treatment group. SAS Version 9.3 or higher (SAS Institute Inc., Cary, NC) will be used to perform all statistical analyses.

Modeling

Modeling is not incorporated in the SAP since it is not required to meet the primary or secondary objectives.

Multiplicity Issues

Not powered to test for treatment group differences; no adjustment for multiple testing is planned for the study analyses.

Project Center Effects

This is a single-site study. Adjustment for project center effects will not be performed.

Interim Analysis

No interim analyses are planned for this study.

4.5.2 Summarize and Characterize Consented Subjects and Enrolled Subjects

Subjects must provide written informed consent if they are willing to participate in the study. However, they only will be enrolled if eligibility is confirmed by responses to the screening questionnaires and results from their physical examination and laboratory tests. For this analysis, the number of subjects screened will be equal to the number of subjects with a date of providing written informed consent. The number of enrolled subjects will equal the number of subjects that have a date of enrollment.

Subject disposition will be displayed in consort diagrams (Figures 1 and 2) that will exhibit the number of subjects across all cohorts and study arms who were: screened, enrolled, assigned or randomized to treatment, infused (received treatment) and discontinued.

Descriptive analyses conducted on enrolled subjects will include: demographics and physical characteristics at entry.

Definitions for Cohorts 1 and 2

The following definitions will generate Figure 1:

- Subjects screened: the total number of subjects with a date of informed consent.
- Subjects discontinued prior to enrollment (i.e., screen failures): the total number of subjects with a date of informed consent minus the total number of subjects with a date of enrollment.
- Reasons subjects discontinued prior to enrollment: any inclusion criteria not met or exclusion criteria met.
- Subjects enrolled/treatment assigned: the total number of subjects with a date of enrollment.
- Subjects discontinued after enrollment but prior to infusion: the total number of subjects with a date of enrollment minus the total number of subjects who received any plasma infusions (Exit Interview CRF).
- Subjects infused: the total number of subjects who did receive any plasma infusions during the study (Exit Interview CRF).
- Subjects discontinued on or after infusion: the total number of subjects infused minus the total number of subjects with a status of 'Completed' (Exit Interview CRF) in each treatment arm.
- Reasons subjects discontinued on or after infusion: the subject's status on the Exit Interview CRF.
- Subjects completed: the total number of subjects with a status of 'Completed' on the Exit Interview CRF in each treatment arm.

Definitions for Cohort 3

The following definitions will generate Figure 2:

- Subjects screened: total number of subjects with a date of informed consent.
- Subjects discontinued prior to enrollment (i.e., screen failures): the total number of subjects with a date of informed consent minus the total number of subjects with a date of enrollment.
- Reasons subjects discontinued prior to enrollment: any inclusion criteria that was not met or exclusion criteria that was met.
- Subjects enrolled: the total number of subjects with a date of enrollment.
- Subjects discontinued after enrollment but prior to randomization: the total number of subjects with a date of enrollment minus the total number of subjects with a date of randomization.
- Reasons subjects discontinued prior to randomization: the subject's status on the Exit Interview CRF for the subjects in the previous bullet.
- Subjects randomized: the total number of subjects with a randomization date.
- Subjects discontinued after randomization but prior to infusion #1 visit: the total number of subjects with a date of randomization minus the total number of subjects with a visit date on the Infusion Form.
- Reasons subjects discontinued after randomization but prior to infusion #1 visit: the subject's status on the Exit Interview CRF for the subjects that meet the criteria in the previous bullet.
- Subjects enter infusion #1 visit: the total number of subjects with a visit date on the Infusion Form.
- Subjects discontinued after entering the infusion #1 visit but prior to receiving infusion #1: the total number of subjects with a visit date on the Infusion Form minus the number of subjects that receive any plasma infusions during the study (Exit Interview CRF).

- Reasons subjects discontinued after entering the infusion #1 visit but prior to receiving infusion #1: the subject's status on the Exit Interview CRF for the subjects that meet the criteria in the previous bullet.
- Subjects receive infusion #1: the number of subjects who did receive any plasma infusions during the study (Exit Interview CRF).
- Subjects discontinued on or after receiving infusion #1 but prior to receiving infusion #2: the number of subjects who received infusion #1 minus the number of subjects with a start date of infusion #2 (Infusion CRF) and > 0 mL administered in each treatment arm.
- Reasons subjects discontinued on or after receiving infusion #1 but prior to receiving infusion #2: the subject's status on the Exit Interview CRF for the subjects that meet the criteria in the previous bullet.
- Subjects receive infusion #2: number of subjects with a start date of infusion #2 (Infusion CRF) and > 0 mL administered in each treatment arm.
- Subjects discontinued on or after infusion #2: the number of subjects who received infusion #2 minus the total number of subjects who had a status of 'Completed' on the Exit Interview CRF in each treatment arm.
- Reasons subjects discontinued on or after infusion #2: the subject's status on the Exit Interview CRF for the subjects that meet the criteria in the previous bullet.
- Subjects completed: the total number of subjects with a status of 'Completed' (Exit Interview CRF) in each treatment arm.

4.5.3 Conduct Safety Analyses (Primary Objective)

To provide the DSMB with formal safety reports for review, analyses required to generate Table 1.1 – Table 8.3 and Figures 1 and 2 will be conducted as prescribed in the FDP-1 DSMB Charter, except for Tables 7.4-7.6. For Cohort 3, Open and Closed session tables will be created. The Open session tables will present overall totals for Cohort 3. The Closed session tables will present the data by masked treatment arm (A or B).

Safety data will be summarized for each cohort using standard descriptive statistics.

- For quantitative variables, the following statistics will be provided:
  - Number of subjects;
  - Mean;
  - Standard deviation, minimum, maximum;
  - Median; and
  - 25^{th} and 75^{th} percentile.
- For categorical variables, percentages will be calculated using the number of subjects with non-missing data for the specific variable.

AEs will be coded using the most recent version of the Medical Dictionary of Regulatory Activities preferred terms and will be grouped by system, organ, and class designation. AEs will be summarized using standard FDA-recommended templates distinguishing those defined as TEAEs. A TEAE will be defined as an AE that emerges during or following treatment (infusion), having been absent pretreatment. For all TEAEs, relatedness to infused product will be presented. TEAEs related to study treatment will be defined as definitely or probably related to study treatment. A SUSAR will be defined as a **S**uspected, **U**nexpected, **S**erious **A**dverse **R**eaction. A listing of SUSARs will be provided by USAMMDA upon reconciliation of their SAE database with the Oracle Clinical database.

Use of the Centers for Disease Control National Healthcare Safety Network Hemovigilance Module criteria will ensure consistent definitions are applied when using transfusion-related event terms, such as

transfusion related acute lung injury or transfusion associated circulatory overload. The National Cancer Institute Common Terminology Criteria will be used to assess all event terms (AEs) for toxicity grade, or severity, regardless of whether the event is transfusion-related (HHS-2010). AEs will also be presented by maximum severity or maximum common terminology criteria for AE (CTCAE) grade (depending on collection). A summary of SAEs and a summary of AEs leading to treatment discontinuation will be presented.

4.5.3.1 Primary Safety Endpoints

The primary safety endpoints to be assessed are AEs, specifically:

- TEAEs;
- SAEs;
- SUSARs; and
- Deaths.

Descriptive statistics will be used to analyze the primary safety endpoints. Tables produced to exhibit the primary safety endpoint data will be presented by the specific type of plasma product infused. In Cohorts 1 and 2, this data will be presented by FDP product type, FDP-ACD and FDP-CPD; in Cohort 3 by experimental product and control product, FDP and FFP. The primary safety data reported to the DSMB for Cohort 3 will be masked. Unblinding during the study will only occur in accordance with Section 3.3.2 following Westat's SOP DA-504 Development of a Plan for Randomization, Masking, and Unmasking.

In general, AEs that occur in Cohort 3 subjects within 14 days after infusion will be attributed to the most recently infused product. However, there may be exceptions to use of this temporal attribution rule to all transfusion-related AEs given the possibility that those AEs that occur after infusion with the second product may potentially be related to infusion with the first infusion product (e.g., an immunogenic response).

4.5.4 Conduct Safety Analyses Comparing FDP-ACD to FFP (Secondary Objective #1)

Using Cohort 3 data, descriptive statistics similar to those described in Section 4.5.3 will be presented for the change between baseline and each time point, where appropriate, of the safety endpoint measures shown in Table 5. Descriptive statistics will be provided for each type of plasma product treatment, treatment period, and treatment sequence arm (FDP-ACD then FFP [Sequence 1] or FFP then FDP-ACD [Sequence 2]). The mean and standard deviation at each time point for each treatment group, based on the original values, will be exhibited in figures. Color-coded spaghetti plots will display by treatment group individual data for each subject over time.

Definitions for Secondary Objectives

- Change from baseline: (Post-baseline value – baseline value).
- Body mass index (kg/m^2): weight (kg)/(height (cm) /100)^2.
- Total amount administered per kg of weight (ml/kg): total amount administered (ml)/weight (kg).

4.5.4.1 Secondary Endpoints

The secondary endpoints for this study and associated time points for analysis are listed in Table 5.

Table 5. Secondary Safety Endpoints and Scheduled Measurements of Secondary Endpoints*

		Post-Infusion			
Safety Endpoints	**Pre-Infusion**	**0.5 Hours**	**4 Hours**	**24 Hours**	**28 Days**
Vital Signs:					
Blood Pressure	X	X	X		
Heart Rate	X	X	X		
Respiration Rate	X	X	X		
Temperature	X	X	X		
Urinalysis:					
Glucose	X	X	X		
Ketones	X	X	X		
Protein	X	X	X		
Blood	X	X	X		
Leukocyte Esterase	X	X	X		
Nitrite	X	X	X		
Bilirubin	X	X	X		
Hematology					
Hematocrit	X	X	X	X	
Hemoglobin	X	X	X	X	
Platelet Count	X	X	X	X	
RBC Count	X	X	X	X	
WBC Count	X	X	X	X	
Direct Antiglobulin Test **(DAT)** (IgG and C3)	X				
Clinical Chemistry:					
ALP	X	X	X		
ALT	X	X	X		
AST	X	X	X		
Ionized Calcium	X	X			
Total Magnesium	X	X			
pH	X	X			
Electrolytes (Calcium, Chloride, Potassium, Sodium, Lactic Acid, and Bicarbonate)	X	X	X		
Glucose	X	X	X		
Total Bilirubin	X	X	X		
Total Protein	X	X	X		
BUN	X	X	X		
Creatinine	X	X	X		
Coagulation Tests:					
PT	X	X	X	X	X
INR	X	X	X	X	X
aPTT	X	X	X	X	X
D-dimer	X	X	X	X	
Cohort 3 safety analyses will also include measurements taken at each Infusion Visit at the following post-infusion time points.					
Factor I	X	X	X		
Factor II	X	X	X		
Factor V	X	X	X		

		Post-Infusion			
Safety Endpoints	**Pre-Infusion**	**0.5 Hours**	**4 Hours**	**24 Hours**	**28 Days**
Factor VII	X	X	X		
Factor VIII	X	X	X		
Factor IX	X	X	X		
Factor X	X	X	X		
Factor XI	X	X	X		
von Willebrand Factor Activity	X	X	X		
Protein C Activity	X	X	X		
Protein S Activity	X	X	X		
PF 1+2	X	X			
TAT	X	X			
Antithrombin III	X	X			
Alpha-2 Antiplasmin	X	X			
C3a des Arg	X	X			

* Grayed cells mean that the time point either was not measured or will not be used in the analysis.

4.5.4 Conduct Exploratory Analyses Comparing FDP-ACD to FFP (Secondary Objective #2)

The analyses conducted for secondary objective #1 will be used to meet secondary objective #2. In addition, descriptive statistics on a post-infusion, abnormal coagulation function assay, which is greater than a 20% change in either direction from baseline for PT/INR and/or aPTT values, will be presented using separate shift tables. Shift tables based on the upper limit of normal (ULN) will also be provided for D-dimer, prothrombin fragment (PF) 1+2, thrombin-antithrombin complex (TAT) and C3a des Arg.

5. PROPOSED SUMMARY TABLES, LISTINGS, AND GRAPHS

The tables, listings, and figures were created using the templates from the Pharmaceutical Users Software Exchange (phUSE) whitepapers. The references are at the end of the SAP. The letter "X" is used as a placeholder in the table numbers, sample sizes, measurement names, and in the presentation of data and represents the next sequential table number, appropriate sample size, the next sequential measurement name or data presentation format as appropriate according to the programming instructions.

Table 1.1.- Table 1.15. Demographic and Clinical Characteristics Summary
Baseline Demographics and Clinical Characteristics – Cohort 1 (270 mL)
Full Analysis Population – F1 (N=XX)
FDP-1
Phase I

Demographic Parameter and Clinical Characteristics		FDP-CPD (N=XX)	FDP-ACD (N=XX)	Total (N=XX)
Sex n (%)	n[a]	xx	xx	xx
	F	xx(x.x)	xx(x.x)	xx(x.x)
	M	xx(x.x)	xx(x.x)	xx(x.x)
	Missing	xx	xx	xx
Age (years)	n[a]	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Q1, Q3	xx,xx	xx,xx	xx,xx
	Min, Max	xx,xx	xx,xx	xx,xx
	Missing	xx	xx	xx
Race n (%)	n[a]	xx	xx	xx
	American Indian or Alaska Native	xx(x.x)	xx(x.x)	xx(x.x)
	Asian	xx(x.x)	xx(x.x)	xx(x.x)
	Black or African American	xx(x.x)	xx(x.x)	xx(x.x)
	Native Hawaiian or Other Pacific Islander	xx(x.x)	xx(x.x)	xx(x.x)
	White	xx(x.x)	xx(x.x)	xx(x.x)
	Multiple	xx(x.x)	xx(x.x)	xx(x.x)
	Missing	xx	xx	xx
Ethnicity n (%)	n[a]	xx	xx	xx
	Hispanic	xx(x.x)	xx(x.x)	xx(x.x)
	Non-Hispanic or Latino	xx(x.x)	xx(x.x)	xx(x.x)
	Missing	xx	xx	xx
Is the subject of childbearing potential? n (%)	n[a]	xx	xx	xx
	Yes	xx(x.x)	xx(x.x)	xx(x.x)
	No	xx(x.x)	xx(x.x)	xx(x.x)
	Missing	xx	xx	xx
Blood Type n (%)	n[a]	xx	xx	xx
	A	xx(x.x)	xx(x.x)	xx(x.x)
	B	xx(x.x)	xx(x.x)	xx(x.x)
	AB	xx(x.x)	xx(x.x)	xx(x.x)
	O	xx(x.x)	xx(x.x)	xx(x.x)
Rh Factor n (%)	n[a]	xx	xx	xx
	Negative	xx(x.x)	xx(x.x)	xx(x.x)
	Positive	xx(x.x)	xx(x.x)	xx(x.x)
Height (cm)	n[a]	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Q1, Q3	xx,xx	xx,xx	xx,xx
	Min, Max	xx,xx	xx,xx	xx,xx

Note: Abbreviations: N=Number of subjects in the population; Q1=25% Percentile; Q3=75% Percentile; and SD=Standard Deviation.
[a]=Number of subjects with non-missing data, used as the denominator.
The variable 'Has the subject ever experienced any diseases and/or surgeries?' will only use the data at screening.

Program Path: Data extract date:
Data source: ADSL Cross Reference: Listing 3, Listing 5, Listing 9

Demographic Parameter and Clinical Characteristics		FDP-CPD (N=XX)	FDP-ACD (N=XX)	Total (N=XX)
	Missing	xx	xx	xx
Weight (kg)	n[a]	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Q1, Q3	xx,xx	xx,xx	xx,xx
	Min, Max	xx,xx	xx,xx	xx,xx
	Missing	xx	xx	xx
BMI n (%)	n[a]	xx	xx	xx
	Underweight (<18.5)	xx(x.x)	xx(x.x)	xx(x.x)
	Normal (18.5-<25)	xx(x.x)	xx(x.x)	xx(x.x)
	Overweight (25.0-<30)	xx(x.x)	xx(x.x)	xx(x.x)
	Obese (≥30)	xx(x.x)	xx(x.x)	xx(x.x)
	Missing	xx	xx	xx
BMI (kg/m^2)	n[a]	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Q1, Q3	xx,xx	xx,xx	xx,xx
	Min, Max	xx,xx	xx,xx	xx,xx
	Missing	xx	xx	xx
Has the subject ever experienced any diseases and/or surgeries?	n[a]	xx	xx	xx
	Yes	xx(x.x)	xx(x.x)	xx(x.x)
	No	xx(x.x)	xx(x.x)	xx(x.x)

Note: Abbreviations: N=Number of subjects in the population; Q1=25% Percentile; Q3=75% Percentile; and SD=Standard Deviation.
[a]=Number of subjects with non-missing data, used as the denominator.
The variable 'Has the subject ever experienced any diseases and/or surgeries?' will only use the data at screening.

Table 1.1.- Table 1.15 (Open). Demographic and Clinical Characteristics Summary
Baseline Demographics and Clinical Characteristics – Cohort 3 (810 mL)
Full Analysis Population – F1 (N=XX)
FDP-1
Phase I

Demographic Parameter and Clinical Characteristics		Total (N=XX)
Sex n (%)	n[a]	xx
	F	xx(x.x)
	M	xx(x.x)
	Missing	xx
Age (years)	n[a]	xx
	Mean	xx.x
	SD	xx.x
	Median	xx.x
	Q1, Q3	xx,xx
	Min, Max	xx,xx
	Missing	xx
Race n (%)	n[a]	xx
	American Indian or Alaska Native	xx(x.x)
	Asian	xx(x.x)
	Black or African American	xx(x.x)
	Native Hawaiian or Other Pacific Islander	xx(x.x)
	White	xx(x.x)
	Multiple	xx(x.x)
	Missing	xx
Ethnicity n (%)	n[a]	xx
	Hispanic	xx(x.x)
	Non-Hispanic or Latino	xx(x.x)
	Missing	xx
Is the subject of childbearing potential? n (%)	n[a]	xx
	Yes	xx(x.x)
	No	xx(x.x)
	Missing	xx
Blood Type n (%)	n[a]	xx
	A	xx(x.x)
	B	xx(x.x)
	AB	xx(x.x)
	O	xx(x.x)
Rh Factor n (%)	n[a]	xx
	Negative	xx(x.x)
	Positive	xx(x.x)
Height (cm)	n[a]	xx
	Mean	xx.x
	SD	xx.x
	Median	xx.x
	Q1, Q3	xx,xx
	Min, Max	xx,xx
	Missing	xx

Note: Abbreviations: N=Number of subjects in the population; Q1=25% Percentile; Q3=75% Percentile; and SD=Standard Deviation.
[a]=Number of subjects with non-missing data, used as the denominator.
The variable 'Has the subject ever experienced any diseases and/or surgeries?' will only use the data at screening.

Demographic Parameter and Clinical Characteristics		Total (N=XX)
Weight (kg)	n[a]	xx
	Mean	xx.x
	SD	xx.x
	Median	xx.x
	Q1, Q3	xx,xx
	Min, Max	xx,xx
	Missing	xx
BMI n (%)	n[a]	xx
	Underweight (<18.5)	xx(x.x)
	Normal (18.5-<25)	xx(x.x)
	Overweight (25.0-<30)	xx(x.x)
	Obese (≥30)	xx(x.x)
	Missing	xx
BMI (kg/m^2)	n[a]	xx
	Mean	xx.x
	SD	xx.x
	Median	xx.x
	Q1, Q3	xx,xx
	Min, Max	xx,xx
	Missing	xx
Has the subject ever experienced any diseases and/or surgeries?	n[a]	xx
	Yes	xx(x.x)
	No	xx(x.x)

Note: Abbreviations: N=Number of subjects in the population; Q1=25% Percentile; Q3=75% Percentile; and SD=Standard Deviation.
[a]=Number of subjects with non-missing data, used as the denominator.
The variable 'Has the subject ever experienced any diseases and/or surgeries?' will only use the data at screening.

Table 1.1.- Table 1.15 (Closed). Demographic and Clinical Characteristics Summary
Baseline Demographics and Clinical Characteristics – Cohort 3 (810 mL)
Full Analysis Population – F1 (N=XX)
FDP-1
Phase I

Demographic Parameter and Clinical Characteristics		A (N=XX)	B (N=XX)	Total (N=XX)
Sex n (%)	n[a]	xx	xx	xx
	F	xx(x.x)	xx(x.x)	xx(x.x)
	M	xx(x.x)	xx(x.x)	xx(x.x)
	Missing	xx	xx	xx
Age (years)	n[a]	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Q1, Q3	xx,xx	xx,xx	xx,xx
	Min, Max	xx,xx	xx,xx	xx,xx
	Missing	xx	xx	xx
Race n (%)	n[a]	xx	xx	xx
	American Indian or Alaska Native	xx(x.x)	xx(x.x)	xx(x.x)
	Asian	xx(x.x)	xx(x.x)	xx(x.x)
	Black or African American	xx(x.x)	xx(x.x)	xx(x.x)
	Native Hawaiian or Other Pacific Islander	xx(x.x)	xx(x.x)	xx(x.x)
	White	xx(x.x)	xx(x.x)	xx(x.x)
	Multiple	xx(x.x)	xx(x.x)	xx(x.x)
	Missing	xx	xx	xx
Ethnicity n (%)	n[a]	xx	xx	xx
	Hispanic	xx(x.x)	xx(x.x)	xx(x.x)
	Non-Hispanic or Latino	xx(x.x)	xx(x.x)	xx(x.x)
	Missing	xx	xx	xx
Is the subject of childbearing potential? n (%)	n[a]	xx	xx	xx
	Yes	xx(x.x)	xx(x.x)	xx(x.x)
	No	xx(x.x)	xx(x.x)	xx(x.x)
	Missing	xx	xx	xx
Blood Type n (%)	n[a]	xx	xx	xx
	A	xx(x.x)	xx(x.x)	xx(x.x)
	B	xx(x.x)	xx(x.x)	xx(x.x)
	AB	xx(x.x)	xx(x.x)	xx(x.x)
	O	xx(x.x)	xx(x.x)	xx(x.x)
Rh Factor n (%)	n[a]	xx	xx	xx
	Negative	xx(x.x)	xx(x.x)	xx(x.x)
	Positive	xx(x.x)	xx(x.x)	xx(x.x)
Height (cm)	n[a]	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Q1, Q3	xx,xx	xx,xx	xx,xx

Note: Abbreviations: N=Number of subjects in the population; Q1=25% Percentile; Q3=75% Percentile; and SD=Standard Deviation.
[a]=Number of subjects with non-missing data, used as the denominator.
The variable 'Has the subject ever experienced any diseases and/or surgeries?' will only use the data at screening.

Program Path: Data extract date:
Data source: ADSL Cross Reference: Listing 3, Listing 5, Listing 9

Demographic Parameter and Clinical Characteristics		A (N=XX)	B (N=XX)	Total (N=XX)
	Min, Max	xx,xx	xx,xx	xx,xx
	Missing	xx	xx	xx
Weight (kg)	n[a]	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Q1, Q3	xx,xx	xx,xx	xx,xx
	Min, Max	xx,xx	xx,xx	xx,xx
	Missing	xx	xx	xx
BMI n (%)	n[a]	xx	xx	xx
	Underweight (<18.5)	xx(x.x)	xx(x.x)	xx(x.x)
	Normal (18.5-<25)	xx(x.x)	xx(x.x)	xx(x.x)
	Overweight (25.0-<30)	xx(x.x)	xx(x.x)	xx(x.x)
	Obese (≥30)	xx(x.x)	xx(x.x)	xx(x.x)
	Missing	xx	xx	xx
BMI (kg/m^2)	n[a]	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Q1, Q3	xx,xx	xx,xx	xx,xx
	Min, Max	xx,xx	xx,xx	xx,xx
	Missing	xx	xx	xx
Has the subject ever experienced any diseases and/or surgeries?	n[a]	xx	xx	xx
	Yes	xx(x.x)	xx(x.x)	xx(x.x)
	No	xx(x.x)	xx(x.x)	xx(x.x)

Programming Instruction: The variable 'Has the subject ever experienced any diseases and/or surgeries?' will only use the data at screening. This table will be repeated for all analysis populations that are determined to be on a different set of subjects as described in Section 4.2 for each cohort (Table 1.2 – Table 1.15). All tables may not be produced based on the table reduction method mentioned in Section 4.2 and may not exactly match the SAP. The table titles will indicate the cohort and population used for each table.

Note: Abbreviations: N=Number of subjects in the population; Q1=25% Percentile; Q3=75% Percentile; and SD=Standard Deviation.
[a]=Number of subjects with non-missing data, used as the denominator.
The variable 'Has the subject ever experienced any diseases and/or surgeries?' will only use the data at screening.

Program Path: Data extract date:
Data source: ADSL Cross Reference: Listing 3, Listing 5, Listing 9

Table 1.X. Demographic and Clinical Characteristics Summary

Baseline Demographics and Clinical Characteristics – Cohort 2 (540 mL)
Full Analysis Population – F1 (N=XXX)
FDP-1
Phase I

Special Note: Cohorts 1 and 2 are not masked; therefore, only one set of tables will be produced showing the unmasked treatment arm. For Cohort 3, there will be an Open and Closed session for the DSMB to protect the mask. For the Open session only, the Total Column will be shown with the table numbers having the word "(Open)" after the table number before the decimal. Open session tables will be produced by the blinded programmers. For the Closed session, the treatment arms will be masked as A and B. The table numbers will have the word "(Closed)" after the table number before the decimal. Closed session tables will be produced by the unblinded programmers. Final data analysis for Cohort 3, will use the labels FDP-ACDxFFP and FFPxFDP-ACD for the treatments after the study is unblinded and the word "(Closed)" will be removed from the table number.

Table 1.X (Open). Demographic and Clinical Characteristics Summary
Baseline Demographics and Clinical Characteristics – Cohort 3 (810 mL)
Full Analysis Population – F1 (N=XXX)
FDP-1
Phase I

Table 1.X (Closed). Demographic and Clinical Characteristics Summary
Baseline Demographics and Clinical Characteristics – Cohort 3 (810 mL)
Full Analysis Population – F1 (N=XXX)
FDP-1
Phase I

Note: Abbreviations: N=Number of subjects in the population; Q1=25% Percentile; Q3=75% Percentile; and SD=Standard Deviation.
[a]=Number of subjects with non-missing data, used as the denominator.
The variable 'Has the subject ever experienced any diseases and/or surgeries?' will only use the data at screening.

Table 1.16. – Table 1.20 (Open). Demographic and Clinical Characteristics Summary - Overall
Baseline Demographic and Clinical Characteristics – Overall
Full Analysis Population – F1 (N=XXX)
FDP - 1
Phase I

		FDP-CPD		FDP-ACD		
Demographic and Clinical Characteristics Parameter		Cohort 1 270 mL (N = XX)	Cohort 2 540 mL (N = XX)	Cohort 1 270 mL (N = XX)	Cohort 2 540 mL (N = XX)	Cohort 3 810 mL (N = XX)
Sex n (%)	n[a]	xx	xx	xx	xx	xx
	F	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	M	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Missing	xx	xx	xx	xx	xx
Age (years)	n[a]	xx	xx	xx	xx	xx
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Q1, Q3	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx
	Min, Max	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx
	Missing	xx	xx	xx	xx	xx
Race n (%)	n[a]	xx	xx	xx	xx	xx
	American Indian or Alaska Native	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Asian	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Black or African American	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Native Hawaiian or Other Pacific Islander	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	White	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Multiple	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Missing	xx	xx	xx	xx	xx
Ethnicity n (%)	n[a]	xx	xx	xx	xx	xx
	Hispanic	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Non-Hispanic or Latino	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Missing	xx	xx	xx	xx	Xx
Is the subject of childbearing potential? n (%)	n[a]	xx	xx	xx	xx	Xx
	Yes	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	No	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Missing	xx	xx	xx	xx	Xx
Blood Type n (%)	n[a]	xx	xx	xx	xx	Xx
	A	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	B	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	AB	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	O	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
Rh Factor n (%)	n[a]	xx	xx	xx	xx	Xx

Note: Abbreviations: N= number of subjects in the population; Q1=25% Percentile; Q3= 75% Percentile; and SD=Standard Deviation.
[a]=Number of subjects with non-missing data, used as the denominator.
The variable 'Has the subject ever experienced any diseases and/or surgeries?' will only use the data at screening.

		FDP-CPD		FDP-ACD		
Demographic and Clinical Characteristics Parameter		Cohort 1 270 mL (N = XX)	Cohort 2 540 mL (N = XX)	Cohort 1 270 mL (N = XX)	Cohort 2 540 mL (N = XX)	Cohort 3 810 mL (N = XX)
	Negative	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Positive	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
Height (cm)	n[a]	xx	xx	xx	xx	Xx
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Q1, Q3	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx
	Min, Max	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx
	Missing	xx	xx	xx	xx	Xx
Weight (kg)	n[a]	xx	xx	xx	xx	Xx
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Q1, Q3	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx
	Min, Max	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx
	Missing	xx	xx	xx	xx	Xx
BMI n (%)	n[a]	xx	xx	xx	xx	Xx
	Underweight (<18.5)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Normal (18.5-<25)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Overweight (25.0-<30)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Obese (≥30)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Missing	xx	xx	xx	xx	Xx
BMI (kg/m2)	n[a]	xx	xx	xx	xx	Xx
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Q1, Q3	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx
	Min, Max	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx
	Missing	xx	xx	xx	xx	Xx
Has the subject ever experienced any diseases and/or surgeries?	n[a]	xx	xx	xx	xx	Xx
	Yes	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	No	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)

Note: Abbreviations: N= number of subjects in the population; Q1=25% Percentile; Q3= 75% Percentile; and SD=Standard Deviation.
[a]=Number of subjects with non-missing data, used as the denominator.
The variable 'Has the subject ever experienced any diseases and/or surgeries?' will only use the data at screening.

Table 1.16. – Table 1.20 (Closed). Demographic and Clinical Characteristics Summary - Overall
Baseline Demographic and Clinical Characteristics – Overall
Full Analysis Population – F1 (N=XXX)
FDP - 1
Phase I

		FDP-CPD		FDP-ACD		Cohort 3	
Demographic and Clinical Characteristics Parameter		Cohort 1 270 mL (N = XX)	Cohort 2 540 mL (N = XX)	Cohort 1 270 mL (N = XX)	Cohort 2 540 mL (N = XX)	A 810 mL (N = XX)	B 810 mL (N = XX)
Sex n (%)	n[a]	xx	xx	xx	xx	xx	Xx
	F	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	M	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Missing	xx	xx	xx	xx	xx	Xx
Age (years)	n[a]	xx	xx	xx	xx	xx	Xx
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	SD	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
	Q1, Q3	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx
	Min, Max	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx
	Missing	xx	xx	xx	xx	xx	Xx
Race n (%)	n[a]	xx	xx	xx	xx	xx	Xx
	American Indian or Alaska Native	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Asian	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Black or African American	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Native Hawaiian or Other Pacific Islander	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	White	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Multiple	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Missing	xx	xx	xx	xx	xx	Xx
Ethnicity n (%)	n[a]	xx	xx	xx	xx	xx	Xx
	Hispanic	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Non-Hispanic or Latino	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Missing	xx	xx	xx	xx	xx	Xx
Is the subject of childbearing potential? n (%)	n[a]	xx	xx	xx	xx	xx	Xx
	Yes	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	No	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Missing	xx	xx	xx	xx	xx	Xx
Blood Type n (%)	n[a]	xx	xx	xx	xx	xx	Xx
	A	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	B	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	AB	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	O	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
Rh Factor n (%)	n[a]	xx	xx	xx	xx	xx	Xx
	Negative	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)

Note: Abbreviations: N= number of subjects in the population; Q1=25% Percentile; Q3= 75% Percentile; and SD=Standard Deviation.
[a]=Number of subjects with non-missing data, used as the denominator.
The variable 'Has the subject ever experienced any diseases and/or surgeries?' will only use the data at screening.

Demographic and Clinical Characteristics Parameter		FDP-CPD		FDP-ACD		Cohort 3	
		Cohort 1 270 mL (N = XX)	Cohort 2 540 mL (N = XX)	Cohort 1 270 mL (N = XX)	Cohort 2 540 mL (N = XX)	A 810 mL (N = XX)	B 810 mL (N = XX)
	Positive	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
Height (cm)	n[a]	xx	xx	xx	xx	xx	Xx
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	SD	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
	Q1, Q3	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx
	Min, Max	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx
	Missing	xx	xx	xx	xx	xx	Xx
Weight (kg)	n[a]	xx	xx	xx	xx	xx	Xx
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	SD	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
	Q1, Q3	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx
	Min, Max	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx
	Missing	xx	xx	xx	xx	xx	Xx
BMI n (%)	n[a]	xx	xx	xx	xx	xx	Xx
	Underweight (<18.5)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Normal (18.5-<25)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Overweight (25.0-<30)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Obese (≥30)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Missing	xx	xx	xx	xx	xx	Xx
BMI (kg/m2)	n[a]	xx	xx	xx	xx	xx	Xx
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	SD	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
	Q1, Q3	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx
	Min, Max	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx
	Missing	xx	xx	xx	xx	xx	Xx
Has the subject ever experienced any diseases and/or surgeries?	n[a]	xx	xx	xx	xx	xx	Xx
	Yes	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	No	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)

Programming Note: The table will be repeated for all analysis populations that are determined to be on a different set of subjects as described in Section 4.2 (Table 1.17 – Table 1.20). Table numbers may differ depending on how many tables are produced and may not exactly match the SAP. The titles for the tables will be the same for the other populations with the name of the population changing based on the population being used. Final data analysis for Cohort 3, will use the labels FDP-ACDxFFP and FFPxFDP-ACD for the treatments after the study is unblinded and the word "(Closed)" will be removed from the table number.

Note: Abbreviations: N= number of subjects in the population; Q1=25% Percentile; Q3= 75% Percentile; and SD=Standard Deviation.
[a]=Number of subjects with non-missing data, used as the denominator.
The variable 'Has the subject ever experienced any diseases and/or surgeries?' will only use the data at screening.

Table 1.21 (Open). Analysis Populations and Subject Disposition

	FDP-CPD (270 mL) n (%)	FDP-ACD (270 mL) n (%)	FDP-CPD (540 mL) n (%)	FDP-ACD (540 mL) n (%)	Cohort 3 (810 mL) n (%)	Overall n (%)
Analysis Populations						
Full Analysis Population – F1 [a]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Full Analysis Population – F2 [b]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Safety Population –S1 [c]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Safety Population – S2 [d]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Safety Population – S3 [e]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Completed the Study [f]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Did Not Complete the Study [f]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Primary Reason for Discontinuation [g]						
Adverse Event	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)
Lost to Follow-up	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)	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)
…	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: Percents are based on the full analysis population – F1.
[a] The full analysis (F1) population includes all subjects that were enrolled, including subjects who were prematurely withdrawn from the study prior to the Infusion Visit and were never infused (F1).
[b] Enrolled and presented for treatment at the Infusion Visit (F2).
[c] The safety population (S1) includes all subjects who received any volume of infused product (in Cohort 3, this includes those who received a partial dose at either infusion visit).
[d] The safety population (S2) includes all subjects who received full infusion and have at least one outcome measure.
[e] The safety population (S3) includes all subjects who receive the full infusion dose and can be fully evaluated, because in Cohorts 1 and 2 the subjects minimally completed the 7-day follow-up visit and in Cohort 3 the subjects had both complete infusion doses and minimally completed the 7-day follow-up visit after the second infusion. (Per protocol population.)
[f] Denominator is the number of subjects that were infused based on the S1 population.
[g] Denominator is the number of subjects that did not complete the study.

Table 1.21 (Closed). Analysis Populations and Subject Disposition

	FDP-CPD (270 mL) n (%)	FDP-ACD (270 mL) n (%)	FDP-CPD (540 mL) n (%)	FDP-ACD (540 mL) n (%)	A (810 mL) n (%)	B (810 mL) n (%)	Overall n (%)
Analysis Populations							
Full Analysis Population – F1 [a]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Full Analysis Population – F2 [b]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Safety Population –S1 [c]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Safety Population – S2 [d]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Safety Population – S3 [e]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Completed the Study [f]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Did Not Complete the Study [f]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Primary Reason for Discontinuation [g]							
Adverse Event	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)
Lost to Follow-up	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)	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)	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)	xx (xx.x)

Special Note: Since this table includes all three cohorts, an Open and Closed session table will be produced for the DSMB to protect the mask for Cohort 3. For the Open session only, for Cohort 3, the overall total counts will be shown as illustrated above with the table number having the word "(Open)" after the table number before the decimal. Open session tables will be produced by the blinded programmers. For the Closed session, the treatment arms will be masked as A and B. The table number will have the word "(Closed)" after the table number before the decimal. Closed session tables will be produced by the unblinded programmers. Final data analysis for Cohort 3, will use the labels FDP-ACDxFFP and FFPxFDP-ACD for the treatments after the study is unblinded and the word "(Closed)" will be removed from the table number.

Note: Percents are based on the full analysis population – F1.
[a] The full analysis (F1) population includes all subjects that were enrolled, including subjects who were prematurely withdrawn from the study prior to the Infusion Visit and were never infused (F1).
[b] Enrolled and presented for treatment at the Infusion Visit (F2).
[c] The safety population (S1) includes all subjects who received any volume of infused product (in Cohort 3, this includes those who received a partial dose at either infusion visit).
[d] The safety population (S2) includes all subjects who received full infusion and have at least one outcome measure.
[e] The safety population (S3) includes all subjects who receive the full infusion dose and can be fully evaluated, because in Cohorts 1 and 2 the subjects minimally completed the 7-day follow-up visit and in Cohort 3 the subjects had both complete infusion doses and minimally completed the 7-day follow-up visit after the second infusion. (Per protocol population.)
[f] Denominator is the number of subjects that were infused based on the S1 population.
[g] Denominator is the number of subjects that did not complete the study.

Figure 1. Subject Disposition – Cohorts 1 and 2

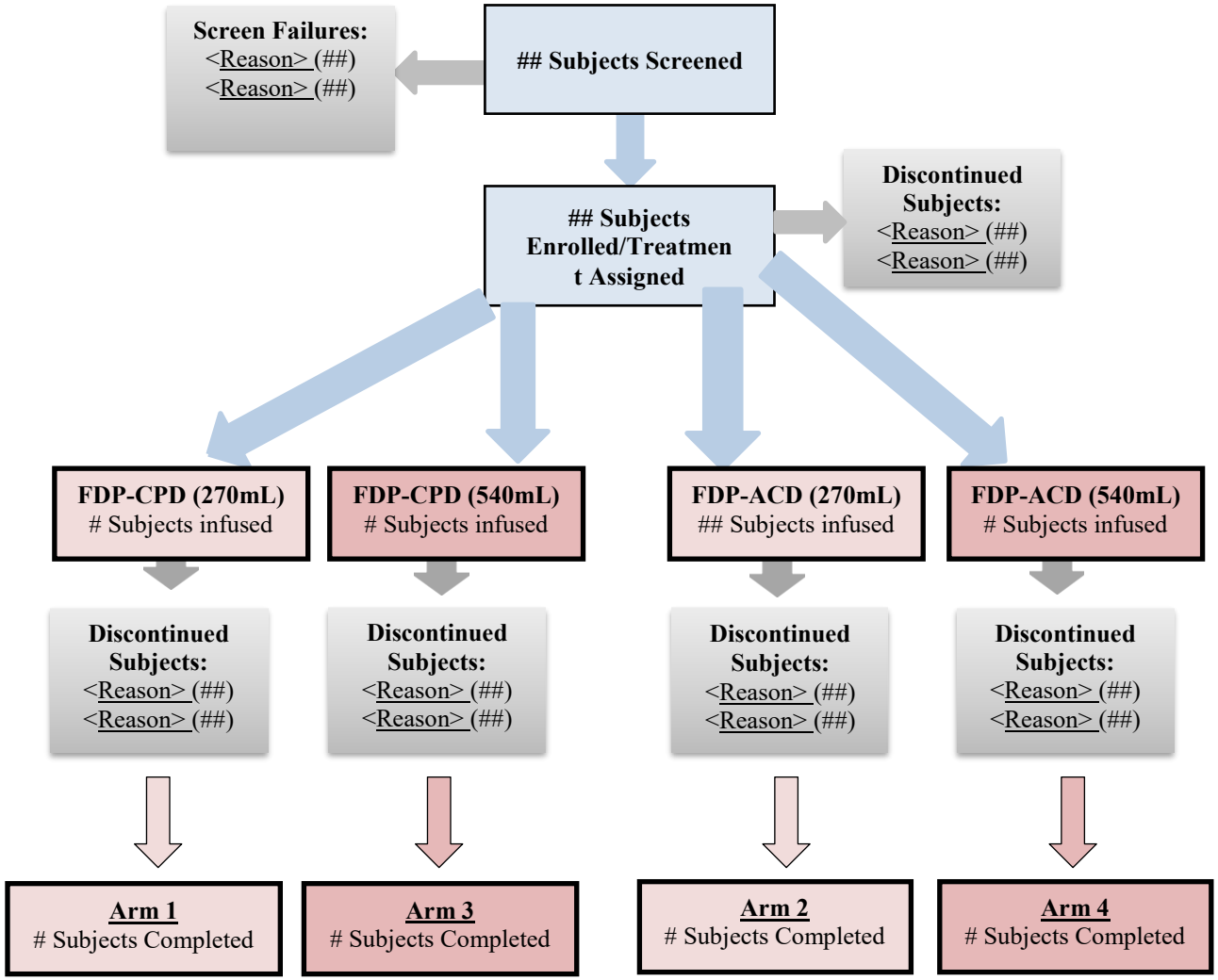


Figure 2 (Open). Subject Disposition – Cohort 3

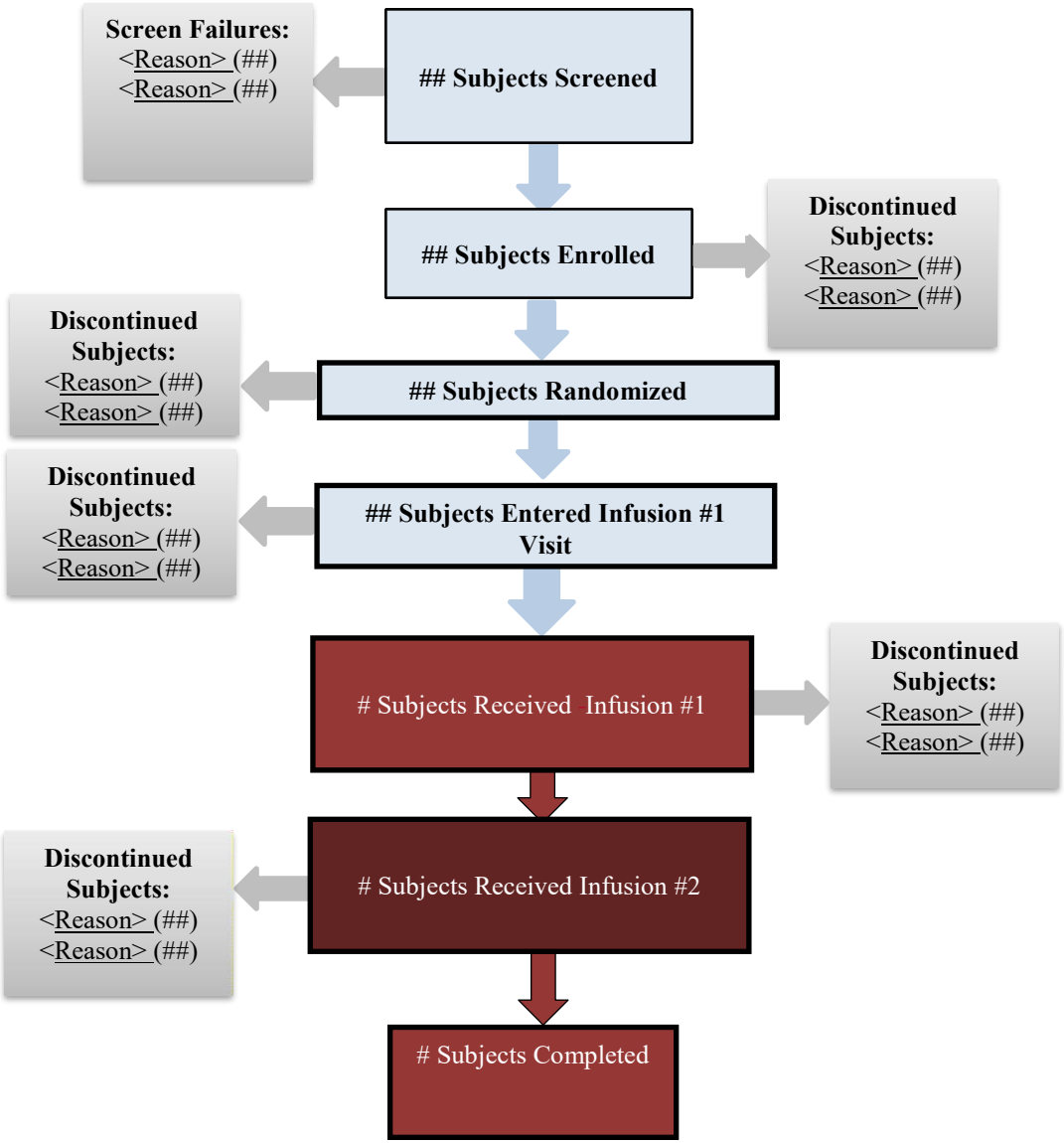
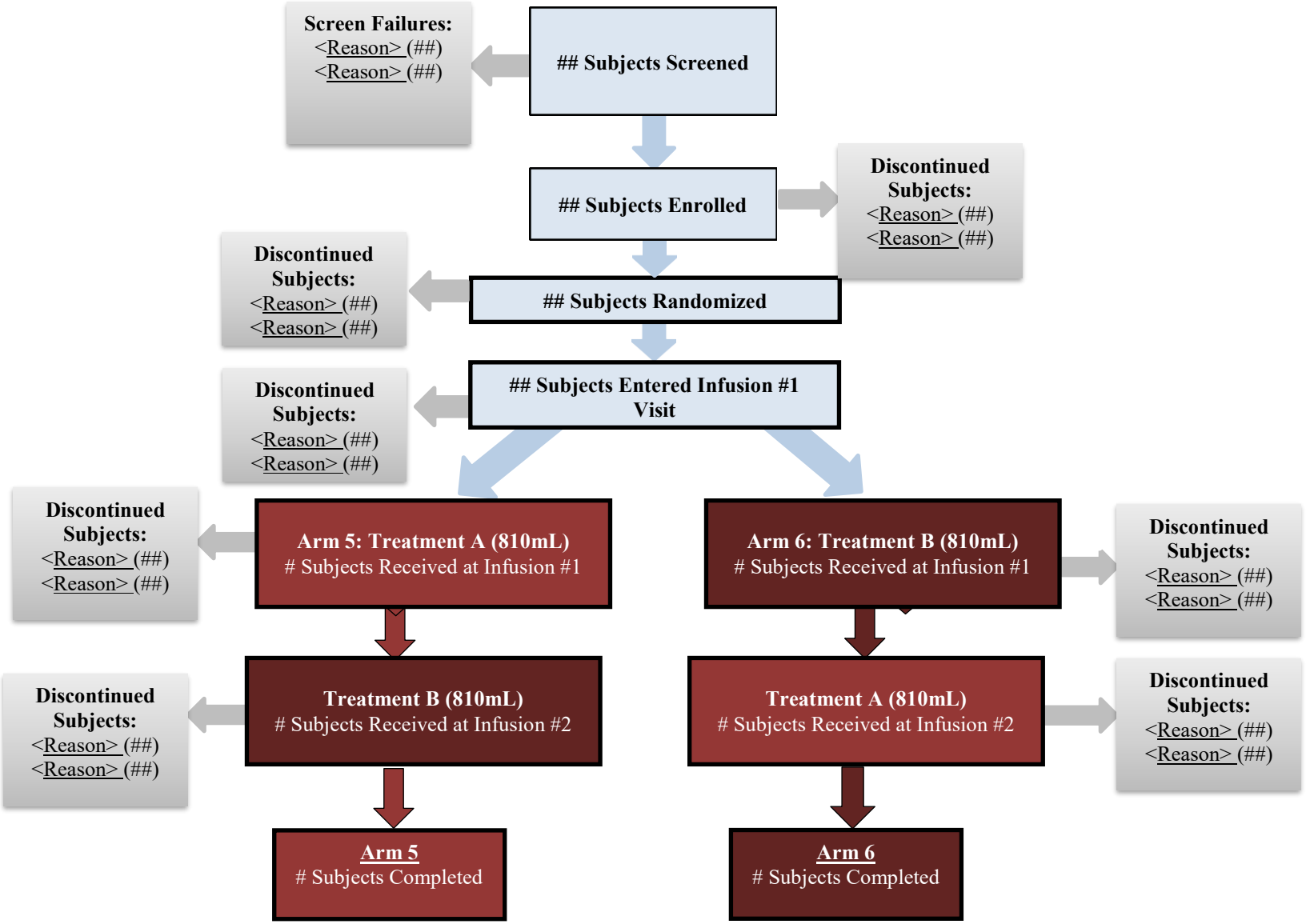


Figure 2 (Closed). Subject Disposition – Cohort 3



Data Source: ADIE Cross Reference: Listing 1, Listing 2 Data Extract Date:

Special Note: For Cohort 3, there will be an Open and Closed session for the DSMB. For the Open session only Figure 2 will only show overall totals as shown above with the figure number having the word "(Open)" after the figure number before the decimal. Open session Figure 2 will be produced by the blinded statistician. For the Closed session, the treatment arms will be masked as A and B as shown above. The figure number will have the word "(Closed)" after the figure number before the decimal. Closed session Figure 2 will be produced by the unblinded statistician. Final data analysis for Cohort 3 will use the labels FDP-ACDxFFP and FFPxFDP-ACD for the treatments after the study is unblinded and the word "(Closed)" will be removed from the figure number.

Table 2.1. - Table 2.15. Overview of Subject Incidence of Adverse Events (AEs)
Subject Incidence of AEs – Cohort 1 (270 mL)
Full Analysis Population – F1 (N=XX)
FDP-1
Phase I

	FDP-CPD (N=XX) n (%[a])	FDP-ACD (N=XX) n (%[a])
Adverse Events	xx (xx.x)	xx (xx.x)
Treatment Emergent Adverse Events	xx (xx.x)	xx (xx.x)
Treatment-Emergent Adverse Events Related to Study Treatment	xx (xx.x)	xx (xx.x)
Serious Adverse Events	xx (xx.x)	xx (xx.x)
Adverse Events Leading to Discontinuation of Investigational Product	xx (xx.x)	xx (xx.x)
Fatal Adverse Events	xx (xx.x)	xx (xx.x)

Table 2.1. - Table 2.15 (Open). Overview of Subject Incidence of Adverse Events (AEs)
Subject Incidence of AEs – Cohort 3 (810 mL)
Full Analysis Population – F1 (N=XX)
FDP-1
Phase I

	Total (N=XX) n (%[a])
Adverse Events	xx (xx.x)
Treatment Emergent Adverse Events	xx (xx.x)
Treatment-Emergent Adverse Events Related to Study Treatment	xx (xx.x)
Serious Adverse Events	xx (xx.x)
Adverse Events Leading to Discontinuation of Investigational Product	xx (xx.x)
Fatal Adverse Events	xx (xx.x)

Notes: Subjects may be counted in more than one row.
[a]=Denominator for each % is the treatment group N.

Table 2.1. - Table 2.15 (Closed). Overview of Subject Incidence of Adverse Events (AEs)
Subject Incidence of AEs – Cohort 3 (810 mL)
Full Analysis Population – F1 (N=XX)
FDP-1
Phase I

	A (N=XX) n (%[a])	B (N=XX) n (%[a])
Adverse Events	xx (xx.x)	xx (xx.x)
Treatment Emergent Adverse Events	xx (xx.x)	xx (xx.x)
Treatment-Emergent Adverse Events Related to Study Treatment	xx (xx.x)	xx (xx.x)
Serious Adverse Events	xx (xx.x)	xx (xx.x)
Adverse Events Leading to Discontinuation of Investigational Product	xx (xx.x)	xx (xx.x)
Fatal Adverse Events	xx (xx.x)	xx (xx.x)

Programming Note: This table will be repeated for all analysis populations that are determined to be on a different set of subjects as described in Section 4.2 for each cohort (Table 2.2 – Table 2.15). All tables may not be produced based on the table reduction method mentioned in Section 4.2 and may not exactly match the SAP. The titles for the tables will be the same for the other populations and cohorts with the name of the population and cohort changing based on the population being used. The titles for Cohort 2 and 3 for the F1 population are listed below:

Table 2.X. Overview of Subject Incidence of AEs
Subject Incidence of AEs – Cohort 2 (540 mL)
Full Analysis Population – F1 (N=XX)
FDP-1
Phase I

Special Note: Cohorts 1 and 2 are not masked; therefore, only one set of tables will be produced showing the unmasked treatment arm. For Cohort 3, there will be an Open and Closed session for the DSMB to protect the mask. For the Open session only, a Total Column will be shown with the table numbers having the word "(Open)" after the table number before the decimal. Open session tables will be produced by the blinded programmers. Footnotes for Open session tables will be modified to reflect total counts. For the Closed session, the treatment arms will be masked as A and B. The table numbers will have the word "(Closed)" after the table number before the decimal. Closed session tables will be produced by the unblinded programmers. Final data analysis for Cohort 3, will use the labels FDP-ACDxFFP and FFPxFDP-ACD for the treatments after the study is unblinded and the word "(Closed)" will be removed from the table number.

Table 2.X (Open). Overview of Subject Incidence of AEs
Subject Incidence of AEs – Cohort 3 (810 mL)
Full Analysis Population – F1 (N=XX)
FDP-1

Notes: Subjects may be counted in more than one row.
[a]=Denominator for each % is the treatment group N.

Program Path:

Data Extract Date:
Data Source: ADAE Cross Reference: Listing 13-14, Listing 18-19

Phase I

Table 2.X (Closed). Overview of Subject Incidence of AEs
Subject Incidence of AEs – Cohort 3 (810 mL)
Full Analysis Population – F1 (N=XX)
FDP-1
Phase I

Notes: Subjects may be counted in more than one row.
[a]=Denominator for each % is the treatment group N.

Program Path:

Data Extract Date:
Data Source: ADAE Cross Reference: Listing 13-14, Listing 18-19

Table 2.16. - Table 2.20 (Open). Overview of Subject Incidence of AEs - Overall
Subject Incidence of AEs – Overall
Full Analysis Population – F1 (N=XX)
FDP-1
Phase I

	Cohort 1		Cohort 2		Cohort 3
	FDP-CPD 270 mL (N = XX) n (%[a])	FDP-ACD 270 mL (N = XX) n (%[a])	FDP-CPD 540 mL (N = XX) n (%[a])	FDP-ACD 540 mL (N = XX) n (%[a])	810 mL (N = XX) n (%[a])
Adverse Events	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treatment Emergent Adverse Events	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treatment-Emergent Adverse Events Related to Study Treatment	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Serious Adverse Events	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Adverse Events Leading to Discontinuation of Investigational Product	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Fatal Adverse Events	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Notes: Subjects may be counted in more than one row.
[a]=Denominator for each % is the treatment group N.

Table 2.16. - Table 2.20 (Closed). Overview of Subject Incidence of AEs - Overall
Subject Incidence of AEs – Overall
Full Analysis Population – F1 (N=XX)
FDP-1
Phase I

	Cohort 1		Cohort 2		Cohort 3	
	FDP-CPD 270 mL (N = XX) n (%[a])	FDP-ACD 270 mL (N = XX) n (%[a])	FDP-CPD 540 mL (N = XX) n (%[a])	FDP-ACD 540 mL (N = XX) n (%[a])	A 810 mL (N = XX) n (%[a])	B 810 mL (N = XX) n (%[a])
Adverse Events	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treatment Emergent Adverse Events	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treatment-Emergent Adverse Events Related to Study Treatment	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Serious Adverse Events	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Adverse Events Leading to Discontinuation of Investigational Product	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Fatal Adverse Events	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Programming Note: The table will be repeated for all analysis populations that are determined to be on a different set of subjects as described in Section 4.2 (Table 2.17 – Table 2.20). All tables may not be produced based on the table reduction method mentioned in Section 4.2 and may not exactly match the SAP. The titles for the tables will be the same for the other populations with the name of the population changing based on the population being used.

Special Note: Since this table includes all three cohorts, an Open and Closed session table will be produced for the DSMB to protect the mask for Cohort 3. For the Open session only, for Cohort 3 the overall totals will be shown with the table numbers having the word "(Open)" after the table number before the decimal as shown above. Open session tables will be produced by the blinded programmers. Footnotes for Open session tables will be modified to reflect total counts. For the Closed session, the treatment arms will be masked as A and B as shown above. The table numbers will have the word "(Closed)" after the table number before the decimal. Closed session tables will be produced by the unblinded programmers. Final data analysis for Cohort 3, will use the labels FDP-ACDxFFP and FFPxFDP-ACD for the treatments after the study is unblinded and the word "(Closed)" will be removed from the table number.

Notes: Subjects may be counted in more than one row.
[a]=Denominator for each % is the treatment group N.

Table 3.1. - Table 3.9. Summary of Treatment-Emergent Adverse Events (TEAEs) by Preferred Term in Descending Frequency within System Organ Class
Subject Incidence of TEAEs – Cohort 1 (270 mL)
Safety Population – S1 (N=XX)
FDP-1
Phase I

System Organ Class Preferred Term	FDP-CPD (N = XX) n (%[a])	FDP-ACD (N = XX) n (%[a])
Number of subjects reporting treatment-emergent adverse events	xx (xx.x)	xx (xx.x)
[System Organ Class #1]	xx (xx.x)	xx (xx.x)
[Preferred Term #1]	xx (xx.x)	xx (xx.x)
[Preferred Term #2][b]	xx (xx.x)	xx (xx.x)
[System Organ Class #2]	xx (xx.x)	xx (xx.x)
[Preferred Term #1][c]	xx (xx.x)	xx (xx.x)
….		

Table 3.1. - Table 3.9 (Open). Summary of Treatment-Emergent Adverse Events (TEAEs) by Preferred Term in Descending Frequency within System Organ Class
Subject Incidence of TEAEs – Cohort 3 (810 mL)
Safety Population – S1 (N=XX)
FDP-1
Phase I

System Organ Class Preferred Term	Total (N = XX) n (%[a])
Number of subjects reporting treatment-emergent adverse events	xx (xx.x)
[System Organ Class #1]	xx (xx.x)
[Preferred Term #1]	xx (xx.x)
[Preferred Term #2][b]	xx (xx.x)
[System Organ Class #2]	xx (xx.x)
[Preferred Term #1][c]	xx (xx.x)
….	

Notes: Subjects are counted at most once on each row. Subjects may be included on more than one row.
[a]=Denominator for each % is the treatment group N.
[b]=Denominator adjusted because gender-specific event for males: N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 1; N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 2; N=XX (Total) for Cohort 3 (Open Session); N=XX (A), N=XX (B) for Cohort 3 (Closed Session) [for applicable PTs].
[c]=Denominator adjusted because gender-specific event for females: N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 1; N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 2; N=XX (Total) for Cohort 3 (Open Session); N=XX (A), N=XX (B) for Cohort 3 (Closed Session) [for applicable PTs].
Preferred Terms within System Organ Class are sorted in descending order of frequency based on the TEAE category.

Table 3.1. - Table 3.9 (Closed). Summary of Treatment-Emergent Adverse Events (TEAEs) by Preferred Term in Descending Frequency within System Organ Class
Subject Incidence of TEAEs – Cohort 3 (810 mL)
Safety Population – S1 (N=XX)
FDP-1
Phase I

System Organ Class Preferred Term	A (N = XX) n (%[a])	B (N = XX) n (%[a])
Number of subjects reporting treatment-emergent adverse events	xx (xx.x)	xx (xx.x)
[System Organ Class #1]	xx (xx.x)	xx (xx.x)
[Preferred Term #1]	xx (xx.x)	xx (xx.x)
[Preferred Term #2][b]	xx (xx.x)	xx (xx.x)
[System Organ Class #2]	xx (xx.x)	xx (xx.x)
[Preferred Term #1][c]	xx (xx.x)	xx (xx.x)
….		

Programming Note: This table will be repeated for all safety analysis populations that are determined to be on a different set of subjects as described in Section 4.2 for each cohort (Table 3.2 – Table 3.9). All tables may not be produced based on the table reduction method mentioned in Section 4.2 and may not exactly match the SAP. The titles for the tables will be the same for the other populations and cohorts with the name of the population and cohort changing based on the population being used. The titles for Cohort 2 and 3 for the S1 population are listed below:

Table 3.X. Summary of TEAEs by Preferred Term in Descending Frequency within System Organ Class
Subject Incidence of TEAEs – Cohort 2 (540 mL)
Safety Population – S1 (N=XXX)
FDP-1
Phase I

Special Note: Cohorts 1 and 2 are not masked; therefore, only one set of tables will be produced showing the unmasked treatment arm. For Cohort 3, there will be an Open and Closed session for the DSMB to protect the mask. For the Open session only, a Total Column will be shown with the table numbers having the word "(Open)" after the table number before the decimal. Footnotes for Open session tables related to gender specific AEs will be modified to reflect total counts for males and females. Open session tables will be produced by the blinded programmers. Footnotes for Open session tables will be modified to reflect total counts. For the Closed session, the treatment arms will be masked as A and B. The table numbers will have the word "(Closed)" after the table number before the decimal. Closed session tables will be produced by the unblinded programmers. Final data analysis for Cohort 3 will use

Notes: Subjects are counted at most once on each row. Subjects may be included on more than one row.
[a]=Denominator for each % is the treatment group N.
[b]=Denominator adjusted because gender-specific event for males: N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 1; N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 2; N=XX (Total) for Cohort 3 (Open Session); N=XX (A), N=XX (B) for Cohort 3 (Closed Session) [for applicable PTs].
[c]=Denominator adjusted because gender-specific event for females: N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 1; N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 2; N=XX (Total) for Cohort 3 (Open Session); N=XX (A), N=XX (B) for Cohort 3 (Closed Session) [for applicable PTs].
Preferred Terms within System Organ Class are sorted in descending order of frequency based on the TEAE category.

the labels FDP-ACDxFFP and FFPxFDP-ACD for the treatments after the study is unblinded and the word "(Closed)" will be removed from the table number.

Table 3.X (Open). Summary of TEAEs by Preferred Term in Descending Frequency within System Organ Class
Subject Incidence of TEAEs – Cohort 3 (810 mL)
Safety Population – S1 (N=XXX)
FDP-1
Phase I

Table 3.X (Closed). Summary of TEAEs by Preferred Term in Descending Frequency within System Organ Class
Subject Incidence of TEAEs – Cohort 3 (810 mL)
Safety Population – S1 (N=XXX)
FDP-1
Phase I

Notes: Subjects are counted at most once on each row. Subjects may be included on more than one row.
[a]=Denominator for each % is the treatment group N.
[b]=Denominator adjusted because gender-specific event for males: N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 1; N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 2; N=XX (Total) for Cohort 3 (Open Session); N=XX (A), N=XX (B) for Cohort 3 (Closed Session) [for applicable PTs].
[c]=Denominator adjusted because gender-specific event for females: N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 1; N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 2; N=XX (Total) for Cohort 3 (Open Session); N=XX (A), N=XX (B) for Cohort 3 (Closed Session) [for applicable PTs].
Preferred Terms within System Organ Class are sorted in descending order of frequency based on the TEAE category.

Table 3.10. – Table 3.12 (Open). Summary of TEAEs by Preferred Term in Descending Frequency within System Organ Class - Overall
Subject Incidence of TEAEs – Overall
Safety Population – S1 (N=XX)
FDP-1
Phase I

	Cohort 1		Cohort 2		Cohort 3
System Organ Class Preferred Term	FDP-CPD 270 mL (N = XX) n (%[a])	FDP-ACD 270 mL (N = XX) n (%[a])	FDP-CPD 540 mL (N = XX) n (%[a])	FDP-ACD 540 mL (N = XX) n (%[a])	810 mL (N = XX) n (%[a])
Number of subjects reporting treatment-emergent adverse events					
[System Organ Class #1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[Preferred Term #1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[Preferred Term #2][b]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[System Organ Class #2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[Preferred Term #1][c]	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)	xx (xx.x)

Notes: Subjects are counted at most once on each row. Subjects may be included on more than one row.
[a]=Denominator for each % is the treatment group N.
[b]=Denominator adjusted because gender-specific event for males: N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 1; N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 2; N=XX (810 mL) for Cohort 3 (Open Session); N=XX (A), N=XX (B) for Cohort 3 (Closed Session) [for applicable PTs].
[c]=Denominator adjusted because gender-specific event for females: N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 1; N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 2; N=XX (810 mL) for Cohort 3 (Open Session); N=XX (A), N=XX (B), N=XX for Cohort 3 (Closed Session) [for applicable PTs].
Preferred Terms within System Organ Class are sorted in descending order of frequency based on the TEAE category.

Table 3.10. – Table 3.12 (Closed). Summary of TEAEs by Preferred Term in Descending Frequency within System Organ Class - Overall
Subject Incidence of TEAEs – Overall
Safety Population – S1 (N=XX)
FDP-1
Phase I

	Cohort 1		Cohort 2		Cohort 3	
System Organ Class Preferred Term	FDP-CPD 270 mL (N = XX) n (%[a])	FDP-ACD 270 mL (N = XX) n (%[a])	FDP-CPD 540 mL (N = XX) n (%[a])	FDP-ACD 540 mL (N = XX) n (%[a])	A 810 mL (N = XX) n (%[a])	B 810 mL (N = XX) n (%[a])
Number of subjects reporting treatment-emergent adverse events						
[System Organ Class #1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[Preferred Term #1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[Preferred Term #2][b]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[System Organ Class #2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[Preferred Term #1][c]	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)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Programming Note: The table will be repeated for all safety analysis populations that are determined to be on a different set of subjects as described in Section 4.2 (Table 3.11 – Table 3.12). All tables may not be produced based on the table reduction method mentioned in Section 4.2 and may not exactly match the SAP. The titles for the tables will be the same for the other populations with the name of the population changing based on the population being used.

Special Note: Since this table includes all three cohorts, an Open and Closed session table will be produced for the DSMB to protect the mask for Cohort 3. For the Open session only for Cohort 3, an overall total column will be shown with the table numbers having the word "(Open)" after the table number before the decimal as shown above. Footnotes for Open session tables related to gender specific AEs will be modified to reflect total counts for males and females. Open session tables will be produced by the blinded programmers. Footnotes for Open session tables will be modified

Notes: Subjects are counted at most once on each row. Subjects may be included on more than one row.
[a]=Denominator for each % is the treatment group N.
[b]=Denominator adjusted because gender-specific event for males: N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 1; N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 2; N=XX (810 mL) for Cohort 3 (Open Session); N=XX (A), N=XX (B) for Cohort 3 (Closed Session) [for applicable PTs].
[c]=Denominator adjusted because gender-specific event for females: N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 1; N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 2; N=XX (810 mL) for Cohort 3 (Open Session); N=XX (A), N=XX (B), N=XX for Cohort 3 (Closed Session) [for applicable PTs].
Preferred Terms within System Organ Class are sorted in descending order of frequency based on the TEAE category.

to reflect total counts. For the Closed session, the treatment arms will be masked as A and B as shown above. The table numbers will have the word "(Closed)" after the table number before the decimal. Closed session tables will be produced by the unblinded programmers. Final data analysis for Cohort 3 will use the labels FDP-ACDxFFP and FFPxFDP-ACD for the treatments after the study is unblinded and the word "(Closed)" will be removed from the table number.

Notes: Subjects are counted at most once on each row. Subjects may be included on more than one row.
[a]=Denominator for each % is the treatment group N.
[b]=Denominator adjusted because gender-specific event for males: N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 1; N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 2; N=XX (810 mL) for Cohort 3 (Open Session); N=XX (A), N=XX (B) for Cohort 3 (Closed Session) [for applicable PTs].
[c]=Denominator adjusted because gender-specific event for females: N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 1; N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 2; N=XX (810 mL) for Cohort 3 (Open Session); N=XX (A), N=XX (B), N=XX for Cohort 3 (Closed Session) [for applicable PTs].
Preferred Terms within System Organ Class are sorted in descending order of frequency based on the TEAE category.

Table 4.1. - Table 4.9. Summary of TEAEs and TEAEs by Relatedness per Investigator by Preferred Term in Descending Frequency within System Organ Class
Subject Incidence of TEAEs and TEAEs Relatedness per Investigator – Cohort 1 (270 mL)
Safety Population – S1 (N=XX)
FDP-1
Phase I

System Organ Class Preferred Term	**TEAEs**		**TEAEs Considered Not Related per Investigator**		**TEAEs Considered Unlikely Related per Investigator**		**TEAEs Considered Possibly Related per Investigator**		**TEAEs Considered Probably Related per Investigator**		**TEAEs Considered Definitely Related per Investigator**	
	FDP-CPD (N = X) n (%[a])	FDP-ACD (N = X) n (%[a])	FDP-CPD (N = X) n (%[a])	FDP-ACD (N = X) n (%[a])	FDP-CPD (N = X) n (%[a])	FDP-ACD (N = X) n (%[a])	FDP-CPD (N = X) n (%[a])	FDP-ACD (N = X) n (%[a])	FDP-CPD (N = X) n (%[a])	FDP-ACD (N = X) n (%[a])	FDP-CPD (N = X) n (%[a])	FDP-ACD (N = X) n (%[a])
Number of subjects reporting 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)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[System Organ Class #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)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[Preferred Term #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)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[Preferred Term #2][b]	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)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[System Organ Class #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)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[Preferred Term #1][c]	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)	xx (xx.x)	xx (xx.x)	xx (xx.x)
….												

Notes: Subjects may be included on more than one row.
[a]=Denominator for each % is the treatment group N.
[b]=Denominator adjusted because gender-specific event for males: N=XX (FDP-CPD), N=XX (FDP-ACD) [for applicable PTs].
[c]=Denominator adjusted because gender-specific event for females: N=XX (FDP-CPD), N=XX (FDP-ACD) [for applicable PTs].
Preferred Terms within System Organ Class are sorted in descending order of frequency based on the TEAE category.
In the columns from Not Related to Definitely Related, subjects are counted at most once per row, in the column with the highest level of relatedness.

Notes: Subjects may be included on more than one row.
[a]=Denominator for each % is the treatment group N.
[b]=Denominator adjusted because gender-specific event for males: N=XX (Total) [for applicable PTs].
[c]=Denominator adjusted because gender-specific event for females: N=XX (Total) [for applicable PTs].
Preferred Terms within System Organ Class are sorted in descending order of frequency based on the TEAE category.
In the columns from Not Related to Definitely Related, subjects are counted at most once per row, in the column with the highest level of relatedness.

Program Path:
Data Source: ADAE Cross Reference: Listing 13 Data Extract Date:

Table 4.1. - Table 4.9 (Open). Summary of TEAEs and TEAEs by Relatedness per Investigator by Preferred Term in Descending Frequency within System Organ Class
Subject Incidence of TEAEs and TEAEs Relatedness per Investigator – Cohort 3 (810 mL)
Safety Population – S1 (N=XX)
FDP-1
Phase I

System Organ Class Preferred Term	**TEAEs**	**TEAEs Considered Not Related per Investigator**	**TEAEs Considered Unlikely Related per Investigator**	**TEAEs Considered Possibly Related per Investigator**	**TEAEs Considered Probably Related per Investigator**	**TEAEs Considered Definitely Related per Investigator**
	Total (N = X) n (%[a])	Total (N = X) n (%[a])	Total (N = X) n (%[a])	Total (N = X) n (%[a])	Total (N = X) n (%[a])	Total (N = X) n (%[a])
Number of subjects reporting adverse events	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[System Organ Class #1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[Preferred Term #1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[Preferred Term #2][b]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[System Organ Class #2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[Preferred Term #1][c]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
….						

Notes: Subjects may be included on more than one row.
[a]=Denominator for each % is the treatment group N.
[b]=Denominator adjusted because gender-specific event for males: N=XX (Total) [for applicable PTs].
[c]=Denominator adjusted because gender-specific event for females: N=XX (Total) [for applicable PTs].
Preferred Terms within System Organ Class are sorted in descending order of frequency based on the TEAE category.
In the columns from Not Related to Definitely Related, subjects are counted at most once per row, in the column with the highest level of relatedness.

Table 4.1. - Table 4.9 (Closed). Summary of TEAEs and TEAEs by Relatedness per Investigator by Preferred Term in Descending Frequency within System Organ Class
Subject Incidence of TEAEs and TEAEs Relatedness per Investigator – Cohort 3 (810 mL)
Safety Population – S1 (N=XX)
FDP-1
Phase I

System Organ Class Preferred Term	**TEAEs**		**TEAEs Considered Not Related per Investigator**		**TEAEs Considered Unlikely Related per Investigator**		**TEAEs Considered Possibly Related per Investigator**		**TEAEs Considered Probably Related per Investigator**		**TEAEs Considered Definitely Related per Investigator**	
	A (N = X) n (%[a])	B (N = X) n (%[a])	A (N = X) n (%[a])	B (N = X) n (%[a])	A (N = X) n (%[a])	B (N = X) n (%[a])	A (N = X) n (%[a])	B (N = X) n (%[a])	A (N = X) n (%[a])	B (N = X) n (%[a])	A (N = X) n (%[a])	B (N = X) n (%[a])
Number of subjects reporting 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)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[System Organ Class #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)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[Preferred Term #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)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[Preferred Term #2][b]	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)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[System Organ Class #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)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[Preferred Term #1][c]	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)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Notes: Subjects may be included on more than one row.
[a]=Denominator for each % is the treatment group N.
[b]=Denominator adjusted because gender-specific event for males: N=XX (A), N=XX (B) [for applicable PTs].
[c]=Denominator adjusted because gender-specific event for females: N=XX (A), N=XX (B) [for applicable PTs].
Preferred Terms within System Organ Class are sorted in descending order of frequency based on the TEAE category.
In the columns from Not Related to Definitely Related, subjects are counted at most once per row, in the column with the highest level of relatedness.

System Organ Class Preferred Term	TEAEs		TEAEs Considered Not Related per Investigator		TEAEs Considered Unlikely Related per Investigator		TEAEs Considered Possibly Related per Investigator		TEAEs Considered Probably Related per Investigator		TEAEs Considered Definitely Related per Investigator	
….												

Programming Note: This table will be repeated for all safety analysis populations that are determined to be on a different set of subjects as described in Section 4.2 for each cohort. (Table 4.2 – Table 4.9). All tables may not be produced based on the table reduction method mentioned in Section 4.2 and may not exactly match the SAP. The titles for the tables will be the same for the other populations and cohorts with the name of the population and cohort changing based on the population being used. The titles for Cohort 2 and 3 for the S1 population are listed below:

Table 4.X. Summary of TEAEs and TEAEs by Relatedness per Investigator by Preferred Term in Descending Frequency within System Organ Class Subject Incidence of TEAEs and TEAE by Relatedness per Investigator – Cohort 2 (540 mL)
Safety Population – S1 (N=XX)
FDP-1
Phase I

Special Note: Cohorts 1 and 2 are not masked; therefore, only one set of tables will be produced showing the unmasked treatment arm. For Cohort 3, there will be an Open and Closed session for the DSMB to protect the mask. For the Open session only, overall totals will be shown for each TEAE category with the table numbers having the word "(Open)" after the table number before the decimal. Footnotes for Open session tables related to gender specific AEs will be modified to reflect total counts for males and females. Open session tables will be produced by the blinded programmers. Footnotes for Open session tables will be modified to reflect total counts. For the Closed session, the treatment arms will be masked as A and B. The table numbers will have the word "(Closed)" after the table number before the decimal. Closed session tables will be produced by the unblinded programmers. Final data analysis for Cohort 3 will use the labels FDP-ACDxFFP and FFPxFDP-ACD for the treatments after the study is unblinded and the word "(Closed)" will be removed from the table number.

Table 4.X (Open). Summary of TEAEs and TEAEs by Relatedness per Investigator by Preferred Term in Descending Frequency within System Organ Class Subject Incidence of TEAEs and TEAEs by Relatedness per Investigator – Cohort 3 (810 mL)
Safety Population – S1 (N=XX)

Notes: Subjects may be included on more than one row.
[a]=Denominator for each % is the treatment group N.
[b]=Denominator adjusted because gender-specific event for males: N=XX (A), N=XX (B) [for applicable PTs].
[c]=Denominator adjusted because gender-specific event for females: N=XX (A), N=XX (B) [for applicable PTs].
Preferred Terms within System Organ Class are sorted in descending order of frequency based on the TEAE category.
In the columns from Not Related to Definitely Related, subjects are counted at most once per row, in the column with the highest level of relatedness.

FDP-1
Phase I

Table 4.X (Closed). Summary of TEAEs and TEAEs by Relatedness per Investigator by Preferred Term in Descending Frequency within System Organ Class Subject Incidence of TEAEs and TEAEs by Relatedness per Investigator – Cohort 3 (810 mL)
Safety Population – S1 (N=XX)
FDP-1
Phase I

Notes: Subjects may be included on more than one row.
[a]=Denominator for each % is the treatment group N.
[b]=Denominator adjusted because gender-specific event for males: N=XX (A), N=XX (B) [for applicable PTs].
[c]=Denominator adjusted because gender-specific event for females: N=XX (A), N=XX (B) [for applicable PTs].
Preferred Terms within System Organ Class are sorted in descending order of frequency based on the TEAE category.
In the columns from Not Related to Definitely Related, subjects are counted at most once per row, in the column with the highest level of relatedness.

Table 5.1. - Table 5.9. Summary of TEAEs by Maximum Severity
Subject Incidence of TEAEs by Maximum Severity – Cohort 1 (270 mL)
Safety Population – S1 (N=XX)
FDP-1
Phase I

System Organ Class Preferred Term	Maximum Severity	FDP-CPD (N = XX) n (%[a])	FDP-ACD (N = XX) n (%[a])
Number of subjects reporting treatment-emergent adverse events	Mild	xx (xx.x)	xx (xx.x)
	Moderate	xx (xx.x)	xx (xx.x)
	Severe	xx (xx.x)	xx (xx.x)
	Life-threatening	xx (xx.x)	xx (xx.x)
	Fatal	xx (xx.x)	xx (xx.x)
	Any Severity	xx (xx.x)	xx (xx.x)
[System Organ Class #1]			
[Preferred Term #1]	Mild	xx (xx.x)	xx (xx.x)
	Moderate	xx (xx.x)	xx (xx.x)
	Severe	xx (xx.x)	xx (xx.x)
	Life-threatening	xx (xx.x)	xx (xx.x)
	Fatal	xx (xx.x)	xx (xx.x)
	Any Severity	xx (xx.x)	xx (xx.x)
[Preferred Term #2][b c]	Mild	xx (xx.x)	xx (xx.x)
	Moderate	xx (xx.x)	xx (xx.x)
	Severe	xx (xx.x)	xx (xx.x)
	Life-threatening	xx (xx.x)	xx (xx.x)
	Fatal	xx (xx.x)	xx (xx.x)
	Any Severity	xx (xx.x)	xx (xx.x)

Notes: On the rows from Mild to Fatal, within a block, subjects are counted at most once, on the row with the highest severity. Subjects may be included on more than one row.
[a]=Denominator for each % is the treatment group N. Grade 1=Mild, 2=Moderate, 3=Severe, 4=Life-threatening, 5=Fatal.
[b]=Denominator adjusted because gender-specific event for males: N=XX (FDP-CPD), N=XX (FDP-ACD) [for applicable PTs].
[c]=Denominator adjusted because gender-specific event for females: N=XX (FDP-CPD), N=XX (FDP-ACD) [for applicable PTs].
Preferred Terms within System Organ Class are sorted in descending order of frequency based on the TEAE category.

Table 5.1. - Table 5.9 (Open). Summary of TEAEs by Maximum Severity
Subject Incidence of TEAEs by Maximum Severity – Cohort 3 (810 mL)
Safety Population – S1 (N=XX)
FDP-1
Phase I

System Organ Class Preferred Term	Maximum Severity	Total (N = XX) n (%[a])
Number of subjects reporting treatment-emergent adverse events	Mild Moderate Severe Life-threatening Fatal Any Severity	xx (xx.x) xx (xx.x) xx (xx.x) xx (xx.x) xx (xx.x) xx (xx.x)
[System Organ Class #1]		
[Preferred Term #1]	Mild Moderate Severe Life-threatening Fatal Any Severity	xx (xx.x) xx (xx.x) xx (xx.x) xx (xx.x) xx (xx.x) xx (xx.x)
[Preferred Term #2][b c]	Mild Moderate Severe Life-threatening Fatal Any Severity	xx (xx.x) xx (xx.x) xx (xx.x) xx (xx.x) xx (xx.x) xx (xx.x)

Notes: On the rows from Mild to Fatal, within a block, subjects are counted at most once, on the row with the highest severity. Subjects may be included on more than one row.
[a]=Denominator for each % is the treatment group N. Grade 1=Mild, 2=Moderate, 3=Severe, 4=Life-threatening, 5=Fatal.
[b]=Denominator adjusted because gender-specific event for males: N=XX (Total) [for applicable PTs].
[c]=Denominator adjusted because gender-specific event for females: N=XX (Total) [for applicable PTs].
Preferred Terms within System Organ Class are sorted in descending order of frequency based on the TEAE category.

Table 5.1. - Table 5.9 (Closed). Summary of TEAEs by Maximum Severity
Subject Incidence of TEAEs by Maximum Severity – Cohort 3 (810 mL)
Safety Population – S1 (N=XX)
FDP-1
Phase I

System Organ Class Preferred Term	Maximum Severity	A (N = XX) n (%[a])	B (N = XX) n (%[a])
Number of subjects reporting treatment-emergent adverse events	Mild	xx (xx.x)	xx (xx.x)
	Moderate	xx (xx.x)	xx (xx.x)
	Severe	xx (xx.x)	xx (xx.x)
	Life-threatening	xx (xx.x)	xx (xx.x)
	Fatal	xx (xx.x)	xx (xx.x)
	Any Severity	xx (xx.x)	xx (xx.x)
[System Organ Class #1]			
[Preferred Term #1]	Mild	xx (xx.x)	xx (xx.x)
	Moderate	xx (xx.x)	xx (xx.x)
	Severe	xx (xx.x)	xx (xx.x)
	Life-threatening	xx (xx.x)	xx (xx.x)
	Fatal	xx (xx.x)	xx (xx.x)
	Any Severity	xx (xx.x)	xx (xx.x)
[Preferred Term #2][b c]	Mild	xx (xx.x)	xx (xx.x)
	Moderate	xx (xx.x)	xx (xx.x)
	Severe	xx (xx.x)	xx (xx.x)
	Life-threatening	xx (xx.x)	xx (xx.x)
	Fatal	xx (xx.x)	xx (xx.x)
	Any Severity	xx (xx.x)	xx (xx.x)

Programming Note: This table will be repeated for all safety analysis populations that are determined to be on a different set of subjects as described in Section 4.2 for each cohort (Table 5.2 – Table 5.9). All tables may not be produced based on the table reduction method mentioned in Section 4.2 and may not exactly match the SAP. The titles for the tables will be the same for the other populations and cohorts with the name of the population and cohort changing based on the population being used. The titles for Cohort 2 and 3 for the S1 population are listed below:

Table 5.X. Summary of TEAEs by Maximum Severity
Subject Incidence of TEAEs by Maximum Severity – Cohort 2 (540 mL)
Safety Population – S1 (N=XX)
FDP-1
Phase I

Special Note: Cohorts 1 and 2 are not masked; therefore, only one set of tables will be produced showing the unmasked treatment arm. For Cohort 3, there will be an Open and Closed session for the DSMB to

Notes: On the rows from Mild to Fatal, within a block, subjects are counted at most once, on the row with the highest severity. Subjects may be included on more than one row.
[a]=Denominator for each % is the treatment group N. Grade 1=Mild, 2=Moderate, 3=Severe, 4=Life-threatening, 5=Fatal.
[b]=Denominator adjusted because gender-specific event for males: N=XX (A), N=XX (B) [For applicable PTs].
[c]=Denominator adjusted because gender-specific event for females: N=XX (A), N=XX (B) [For applicable PTs].
Preferred Terms within System Organ Class are sorted in descending order of frequency based on the TEAE category.

protect the mask. For the Open session only, a Total Column will be shown with the table numbers having the word "(Open)" after the table number before the decimal. Footnotes for Open session tables related to gender specific AEs will be modified to reflect total counts for males and females. Open session tables will be produced by the blinded programmers. Footnotes for Open session tables will be modified to reflect total counts. For the Closed session, the treatment arms will be masked as A and B. The table numbers will have the word "(Closed)" after the table number before the decimal. Closed session tables will be produced by the unblinded programmers. Final data analysis for Cohort 3 will use the labels FDP- ACDxFFP and FFPxFDP-ACD for the treatments after the study is unblinded and the word "(Closed)" will be removed from the table number.

Table 5.X (Open). Summary of TEAEs by Maximum Severity
Subject Incidence of TEAEs by Maximum Severity – Cohort 3 (810 mL)
Safety Population – S1 (N=XX)
FDP-1
Phase I

Table 5.X (Closed). Summary of TEAEs by Maximum Severity
Subject Incidence of TEAEs by Maximum Severity – Cohort 3 (810 mL)
Safety Population – S1 (N=XX)
FDP-1
Phase I

Notes: On the rows from Mild to Fatal, within a block, subjects are counted at most once, on the row with the highest severity. Subjects may be included on more than one row.
[a]=Denominator for each % is the treatment group N. Grade 1=Mild, 2=Moderate, 3=Severe, 4=Life-threatening, 5=Fatal.
[b]=Denominator adjusted because gender-specific event for males: N=XX (A), N=XX (B) [For applicable PTs].
[c]=Denominator adjusted because gender-specific event for females: N=XX (A), N=XX (B) [For applicable PTs].
Preferred Terms within System Organ Class are sorted in descending order of frequency based on the TEAE category.

Table 6.1. - Table 6.9. Summary of TEAEs by Maximum CTCAE Grade
Subject Incidence of TEAEs by Maximum CTCAE Grade – Cohort 1 (270 mL)
Safety Population – S1 (N=XX)
FDP-1
Phase I

System Organ Class Preferred Term	Maximum CTCAE Grade	FDP-CPD (N = XX) n (%[a])	FDP-ACD (N = XX) n (%[a])
Number of subjects reporting treatment-emergent adverse events	Grade ≥ 2 Grade ≥ 3 Grade ≥ 4 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)
[System Organ Class #1]			
[Preferred Term #1]	Grade ≥ 2 Grade ≥ 3 Grade ≥ 4 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)
[Preferred Term #2][b c]	Grade ≥ 2 Grade ≥ 3 Grade ≥ 4 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)

Notes: Subjects may be included on more than one row.
[a]=Denominator for each % is the treatment group N. Grade 1=Mild, 2=Moderate, 3=Severe, 4=Life-threatening, 5=Fatal.
[b]=Denominator adjusted because gender-specific event for males: N=XX (FDP-CPD), N=XX (FDP-ACD) [for applicable PTs].
[c]=Denominator adjusted because gender-specific event for females: N=XX (FDP-CPD), N=XX (FDP-ACD) [for applicable PTs].
Preferred Terms within System Organ Class are sorted in descending order of frequency based on the TEAE category.

Table 6.1. - Table 6.9 (Open). Summary of TEAEs by Maximum CTCAE Grade
Subject Incidence of TEAEs by Maximum CTCAE Grade – Cohort 3 (810 mL)
Safety Population – S1 (N=XX)
FDP-1
Phase I

System Organ Class Preferred Term	Maximum CTCAE Grade	Total (N = XX) n (%[a])
Number of subjects reporting treatment-emergent adverse events	Grade ≥ 2 Grade ≥ 3 Grade ≥ 4 Fatal	xx (xx.x) xx (xx.x) xx (xx.x) xx (xx.x)
[System Organ Class #1]		
[Preferred Term #1]	Grade ≥ 2 Grade ≥ 3 Grade ≥ 4 Fatal	xx (xx.x) xx (xx.x) xx (xx.x) xx (xx.x)
[Preferred Term #2][b c]	Grade ≥ 2 Grade ≥ 3 Grade ≥ 4 Fatal	xx (xx.x) xx (xx.x) xx (xx.x) xx (xx.x)

Notes: Subjects may be included on more than one row.
[a]=Denominator for each % is the treatment group N. Grade 1=Mild, 2=Moderate, 3=Severe, 4=Life-threatening, 5=Fatal.
[b]=Denominator adjusted because gender-specific event for males: N=XX (Total) [for applicable PTs].
[c]=Denominator adjusted because gender-specific event for females: N=XX (Total) [for applicable PTs].
Preferred Terms within System Organ Class are sorted in descending order of frequency based on the TEAE category.

Table 6.1. - Table 6.9 (Closed). Summary of TEAEs by Maximum CTCAE Grade
Subject Incidence of TEAEs by Maximum CTCAE Grade – Cohort 3 (810 mL)
Safety Population – S1 (N=XX)
FDP-1
Phase I

System Organ Class Preferred Term	Maximum CTCAE Grade	A (N = XX) n (%[a])	B (N = XX) n (%[a])
Number of subjects reporting treatment-emergent adverse events	Grade ≥ 2 Grade ≥ 3 Grade ≥ 4 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)
[System Organ Class #1]			
[Preferred Term #1]	Grade ≥ 2 Grade ≥ 3 Grade ≥ 4 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)
[Preferred Term #2][b c]	Grade ≥ 2 Grade ≥ 3 Grade ≥ 4 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)

Programming Note: This table will be repeated for all safety analysis populations that are determined to be on a different set of subjects as described in Section 4.2 for each cohort (Table 6.2 – Table 6.9). All tables may not be produced based on the table reduction method mentioned in Section 4.2 and may not exactly match the SAP. The titles for the tables will be the same for the other populations and cohorts with the name of the population and cohort changing based on the population being used. The titles for Cohort 2 and 3 for the S1 population are listed below:

Table 6.X. Summary of TEAEs by Maximum CTCAE Grade
Subject Incidence of TEAEs by Maximum CTCAE Grade – Cohort 2 (540 mL)
Safety Population – S1 (N=XX)
FDP-1
Phase I

Special Note: Cohorts 1 and 2 are not masked; therefore, only one set of tables will be produced showing the unmasked treatment arm. For Cohort 3, there will be an Open and Closed session for the DSMB to protect the mask. For the Open session only a Total Column will be shown with the table numbers having the word "(Open)" after the table number before the decimal. Open session tables will be produced by the blinded programmers. Footnotes for Open session tables will be modified to reflect total counts. For the Closed session, the treatment arms will be masked as A and B. The table numbers will have the word "(Closed)" after the table number before the decimal. Closed session tables will be produced by the unblinded programmers. Final data analysis for Cohort 3 will use the labels FDP-ACDxFFP and FFPxFDP-ACD for the treatments after the study is unblinded and the word "(Closed)" will be removed from the table number.

Notes: Subjects may be included on more than one row.
[a]=Denominator for each % is the treatment group N. Grade 1=Mild, 2=Moderate, 3=Severe, 4=Life-threatening, 5=Fatal.
[b]=Denominator adjusted because gender-specific event for males: N=XX (A), N=XX (B) [for applicable PTs].
[c]=Denominator adjusted because gender-specific event for females: N=XX (A), N=XX (B) [for applicable PTs].
Preferred Terms within System Organ Class are sorted in descending order of frequency based on the TEAE category.

Table 6.X (Open). Summary of TEAEs by Maximum CTCAE Grade
Subject Incidence of TEAEs by Maximum CTCAE Grade – Cohort 3 (810 mL)
Safety Population – S1 (N=XX)
FDP-1
Phase I

Table 6.X (Closed). Summary of TEAEs by Maximum CTCAE Grade
Subject Incidence of TEAEs by Maximum CTCAE Grade – Cohort 3 (810 mL)
Safety Population – S1 (N=XX)
FDP-1
Phase I

Notes: Subjects may be included on more than one row.
[a]=Denominator for each % is the treatment group N. Grade 1=Mild, 2=Moderate, 3=Severe, 4=Life-threatening, 5=Fatal.
[b]=Denominator adjusted because gender-specific event for males: N=XX (A), N=XX (B) [for applicable PTs].
[c]=Denominator adjusted because gender-specific event for females: N=XX (A), N=XX (B) [for applicable PTs].
Preferred Terms within System Organ Class are sorted in descending order of frequency based on the TEAE category.

Table 7.1. - Table 7.3 (Open). Summary of Serious Adverse Events (SAEs)
Subject Incidence of SAEs
Safety Population – S1 (N=XXX)
FDP-1
Phase I

	Cohort 1		Cohort 2		Cohort 3
Preferred Term	FDP-CPD 270 mL (N = XX) n (%[a])	FDP-ACD 270 mL (N = XX) n (%[a])	FDP-CPD 540 mL (N = XX) n (%[a])	FDP-ACD 540 mL (N = XX) n (%[a])	810 mL (N = XX) n (%[a])
Number of subjects reporting serious 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)	xx (xx.x)
[Preferred Term #1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[Preferred Term #2][b c]	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)	xx (xx.x)

Notes: Subjects are counted at most once on each row. Subjects may be included on more than one row.
[a]=Denominator for each % is the treatment group N.
[b]=Denominator adjusted because gender-specific event for males: N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 1; N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 2; N=XX (810mL) for Cohort 3 [for applicable PTs].
[c]=Denominator adjusted because gender-specific event for females: N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 1; N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 2; N=XX (810mL) for Cohort 3 [for applicable PTs].
Preferred Terms within System Organ Class are sorted in descending order of frequency based on the serious adverse event category.

Table 7.1. – Table 7.3 (Closed). Summary of Serious Adverse Events (SAEs)
Subject Incidence of SAEs
Safety Population – S1 (N=XXX)
FDP-1
Phase I

	Cohort 1		Cohort 2		Cohort 3	
Preferred Term	FDP-CPD 270 mL (N = XX) n (%[a])	FDP-ACD 270 mL (N = XX) n (%[a])	FDP-CPD 540 mL (N = XX) n (%[a])	FDP-ACD 540 mL (N = XX) n (%[a])	A 810 mL (N = XX) n (%[a])	B 810 mL (N = XX) n (%[a])
Number of subjects reporting serious 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)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[Preferred Term #1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[Preferred Term #2][b c]	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)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Programming Note: This table will be repeated for all safety analysis populations that are determined to be on a different set of subjects as described in Section 4.2 for each cohort (Table 7.2- Table 7.3). All tables may not be produced based on the table reduction method mentioned in Section 4.2 and may not exactly match the SAP. The titles for the tables will be the same for the other populations with the name of the population changing based on the population being used.

Special Note: For Cohort 3, there will be an Open and Closed session for the DSMB. For the Open session only for Cohort 3, an overall total column will be shown with the table numbers having the word "(Open)" after the table number before the decimal as shown above. Footnotes for Open session tables related to gender specific AEs will be modified to reflect total counts for males and females. Open session tables will be produced by the blinded programmers. Footnotes for Open session tables will be modified to reflect total counts. For the Closed session, the treatment arms will be masked as A and B as shown above. The table numbers will have the word "(Closed)" after the table number before the decimal. Closed session tables will be produced by the unblinded programmers. Final data analysis for Cohort 3 will use the labels FDP-ACDxFFP and FFPxFDP-ACD for the treatments after the study is unblinded and the word "(Closed)" will be removed from the table number.

Notes: Subjects are counted at most once on each row. Subjects may be included on more than one row.
[a]=Denominator for each % is the treatment group N.
[b]=Denominator adjusted because gender-specific event for males: N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 1; N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 2; N=XX (A), N=XX (B)for Cohort 3 [for applicable PTs].
[c]=Denominator adjusted because gender-specific event for females: N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 1; N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 2; N=XX (A), N=XX (B) for Cohort 3 [for applicable PTs].
Preferred Terms within System Organ Class are sorted in descending order of frequency based on the treatment-emergent adverse event category.

Table 7.4. - Table 7.6 . Summary of Suspected Unexpected Serious Adverse Reactions (SUSARs)
Subject Incidence of SUSARs
Safety Population – S1 (N=XX)
FDP-1
Phase I

	Cohort 1		Cohort 2		Cohort 3	
Preferred Term	FDP-CPD 270 mL (N = XX) n (%[a])	FDP-ACD 270 mL (N = XX) n (%[a])	FDP-CPD 540 mL (N = XX) n (%[a])	FDP-ACD 540 mL (N = XX) n (%[a])	FDP-ACD X FFP 810 mL (N = XX) n (%[a])	FFP X FDP-ACD 810 mL (N = XX) n (%[a])
Number of subjects reporting serious 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)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[Preferred Term #1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[Preferred Term #2][b c]	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)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Programming Note: This table will not be produced until final data analysis. This table will be repeated for all safety analysis populations that are determined to be on a different set of subjects as described in Section 4.2 for each cohort (Table 7.5- Table 7.6). All tables may not be produced based on the table reduction method mentioned in Section 4.2 and may not exactly match the SAP. The titles for the tables will be the same for the other populations with the name of the population changing based on the population being used.

Special Note: For Cohort 3, there will be an Open and Closed session for the DSMB. For the Open session only for Cohort 3, an overall total column will be shown with the table numbers having the word "(Open)" after the table number before the decimal as shown above. Footnotes for

Notes: Subjects are counted at most once on each row. Subjects may be included on more than one row.
[a]=Denominator for each % is the treatment group N.
[b]=Denominator adjusted because gender-specific event for males: N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 1; N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 2; N=XX (A), N=XX (B) for Cohort 3 [for applicable PTs].
[c]=Denominator adjusted because gender-specific event for females: N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 1; N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 2; N=XX (A), N=XX (B)for Cohort 3 [for applicable PTs].
Preferred Terms within System Organ Class are sorted in descending order of frequency based on the treatment-emergent adverse event category.

Open session tables related to gender specific AEs will be modified to reflect total counts for males and females. Open session tables will be produced by the blinded programmers. Footnotes for Open session tables will be modified to reflect total counts. For the Closed session, the treatment arms will be masked as A and B as shown above. The table numbers will have the word "(Closed)" after the table number before the decimal. Closed session tables will be produced by the unblinded programmers. Final data analysis for Cohort 3 will use the labels FDP-ACDxFFP and FFPxFDP-ACD for the treatments after the study is unblinded and the word "(Closed)" will be removed from the tablenumber.

Table 8.1. - Table 8.3 (Open). Summary of AEs Leading to Treatment Discontinuation
Subject Incidence of AEs Leading to Treatment Discontinuation
Safety Population – S1 (N=XX)
FDP-1
Phase I

	Cohort 1		Cohort 2		Cohort 3
Preferred Term	FDP-CPD 270 mL (N = XX) n (%[a])	FDP-ACD 270 mL (N = XX) n (%[a])	FDP-CPD 540 mL (N = XX) n (%[a])	FDP-ACD 540 mL (N = XX) n (%[a])	810 mL (N = XX) n (%[a])
Number of subjects reporting adverse events leading to treatment discontinuation	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)	xx (xx.x)
[Preferred Term #1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[Preferred Term #2][b c]	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)	xx (xx.x)

Notes: Subjects are counted at most once on each row. Subjects may be included on more than one row.
[a]=Denominator for each % is the treatment group N.
[b]=Denominator adjusted because gender-specific event for males: N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 1; N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 2; N=XX (A), N=XX (B) for Cohort 3 [for applicable PTs].
[c]=Denominator adjusted because gender-specific event for females: N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 1; N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 2; N=XX (A), N=XX (B) for Cohort 3 [for applicable PTs].
Preferred Terms within System Organ Class are sorted in descending order of frequency based on the treatment-emergent adverse event category.

Table 8.1. - Table 8.3 (Closed). Summary of AEs Leading to Treatment Discontinuation
Subject Incidence of AEs Leading to Treatment Discontinuation
Safety Population – S1 (N=XX)
FDP-1
Phase I

	Cohort 1		Cohort 2		Cohort 3	
Preferred Term	FDP-CPD 270 mL (N = XX) n (%[a])	FDP-ACD 270 mL (N = XX) n (%[a])	FDP-CPD 540 mL (N = XX) n (%[a])	FDP-ACD 540 mL (N = XX) n (%[a])	A 810 mL (N = XX) n (%[a])	B 810 mL (N = XX) n (%[a])
Number of subjects reporting adverse events leading to treatment discontinuation	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)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[Preferred Term #1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[Preferred Term #2][b c]	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)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Programming Note: This table will be repeated for all safety analysis populations that are determined to be on a different set of subjects as described in Section 4.2 for each cohort (Table 8.2- Table 8.3). All tables may not be produced based on the table reduction method mentioned in Section 4.2 and may not exactly match the SAP. The titles for the tables will be the same for the other populations with the name of the population changing based on the population being used.

Special Note: For Cohort 3, there will be an Open and Closed session for the DSMB. For the Open session only for Cohort 3 an overall total column will be shown with the table numbers having the word "(Open)" after the table number before the decimal as shown above. Footnotes for Open session tables related to gender specific AEs will be modified to reflect total counts for males and females. Open session tables will be produced by the blinded programmers. Footnotes for Open session tables will be modified to reflect total counts. For the Closed session, the treatment arms will be masked as A and B as shown above. The table numbers will have the word "(Closed)" after the table number before the decimal. Closed session tables will be produced by the unblinded programmers. Final data analysis for Cohort 3 will use the labels FDP-ACDxFFP and FFPxFDP-ACD for the treatments after the study is unblinded and the word "(Closed)" will be removed from the table number.

Notes: Subjects are counted at most once on each row. Subjects may be included on more than one row.
[a]=Denominator for each % is the treatment group N.
[b]=Denominator adjusted because gender-specific event for males: N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 1; N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 2; N=XX (A), N=XX (B) for Cohort 3 [for applicable PTs].
[c]=Denominator adjusted because gender-specific event for females: N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 1; N=XX (FDP-CPD), N=XX (FDP-ACD) for Cohort 2; N=XX (A), N=XX (B) for Cohort 3 [for applicable PTs].
Preferred Terms within System Organ Class are sorted in descending order of frequency based on the treatment-emergent adverse event category.

Program Path: Data extract date:
Data source: ADAE Cross Reference: Listing 13

Table 9.1. - Table 9.146. XX Measures (Units) Change from Baseline Over Time (Since Treatment Emergent Change)
XX Measures (Units) Change from Baseline Over Time (Since Treatment Emergent Change) – Cohort 1 (270 mL)
Safety Population – S3 (N=XX)
FDP-1
Phase I

			Post-Infusion				Follow-Up Visit	
	Pre-Infusion		Change from Baseline to 30 Minutes		Change from Baseline to 4 Hours		Change from Baseline to 24 Hours	
Treatment	FDP-CPD	FDP - ACD	FDP-CPD	FDP-ACD	FDP-CPD	FDP-ACD	FDP-CPD	FDP-ACD
N	xx	xx	xx	xx	xx	xx	xx	xx
Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Q1	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Q3	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Max	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
>ULN[a]	xx (x.x)	xx (x.x)	xx (x.x)	xx (x.x)	xx (x.x)	xx (x.x)	xx (x.x)	xx (x.x)

Programming Note: This table has been restricted to the time points pre-infusion, 30 minutes and 4 hours post infusion at the request of the investigator, except for the hematology variables where pre-infusion, 30 minutes, 4 hours, and 24 hours will be shown. This table will be generated in the S3 population only. This table will be produced for the following endpoints where data is available:

- Vital Signs:
  - Blood Pressure (mmHg)
    - Table 9.1 (Diastolic Blood Pressure (mmHg))
    - Table 9.2 (Systolic Blood Pressure (mmHg))
  - Heart Rate (beats/min) (Table 9.3)

Note: [a]=Denominator for each % is the treatment group N at each individual time point

- Respiration Rate (breaths/min) (Table 9.4)
- Temperature (ºF) (Table 9.5)

- Hematology:
  - Hematocrit (%) (Table 9.6)
  - Hemoglobin (g/dL) (Table 9.7)
  - Platelet Count (10^9/L) (Table 9.8)
  - RBC Count (10^12/L) (Table 9.9)
  - WBC Count (10^9/L) (Table 9.10)

- Clinical Chemistry:
  - ALP (U/L) (Table 9.11)
  - ALT (U/L) (Table 9.12)
  - AST (U/L) (Table 9.13)
  - Ionized Calcium (mg/dL) (Table 9.14)
  - Total Magnesium (mg/dL) (Table 9.15)
  - Serum pH (Table 9.16)
  - Calcium (mg/dL) (Table 9.17)
  - Chloride (mmol/L) (Table 9.18)
  - Potassium (mmol/L) (Table 9.19)
  - Sodium (mmol/L) (Table 9.20)
  - Lactic Acid (mmol/L) (Table 9.21)
  - Bicarbonate (mmol/L) (Table 9.22)
  - Glucose (mg/dL) (Table 9.23)
  - Total Bilirubin (mg/dL) (Table 9.24)
  - Total Protein (g/dL) (Table 9.25)
  - BUN (mg/dL) (Table 9.26)
  - Creatinine (mg/dL) (Table 9.27)

- Coagulation Factor Tests (All Cohorts):
  - PT (sec) (Table 9.28)
  - INR(Table 9.29)
  - aPTT (sec) (Table 9.30)

Programming Note: T his table will be repeated for Cohort 2 (Table 9.31-9.60) as follows:

- Vital Signs:
  - Blood Pressure (mmHg)

Note: [a]=Denominator for each % is the treatment group N at each individual time point

    - Table 9.31 (Diastolic Blood Pressure (mmHg))
    - Table 9.32 (Systolic Blood Pressure (mmHg))
  - Heart Rate (beats/min) (Table 9.33)
  - Respiration Rate (breaths/min) (Table 9.34)
  - Temperature (ºF) (Table 9.35)

- Hematology:
  - Hematocrit (%) (Table 9.36)
  - Hemoglobin (g/dL) (Table 9.37)
  - Platelet Count (10^9/L) (Table 9.38)
  - RBC Count (10^12/L) (Table 9.39)
  - WBC Count (10^9/L) (Table 9.40)

- Clinical Chemistry:
  - ALP (U/L) (Table 9.41)
  - ALT (U/L) (Table 9.42)
  - AST (U/L) (Table 9.43)
  - Ionized Calcium (mg/dL) (Table 9.44)
  - Total Magnesium (mg/dL) (Table 9.45)
  - Serum pH (Table 9.46)
  - Calcium (mg/dL) (Table 9.47)
  - Chloride (mmol/L) (Table 9.48)
  - Potassium (mmol/L) (Table 9.49)
  - Sodium (mmol/L) (Table 9.50)
  - Lactic Acid (mmol/L) (Table 9.51)
  - Bicarbonate (mmol/L) (Table 9.52)
  - Glucose (mg/dL) (Table 9.53)
  - Total Bilirubin (mg/dL) (Table 9.54)
  - Total Protein (g/dL) (Table 9.55)
  - BUN (mg/dL) (Table 9.56)
  - Creatinine (mg/dL) (Table 9.57)

- Coagulation Factor Tests:
  - PT (sec) (Table 9.58)
  - INR(Table 9.59)
  - aPTT (sec) (Table 9.60)

Note: [a]=Denominator for each % is the treatment group N at each individual time point

The title for Cohort 2 is listed below:

Table XX. XX Measures (Units) Change from Baseline Over Time Since Treatment Emergent Change
XX Measures (Units) Change from Baseline Over Time Since Treatment Emergent Change – Cohort 2 (540 mL)
Safety Population – S3 (N=XX)
FDP-1
Phase I

Programming Note: For Cohort 3, the treatment arms will be unmasked for final data analysis once the study has been unblinded. This table will also be repeated for Cohort 3 for the first infusion:

- Vital Signs:
  - Blood Pressure (mmHg)
    - Table 9.61 (Diastolic Blood Pressure (mmHg))
    - Table 9.62 (Systolic Blood Pressure (mmHg))
  - Heart Rate (beats/min) (Table 9.63)
  - Respiration Rate (breaths/min) (Table 9.64)
  - Temperature (ºF) (Table 9.65)

- Hematology:
  - Hematocrit (%) (Table 9.66)
  - Hemoglobin (g/dL) (Table 9.67)
  - Platelet Count (10^9/L) (Table 9.68)
  - RBC Count (10^12/L) (Table 9.69)
  - WBC Count (10^9/L) (Table 9.70)

- Clinical Chemistry:
  - ALP (U/L) (Table 9.71)
  - ALT (U/L) (Table 9.72)
  - AST (U/L) (Table 9.73)
  - Ionized Calcium (mg/dL) (Table 9.74)
  - Total Magnesium (mg/dL) (Table 9.75)
  - Serum pH (Table 9.76)
  - Calcium (mg/dL) (Table 9.77)
  - Chloride (mmol/L) (Table 9.78)
  - Potassium (mmol/L) (Table 9.79)

Note: [a]=Denominator for each % is the treatment group N at each individual time point

- Sodium (mmol/L) (Table 9.80)
- Lactic Acid (mmol/L) (Table 9.81)
- Bicarbonate (mmol/L) (Table 9.82)
- Glucose (mg/dL) (Table 9.83)
- Total Bilirubin (mg/dL) (Table 9.84)
- Total Protein (g/dL) (Table 9.85)
- BUN (mg/dL) (Table 9.86)
- Creatinine (mg/dL) (Table 9.87)

- Coagulation Factor Tests (All Cohorts):
  - PT (sec) (Table 9.88)
  - INR(Table 9.89)
  - aPTT (sec) (Table 9.90)

- Coagulation Factor Tests (Cohort 3 only):
  - Factor I (mg/dL) (Table 9.91)
  - Factor II (% Normal) (Table 9.92)
  - Factor V (% Normal) (Table 9.93)
  - Factor VII (% Normal) (Table 9.94)
  - Factor VIII (% Normal) (Table 9.95)
  - Factor IX (% Normal) (Table 9.96)
  - Factor X (% Normal) (Table 9.97)
  - Factor XI (% Normal) (Table 9.98)
  - von Willebrand Factor Activity (%) (Table 9.99)
  - Protein C (Factor XIV Activity) (% Normal) (Table 9.100)
  - Protein S (% Normal) (Table 9.101)
  - Antithrombin III (% Normal) (Table 9.102)
  - Alpha-2 Antiplasmin (% Normal) (Table 9.103)

The title for Cohort 3 for the first infusion is shown below:

Table XX.XX Measures (Units) Change from Baseline Over Time Since Treatment Emergent Change
XX Measures (Units) Change from Baseline Over Time Since Treatment Emergent Change – Cohort 3 (810 mL) – Infusion #1
Safety Population – S3 (N=XX)
FDP-1
Phase I

Note: [a]=Denominator for each % is the treatment group N at each individual time point

Programming Note: This table will also be repeated for Cohort 3 for the second infusion:

- Vital Signs:
  - Blood Pressure (mmHg)
    - Table 9.104 (Diastolic Blood Pressure (mmHg))
    - Table 9.105 (Systolic Blood Pressure (mmHg))
  - Heart Rate (beats/min) (Table 9.106)
  - Respiration Rate (breaths/min) (Table 9.107)
  - Temperature (ºF) (Table 9.108)

- Hematology:
  - Hematocrit (%) (Table 9.109)
  - Hemoglobin (g/dL) (Table 9.110)
  - Platelet Count (10^9/L) (Table 9.111)
  - RBC Count (10^12/L) (Table 9.112)
  - WBC Count (10^9/L) (Table 9.113)

- Clinical Chemistry:
  - ALP (U/L) (Table 9.114)
  - ALT (U/L) (Table 9.115)
  - AST (U/L) (Table 9.116)
  - Ionized Calcium (mg/dL) (Table 9.117)
  - Total Magnesium (mg/dL) (Table 9.118)
  - Serum pH (Table 9.119)
  - Calcium (mg/dL) (Table 9.120)
  - Chloride (mmol/L) (Table 9.121)
  - Potassium (mmol/L) (Table 9.122)
  - Sodium (mmol/L) (Table 9.123)
  - Lactic Acid (mmol/L) (Table 9.124)
  - Bicarbonate (mmol/L) (Table 9.125)
  - Glucose (mg/dL) (Table 9.126)
  - Total Bilirubin (mg/dL) (Table 9.127)
  - Total Protein (g/dL) (Table 9.128)
  - BUN (mg/dL) (Table 9.129)
  - Creatinine (mg/dL) (Table 9.130)

Note: [a]=Denominator for each % is the treatment group N at each individual time point

- Coagulation Factor Tests (All Cohorts):
  - PT (sec) (Table 9.131)
  - INR(Table 9.132)
  - aPTT (sec) (Table 9.133)

- Coagulation Factor Tests (Cohort 3 only):
  - Factor I (mg/dL) (Table 9.134)
  - Factor II (% Normal) (Table 9.135)
  - Factor V (% Normal) (Table 9.136)
  - Factor VII (% Normal) (Table 9.137)
  - Factor VIII (% Normal) (Table 9.138)
  - Factor IX (% Normal) (Table 9.139)
  - Factor X (% Normal) (Table 9.140)
  - Factor XI (% Normal) (Table 9.141)
  - von Willebrand Factor Activity (%) (Table 9.142)
  - Protein C (Factor XIV Activity) (% Normal) (Table 9.143)
  - Protein S (% Normal) (Table 9.144)
  - Antithrombin III (% Normal) (Table 9.145)
  - Alpha-2 Antiplasmin (% Normal) (Table 9.146)

The title for Cohort 3 for the second infusion is shown below:

Table XX.XX Measures (Units) Change from Baseline Over Time Since Treatment Emergent Change
XX Measures (Units) Change from Baseline Over Time Since Treatment Emergent Change – Cohort 3 (810 mL) – Infusion #2
Safety Population – S3 (N=XX)
FDP-1
Phase I

Note: [a]=Denominator for each % is the treatment group N at each individual time point

Table 10.1. – Table 10.36. XX Measures (Percentage) Over Time Since Treatment Emergent Change
XX Measures (Percentage) Over Time Since Treatment Emergent Change – Cohort 1 (270 mL)
Safety Population – S3 (N=XX)
FDP-1
Phase I

	Pre-Infusion		Post-Infusion			
			30 min		4 hrs	
Treatment	FDP-CPD	FDP-ACD	FDP-CPD	FDP-ACD	FDP-CPD	FDP-ACD
n[a]	xx	xx	xx	xx	xx	xx
Negative	xx (x.x)	xx (x.x)	xx (x.x)	xx (x.x)	xx (x.x)	xx (x.x)
Positive	xx (x.x)	xx (x.x)	xx (x.x)	xx (x.x)	xx (x.x)	xx (x.x)

[a]Number of subjects with non-missing data, used as the denominator

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Programming Note: This table has been restricted to the time points pre-infusion, 30 minutes and 4 hours post infusion at the request of the investigator. This table will be produced for the following endpoints where data are available:

- Urinalysis:
  - Glucose (Table 10.1)
  - Ketones (Table 10.2)
  - Protein (Table 10.3)
  - Blood (Table 10.4)
  - Leukocyte esterase (Table 10.5)
  - Nitrite (Table 10.6)
  - Bilirubin (Table 10.7)

- Direct Antiglobulin Test (DAT):
  - Immunoglobulin G (Table 10.8)
  - Complement C3 (Table 10.9)

Programming Note: This table will be repeated for Cohort 2 (Table 10.10-10.18) as follows:

- Urinalysis:

Note: a=Denominator for each % is the treatment group N.

- Glucose (Table 10.10)
- Ketones (Table 10.11)
- Protein (Table 10.12)
- Blood (Table 10.13)
- Leukocyte esterase (Table 10.14)
- Nitrite (Table 10.15)
- Bilirubin (Table 10.16)

- Direct Antiglobulin Test (DAT):
  - Immunoglobulin G (Table 10.17)
  - Complement C3 (Table 10.18)

The title for Cohort 2 are listed below:

Table XX. Measures (Percentage) Over Time Since Treatment Emergent Change
XX Measures (Percentage) Over Time Since Treatment Emergent Change – Cohort 2 (540 mL)
Safety Population – S3 (N=XX)
FDP-1
Phase I

Programming Note: This table will also be repeated for Cohort 3 (Table 10.19-10.27) for the first infusion:

- Urinalysis:
  - Glucose (Table 10.19)
  - Ketones (Table 10.20)
  - Protein (Table 10.21)
  - Blood (Table 10.22)
  - Leukocyte esterase (Table 10.23)
  - Nitrite (Table 10.24)
  - Bilirubin (Table 10.25)

- Direct Antiglobulin Test (DAT):
  - Immunoglobulin G (Table 10.26)
  - Complement C3 (Table 10.27)

Note: a=Denominator for each % is the treatment group N.

Programming Note: This table will also be repeated for Cohort 3 (Table 10.28-10.36) for the second infusion:

- Urinalysis:
  - Glucose (Table 10.28)
  - Ketones (Table 10.29)
  - Protein (Table 10.30)
  - Blood (Table 10.31)
  - Leukocyte esterase (Table 10.32)
  - Nitrite (Table 10.33)
  - Bilirubin (Table 10.34)

- Direct Antiglobulin Test (DAT):
  - Immunoglobulin G (Table 10.35)
  - Complement C3 (Table 10.36)

Programming Note: For Cohort 3, the treatment arms will be unmasked for final data analysis once the study has been unblinded. The titles for Cohort 3 are shown below:

Table XX. Measures (Percentage) Over Time Since Treatment Emergent Change
XX Measures (Percentage) Over Time Since Treatment Emergent Change – Cohort 3 (810 mL) – Infusion #1
Safety Population – S3 (N=XX)
FDP-1
Phase I

Table XX. Measures (Percentage) Over Time Since Treatment Emergent Change
XX Measures (Percentage) Over Time Since Treatment Emergent Change – Cohort 3 (810 mL) – Infusion #2
Safety Population – S3 (N=XX)
FDP-1
Phase I

Note: a=Denominator for each % is the treatment group N.

Table 11.1. – Table 11.34. Shift Table Summary of Number of Subjects with Absolute Laboratory Values for XX Measure (Unit) Pre-Infusion vs. Max Post-Infusion
Absolute Lab Values for XX Measure (Unit) Pre-Infusion vs. Max Post- Infusion – Cohort 1 (270 mL)
Safety Population – S3 (N=XX)
FDP-1
Phase I

	Treatment Emergent High		
Treatment	N	n	%
FDP-CPD			
FDP-ACD			

Programming Note: This table will be produced for the following endpoints for Cohort 1 (Table 11.1-11.4):

- Coagulation Factor Tests:
  - PT (Table 11.1)
  - INR (Table 11.2)
  - aPTT (Table 11.3)
  - D-Dimer (ug/mL FEU) (Table 11.4)

Programming Note: This table will be produced for the following endpoints for Cohort 2 (Table 11.5-11.8):

- Coagulation Factor Tests:
  - PT (Table 11.5)
  - INR (Table 11.6)
  - aPTT (Table 11.7)
  - D-Dimer (ug/mL FEU) (Table 11.8)

The titles for Cohort 2 is listed below:

Table XX. Shift Table Summary of Number of Subjects with Absolute Laboratory Values for XX Measure (Unit) Pre-Infusion vs. Max Post-Infusion
Absolute Laboratory Values for XX Measure (Unit) Pre-Infusion vs. Max Post- Infusion – Cohort 2 (540 mL)

N=number of subjects with pre-infusion 'normal' and at least one post-infusion value; n=among the 'N', number of subjects with Max. post-infusion 'high'. High will be a greater than or equal to 20% increase from pre-infusion for PT, INR and aPTT and greater than the upper limit of normal (ULN) for all other endpoints except for D-Dimer. Normal will be a less than 20% increase from pre-infusion for PT, INR, and aPTT and lower than or equal to the ULN for all other endpoints except for D-Dimer. D-Dimer will be converted to a categorical variable where normal will be < 0.5 ug/mL FEU and high will be ≥ 0.5 ug/mL FEU.

Safety Population – S3 (N=XX)
FDP-1
Phase I

Programming Note: For Cohort 3, the treatment arms will be unmasked for final data analysis once the study has been unblinded. This table will be produced for the following endpoints for Cohort 3 for the first infusion (Table 11.9-11.15):

- Coagulation Factor Tests:
  - PT (Table 11.9)
  - INR (Table 11.10)
  - aPTT (Table 11.11)
  - D-Dimer (ug/mL FEU) (Table 11.12)
  - PF 1+2 (pmol/L) (Table 11.13)
  - TAT (ng/mL) (Table 11.14)
  - C3a des Arg (ng/mL) (Table 11.15)

Programming Note: This table will be produced for the following endpoints for Cohort 3 for the second infusion (Table 11.16-11.22):

- Coagulation Factor Tests:
  - PT (Table 11.16)
  - INR (Table 11.17)
  - aPTT (Table 11.18)
  - D-Dimer (ug/mL FEU) (Table 11.19)
  - PF 1+2 (pmol/L) (Table 11.20)
  - TAT (ng/mL) (Table 11.21)
  - C3a des Arg (ng/mL) (Table 11.22)

Programming Note: For Cohort 3, the treatment arms will be unmasked for final data analysis after the study has been unblinded.

Table XX. Shift Table Summary of Number of Subjects with Absolute Laboratory Values for XX Measure (Unit) Pre-Infusion vs. Max Post-Infusion
Absolute Laboratory Values for XX Measure (Unit) Pre-Infusion vs. Max Post- Infusion – Cohort 3 (810 mL) – Infusion #1
Safety Population – S3 (N=XX)

N=number of subjects with pre-infusion 'normal' and at least one post-infusion value; n=among the 'N', number of subjects with Max. post-infusion 'high'. High will be a greater than or equal to 20% increase from pre-infusion for PT, INR and aPTT and greater than the upper limit of normal (ULN) for all other endpoints except for D-Dimer. Normal will be a less than 20% increase from pre-infusion for PT, INR, and aPTT and lower than or equal to the ULN for all other endpoints except for D-Dimer. D-Dimer will be converted to a categorical variable where normal will be < 0.5 ug/mL FEU and high will be ≥ 0.5 ug/mL FEU.

FDP-1
Phase I

Table XX. Shift Table Summary of Absolute Laboratory Values for XX Measure (Unit) Pre-Infusion vs. Max Post-Infusion
Absolute Laboratory Values for XX Measure (Unit) Pre-Infusion vs. Max Post- Infusion – Cohort 3 (810 mL) – Infusion #2
Safety Population – S3 (N=XX)
FDP-1
Phase I

N=number of subjects with pre-infusion 'normal' and at least one post-infusion value; n=among the 'N', number of subjects with Max. post-infusion 'high'. High will be a greater than or equal to 20% increase from pre-infusion for PT, INR and aPTT and greater than the upper limit of normal (ULN) for all other endpoints except for D-Dimer. Normal will be a less than 20% increase from pre-infusion for PT, INR, and aPTT and lower than or equal to the ULN for all other endpoints except for D-Dimer. D-Dimer will be converted to a categorical variable where normal will be < 0.5 ug/mL FEU and high will be ≥ 0.5 ug/mL FEU.

Programming Note: These tables will also be repeated for Treatment Emergent Low for PT, INR, and aPTT only. Low will be defined as a greater than or equal 20% decrease from pre-infusion. N=Number of subjects with pre-infusion 'normal' and at least one post-infusion value; n=among the 'N,' number of subjects with Min. post-infusion 'low.' Normal will be a less than 20% decrease from pre-infusion for PT, INR and aPTT (Table 11.23 – Table 11.34). The titles are listed below:

Table XX. Shift Table Summary of Number of Subjects with Absolute Laboratory Values for XX Measure (Unit) Pre-Infusion vs. Min Post-Infusion
Absolute Laboratory Values for XX Measure (Unit) Pre-Infusion vs. Min Post-Infusion – Cohort 1 (540 mL)
Safety Population – S3 (N=XX)
FDP-1
Phase I

Table XX. Shift Table Summary of Number of Subjects with Absolute Laboratory Values for XX Measure (Unit) Pre-Infusion vs. Min Post-Infusion
Absolute Laboratory Values for XX Measure (Unit) Pre-Infusion vs. Min Post-Infusion – Cohort 2 (540 mL)
Safety Population – S3 (N=XX)
FDP-1
Phase I

Table XX. Shift Table Summary of Number of Subjects with Absolute Laboratory Values for XX Measure (Unit) Pre-Infusion vs. Min Post-Infusion
Absolute Laboratory Values for XX Measure (Unit) Pre-Infusion vs. Min Post-Infusion – Cohort 3 (810 mL) – Infusion #1
Safety Population – S3 (N=XX)
FDP-1
Phase I

Table XX. Shift Table Summary of Number of Subjects with Absolute Laboratory Values for XX Measure (Unit) Pre-Infusion vs. Min Post-Infusion
Absolute Laboratory Values for XX Measure (Unit) Pre-Infusion vs. Min Post- Infusion – Cohort 3 (810 mL) – Infusion #2
Safety Population – S3 (N=XX)
FDP-1
Phase I

Table 12.1. - Table 12.38. Treatment Group (Sequence) by Period Descriptive Statistics for XX Measure (Unit) Since Treatment Emergent Change Treatment Group (Sequence) by Period Descriptive Statistics for XX Measure (Unit) Since Treatment Emergent Change – Cohort 3 (810 mL)
Safety Population – S3 (N=XX)
FDP-1
Phase I

		Period 1 (Infusion #1)				Period 2 (Infusion #2)			
FDP-ACD X FFP (Sequence)		Pre-Infusion	Change from Baseline to 30 Minutes	Change from Baseline to 4 Hours	Change from Baseline to 24 Hour	Pre-Infusion	Change from Baseline to 30 Minutes	Change from Baseline to 4 Hours	Change from Baseline to 24 Hour
	N	xx	xx	xx	xx	xx	xx	xx	xx
	Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Min	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Q1	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Q3	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Max	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
FFP X FDP-ACD (Sequence)		Pre-Infusion	Change from Baseline to 30 Minutes	Change from Baseline to 4 Hours	Change from Baseline to 24 Hour	Pre-Infusion	Change from Baseline to 30 Minutes	Change from Baseline to 4 Hours	Change from Baseline to 24 Hour
	N	xx	xx	xx	xx	xx	xx	xx	xx
	Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Min	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Q1	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Q3	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Max	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Total		Pre-Infusion	Change from Baseline to 30 Minutes	Change from Baseline to 4 Hours	Change from Baseline to 24 Hour	Pre-Infusion	Change from Baseline to 30 Minutes	Change from Baseline to 4 Hours	Change from Baseline to 24 Hour
	N	xx	xx	xx	xx	xx	xx	xx	xx
	Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

		Period 1 (Infusion #1)				Period 2 (Infusion #2)			
	SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Min	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Q1	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Q3	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Max	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Programming Note: This table has been restricted to the time points pre-infusion, 30 minutes, and 4 hours post infusion at the request of the investigator except for the hematology variables where pre-infusion, 30 minutes, 4 hours, and 24 hours will be shown. For Cohort 3, the treatment arms will be unmasked for final data analysis once the study has been unblinded. This table will be produced for the following endpoints where data is available:

- Hematology:
  - Hematocrit (%) (Table 12.1)
  - Hemoglobin (g/dL) (Table 12.2)
  - Platelet Count (10^9/L) (Table 12.3)
  - RBC Count (10^12/L) (Table 12.4)
  - WBC Count (10^9/L) (Table 12.5)

- Clinical Chemistry:
  - ALP (U/L) (Table 12.6)
  - ALT (U/L) (Table 12.7)
  - AST (U/L) (Table 12.8)
  - Ionized Calcium (mg/dL) (Table 12.9)
  - Total Magnesium (mg/dL) (Table 12.10)
  - Serum pH (Table 12.11)
  - Calcium (mg/dL) (Table 12.12)
  - Chloride (mmol/L) (Table 12.13)
  - Potassium (mmol/L) (Table 12.14)
  - Sodium (mmol/L) (Table 12.15)
  - Lactic Acid (mmol/L) (Table 12.16)
  - Bicarbonate (mmol/L) (Table 12.17)
  - Glucose (mg/dL) (Table 12.18)
  - Total Bilirubin (mg/dL) (Table 12.19)
  - Total Protein (g/dL) (Table 12.20)

- BUN (mg/dL) (Table 12.21)
- Creatinine (mg/dL) (Table 12.22)

- Coagulation Factor Tests:
  - PT (sec) (Table 12.23)
  - INR (Table 12.24)
  - aPTT (sec) (Table 12.25)
  - Factor I (mg/dL) (Table 12.26)
  - Factor II (% Normal) (Table 12.27)
  - Factor V (% Normal) (Table 12.28)
  - Factor VII (% Normal) (Table 12.29)
  - Factor VIII (% Normal) (Table 12.30)
  - Factor IX (% Normal) (Table 12.31)
  - Factor X (% Normal) (Table 12.32)
  - Factor XI (% Normal) (Table 12.33)
  - von Willebrand Factor Activity (%) (Table 12.34)
  - Protein C (Factor XIV Activity) (% Normal) (Table 12.35)
  - Protein S (% Normal) (Table 12.36)
  - Antithrombin III (% Normal) (Table 12.37)
  - Alpha-2 Antiplasmin (% Normal) (Table 12.38)

Table 13.1-Table 13.2. Treatment Group (Sequence) by Period Descriptive Statistics for Number of Subjects with XX Measures (Percentage)
Treatment Group (Sequence) by Period Descriptive Statistics for Number of Subjects with XX Measures (Percentage) – Cohort 3 (810 mL)
Safety Population – S3 (N=XX)
FDP-1
Phase I

		Period 1	Period 2
FDP-ACD X FFP (Sequence)		Pre-Infusion	Pre-Infusion
	N	xx	xx
	Negative	xx(x.x)	xx(x.x)
	Positive	xx(x.x)	xx(x.x)
FFP X FDP-ACD (Sequence)		Pre-Infusion	Pre-Infusion
	N	xx	xx
	Negative	xx(x.x)	xx(x.x)
	Positive	xx(x.x)	xx(x.x)
Total		Pre-Infusion	Pre-Infusion
	N	xx	xx
	Negative	xx(x.x)	xx(x.x)
	Positive	xx(x.x)	xx(x.x)

Programming Note: This table will be produced for the following endpoints where data is available:

- Direct Antiglobulin Test (DAT):
  - Immunoglobulin G (Table 13.1)
  - Complement C3 (Table 13.2)

For Cohort 3, the treatment arms will be unmasked for final data analysis once the study has been unblinded.

Note: Denominator for each % is the time point column N.

Table 14. Summary of Subject Exposure to Study Drug
Safety Population – S1 (N=XX)
FDP-1
Phase I

		FDP-CPD (270 mL) N=XX	FDP-ACD (270 mL) N=XX	FDP-CPD (540 mL) N=XX	FDP-ACD (540 mL) N=XX	FDP-ACD X FFP (810 mL) N=XX	FFP X FDP-ACD (810 mL) N=XX	Overall N=XX
Total Amount Administered (mL) – Infusion #1								
	n[a]	xx	xx	xx	xx	xx	xx	xx
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	SD	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
	Q1, Q3	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx
	Min, Max	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx
	Missing	xx	xx	xx	xx	xx	xx	xx
Total Amount Administered per kg of weight (mL/kg)– Infusion #1								
	n[a]	xx	xx	xx	xx	xx	xx	xx
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	SD	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
	Q1, Q3	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx
	Min, Max	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx	xx,xx
	Missing	xx	xx	xx	xx	xx	xx	xx
Total Amount Administered (mL) – Infusion #2 (Cohort 3 only)								
	n[a]					xx	xx	xx

Note: Abbreviations: N=number of subjects in the population; Q1=25% Percentile; Q3=75% Percentile; SD=Standard Deviation.
[a]=Number of subjects with non-missing data, used as the denominator.

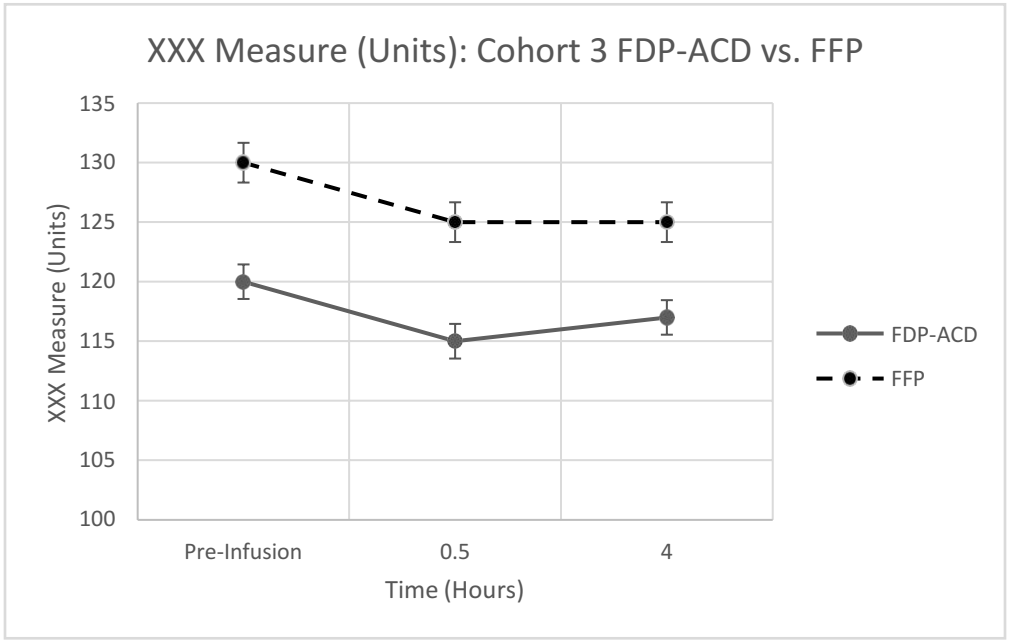
Program Path: Data extract date:
Data source: ADEX Cross Reference: Listing 8

		FDP-CPD (270 mL) N=XX	FDP-ACD (270 mL) N=XX	FDP-CPD (540 mL) N=XX	FDP-ACD (540 mL) N=XX	FDP-ACD X FFP (810 mL) N=XX	FFP X FDP-ACD (810 mL) N=XX	Overall N=XX
	Mean					**xx.x**	**xx.x**	**xx.x**
	SD					**xx.x**	**xx.x**	**xx.x**
	Median					**xx.x**	**xx.x**	**xx.x**
	Q1, Q3					**xx,xx**	**xx,xx**	**xx,xx**
	Min, Max					**xx,xx**	**xx,xx**	**xx,xx**
	Missing					**xx**	**xx**	**xx**
Total Amount Administered per kg of weight (mL/kg) – Infusion #2 (Cohort 3 only)								
	n[a]					**xx**	**xx**	**xx**
	Mean					**xx.x**	**xx.x**	**xx.x**
	SD					**xx.x**	**xx.x**	**xx.x**
	Median					**xx.x**	**xx.x**	**xx.x**
	Q1, Q3					**xx,xx**	**xx,xx**	**xx,xx**
	Min, Max					**xx,xx**	**xx,xx**	**xx,xx**
	Missing					**xx**	**xx**	**xx**

Programming Note: Grayed out cells mean no data is expected. For Cohort 3, the treatment arms will be unmasked for final data analysis once the study has been unblinded.

Note: Abbreviations: N=number of subjects in the population; Q1=25% Percentile; Q3=75% Percentile; SD=Standard Deviation.
[a]=Number of subjects with non-missing data, used as the denominator.

Figure 3.1.-3.5. XXX Measure (Units): Cohort 3 FDP-ACD vs. FFP: Means and Standard Deviations Over Time
Safety Population – S3 (N=XX)
FDP-1
Phase I



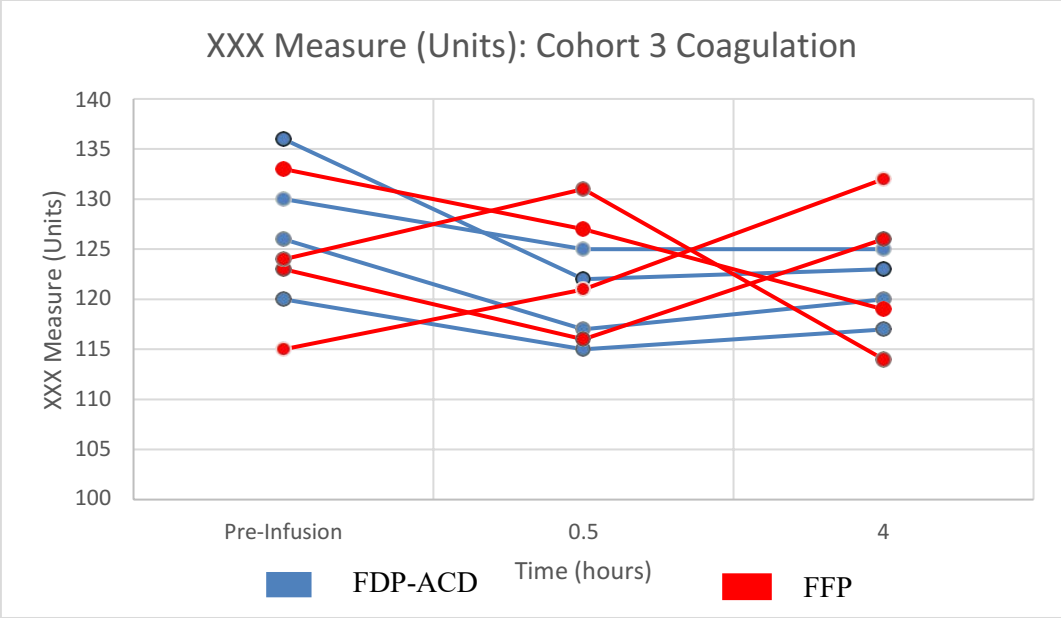
Programming Note: This figure will be repeated for the following vital sign endpoints:

- Temperature (ºF) (Figure 3.1)
- Heart Rate (beats/min) (Figure 3.2)
- Diastolic Blood Pressure (mmHg) (Figure 3.3)
- Systolic Blood Pressure (mmHg) (Figure 3.4)
- Respiratory Rate (breaths/min) (Figure 3.5)

For Cohort 3, the treatment arms will be unmasked for final data analysis once the study has been unblinded.

Note: This figure displays the mean +/- the standard deviation at each time point.

Figure 4.1-4.19. XXX Measures (Units): Cohort 3 FDP-ACD x FFP Spaghetti Plots
Safety Population – S3 (N=XX)
FDP-1
Phase I



Programming Note: The blue lines will represent FDP-ACD and the red lines will represent FFP. For Cohort 3, the treatment arms will be unmasked for final data analysis once the study has been unblinded. This figure will be repeated for the following coagulation endpoints:

- PT (sec) (Figure 4.1)
- INR (Figure 4.2)
- aPTT (sec) (Figure 4.3)
- Factor I (mg/dL) (Figure 4.4)
- Factor II (% Normal) (Figure 4.5)
- Factor V (% Normal) (Figure 4.6)
- Factor VII (% Normal) (Figure 4.7)
- Factor VIII (% Normal) (Figure 4.8)

Note: This figure displays the individual data at each time point.

- Factor IX (% Normal) (Figure 4.9)
- Factor X (% Normal) (Figure 4.10)
- Factor XI (% Normal) (Figure 4.11)
- von Willebrand Factor Activity (%) (Figure 4.12)
- Protein C (Factor XIV Activity) (% Normal) (Figure 4.13)
- Protein S (% Normal) (Figure 4.14)
- PF 1+2 (pmol/L) (Figure 4.15)
- TAT (ng/mL) (Figure 4.16)
- Antithrombin III (% Normal) (Figure 4.17)
- Alpha-2 Antiplasmin (% Normal) (Figure 4.18)
- C3a des Arg (ng/mL) (Figure 4.19)

Note: This figure displays the individual data at each time point.

Listing 1. Subject Disposition

Arm: XXXXXXX

Subject ID	Sex/Age	Date of Enrollment	Randomization Date	Date of Study Completion or Termination	Last Date of Infusion	Was the collection performed?	Had an Infusion Visit?	Received any Plasma Infusion During the Study?	Received Second Infusion?	Subject's Status
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	X	X	X	X	XXXXXXX
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	X	X	X	X	XXXXXXX
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	X	X	X	X	XXXXXXX
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	X	X	X	X	XXXXXXX
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	X	X	X	X	XXXXXXX

Program Path:
Data source: ADSL

Data extract date:

Listing 2. Eligibility Criteria Not Met

Arm: XXXXXXX

Subject ID	Sex/Age	Date of Informed Consent	Category of the Criterion	Identifier of the Criterion	Criterion Description
XXXXXX	X/XX	DDMMMYYYY	XXXXXXXXX	XXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXX	X/XX	DDMMMYYYY	XXXXXXXXX	XXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXX	X/XX	DDMMMYYYY	XXXXXXXXX	XXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXX	X/XX	DDMMMYYYY	XXXXXXXXX	XXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXX	X/XX	DDMMMYYYY	XXXXXXXXX	XXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

Program Path:
Data source: ADIE

Data extract date:

Listing 3. Demographics

Arm: XXXXXXX

Subject ID	Sex/Age	Date of Enrollment	Randomization Date	Date of Birth	Ethnicity	Race	Height (cm)	Weight (kg)	DASI score [1]	Childbearing Potential?
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXX	XXXXXXXX	XXX.X	XXX.X	XX.XX	X
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXX	XXXXXXXX	XXX.X	XXX.X	XX.XX	X
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXX	XXXXXXXX	XXX.X	XXX.X	XX.XX	X
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXX	XXXXXXXX	XXX.X	XXX.X	XX.XX	X
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXX	XXXXXXXX	XXX.X	XXX.X	XX.XX	X

[1] DASI stands for Duke Activity Status Index.

Program Path:

Data extract date:

Data source: ADSL

Listing 4. Visit Adherence

Arm: XXXXXXX

	Subject ID	Sex/Age	Visit	Collection Date/Time	Result
Visit Performed Within the Study Visit Window?	XXXXXX	X/XX	X	X	X
	XXXXXX	X/XX	X	X	X

Listing 5. Blood Screening Tests

Arm: XXXXXXX

Subject ID	Sex/Age	Date of Enrollment	Randomization Date	ABO Blood Group at Screening	ABO Blood Group at First Infusion	ABO Blood Group at Second Infusion	Rh Factor	Syphilis Detection Test	HTLV-1/2 Antibody	Red-Cell Antibody
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	XX	XX	XX	XXXXXXXX	XXXXXXXX	XXXXXXXX	XXXXXXXX
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	XX	XX	XX	XXXXXXXX	XXXXXXXX	XXXXXXXX	XXXXXXXX
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	XX	XX	XX	XXXXXXXX	XXXXXXXX	XXXXXXXX	XXXXXXXX
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	XX	XX	XX	XXXXXXXX	XXXXXXXX	XXXXXXXX	XXXXXXXX
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	XX	XX	XX	XXXXXXXX	XXXXXXXX	XXXXXXXX	XXXXXXXX

Program Path:
Data source: ADSL

Data extract date:

Listing 6. Nucleic Acid Amplification Test

Arm: XXXXXXX

Subject ID	Sex/Age	Visit	Collection Date/Time	Lab Test	Result
XXXXX X	X/XX	X	DDMMMYYYY:TT	XXXXXXXXXXXXX X	XXXXX
		X	DDMMMYYYY:TT	XXXXXXXXXXXXX X	XXXXX
		X	DDMMMYYYY:TT	XXXXXXXXXXXXX X	XXXXX
		X	DDMMMYYYY:TT	XXXXXXXXXXXXX X	XXXXX
		X	DDMMMYYYY:TT	XXXXXXXXXXXXX X	XXXXX
XXXXX X	X/XX	X	DDMMMYYYY:TT	XXXXXXXXXXXXX X	XXXXX
		X	DDMMMYYYY:TT	XXXXXXXXXXXXX X	XXXXX
		X	DDMMMYYYY:TT	XXXXXXXXXXXXX X	XXXXX

Listing 7. RBC Crossmatch and Reverse Blood Type

Arm: XXXXXXX

Subject ID	Sex/Age	Date of Enrollment	Randomization Date	Crossmatch at First Infusion [1]	Crossmatch at Second Infusion [1]	ABO Blood Group at Screening	ABO Blood Group at First Infusion	ABO Blood Group at Second Infusion
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	X	X	XX	XX	XX
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	X	X	XX	XX	XX
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	X	X	XX	XX	XX
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	X	X	XX	XX	XX
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	X	X	XX	XX	XX

[1] C=Compatible N=Not Compatible.

Listing 8. FDP-CPD/FDP-ACD/FFP – Subject Exposure to Study Drug

Arm: XXXXXXX

Subject ID	Sex/Age	Date of Enrollment	Randomization Date	Infusion Start Date for First Infusion	Infusion Start Date for Second Infusion	Weight (kg)	Total Amount Administered at First Infusion (mL)	Total Amount Administered at Second Infusion (mL)	Dose Adjusted from Planned	Reason Dose Adjusted from Planned
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXX.X	XXX.X	XXX.X	X	XXXXXXXXXX
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXX.X	XXX.X	XXX.X	X	XXXXXXXXXX
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXX.X	XXX.X	XXX.X	X	XXXXXXXXXX
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXX.X	XXX.X	XXX.X	X	XXXXXXXXXX
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXX.X	XXX.X	XXX.X	X	XXXXXXXXXX

Program Path:
Data source: ADEX

Data extract date:

Listing 9. Medical History at Screening

Arm: XXXXXXX

Subject ID	Sex/Age	Date of Informed Consent	Screen Date	Medical History Term
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXXXXXXXXXXXXXXXX

Program Path:
Data source: ADSL, MH

Data extract date:

Note: Only Subjects with medical conditions identified at screening that do not exclude them from study participation are listed.

Listing 10. Vital Signs (Infusion – Post Start)

Arm: XXXXXXX

Subject ID	Sex/Age	Infusion Number [1]	Visit	Collection Date/Time	Vital Sign Test	Result	Unit
XXXXXX	X/XX	X	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX
		X	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX
		X	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX
		X	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX
XXXXXX	X/XX	X	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX
		X	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX
		X	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX
		X	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX

[1] Infusion Number: 1=Infusion #1; 2=Infusion #2.

Listing 11. Vital Signs (Infusion – Post End)

Arm: XXXXXXX

Subject ID	Sex/Age	Infusion Number [1]	Visit	Collection Date/Time	Vital Sign Test	Result	Unit
XXXXXX	X/XX	X	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX
		X	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX
		X	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX
		X	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX
XXXXXX	X/XX	X	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX
		X	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX
		X	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX
		X	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX

[1] Infusion Number: 1=Infusion #1; 2=Infusion #2.

Listing 12. Vital Signs (Outside of Infusion)

Arm: XXXXXXX

Subject ID	Sex/Age	Infusion Number [1]	Visit	Collection Date/Time	Vital Sign Test	Result	Unit
XXXXXX	X/XX	X	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX
		X	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX
		X	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX
		X	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX
XXXXXX	X/XX	X	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX
		X	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX
		X	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX
		X	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX

[1] Infusion Number: 1=Infusion #1; 2=Infusion #2.

Listing 13. Treatment-Emergent Adverse Events

Arm: XXXXXXX

Subject ID	Sex/Age	Date of Enrollment	Randomization Date	Adverse Event Start Date	Body System or Organ Class	Preferred Term	Ongoing	Toxicity Grade [1]	Serious	Related to Study Drug [2]	Action Taken [3]	Outco [4]
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXX	XXXXXXXXXX	X	X	X	X	X	X
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXX	XXXXXXXXXX	X	X	X	X	X	X
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXX	XXXXXXXXXX	X	X	X	X	X	X
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXX	XXXXXXXXXX	X	X	X	X	X	X
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXX	XXXXXXXXXX	X	X	X	X	X	X

[1] Grade 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening; 5=Fatal.
[2] Related to Study Drug: 1=Not Related; 2=Unlikely; 3=Possible; 4=Probable; 5=Definite.
[3] Action Taken: 1=Dose Increased; 2=Dose Not Changed; 3=Dose Reduced; 4=Drug Interrupted; 5=Drug Withdrawn; 6=Not Applicable; 7=Unknown.
[4] Outcome: 1=Recovered/Resolved; 2=Recovered/Resolved with Sequelae; 3=Recovering/Resolving; 4=Not Recovered/Not Resolved; 5=Fatal; 6=Unknown.

Program Path:
Data extract date:
Data source: ADAE

Listing 14. Listing of Unique Adverse Events

Arm: XXXXXXX

Body System or Organ Class	Preferred Term	Reported Term for the Adverse Event
XXXXXXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX
XXXXXXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX
XXXXXXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX
XXXXXXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX
XXXXXXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX

Note: Terms are sorted by reported term.

Listing 15. Treatment-Emergent Adverse Events at Least Probably Related to Study Drug

Arm: XXXXXXX

Subject ID	Sex/Age	Date of Enrollment	Randomization Date	Adverse Event Start Date	Body System or Organ Class	Preferred Term	Ongoing	Toxicity Grade [1]	Serious	Related to Study Drug [2]	Action Taken [3]	Outc [4
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	X	X	X	X	X	X
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	X	X	X	X	X	X
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	X	X	X	X	X	X
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	X	X	X	X	X	X
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	X	X	X	X	X	X

[1] Grade 1=Mild; 2=Moderate; 3=Severe; 4=Life-threatening; 5=Fatal.
[2] Related to Study Drug: 1=Not Related; 2=Unlikely; 3=Possible; 4=Probable; 5=Definite.
[3] Action Taken: 1=Dose Increased; 2=Dose Not Changed; 3=Dose Reduced; 4=Drug Interrupted; 5=Drug Withdrawn; 6=Not Applicable; 7=Unknown.
[4] Outcome: 1=Recovered/Resolved; 2=Recovered/Resolved with Sequelae; 3=Recovering/Resolving; 4=Not Recovered/Not Resolved; 5=Fatal; 6=Unknown.

Program Path:
Data extract date:
Data source: ADAE

Listing 16. Treatment-Emergent Adverse Events Ongoing at Study End

Arm: XXXXXXX

Subject ID	Sex/Age	Date of Enrollment	Randomization Date	Adverse Event Start Date	Body System or Organ Class	Preferred Term	Toxicity Grade [1]	Serious	Related to Study Drug [2]	Action Taken [3]	Outcome [4]
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	X	X	X	X	X
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	X	X	X	X	X
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	X	X	X	X	X
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	X	X	X	X	X
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	X	X	X	X	X

[1] Grade 1=Mild; 2=Moderate; 3=Severe; 4=Life-threatening; 5=Fatal.
[2] Related to Study Drug: 1=Not Related; 2=Unlikely; 3=Possible; 4=Probable; 5=Definite.
[3] Action Taken: 1=Dose Increased; 2=Dose Not Changed; 3=Dose Reduced; 4=Drug Interrupted; 5=Drug Withdrawn; 6=Not Applicable; 7=Unknown.
[4] Outcome: 1=Recovered/Resolved; 2=Recovered/Resolved with Sequelae; 3=Recovering/Resolving; 4=Not Recovered/Not Resolved; 5=Fatal; 6=Unknown.
*SUSAR column will only be produced during final data analysis.

Program Path:
Data source: ADAE

Data extract date:

Listing 17. Adverse Events Occurring Prior to Dosing of Study Drug

Arm: XXXXXXX

Subject ID	Sex/Age	Date of Enrollment	Randomization Date	Adverse Event Start Date	Body System or Organ Class	Preferred Term	Ongoing	Toxicity Grade [1]	Serious	Related to Study Drug [2]	Action Taken [3]	Outc [4
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	X	X	X	X	X	X
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	X	X	X	X	X	X
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	X	X	X	X	X	X
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	X	X	X	X	X	X
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	X	X	X	X	X	X

[1] Grade 1=Mild; 2=Moderate; 3=Severe; 4=Life-threatening; 5=Fatal.
[2] Related to Study Drug: 1=Not Related; 2=Unlikely; 3=Possible; 4=Probable; 5=Definite.
[3] Action Taken: 1=Dose Increased; 2=Dose Not Changed; 3=Dose Reduced; 4=Drug Interrupted; 5=Drug Withdrawn; 6=Not Applicable; 7=Unknown.
[4] Outcome: 1=Recovered/Resolved; 2=Recovered/Resolved with Sequelae; 3=Recovering/Resolving; 4=Not Recovered/Not Resolved; 5=Fatal; 6=Unknown.
*SUSAR column will only be produced during final data analysis.

Program Path:
Data extract date:
Data source: ADAE

Listing 18. Serious Adverse Events

Arm: XXXXXXX

Subject ID	Sex/Age	Date of Enrollment	Randomization Date	Adverse Event Start Date	Body System or Organ Class	Preferred Term	Ongoing	Toxicity Grade [1]	Related to Study Drug [2]	Action Taken [3]	Outcome [4]	SU
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	X	X	X	X	X	X
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	X	X	X	X	X	X
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	X	X	X	X	X	X
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	X	X	X	X	X	X
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	X	X	X	X	X	X

[1] Grade 1=Mild; 2=Moderate; 3=Severe; 4=Life-threatening; 5=Fatal.
[2] Related to Study Drug: 1=Not Related; 2=Unlikely; 3=Possible; 4=Probable; 5=Definite.
[3] Action Taken: 1=Dose Increased; 2=Dose Not Changed; 3=Dose Reduced; 4=Drug Interrupted; 5=Drug Withdrawn; 6=Not Applicable; 7=Unknown.
[4] Outcome: 1=Recovered/Resolved; 2=Recovered/Resolved with Sequelae; 3=Recovering/Resolving; 4=Not Recovered/Not Resolved; 5=Fatal; 6=Unknown.
*SUSAR column will only be produced during final data analysis.

Program Path:
Data source: ADAE

Data extract date:

Listing 19. Treatment-Emergent Fatal Adverse Events

Arm: XXXXXXX

Subject ID	Sex/Age	Race	Start Date of First Infusion	Date of Last Infusion	Date of Death	Body System or Organ Class	Preferred Term	Reported Term for the Adverse Event	Related to Study Drug [1]
XXXXXX	X/XX	XXXXXX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	X
XXXXXX	X/XX	XXXXXX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	X
XXXXXX	X/XX	XXXXXX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	X
XXXXXX	X/XX	XXXXXX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	X
XXXXXX	X/XX	XXXXXX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	X

[1] Related to Study Drug: 1=Not Related; 2=Unlikely; 3=Possible; 4=Probable; 5=Definite.

Program Path:
Data source: ADAE

Data extract date:

Listing 20. Hematology (Infusion)

Arm: XXXXXXX

Subject ID	Sex/Age	Visit	Collection Date/Time	Lab Test	Result	Unit	Normal Range Lower-Upper	Abnormal Flag [1]
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
							XXXX,XXXX	
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX		X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X

[1] Abnormal Flag: H=Above the upper limit of normal; L=Below the lower limit of normal.
Note: C3 stands for the Cohort 3 second infusion.
Note: In cases of repeat testing, the original is shown in the table.

Listing 21. Hematology (Outside of Infusion)

Arm: XXXXXXX

Subject ID	Sex/Age	Visit	Collection Date/Time	Lab Test	Result	Unit	Normal Range Lower-Upper	Abnormal Flag [1]
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
							XXXX,XXXX	
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX		X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X

[1] Abnormal Flag: H=Above the upper limit of normal; L=Below the lower limit of normal.
Note: C3 stands for the Cohort 3 second infusion.
Note: In cases of repeat testing, the original result is shown in the table.

Listing 22. Clinical Chemistry (Infusion)

Arm: XXXXXXX

Subject ID	Sex/Age	Visit	Collection Date/Time	Lab Test	Result	Unit	Normal Range Lower-Upper	Abnormal Flag [1]
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
							XXXX,XXXX	
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX		X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X

[1] Abnormal Flag: H=Above the upper limit of normal; L=Below the lower limit of normal.
Note: C3 stands for the Cohort 3 second infusion.
Note: In cases of repeat testing, the original result is shown in the table.

Listing 23. Clinical Chemistry (Outside of Infusion)

Arm: XXXXXXX

Subject ID	Sex/Age	Visit	Collection Date/Time	Lab Test	Result	Unit	Normal Range Lower-Upper	Abnormal Flag [1]
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
							XXXX,XXXX	
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX		X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X

[1] Abnormal Flag: H=Above the upper limit of normal; L=Below the lower limit of normal.
Note: C3 stands for the Cohort 3 second infusion.
Note: In cases of repeat testing, the original result is shown in the table.

Listing 24. Urinalysis (Infusion) – Specific Gravity, pH, and Urobilinogen

Arm: XXXXXXX

Subject ID	Sex/Age	Visit	Collection Date/Time	Lab Test	Result	Unit	Normal Range Lower-Upper	Abnormal Flag [1]
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
							XXXX,XXXX	
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX		X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X

[1] Abnormal Flag: H=Above the upper limit of normal; L=Below the lower limit of normal.
Note: C3 stands for the Cohort 3 second infusion.
Note: In cases of repeat testing, the original result is shown in the table.

Listing 25. Urinalysis (Infusion) – Qualitative Test Results

Arm: XXXXXXX

Subject ID	Sex/Age	Visit	Collection Date/Time	Lab Test	Result
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX

[1] Abnormal Flag: H=Above the upper limit of normal; L=Below the lower limit of normal.
Note: C3 stands for the Cohort 3 second infusion.
Note: In cases of repeat testing, the original result is shown in the table.

Listing 26. Urinalysis (Outside of Infusion) - Specific Gravity, pH, and Urobilinogen

Arm: XXXXXXX

Subject ID	Sex/Age	Visit	Collection Date/Time	Lab Test	Result	Unit	Normal Range Lower-Upper	Abnormal Flag [1]
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
							XXXX,XXXX	
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX		X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X

[1] Abnormal Flag: H=Above the upper limit of normal; L=Below the lower limit of normal.
Note: C3 stands for the Cohort 3 second infusion.
Note: In cases of repeat testing, the original result is shown in the table.

Listing 27. Urinalysis (Outside of Infusion) – Qualitative Test Results

Arm: XXXXXXX

Subject ID	Sex/Age	Visit	Collection Date/Time	Lab Test	Result
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX

[1] Abnormal Flag: H=Above the upper limit of normal; L=Below the lower limit of normal.
Note: C3 stands for the Cohort 3 second infusion.
Note: In cases of repeat testing, the original result is shown in the table.

Listing 28. Coagulation (Infusion)

Arm: XXXXXXX

Subject ID	Sex/Age	Visit	Collection Date/Time	Lab Test	Result	Unit	Normal Range Lower-Upper	Abnormal Flag [1]
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
							XXXX,XXXX	
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX		X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X

[1] Abnormal Flag: H=Above the upper limit of normal; L=Below the lower limit of normal.
Note: C3 stands for the Cohort 3 second infusion.
Note: In cases of repeat testing, the original result is shown in the table.

Listing 29. Coagulation (Outside of Infusion)

Arm: XXXXXXX

Subject ID	Sex/Age	Visit	Collection Date/Time	Lab Test	Result	Unit	Normal Range Lower-Upper	Abnormal Flag [1]
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
							XXXX,XXXX	
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX		X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X

[1] Abnormal Flag: H=Above the upper limit of normal; L=Below the lower limit of normal.
Note: C3 stands for the Cohort 3 second infusion.
Note: In cases of repeat testing, the original result is shown in the table.

Listing 30. Direct Antiglobulin Test

Arm: XXXXXXX

Subject ID	Sex/Age	Visit	Collection Date/Time	Lab Test	Result
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX

[1] Abnormal Flag: H=Above the upper limit of normal; L=Below the lower limit of normal.
Note: C3 stands for the Cohort 3 second infusion.
Note: In cases of repeat testing, the original is shown in the table.

Listing 31. Serum Protein Electrophoresis

Arm: XXXXXXX

Subject ID	Sex/Age	Visit	Collection Date/Time	Lab Test	Result	Unit	Normal Range Lower-Upper	Abnormal Flag [1]
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
							XXXX,XXXX	
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX		X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X
		X	DDMMMYYYY:TT	XXXXX	XXXXX	XXXXX	XXXX,XXXX	X

Note: In cases of repeat testing, the original result is shown in the table.

[1] Abnormal Flag: H=Above the upper limit of normal; L=Below the lower limit of normal.

Note: In cases of repeat testing, the original result is shown in the table.

Listing 32. Urine Pregnancy Test

Arm: XXXXXXX

Subject ID	Sex/Age	Visit	Collection Date/Time	Lab Test	Result
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX

Note: In cases of repeat testing, the original result is shown in the table.

Note: C3 stands for the Cohort 3 second infusion.

Note: In cases of repeat testing, the original result is shown in the table.

Listing 33. Urine Drug Screen

Arm: XXXXXXX

Subject ID	Sex/Age	Visit	Collection Date/Time	Lab Test	Result
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX
XXXXXX	X/XX	X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX
		X	DDMMMYYYY:TT	XXXXX	XXXXX

Listing 34. Repeat Labs

Arm: XXXXXXX

						Original Measurement		Repeated Measurement	
Subject ID	Sex/Age	Category for Lab Test	Visit Name	Lab Test	Unit	Collection Date/Time	Result in Original Units	Collection Date/Time	Result in Original Units
XXXXXX	X/XX	XXXXXXXX	XXXX	XXXXX	XXXXX	DDMMMYYYY:TT	XXXXX	DDMMMYYYY:TT	XXXXX
				XXXXX	XXXXX	DDMMMYYYY:TT	XXXXX	DDMMMYYYY:TT	XXXXX
				XXXXX	XXXXX	DDMMMYYYY:TT	XXXXX	DDMMMYYYY:TT	XXXXX
				XXXXX	XXXXX	DDMMMYYYY:TT	XXXXX	DDMMMYYYY:TT	XXXXX
				XXXXX	XXXXX	DDMMMYYYY:TT	XXXXX	DDMMMYYYY:TT	XXXXX

Listing 35. Additional Screening Results for Subjects Rescreened

Arm: XXXXXXX

						Original Measurement		Repeated Measurement	
Subject ID	Sex/Age	Category for Lab Test	Visit Name	Lab Test	Unit	Collection Date/Time	Result in Original Units	Collection Date/Time	Result in Original Units
XXXXXX	X/XX	XXXXXXXX	XXXX	XXXXX	XXXXX	DDMMMYYYY:TT	XXXXX	DDMMMYYYY:TT	XXXXX
				XXXXX	XXXXX	DDMMMYYYY:TT	XXXXX	DDMMMYYYY:TT	XXXXX
				XXXXX	XXXXX	DDMMMYYYY:TT	XXXXX	DDMMMYYYY:TT	XXXXX
				XXXXX	XXXXX	DDMMMYYYY:TT	XXXXX	DDMMMYYYY:TT	XXXXX
				XXXXX	XXXXX	DDMMMYYYY:TT	XXXXX	DDMMMYYYY:TT	XXXXX

Listing 36. Prior Concomitant Medications

Arm: XXXXXXX

Subject ID	Sex/Age	Date of Enrollment	Randomization Date	Start Date	End Date [1]	Medication or Therapy	Dose (units)	Frequency	Route of Admin [2]	Indication
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXX	XXX (XX)	XXXXX	XXXX	XXXXXXX
		DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXX	XXX (XX)	XXXXX	XXXX	XXXXXXX
		DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXX	XXX (XX)	XXXXX	XXXX	XXXXXXX
		DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXX	XXX (XX)	XXXXX	XXXX	XXXXXXX
		DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXX	XXX (XX)	XXXXX	XXXX	XXXXXXX
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXX	XXX (XX)	XXXXX	XXXX	XXXXXXX
		DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXX	XXX (XX)	XXXXX	XXXX	XXXXXXX
		DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXX	XXX (XX)	XXXXX	XXXX	XXXXXXX
		DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXX	XXX (XX)	XXXXX	XXXX	XXXXXXX
		DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXX	XXX (XX)	XXXXX	XXXX	XXXXXXX

[1] Drugs continuing at the end of the study are labelled as ongoing.
[2] IL = Intralesional; IP = Intraperitoneal; R = Rectal; TOP = Topical.
IM = Intramuscular; N = Nasal; INH = Respiratory (Inhalation); TD = Transdermal.
IO = Intraocular; PO = Oral; SC = Subcutaneous; VAGL = Vaginal.
Program Path:
Data source: ADSL, CM

Data extract date:

Listing 37. Protocol Deviations

Arm: XXXXXXX

Subject ID	Sex/ Age	Date of Enrollment	Randomization Date	Protocol Deviation Start Date	Protocol Deviation	Protocol Deviation Term	Impact of Deviation [1]	Action Taken [2]	Other/Multiple Actions Taken
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	X	X	XXXXXXXXXXX
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	X	X	XXXXXXXXXXX
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	X	X	XXXXXXXXXXX
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	X	X	XXXXXXXXXXX
XXXXXX	X/XX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXX	XXXXXXXXXX	X	X	XXXXXXXXXXX

[1] S=Significant; N=Nonsignificant.
[2] 1=None; 2=Only Investigator Notified; 3=Only IRB and ORP Human Research Protection Office (HRPO) Notified.
4=Only Sponsor Notified; 5=IRB, ORP HRPO and Sponsor Notified.
6=All Parties (Investigator/IRB/ORP HRPO/Sponsor) Notified.
7=Staff Retrained; 8=Subject Re-Educated; 9=Protocol Amendment Submitted.
10=Other/Multiple Actions Taken
Program Path:
Data source: ADSL, DV

Data extract date:

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