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STATISTICAL ANALYSIS PLAN

For:

Grifols Therapeutics LLC.

SPONSOR PROTOCOL No. GC1703

A Prospective, Open-Label, Single-Arm Clinical Trial to Assess the Anti-Hepatitis A Virus (HAV) Antibody Levels, Pharmacokinetics, and Safety of a Single Intramuscular Dose of a Polyvalent Human Immune Globulin in HAV-Seronegative Healthy Subjects

[redacted]

Prepared by:

[redacted]

Version: FINAL 1.0

Date: 2018/04/24

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[redacted]

STATISTICAL ANALYSIS PLAN APPROVAL

We have carefully read this Statistical Analysis Plan and agree it contains the necessary information required to handle the statistical analysis of study data.

[redacted]

26-04-2018
Date

for [redacted]

2018/04/27
Date

On behalf of the Sponsor:

[redacted]

26 April 2018
Date

Biostatistician
Grifols Therapeutics, LLC

[redacted]

25 April 2018
Date

[redacted]
Medical Manager Clinical Trials
Bioscience Clinical and Pharmacovigilance
Grifols Bioscience Industrial Group

[redacted]

25 APR 2018
Date

[redacted]
Director, Clinical Development
Grifols Therapeutics, LLC

[redacted]

VERSION CONTROL

Version Number	Version Date	Author	Description of Significant Changes from Previous Approved Version
DRAFT 0.1	2018/02/12	[redacted]	Not Applicable – First Version
DRAFT 0.2	2018/03/16		Second version after first round of comments. Mock shells were added
DRAFT 0.3	2018/04/06		Third version after second round of comments
DRAFT 0.4	2018/04/19		Fourth version after third round of comments
FINAL 1.0	2018/04/24		Final Version

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CONTENTS

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ABBREVIATIONS

ADR	Adverse Drug Reaction
AE	Adverse Event
Anti-HAV	Anti-Hepatitis A Virus
ALP	Alkaline Phosphatase
ALT	Alanine Aminotransferase
aPTT	Activated Partial Thromboplastin Time
AR	Adverse Reaction
AST	Aspartate Aminotransferase
ATC	Anatomical/Therapeutic/Chemical
$AUC_{0-\infty}$	Area under the serum concentration time curve extrapolated to infinity
AUC_{0-T}	Cumulative area under the or serum concentration time curve calculated from 0 to time of last observed quantifiable serum concentration
BLQ	Below Limit of Quantitation
BMI	Body Mass Index
BUN	Blood Urea Nitrogen
CI	Confidence Interval
Cl_{TOT}/F	Apparent total serum clearance
C_{max}	Maximum observed serum concentration
CRF	Case Report Form
CS	Clinically Significant
CSR	Clinical Study Report
CV	Coefficient of Variation
DNA	DeoxyriboNucleic Acid
ECG	Electrocardiogram
GGT	Gamma-glutamyl Transferase
HAV	Hepatitis A Virus
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human Immunodeficiency Virus
IM	Intramuscular
IP	Investigational Product
λ_z	Apparent elimination rate constant
LDH	Lactate Dehydrogenase
Max	Maximum
MedDRA	Medical Dictionary for Regulatory Activities
Min	Minimum
NAT	Nucleic Acid Test
NCA	Non-compartmental Analysis

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NCS	Not Clinically Significant
PE	Physical Examination
PK	Pharmacokinetic(s)
PT	Prothrombin Time
RNA	RiboNucleic Acid
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SOC	System Organ Class
TEAE	Treatment-Emergent Adverse Event
T_{half}	Terminal elimination half-life
T_{max}	Time of maximum observed serum concentration
TFLs	Tables, Figures, and Listings
WHO-DDE	World Health Organization Drug Dictionary Enhanced
V_D/F	Apparent volume of distribution

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1. INTRODUCTION

This statistical analysis plan (SAP) provides a detailed description of the statistical methods and procedures to be implemented for the analyses of data to support the completion of the clinical study report (CSR). The analyses described in the SAP are based upon the final protocol GC1703/Protocol Version 5.0, dated 2018/01/22. Additional post-hoc or unplanned analyses, which are not defined in this SAP, may be performed to support the clinical development program. Such analyses will be documented in the CSR.

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2. STUDY OBJECTIVES

Primary Efficacy Objective

The primary efficacy objective is to evaluate whether a single 0.2 mL/kg intramuscular (IM) dose of the study treatment will provide protective levels of antibodies to Hepatitis A Virus (anti-HAV) in HAV-seronegative healthy subjects for up to 60 days.

Pharmacokinetic (PK) Objectives

The pharmacokinetic objectives are to evaluate the PK parameters of anti-HAV antibodies following a single 0.2 mL/kg IM dose of the study treatment in HAV-seronegative healthy subjects.

The PK parameters of interest are:

- Area under the serum concentration time curve extrapolated to infinity ($AUC_{0-\infty}$)
- Cumulative area under the serum concentration time curve calculated from 0 to time of last observed quantifiable serum concentration (AUC_{0-T})
- Maximum observed serum concentration (C_{max})
- Time of maximum observed serum concentration (T_{max})
- Apparent elimination rate constant (λ_z)
- Terminal elimination half-life (T_{half})
- Apparent total serum clearance (Cl_{TOT}/F)
- Apparent volume of distribution (V_D/F)

Safety Objective

The safety objective is to evaluate the safety and tolerability of a single 0.2 mL/kg IM dose of the study treatment in HAV-seronegative healthy subjects.

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3. STUDY DESIGN

General Description

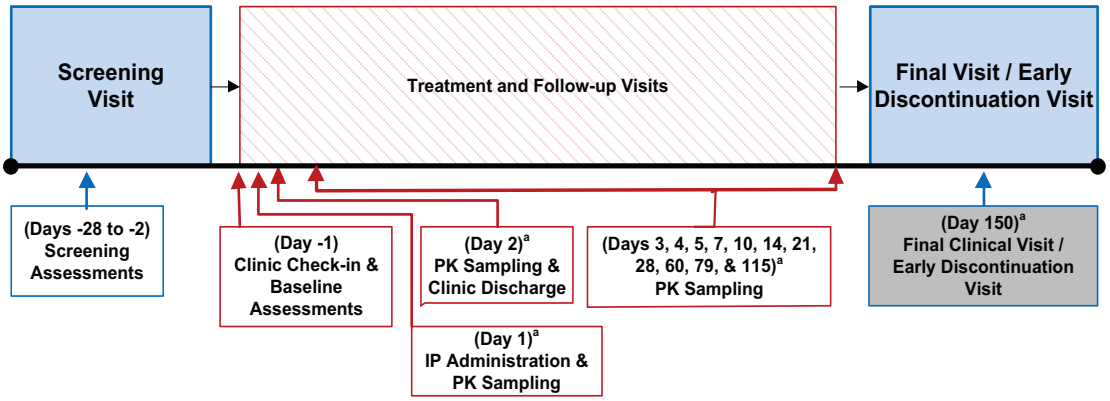
This is a single center, open-label, single-arm study. Approximately 28 HAV-seronegative healthy subjects will be enrolled and treated after obtaining their written informed consents. There will be a screening period of up to 28 days during which subjects will be screened for enrollment. Subjects will be male and 18 to 55 years of age, or female and 18 to 65 years of age, inclusive; and will weigh at least 50 kg at screening with a body mass index (BMI) of 18.5 to 29.9 kg/m^2. The healthy subjects will receive a single IM dose of GamaSTAN (0.2 mL/kg), which is followed by a PK sampling period of 150 days (approximately 5 half-lives). The protective levels of anti-HAV antibodies will be assessed up to 60 days after the administration of GamaSTAN. A PK curve will be obtained during the PK sampling period.

Treatment

A single 0.2 mL/kg IM dose of GamaSTAN [Immune Globuin (Human)] will be administered in the anterolateral aspects of the upper thigh or the deltoid muscle of the upper arm. Doses over 5 mL are to be divided and injected into several muscle sites to reduce local pain and discomfort.

Study procedures

The study consists of a Screening Visit, Treatment and Follow-up Visits, and Final Visit / Early Discontinuation Visit. Subjects will be qualified by screening assessments and procedures for reporting to the clinical site on Day -1. Subjects will be discharged from the clinic on Day 2, following the scheduled assessments and procedures, and will return to the clinical site for the remaining ambulatory PK samples and safety monitoring, and again for the final visit (Day 150). The total duration of study participation for subjects who complete the study will be approximately 178 days. For complete details on the study procedures and events, refer to Appendix A. The overall study schema is presented below:



[a] *PK sampling visits will be conducted as close as possible to the exact time points. The PK sampling visits: Day 1: prior to study drug injection, 60 minutes (±10 minutes) post study drug injection and 12 hours post study drug injection (a window of ±1 hour is permitted); Day 2 (window of ±1 hour); Days 3, 4 and 5 (visits have a window of ±4 hours); Days 7, 10, and 14 (all 3 visits have a window of ±1 day); Days 21 and 28 (both visits have a window of ±2 days); Days 60, 79 and 115 (all 3 visits have a window of ±4 days); Day 150 (a window of ±7 days)*

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Randomization and Unblinding Procedures

This is an open label, single arm study, so blinding is not applicable and subjects are not randomized.

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4. STUDY ENDPOINTS

Efficacy Endpoints

The primary efficacy endpoint is the proportion of subjects maintaining protective anti-HAV antibody levels (defined as anti-HAV antibody titer ≥10 mIU/mL in serum) after T_{max} up to 60 days after study treatment administration.

Pharmacokinetic Endpoints

With respect to the PK endpoint, the parameters of interest for this study are: $AUC_{0-\infty}$, AUC_{0-T}, C_{max}, T_{max}, λ_z, T_{half}, $Cl_{TOT/F}$ and $V_{D/F}$.

Safety Endpoints

The safety endpoints will include a summary of the incidence of adverse events (AEs), serious adverse events (SAEs), suspected adverse drug reactions (ADRs) and adverse reactions (ARs), as well as descriptive summary and statistics of the safety parameters (clinical laboratory values, vital signs and physical examination findings).

Sample Size Determination

Approximately 28 healthy subjects will be enrolled and treated in this study which will provide about 20 evaluable subjects based on approximately 30% dropout rate. The sample size is chosen based on clinical considerations but not on a formal sample size calculation.

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5. ANALYSIS POPULATIONS

Safety Population

The safety population consists of all subjects who received any amount of investigational product (IP).

Evaluable Population

The evaluable population consists of all subjects who received the entire dose of IP and had no major protocol deviations that would impact the efficacy analysis up to Day 60. Any deviations from the protocol will be recorded and evaluated before database lock.

Pharmacokinetic Population

The PK population consists of all subjects who received the entire dose of the IP and who provided sufficient serum concentration data to facilitate calculation of PK parameters. Subjects who did not complete the PK sampling schedule may be included in the PK analysis only for the PK parameters that are judged not to be affected by the missing sample(s). This decision is to be documented and approved by the sponsor before the database lock.

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6. STATISTICAL METHODOLOGY

All analyses will be conducted using the SAS® software, version 9.4.Pharmacokinetic analyses will be performed using Phoenix WinNonlin version 6.3 or later.

Adverse events and medical history will be classified using standard Medical Dictionary for Regulatory Activities (MedDRA) terminology Version 20.1.

Prior and concomitant medications will be coded with the World Health Organization Drug Dictionary Enhanced (WHO-DDE) dictionary version March 1, 2017.

Unless otherwise specified, the data listings will include all dosed subjects up to the point of study completion or discontinuation; exceptions will be listings pertaining to a subset of subjects only (e.g., subjects with protocol deviations) or a subset of records/events (e.g., abnormal laboratory values).

Categorical variables will be summarized using the PROC FREQ procedure. Continuous variables will be summarized using the PROC UNIVARIATE procedure. For ln-transformed endpoints, geometric mean, geometric standard deviation, and coefficient of variation will also be presented.

The following general comments also apply to all statistical analyses and data presentations:

- Duration variables will be calculated using the general formula: (end date - start date) +1.
- If the reported value of a clinical laboratory parameter cannot be used in a statistical summary table (e.g., a character string is reported for a parameter of the numerical type), a coded value must be appropriately determined and used in the statistical analyses. In general, a value involving lower and upper limit of normal range such as '<10' or '≤5' will be treated as '10' or '5' respectively, and a value such as '>100' will be treated as '100'. However, the actual values as reported in the database will be presented in data listings.
- Individual subject listings of all data represented on the CRFs will be provided to facilitate the investigation of tabulated values and to allow for the clinical review of all efficacy, PK, and safety parameters.
- When non-PK assessments are repeated for a given time point, only the non-missing result which is the closest to the dosing time will be included in summary tables

The analyses described in this plan are considered a priori, in that they have been defined prior to database lock. Any analyses performed subsequent to database lock will be considered post hoc and exploratory. Post hoc analyses will be labeled as such in the corresponding statistical output and identified in the CSR.

Analysis Timepoints

Unless otherwise specified, the baseline value will be defined as the last non-missing evaluation prior to the administration of the IP.

Methods for Handling Missing Data

No imputations of values for missing data will be performed.

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7. STUDY SUBJECTS

Unless otherwise specified, summary tables for protocol deviations, demographics and other baseline characteristics will be presented for the Safety Population.

Disposition

Subject disposition will be summarized for all screened subjects who always include the re-screened subjects, including:

- Number of subjects screened (i.e., count of all unique subject numbers) and within that the number of subjects re-screened;
- Number of subjects not dosed: count of all qualifying unique subject numbers, including the initial failure of re-screened subjects who ended up being dosed or failures for both times;
- Number of subjects dosed;
- Number and percentage of dosed subjects who completed the study;
- Number and percentage of dosed subjects discontinued from the study by primary reason for discontinuation and overall;
- Number and percentage of dosed subjects included in each of the study populations

The percentages will be calculated using the number of subjects dosed as denominator.

A listing of all screened subject's disposition will be provided. A listing of subjects included in each of the analysis populations will also be provided.

Protocol Deviations

Protocol deviations will be identified during the study and evaluated before database lock. Protocol deviation criteria and severity will be summarized and listed.

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8. DEMOGRAPHIC AND OTHER BASELINE CHARACTERISTICS

Demographic and Baseline Characteristics

Demographic data and baseline characteristics will be presented in a data listing and summarized in a table by analysis population. Subject demographics include sex, age, ethnicity, and race. Baseline characteristics include height, weight, and BMI.

Clinical lab assessments only performed at screening and/or baseline will be provided in data listings, including pregnancy test, urine alcohol and drug panel testing, IgA, virus safety testing, and coagulation.

Medical History

Any medical history findings will be recorded and presented in a listing.

Contraceptive Methods

Contraceptive methods will be presented in a subject listing.

Electrocardiogram

Electrocardiograms (ECGs) will occur at Screening and on Day -1 for eligibility evaluation before IP administration. All data will be listed. Values out of the normal range judged by an Investigator as clinically significant will be considered AEs.

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9. EFFICACY

Analysis of Anti-HAV Antibody Endpoint(s)

The percentage of subjects maintaining anti-HAV antibody levels ≥10 mIU/mL after T_{max} up to Day 60 following study treatment administration will be summarized.

The efficacy analysis will be performed on the evaluable and safety populations.

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10. Pharmacokinetics

Analysis of Pharmacokinetic Endpoint(s)

PK analyses will be performed on the PK population.

Concentration Data

Below limit of quantitation concentrations (coded BLQ) will be treated as zero for descriptive statistics. In the case where concentrations for anti-HAV antibodies cannot be determined due to bioanalytical or clinical reasons, these values will be set to missing for the statistical and pharmacokinetic analysis and will not be included for subsequent analysis.

Pre-dose concentration will be used as baseline for calculation of baseline corrected levels of anti-HAV antibodies. Baseline correction will be performed by subtracting predose values from post-dose values.

The anti-HAV antibody levels during the PK sampling period (up to Day 150 following study treatment administration) will be listed

The individual serum concentration/time figures will be presented using the actual sampling times whereas the mean and median serum concentration/time figures will be presented using the nominal sampling times.

Descriptive statistics will be calculated at each individual scheduled time point. serum concentration data will be summarized using the following descriptive statistics: number of non-missing values (N), arithmetic mean, standard deviation (SD), 90% CI for mean, coefficient of variation (CV%), median, minimum (min), maximum (max), geometric mean.The actual elapsed time between IP administration and each PK blood sample draw will be calculated and presented in concentration listing. The PK parameter calculation for each subject will be based on the actual elapsed time instead of the scheduled time or nominal time.

The PK blood sampling schedule and nominal time are shown below:

Study Day	Scheduled Time Points	Nominal Time (Hours)
1	Prior to treatment	0
1	60 minutes post treatment	1
1	12 hours post treatment	12
2	24 hours post treatment	24
3	48 hours post treatment	48
4	72 hours post treatment	72
5	96 hours post treatment	96
7	Day 7	144
10	Day 10	216
14	Day 14	312
21	Day 21	480
28	Day 28	648
60	Day 60	1416
79	Day 79	1872

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115	Day 115	2736
150	Day 150	3576

Pharmacokinetic Parameters

Below limit of quantitation concentrations (coded BLQ) will be treated as zero for noncompartmental analysis (NCA).

The PK parameters will be derived from the anti-HAV antibody baseline uncorrected and baseline corrected serum concentrations versus time using NCA, with Phoenix WinNonlin version 6.3 or later (Model 200–202 Extravascular). Parameters to be calculated are listed in the table below:

C_{max}	Maximum observed serum concentration
T_{max}	Time of maximum observed serum concentration; if it occurs at more than one time point, T_{max} is defined as the first time point with this value
T_{LQC}	Time of last observed quantifiable serum concentration
AUC_{0-T}	Cumulative area under the serum concentration time curve calculated from 0 to T_{LQC} using the linear trapezoidal method, where T_{LQC} represents time of last observed quantifiable serum concentration
$AUC_{0-\infty}$	Area under the serum concentration time curve extrapolated to infinity, calculated as $AUC_T + C_{LQC}/\lambda z$, where C_{LQC} is the measured concentration at time T_{LQC}
$AUC_{\%Extrap}$	Percentage of $AUC_{0-\infty}$ due to extrapolation from T_{QLC} to infinity
T_{LIN}	Time point where the log-linear elimination phase begins
λz	Apparent elimination rate constant, estimated by linear regression of the terminal linear portion of the log concentration *versus* time curve
T_{half}	Terminal elimination half-life, calculated as $\ln(2)/\lambda z$
V_D/F	Apparent Volume of Distribution calculated as follows: $V_D / F = \left(\frac{Dose}{K_{el} * AUC_{\infty}} \right)$ Where Kel = λz.
Cl_{TOT}/F	Apparent Total serum Clearance calculated as follows: $Cl_{TOT} / F = \left(\frac{Dose}{AUC_{\infty}} \right)$

Actual sampling times (hours, relative to the corresponding administration time) will be used for calculation of PK parameters. It is recognized that there may be circumstances where PK sampling may fall outside of the time windows.

In the case where less than 3 consecutive measurable concentrations of anti-HAV antibodies are observed, the AUC parameters will not be estimated for that specific profile for the analyte in question.

The main absorption and disposition parameters will be estimated using a non-compartmental approach with a log-linear terminal phase assumption. The linear trapezoidal rule will be used to estimate the area under the curve (linear trapezoidal linear interpolation) and the terminal phase will be estimated by maximizing the coefficient of determination estimated from the log-linear regression model. However, $AUC_{0-\infty}$, λz, T_{half}, Cl_{TOT}/F and V_D/F parameters will be estimated for individual concentration-time profiles only when the terminal log-linear phase can be reliably characterized using the following criteria:

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- Phoenix® WinNonlin® Best fit range selection (kel selection is to be reviewed and adjusted (time range) as appropriate)
- R^2 of at least 80%

Descriptive statistics for PK parameters of interest ($AUC_{0-\infty}$, AUC_{0-T}, C_{max}, T_{max}, λ_z, T_{half}, $Cl_{TOT/F}$ and $V_{D/F}$) will be summarized using the following descriptive statistics: N, arithmetic mean, SD, 90% CI for mean, CV%, median, min, max, geometric mean (except T_{max}), and 90% CI for geometric mean (except T_{max}).

Additional PK parameters may be calculated if required.

Data Precision

Individual baseline uncorrected and baseline corrected PK concentrations will be displayed with the same precision used in the results from the bioanalytical laboratory.

Precision for individual PK parameters will be displayed with the same precision as per the bioanalytical results, except for the following:

- Observed PK parameters associated with time (e.g. T_{max}, T_{LQC}, T_{LIN}) with 2 decimals places;
- Number of point (terminal phase characterization) with 0 decimal places;
- R^2 and λ_z [Lambda z] with 4 decimal places;
- Percentages will be displayed with two decimal places.

Summary statistics for raw concentrations and PK parameters will be displayed with the same number of decimal places as the individual values unless specified otherwise

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11. SAFETY

Safety analyses will be performed on the safety population. Safety data will be summarized with descriptive statistics and frequency tables and will include clinical laboratory values, vital signs and physical examination findings. The incidence of AEs, suspected ADRs, ARs, and AEs by severity and causality will be summarized. Deaths, subjects with SAEs and AEs leading to premature discontinuation from the study will be listed and presented in narrative form.

Adverse Events

Suspected ADRs are the AEs with causality assessment of possibly or definitely related. Adverse reactions (ARs) are the AEs with causality assessment of definitely related.

Adverse events will be coded and classified using MedDRA® terms (system organ class and preferred terms). Adverse events will be classified as Treatment-Emergent Adverse Events (TEAEs) or non-TEAEs depending on the comparison of AE onset date/time with the start date/time of study treatment with the IP. A TEAE will be defined as an AE which occurs on or between the beginning of the study drug injection and the final visit of the clinical trial. A non-TEAE will be defined as an AE which occurs prior to the start of study treatment. For AEs with incomplete start dates, the same algorithm for missing or partial end date information described for prior and concomitant medication below will be used for determination of treatment emergent or not. Non-TEAEs and TEAEs will be summarized separately. All AEs will be summarized by presenting subject incidences and percentages, and they will also be listed by body systems with subject number. In addition, TEAEs, including suspected ADRs, will be summarized by system organ class, preferred term, causal-relationship, intensity (severity) and seriousness (serious vs non-serious) and injection site reactions (by severity and by location) using descriptive statistics. For the summary by severity or causality at each level of summarization (number of subjects, System Organ Class (SOC), or Preferred Term), a subject will only be counted once per system organ class or preferred term using the most severe AE or the AE with the strongest causal relationship to the IP. Subjects with an SAE or who withdraw from the study because of an AE will also be individually listed and summarized.In addition, a table summarizing the temporally-associated AEs defined as AEs happening during IP injection or within 24 hours following the end of IPinjection and within 72 hours following the end of IP injection will be presented.

In the overall summary table of TEAEs, the following will be presented:

- Number and percentage of subjects with TEAEs, total number of TEAEs;
- Number and percentage of subjects with suspected ADRs, total number of suspected ADRs;
- Number and percentage of subjects with ARs, total number of ARs;
- Number and percentage of subjects with SAEs, total number of SAEs;
- Number and percentage of subjects with AEs leading discontinuation from the study, total number of such events;
- Number and percentage of subjects with AEs with death as outcome, total number of such events;
- Number and percentage of subjects with injection site reactions, total number of such events
- Number and percentage of subjects with TEAEs during/within 24 Hours post end of IP injection
- Number and percentage of subjects with TEAEs during/within 72 Hours post end of IP injection

Subject listings of all AEs including severity and relationship to study drug, as well as the time from the injection start date will be provided. AEs leading to discontinuation from the study, SAEs, and deaths will also be presented in separate listings.

Prior and Concomitant Medications

Any prior and concomitant medications recorded will be presented in a data listing and summarized in a table.

Prior medications are those taken in the 30 days prior to screening visit and stopped before the start of the IP administration

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Concomitant medications are defined as medications with a start date/time on or after the first study drug dosing, or ongoing or with an end date/time after the first dosing.

The following convention will be used for missing or partial end date information in order to determine whether a medication is prior or concomitant:

The unknown portions of a medication end date will be assumed to be as late as possible. If a medication end date is incomplete but the month/year of medication end date is prior to the month/year of the start of study treatment, then the medication will be considered a prior medication. If a medication end date is incomplete but the month/year of medication end date is the same as the month/year of the start of study treatment, then the medication will be considered a concomitant medication. All other incomplete medication end dates and all medications with missing end dates will be assumed to be concomitant medications.

The medication name, dose, units, route, formulation, frequency, indication or reason taken, any relationship to medical history or an AE, code, date and time taken will be presented. The start or end dates will be displayed in listings as recorded in CRF.The listing will include the coding terms (e.g., Anatomical/Therapeutic/Chemical terms (ATCs)).

The summary table will be sorted alphabetically by medication class (i.e., ATC Level 2) and medication sub-class (i.e., ATC level 4). If the ATC Level 4 term is missing, the ATC Level 3 term will be used in the medication summary table and data listing. For the summary tables, if a subject has taken a medication more than once, the subject will be counted only once at the ATC level.

Extent of Exposure

A listing summarizing date and time of study drug administration, dose administered, total volume prepared, route of administration, injection site, volume administered per site, needle size, total volume administered, percentage of volume administered (Volume Administered (mL)/ Volume Prepared (mL)*100), and comments about dosing issues and deviations, where applicable, will be presented. A summary table of total volume prepared (mL), total volume administered (mL), treatment compliance (=total volume administered / total volume prepared x 100%), duration of treatment administration (minute), and injection site will be provided by analysis population as well.

Clinical Laboratory Evaluations

All clinical laboratory data (Table 1) will be listed for each subject. Complete results of each category of laboratory tests will be presented in respective listings. Clinical laboratory assessments will include hematology, chemistry, and urinalysis . Hematology panel: hemoglobin, hematocrit, platelets, red blood cell count, and white blood cell count (absolute and % with differential). Chemistry panel: Sodium, potassium, creatinine, blood urea nitrogen (BUN), calcium, lactate dehydrogenase (LDH), aspartate aminotransferase (AST), alanine aminotransferase (ALT), gamma-glutamyl transferase (GGT), alkaline phosphatase (ALP), glucose, total bilirubin, direct and indirect bilirubin. Urinalysis panel: Microscopic evaluation is done only with cause, pH, protein, glucose, and blood.

Subject listings of laboratory values will be provided. Values out of the normal range judged by an Investigator as clinically significant (CS) will be considered AEs. Summary tables of change from baseline and shift from baseline by visit will be provided for hematology, chemistry, and urinalysis. In addition, a summary of HAV ribonucleic acid (RNA) at baseline will be presented for all subjects.

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Table 1: Name, Description, and Location of Laboratory Tests and Procedures

Test Panel	Description	Location
Hematology	Hemoglobin, hematocrit, platelets, red blood cell count, white blood cell count (absolute and % with differential)	Central
Chemistry	Sodium, potassium, creatinine, calcium, BUN, LDH, AST, ALT, GGT, ALP, glucose, total bilirubin, direct and indirect bilirubin	Central
Coagulation [1]	Prothrombin time (PT) and activated partial thromboplastin time (aPTT)	Central
Immunoglobulin A (IgA)[1]	Quantitative	Central
Urine pregnancy test [2]	Qualitative urine β-HCG for female subjects	Local
Urine test for alcohol and drugs of abuse	Alcohol, marijuana, opiates, cocaine, amphetamines, methamphetamines, and benzodiazepines	Central
Urinalysis	Microscopic evaluation is done only with cause. pH, protein, glucose and blood	Central
Virus safety (nucleic acid test (NAT)) testing	Screening: HAV ribonucleic acid (RNA), Hepatitis B virus (HBV) DeoxyriboNucleic Acid (DNA), Hepatitis C virus (HCV) RNA, Human Immunodeficiency Virus (HIV)-1 RNA, and B19V DNA testing	Central
Virus safety (serology) testing	Screening: hepatitis A antibody differential (IgM/IgG), hepatitis B core antibody differential (IgM/IgG), hepatitis C antibody, HIV-1/-2 + Group O antibody, and B19V antibody differential (IgM/IgG) testing	Central
Virus safety (NAT and serology) retain samples [3]	Day 1 prior to study drug injection and final visit	

1. Screening visit only.
2. Screening and on Day -1, prior to study treatment administration.
3. Virus safety (NAT and serology) retain samples collected during the study will only be tested if subject exhibits clinical signs and symptoms consistent with HAV, HBV, HCV, HIV or B19V infection while participating in the study. Virus safety retain samples will be retained until all analyses in support of the study are complete.

Vital Signs

Blood pressure (systolic and diastolic), heart rate, respiratory rate and body temperature, will be measured at screening and on study Days -1, 1, 5, 28 and 60, and at final visit on Day 150 (or early discontinuation visit). Results of vital signs will be presented in a listing. Values out of the normal range judged by an Investigator as CS will be considered AEs. Summary table for change from baseline by visit will be provided.

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Physical Examination Findings

Physical examination (PE) includes a review of the following: head and neck, heart, lungs, abdomen and general appearance. This will occur at Screening visit and at final visit on Day 150 (or early discontinuation visit) for the complete PE, study Days -1, 2, 5, 28 and 60 for the symptom-directed PE. Results of physical examination will be presented in a listing and summarized by body system and by visit. Values out of the normal range judged by an Investigator as CS will be considered AEs.

[redacted]

[redacted]

12. INTERIM ANALYSES AND DATA SAFETY MONITORING

No interim analysis is planned for this study.

[redacted]

[redacted]

13. CHANGES TO PROTOCOL-SPECIFIED ANALYSES

There are no changes to protocol or to specified analyses for this study.

[redacted]

[redacted]

14. GENERAL INFORMATION RELATED TO DATA PRESENTATIONS

All programs used to generate statistical analyses will be validated according to Algorithme Pharma's standard operating procedures.

Tables, Figures, and Listings (TFLs) will be displayed on letter size paper, 8 ½ inches by 11 inches, using the Courier New font.

In general, summary statistics for raw variables (i.e., variables measured at the study site or central laboratory) will be displayed as follows: minima and maxima will be displayed to the same number of decimal places as the raw data. Means, medians, and quartiles will be displayed to one additional decimal place and standard deviations will be displayed to two additional decimal places.

Percentages will be displayed to one decimal place. Percentages between 0 and 0.1 (exclusive) will be displayed as '<0.1'. P-values will be displayed to 3 decimal places. P-values that are less than 0.001 will be displayed as '<0.001'.

The numbers of decimal places for summary statistics of derived variables (i.e., variables that are not measured by the study site but are calculated for analysis based on other measured variables) will be determined on a case by case basis. In general, minima and maxima will be displayed to the commonly used unit of precision for the parameter. Means, medians, quartiles, and confidence limits will be displayed to one additional decimal place and standard deviations will be displayed to two additional decimal places.

The formats and layouts of TFLs are provided in subsequent sections. Actual formats and layouts may be altered slightly from those presented in the templates as necessary to accommodate actual data or statistics. Minor format changes will not require updates to the SAP.

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PLANNED LISTINGS

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APPENDIX A

STUDY SCHEDULES

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Visits Procedures and Evaluation	Screening Visit Days -28 to -2	Day -1	Day 1[a]	Day 2	PK Sampling Visits [b] Days 3, 4, 5, 7, 10, 14, 21, 28, 60, 79, 115	Final Visit (Day 150)[b]/ Early Discontinuation Visit
Informed consent	X					
Admission to clinical research unit		X				
Inclusion/exclusion criteria	X					
Continued eligibility verification		X				
Medical history & demographics	X					
Height and weight	X					
ECG	X	X				
Full physical exam [c]	X					X
Symptom-directed physical exam		X		X	X (Days 5, 28, and 60 visits only)	
Vital signs [d]	X	X	X		X (Days 5, 28, and 60 visits only)	X
Clinical lab assessments [e]	X	X			X (Days 5, 28, and 60 visits only)	X
Coagulation tests (INR, aPTT)	X					
Immunoglobulin A (IgA)	X					
Pregnancy test [f]	X	X				
Urine alcohol and drug panel testing [g]	X	X				
Virus safety testing [h]	X					
Virus safety retain samples [i]			X			X
IP injection			X			
Injection site evaluation			X	X		

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Visits Procedures and Evaluation	Screening Visit Days -28 to -2	Day -1	Day 1[a]	Day 2	PK Sampling Visits[b] Days 3, 4, 5, 7, 10, 14, 21, 28, 60, 79, 115	Final Visit (Day 150)[b]/ Early Discontinuation Visit
PK sampling (anti-HAV antibody level)			X	X	X	X
Concomitant medications	X	X	X	X	X	X
Adverse events	X	X	X	X	X	X
Discharge from clinical research unit				X		

[a] Collection of virus safety retain samples on Day 1 will be performed prior to study treatment administration. Vital signs will be measured prior to study drug injection, approximately 60 minutes (±10 minutes) and 12 hours (±10 minutes) after study treatment administration. Injection site evaluation will be performed approximately 60 minutes after study treatment administration. PK blood sampling on Day 1: prior to study drug injection, 60 minutes (±10 minutes) post study drug injection and 12 hours post study drug injection (a window of ±1 hour is permitted)

[b] PK sampling visits will be conducted as close as possible to the exact time points. The PK sampling visits: Day 2 (window of ±1 hour); Days 3, 4 and 5 (visits have a window of ±4 hours); Days 7, 10, and 14 (all 3 visits have a window of ±1 day); Days 21 and 28 (both visits have a window of ±2 days); Days 60, 79 and 115 (all 3 visits have a window of ±4 days); Day 150 (a window of ±7 days)

[c] Full physical examination (excluding breast and genitourinary examination)

[d] Vital signs include systolic blood pressure, diastolic blood pressure, body temperature, heart rate, respiratory rate

[e] Clinical laboratory assessments will include hematology, chemistry, and urinalysis. Hematology panel: hemoglobin, hematocrit, platelets, red blood cell count, and white blood cell count (absolute and % with differential). Chemistry panel: Sodium, potassium, creatinine, BUN, calcium, LDH, AST, ALT, GGT, ALP, glucose, total bilirubin, direct and indirect bilirubin. Urinalysis panel: Microscopic evaluation is done only with cause, pH, protein, glucose, and blood.

[f] Dipstick urine pregnancy test at screening visit and on Day -1 administration.

[g] Urine alcohol and drug panel testing (drug panel includes marijuana, opiates, cocaine, amphetamines, methamphetamines and benzodiazepines)

[h] Virus safety testing: HAV RNA, HBV DNA, HCV RNA, HIV-1 RNA and B19V DNA by NAT methods as well as HAV antibody differential (IgM/IgG), hepatitis B core antibody differential (IgM/IgG), hepatitis C antibody, HIV-1/-2 + Group O antibody and B19V antibody differential (IgM/IgG) testing by serological methods.

[i] Virus safety retain samples: serum and/or plasma samples for HAV RNA, HBV DNA, HCV RNA, HIV-1 RNA and B19V DNA testing by NAT methods as well as HAV antibody differential (IgM/IgG), hepatitis B core antibody differential (IgM/IgG), hepatitis C antibody, HIV-1/-2 + Group O antibody and B19V antibody differential (IgM/IgG) testing by serological methods will be collected on Day 1 prior to IP injection and at final visit (Day 150)/early discontinuation visit. These samples will be tested only if the subject exhibits clinical signs and symptoms consistent with HAV, HBV, HCV, HIV or B19V infection while participating in the study. Virus safety retain samples will be retained until all analyses in support of the study are complete.

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APPENDIX B

TABLE SHELLS

GENERAL PROGRAMMING NOTE: The displayed of decimals will follow Section 14 of the SAP for efficacy and safety outputs.

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Table 14.1.1
Subject Disposition
(All Subjects)

		Overall
Subjects Included [N]	Screened [1]	xx
	Re-Screened	xx
Subjects not Dosed [N]		xx
Subjects Dosed [N]		xx
Subjects Completed the Study [n(%)]	YES	xx (xx.x)
	NO	xx (xx.x)
If No, Reason(s) of Study Discontinuation [n(%)]	Reason 1	xx (xx.x)
	Reason 2	xx (xx.x)
	Reason 3	xx (xx.x)
	Etc.	xx (xx.x)
Number of Subjects Included in Each Analysis Population [n(%)]		xx (xx.x)
	Safety Population	
	Evaluable Population	xx (xx.x)
	Pharmacokinetic Population	xx (xx.x)

Note: The percentages are calculated using the number of subjects dosed as denominator.
[1] Screened subjects include re-screened subjects.

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Table 14.1.2
Demographic Characteristics by Analysis Population
(Safety Population, Evaluable Population, PK Population)

		Safety Population (N=XX)	Evaluable Population (N=XX)	Pharmacokinetic Population (N=XX)
Age (years)	N	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Gender [n(%)]	MALE	xx (xx.x)	xx (xx.x)	xx (xx.x)
	FEMALE	xx (xx.x)	xx (xx.x)	xx (xx.x)
Childbearing Potential [n(%)] (Female Only)	Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ethnicity [n(%)]	HISPANIC OR LATINO	xx (xx.x)	xx (xx.x)	xx (xx.x)
	NOT HISPANIC OR LATINO	xx (xx.x)	xx (xx.x)	xx (xx.x)
	UNKNOWN	xx (xx.x)	xx (xx.x)	xx (xx.x)
Race [n(%)]	WHITE	xx (xx.x)	xx (xx.x)	xx (xx.x)
	AMERICAN INDIAN OR ALASKA NATIVE	xx (xx.x)	xx (xx.x)	xx (xx.x)
	ASIAN	xx (xx.x)	xx (xx.x)	xx (xx.x)
	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	xx (xx.x)	xx (xx.x)	xx (xx.x)
	BLACK OR AFRICAN AMERICAN	xx (xx.x)	xx (xx.x)	xx (xx.x)
Weight (kg)	N	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Height (cm)	N	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Body Mass Index (kg/m^2)	N	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx

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Notes: Fertility status percentage is based on the number of female subjects in the analysis population.
Subjects can contribute to more than one race category.

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Table 14.1.3
Reasons for Subjects not Dosed
(All Subjects)

		Overall
Subjects not Dosed [N]		xx
If No, Reason(s) of not Dose [n]	SCREEN FAILURE (INCLUSION/EXCLUSION CRITERIA)	xx
	OTHER	xx

PROGRAMMING NOTE: 'OTHER' will be presented only if at least one subject that not dose have another reason for not dose than screen failure

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Table 14.1.4
Protocol Deviations
(Safety Population)

Characteristics	Overall (N=XX)
Number of Protocol Deviations	xxxx
Subjects with at Least One Protocol Deviation	xxx (xx.x)
Type of Protocol Deviation [1][2]	
Deviation Category #1	xx (xx.x)
Deviation Category #2	xx (xx.x)
Deviation Category #3	xx (xx.x)
Number of Major Protocol Deviations	xxxx
Subjects with at Least One Major Protocol Deviation	xxxx
Type of Major Protocol Deviation [1][2]	
Deviation Category #1	xx (xx.x)
Deviation Category #2	xx (xx.x)
Deviation Category #3	xx (xx.x)

PROGRAMMING NOTE: the Deviation Category will be repoted in the raw protocol deviation file and could be incluse (but not limited to) Inclusion / Exclusion criteria, ICF , etc.

[1] The denominator is the number of subjects in the Safety Population.
[2] Options are not mutually exclusive to each other. At each level of summary, each subject is only counted once.

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Table 14.1.5
Study Drug Exposure by Analysis Population
(Safety Population, Evaluable Population, PK Population)

			Safety Population (N=XX)	Evaluable Population (N=XX)	Pharmacokinetic Population (N=XX)
Total Volume Prepared (mL)		N	xx	xx	xx
		Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
Total Volume Administrated (mL)		N	xx	xx	xx
		Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
Treatment Compliance (%)		N	xx	xx	xx
		Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
Duration of Treatment Administration (min)		N	xx	xx	xx
		Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
Injection site	Right Upper Arm	n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Left Upper Arm	n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Right Upper Thigh	n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Left Upper Thigh	n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: Treatment Compliance is defined as the total volume administered / total volume prepared x 100%

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Table 14.1.6
HAV Ribonucleic Acid (RNA) at Screening
(Safety Population)

		Overall (N=XX)
Positive	n(%)	xx (xx.x)
Negative	n(%)	xx (xx.x)

PROGRAMMING NOTE: if the LBTEST=HCV Viral Load had a result showing 'NOT DETECTED', it will be considered as NEGATIVE; Otherwise, if the virus present a detected result, it will be considered as POSITIVE.

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Table 14.1.7
Prior Medications
(Safety Population)

ATC Level 2 / ATC Level 4	Overall (N=XX)
Any Medication [n(%)]	xx (xx.x)
Classification #1 [n(%)]	
Medication #1* [n(%)]	xx (xx.x)
Medication #2 [n(%)]	xx (xx.x)
Medication #3 [n(%)]	xx (xx.x)
	xx (xx.x)
Classification #2 [n(%)]	
Medication #1 [n(%)]	xx (xx.x)
Medication #2 [n(%)]	xx (xx.x)
Medication #3 [n(%)]	xx (xx.x)
Etc.	xx (xx.x)
Etc.	

Note(s): ATC= Anatomical Therapeutic Chemical.
Medication classifications are coded to ATC Levels 2 and 4 using WHO-DDE dictionary version March 1, 2017
* The higher ATC level term is used if ATC Level 2 or 4 are missing.
All medications stopped prior to the start of IP injection are included.
Each subject is only counted once at each level of summation.

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Table 14.1.8
Concomitant Medications
(Safety Population)

ATC Level 2 / ATC Level 4	Overall (N=XX)
Any Medication [n(%)]	xx (xx.x)
Classification #1 [n(%)]	
Medication #1* [n(%)]	xx (xx.x)
Medication #2 [n(%)]	xx (xx.x)
Medication #3 [n(%)]	xx (xx.x)
	xx (xx.x)
Classification #2 [n(%)]	
Medication #1 [n(%)]	xx (xx.x)
Medication #2 [n(%)]	xx (xx.x)
Medication #3 [n(%)]	xx (xx.x)
Etc.	xx (xx.x)
Etc.	

Note(s): ATC= Anatomical Therapeutic Chemical.
Medication classifications are coded to ATC Levels 2 and 4 using WHO-DDE dictionary version March 1, 2017
* The higher ATC level term is used if ATC Level 2 or 4 are missing.
All medications started on or after the start of IP injection, or taken prior to and continued after the start of IP injection are included.
Each subject is only counted once at each level of summation.

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Table 14.2.1
Percentage of Subjects Maintaining Anti-HAV Antibody Levels ⩾10 mIU/mL up to Day 60 **by Analysis Population**
(Safety Population and Evaluable Population)

		Safety Population (N=XX)	Evaluable Population (N=XX)
Subjects Maintaining Anti-HAV Antibody Levels ⩾10 mIU/mL up to Day 60	n (%)	xx (xx.x)	xx (xx.x)

Table 14.3.1.1
Overall Treatment-Emergent Adverse Events
(Safety Population)

	Statistic	Overall (N=XX)
Subjects with Any Treatment-Emergent Adverse Events (TEAEs)	N (%)	xx (xx.x)
Total Number of TEAEs	N	xxx
Subjects with Suspected Adverse Drug Reactions (ADRs)[1]	N (%)	xx (xx.x)
Total Number of Suspected ADRs	N	xxx
Subjects with Adverse Reactions (ARs) [2]	N (%)	xx (xx.x)
Total Number of ARs	N	xxx
Subjects with Serious Adverse Events (SAEs)	N (%)	xx (xx.x)
Total Number of SAEs	N	xxx
Subjects with TEAEs Leading to Discontinuation from Study	N (%)	xx (xx.x)
Total Number of TEAEs Leading to Discontinuation	N	xxx
Subjects with TEAEs with Outcome of Death	N (%)	xx (xx.x)
Total Number of Deaths	N	xxx
Subjects with Injection Site Reactions	N (%)	xx (xx.x)
Total Injection Site Reactions	N	xxx
Subjects with TEAEs during/within 24 Hours post IP Injection	N (%)	xx (xx.x)
Total Number of TEAEs during/within 24 Hours post IP Injection	N	xxx
Subjects with TEAEs during/within 72 Hours post IP Injection	N (%)	xx (xx.x)
Total Number of TEAEs during/within 72 Hours post IP Injection	N	xxx

[1] A suspected adverse drug reaction is an adverse event with investigator’s causality assessment of 'definitely related' or ‘possibly related'.
[2] An adverse reaction is a suspected adverse drug reaction with a causal relationship of “definitely related”.

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Table 14.3.1.2.2
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Population)

System Organ Class / Preferred Term	Statistic	Overall Subjects (N=XX)	Overall Events (N=XX)
Any TEAEs	N (%)	xx (xx.x)	xx (xx.x)
System Organ Class 1			
Preferred Term 1	N (%)	xx (xx.x)	xx (xx.x)
Preferred Term 2	N (%)	xx (xx.x)	xx (xx.x)
System Organ Class 2			
Preferred Term 1	N (%)	xx (xx.x)	xx (xx.x)
Preferred Term 2	N (%)	xx (xx.x)	xx (xx.x)

Notes: Adverse Events are coded using MedDRA, version 20.1.
At each level of summation, each subject is counted only once.
'N' for events in the column headers is the total number of TEAEs and is used as the denominator for all % in that column.

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Similar Tables

Table 14.3.1.2.1 Non-Treatment-Emergent Adverse Events by System Organ Class and Preferred Term

Table 14.3.1.4 Suspected Adverse Drug Reactions by System Organ Class and Preferred Term
PROGRAMMING NOTE: Note:] A suspected adverse drug reaction is an adverse event with investigator's causality assessment of 'definitely related' or 'possibly related'.

Table 14.3.1.3
Treatment-Emergent Adverse Events by Relationship to Study Drug
(Safety Population)

System Organ Class / Preferred Term		Statistic	Overall Subjects (N=XX)	Overall Events (N=XX)
Any TEAEs	Unrelated/Not Related	N (%)	xx (xx.x)	xx (xx.x)
	Possibly Related	N (%)	xx (xx.x)	xx (xx.x)
	Definitely Related	N (%)	xx (xx.x)	xx (xx.x)
System Organ Class 1	Unrelated/Not Related	N (%)	xx (xx.x)	xx (xx.x)
	Possibly Related	N (%)	xx (xx.x)	xx (xx.x)
	Definitely Related	N (%)	xx (xx.x)	xx (xx.x)
Preferred Term 1	Unrelated/Not Related	N (%)	xx (xx.x)	xx (xx.x)
	Possibly Related	N (%)	xx (xx.x)	xx (xx.x)
	Definitely Related	N (%)	xx (xx.x)	xx (xx.x)

Notes: Adverse Events are coded using MedDRA, version 20.1.
At each level of summation by subject (Overall, System Organ Class, and Preferred Term), each subject is only counted once under the greatest causality.

Date: VERSION – YYYY-MM-DD Data Source: XXXX Program Source: XXXXX.sas

Table 14.3.1.5
Treatment-Emergent Adverse Events by Severity
(Safety Population)

System Organ Class / Preferred Term		Statistic	Overall Subjects (N=XX)	Overall Events (N=XX)
Any TEAEs	Mild	N (%)	xx (xx.x)	xx (xx.x)
	Moderate	N (%)	xx (xx.x)	xx (xx.x)
	Severe	N (%)	xx (xx.x)	xx (xx.x)
System Organ Class 1	Mild	N (%)	xx (xx.x)	xx (xx.x)
	Moderate	N (%)	xx (xx.x)	xx (xx.x)
	Severe	N (%)	xx (xx.x)	xx (xx.x)
Preferred Term 1	Mild	N (%)	xx (xx.x)	xx (xx.x)
	Moderate	N (%)	xx (xx.x)	xx (xx.x)
	Severe	N (%)	xx (xx.x)	xx (xx.x)

Notes: Adverse Events are coded using MedDRA, version 20.1.
At each level of summation by subject (Overall, System Organ Class, and Preferred Term), each subject is only counted once under the greatest severity.

Date: VERSION – YYYY-MM-DD Data Source: XXXX Program Source: XXXXX.sas

Similar Table:
Table 14.3.1.8 Injection Site Reactions by Severity

Table 14.3.1.6
Treatment-Emergent Adverse Events by Seriousness
(Safety Population)

System Organ Class / Preferred Term		Statistic	Overall Subjects (N=XX)	Overall Events (N=XX)
Any TEAEs	Serious	N (%)	xx (xx.x)	xx (xx.x)
	Not Serious	N (%)	xx (xx.x)	xx (xx.x)
System Organ Class 1	Serious	N (%)	xx (xx.x)	xx (xx.x)
	Not Serious	N (%)	xx (xx.x)	xx (xx.x)
Preferred Term 1	Serious	N (%)	xx (xx.x)	xx (xx.x)
	Not Serious	N (%)	xx (xx.x)	xx (xx.x)

Notes: Adverse Events are coded using MedDRA, version 20.1.

At each level of summation by subject (Overall, System Organ Class, and Preferred Term), each subject is only counted once, and being serious has higher priority than not serious

Date: VERSION – YYYY-MM-DD Data Source: XXXX Program Source: XXXXX.sas

Table 14.3.1.7
Injection Site Reactions by Location
(Safety Population)

System Organ Class / Preferred Term		Statistic	Overall Subjects (N=XX)	Overall Events (N=XX)
Any TEAEs	Right Upper Arm	N (%)	xx (xx.x)	xx (xx.x)
	Left Upper Arm	N (%)	xx (xx.x)	xx (xx.x)
	Right Upper Thigh	N (%)	xx (xx.x)	xx (xx.x)
	Left Upper Thigh	N (%)	xx (xx.x)	xx (xx.x)
System Organ Class 1	Right Upper Arm	N (%)	xx (xx.x)	xx (xx.x)
	Left Upper Arm	N (%)	xx (xx.x)	xx (xx.x)
	Right Upper Thigh	N (%)	xx (xx.x)	xx (xx.x)
	Left Upper Thigh	N (%)	xx (xx.x)	xx (xx.x)
Preferred Term 1	Right Upper Arm	N (%)	xx (xx.x)	xx (xx.x)
	Left Upper Arm	N (%)	xx (xx.x)	xx (xx.x)
	Right Upper Thigh	N (%)	xx (xx.x)	xx (xx.x)
	Left Upper Thigh	N (%)	xx (xx.x)	xx (xx.x)

Notes: Adverse Events are coded using MedDRA, version 20.1.
At each level of summation by subject (Overall, System Organ Class, and Preferred Term), each subject is only counted once under each location.

Date: VERSION – YYYY-MM-DD Data Source: XXXX Program Source: XXXXX.sas

Table 14.3.1.9
Temporally-Associated Adverse Events
(Safety Population)

System Organ Class / Preferred Term		Statistic	Overall Subjects (N=XX)	Overall Events (N=XX)
Any TEAEs	During/Within 24 hours Post Injection	N (%)	xx (xx.x)	xx (xx.x)
	During/Within 72 hours Post Injection	N (%)	xx (xx.x)	xx (xx.x)
System Organ Class 1	During/Within 24 hours Post Injection	N (%)	xx (xx.x)	xx (xx.x)
	During/Within 72 hours Post Injection	N (%)	xx (xx.x)	xx (xx.x)
Preferred Term 1	During/Within 24 hours Post Injection	N (%)	xx (xx.x)	xx (xx.x)
	During/Within 72 hours Post Injection	N (%)	xx (xx.x)	xx (xx.x)

Notes: Adverse Events are coded using MedDRA, version 20.1.
At each level of summation by subject (Overall, System Organ Class, and Preferred Term), each subject is only counted once for each duration.
A temporally-associated AEs is defined as AEs happening during IP injection or within 24 hours following the end of IP Injection and within 72 hours following the end of IP injection

Date: VERSION – YYYY-MM-DD Data Source: XXXX Program Source: XXXXX.sas

Similar Table:
Table 14.3.1.10 Adverse Events Leading to Discontinuation

[redacted]

Table 14.3.2
Deaths and Other Serious Adverse Events
(Safety Population)

Subject ID	Injection site reaction?/ Injection Site Reaction Location / AE #	SOC/ Preferred Term/ Description of AE	Onset Date Time (Time since Start of Study Treatment[1])	Resolution Date Time (Time since Start of Study Treatment [1]) (AE Duration [2]))	S: Severity R: Relationship to IP F: Frequency	O: Outcome S: Serious AE D: AE leading to Study Discontinuation	A: Action Taken with Study Treatment ANDT: Additional Non-Drug Treatment TRT: Specify treatment C: Concomitant Given	If any, Reason for Seriousness

PROGRAMMING NOTE: Subject with SAE or ar least one Reason for Seriousness or dead will be included in this listing

Notes: Adverse Events are coded using MedDRA, version 20.1.
[1] Time since start of study treatment is presented in days if >24 hours or in hh:mm if <=24 hours.
[2] AE duration is presented in days if >24 hours or in hh:mm if <=24 hours.

Date: VERSION – YYYY-MM-DD Data Source: XXXX Program Source: XXXXX.sas

Table 14.3.3.1
Hematology
(Safety Population)

Parameter (unit)	Visit			Overall (N=XX) Actual Value	Change from Baseline
Lab Test 1					
	xxx	Value	N	xx	
			Mean (SD)	xx (xx.x)	
			Median	xx.x	
			Min, Max	xx, xx	
			IQR	xx; xx	
	xxx	Value	N	xx	
			Mean (SD)	xx (xx.x)	
			Median	xx.x	
			Min, Max	xx, xx	
			IQR	xx; xx	
	xxx	Value	N	xx	xx
			Mean (SD)	xx (xx.x)	xx (xx.x)
			Median	xx.x	xx.x
			Min, Max	xx, xx	xx, xx
			IQR	xx; xx	xx; xx
	Etc…				
Etc…					

Date: VERSION – YYYY-MM-DD Data Source: XXXX Program Source: XXXXX.sas

Similar Table:

Table 14.3.3.2 Chemistry
Table 14.3.3.3 Urinalysis

Table 14.3.3.4
Shift from Baseline for Hematology
(Safety Population)

			Baseline Result			
Parameter (unit)	Post-Baseline Visit	Result	Low n(%)	Normal n(%)	High n(%)	Total n(%)
xxxx	xxxx	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note(s): Only patients with a baseline result and post-baseline visit result are included.
For each parameter, percentages are based on total number of subjects with available results at both the baseline and the corresponding visit.

Date: VERSION – YYYY-MM-DD Data Source: XXXX Program Source: XXXXX.sas

Similar Table:

Table 14.3.3.5 Shift from Baseline for Chemistry
Table 14.3.3.6 Shift from Baseline for Urinalysis

Table 14.3.4
Vital Signs
(Safety Population)

Parameter (unit)	Visit	Timepoint			Overall (N=XX) Actual Value	Overall (N=XX) Change from Baseline
Systolic Blood Pressure (mmHg)	xxx		Value	N	xx	
				Mean (SD)	xx (xx.x)	
				Median	xx.x	
				Min, Max	xx, xx	
	xxx		Value	N	xx	
				Mean (SD)	xx (xx.x)	
				Median	xx.x	
				Min, Max	xx, xx	
	xxx	Pre-Dose	Value	N	xx	
				Mean (SD)	xx (xx.x)	
				Median	xx.x	
				Min, Max	xx, xx	
		60 Minutes Post-Dose	Value	N	xx	xx
				Mean (SD)	xx (xx.x)	xx (xx.x)
				Median	xx.x	xx.x
				Min, Max	xx, xx	xx, xx
	Etc.					
Etc.						

PROGRAMMING NOTE: All visits outlined in Appendix A will be included.

Date: VERSION – YYYY-MM-DD Data Source: XXXX Program Source: XXXXX.sas

APPENDIX C

LISTING SHELLS

Listing 16.2.1
Study Disposition
(All Subjects)

Subject ID	Re-Screened Subject? / Previous Subject ID	Date of Completion or Discontinuation (Study Day)	Subject Status	Specify	AE #	Date of Death

Note: Study Day is relative to the start of study treatment.

Date: VERSION – YYYY-MM-DD Data Source: XXXX Program Source: XXXXX.sas

Listing 16.2.2
Protocol Deviations
(Safety Population)

Subject ID	Deviation Category	Description	Deviation Criteria	Severity	Action Taken	Start Date (Study Day)

Note: Study Day is relative to the start of study treatment.

Date: VERSION – YYYY-MM-DD Data Source: XXXX Program Source: XXXXX.sas

[redacted]

Listing 16.2.3
Analysis Populations

Subject ID	Safety Population	Reason of Exclusion of the Safety Population	Evaluable Population	Reason of Exclusion of the Evaluable Population	PK Population	Reason of Exclusion of the PK population

Listing 16.2.4.1
Demographic Characteristics
(Safety Population)

Subject ID	Age (years)	Gender	Ethnicity	Race/ Other Race	Weight (kg)	Height (cm)	BMI (kg/m^2)

Date: VERSION – YYYY-MM-DD Data Source: XXXX Program Source: XXXXX.sas

[redacted]

Listing 16.2.4.2
Medical History
(Safety Population)

Subject ID	MH #	SOC Preferred Term Description of MH	Start Date (Study Day)	Currently taking medication for this condition ?	End Date (Study Day)	MD Safety Review [1]

[1] NCS: Not Clinically Significant / CS: Clinically Significant
Note: Medical History is classified using MedDRA, version 20.1.
Study Day is relative to the start of study treatment.

Date: VERSION – YYYY-MM-DD Data Source: XXXX Program Source: XXXXX.sas

Listing 16.2.4.3
Contraceptive Methods
(Safety Population)

Subject ID	Category	Contraceptive Method

PROGRAMMING NOTE: The category will correspond to Childbearing Potential, Birth Control Method and Non-Childbearing Birth Control Method

Date: VERSION – Data Source: XXXX
YYYY-MM-DD

Program Source: XXXXX.sas

Listing 16.2.5
Investigational Product Administration
(Safety Population)

Subject ID	Visit	Start Date/Time (Study Day)	End Date/Time (Study Day)	Treatment	Dose Administered	Route of Administration	Injection Site	% Volume Administered	Volumne Administered per Injection Site (mL)	Needle Size	Total volume Prepared (mL)/Total Volume Administered (mL)	Comment

Note: Percentage of Volume Administered is defined as follow: (Volume Administered (mL)/ Volume Prepared (mL)*100
Study Day is relative to the start of study treatment.

Date: VERSION – YYYY-MM-DD Data Source: XXXX Program Source: XXXXX.sas

[redacted]

Listing 16.2.7
Adverse Events
(Safety Population)

Subject ID	Injection site reaction?/ Injection Site Reaction Location / AE #	SOC/ Preferred Term/ Description of AE	Onset Date Time (Time since Start of Study Treatment [1])	Resolution Date Time (Time since Start of Study Treatment [1]) (AE Duration [2])	S: Severity R: Relationship to IP F: Frequency	O: Outcome S: Serious AE D: AE leading to Study Discontinuation	A: Action Taken with Study Treatment ANDT: Additional Non-Drug Treatment TRT: Specify treatment C: Concomitant Given	If any, Reason for Seriousness

Note: Adverse Events as coded using MedDRA, version 20.1.
[1] Time since start of study treatment is presented in days if >24 hours or in hh:mm if <=24 hours.
[2] AE duration is presented in days if >24 hours or in hh:mm if <=24 hours.

Date: VERSION – YYYY-MM-DD Data Source: XXXX Program Source: XXXXX.sas

Listing 16.2.8.1
Chemistry
(Safety Population)

Subject ID	Visit	Collection Date/Time	Parameter (Unit)	Reference Range	Value	Change From Baseline	Flag

Date: VERSION – YYYY-MM-DD Data Source: XXXX Program Source: XXXXX.sas

L16.2.8.2 Hematology
L16.2.8.3 Urinalysis
L16.2.8.4 Coagulation
L16.2.8.5 Virus Safety (Serology and NAT) Lab
L16.2.8.6 Urine Drug Screen
L16.2.8.7 Pregnancy Test

Listing 16.2.8.8
Prior and Concomitant Medications
(Safety Population)

Subject ID	CM#/ Prior or Concomitant?	Related to AE#/ MH#	ATC Level 2 / ATC Level 4 / Medication Name	Indication	Dose (unit)	Frequency	Formulation	Route	Start Date/Time (Study Day)	End Date/Time (Study Day)

Note: Medication classifications are coded to ATC Levels 2 and 4 using the WHO-DDE dictionary, Version March 1, 2017. The higher ATC level term is used if ATC Level 2 or 4 are missing.

Study Day is relative to the start of study treatment.

Date: VERSION – YYYY-MM-DD Data Source: XXXX Program Source: XXXXX.sas

Listing 16.2.8.9
Physical Examination
(Safety Population)

Subject ID	Visit	Date/Time	Assessment	Result (Abnormal Findings) [1]

[1] NCS: Not Clinically Significant / CS: Clinically Significant

Date: VERSION – YYYY-MM-DD Data Source: XXXX Program Source: XXXXX.sas

[redacted]

Listing 16.2.8.10
Vital Signs
(Safety Population)

Subject ID	Visit	Position	Date/Time	Assessment (Unit)	Range	Value	Change From Baseline	Safety Review [1]

[1] NCS: Not Clinically Significant / CS: Clinically Significant

Date: VERSION – YYYY-MM-DD Data Source: XXXX Program Source: XXXXX.sas

Listing 16.2.8.11
Electrocardiogram Assessments
(Safety Population)

Subject ID	Visit	Date/Time	Position	Parameter (Unit)	Result[1]
xxxxx	xxxxxx	YYYY-MM-DD/HH:MM	xxxxxx	ECG Parameter 1	xx. x
			xxxxxx	ECG Parameter 2	xx.x
			xxxxxx	Etc.	xx.x
				Interpretation	xx.x
		YYYY-MM-DD/HH:MM	xxxxxx	xxxxxx	xx.x
		YYYY-MM-DD/HH:MM	xxxxxx	xxxxxx	xx.x
xxxxx	xxxxxx	YYYY-MM-DD/HH:MM	xxxxxx	xxxxxx	xx.x
xxxxx	xxxxxx	YYYY-MM-DD/HH:MM	xxxxxx	Xxxxxx	xx.x

[1] NCS: Not Clinically Significant / CS: Clinically Significant

Date: VERSION – YYYY-MM-DD Data Source: XXXX Program Source: XXXXX.sas

APPENDIX D

SHELLS (FROM WINNONLIN)

Table 14.2.2.1 Anti-HAV antibody Serum Baseline Uncorrected Concentrations by Analysis Population (Safety Population, Evaluable Population, PK Population)

Population	Parameter	Pre Injection	1Hour	12 Hours	24 Hours	48 Hours	...	2736 Hours	3576 Hours
Safety Population	N								
	Mean								
	SD								
	Min								
	Median								
	Max								
	CV%								
	CI 90% Lower								
	CI 90% Upper								
	Geometric Mean								
Evaluable Population	N								
	Mean								
	SD								
	Min								
	Median								
	Max								
	CV%								
	CI 90% Lower								
	CI 90% Upper								
	Geometric Mean								

PK Population	N
	Mean
	SD
	Min
	Median
	Max
	CV%
	CI 90% Lower
	CI 90% Upper
	Geometric Mean

Similar Table(s):
Table 14.2.2.2 Anti-HAV antibody Serum Baseline Corrected Concentrations by Analysis Population (Safety Population, Evaluable Population, PK Population)

[redacted]

Table 14.2.3.1 Baseline Uncorrected PK parameters of Anti-HAV Antibody (PK Population)

Parameter	$AUC_{0-\infty}$	AUC_{0-T}	C_{max}	T_{max}	T_{half}	Cl_{TOT}/F	V_D/F	λz
N								
Mean								
SD								
Min								
Median								
Max								
CV%								
Geometric Mean								
CV% Geometric Mean								
CI 90% Lower								
CI 90% Upper								
CI 90% Lower GEO Mean								
CI 90% Upper GEO Mean								

Similar Table(s):
Table 14.2.3.2 Baseline Corrected PK parameters of Anti-HAV Antibody (PK Population)

[redacted]

Listing 16.2.6.1 Individual Serum Baseline Uncorrected Concentration Data of Anti-HAV antibody by Timepoint Following a Single 0.2 mL/kg Intramuscular injection Administration of GamaSTAN in HAV-seronegative healthy subjects (Safety Population)

Subject	Scheduled Timepoint	Date	Time	Nominal Time (units)	Actual Elapsed Time (units)	Time Deviation	Concentration (units)

Similar Listing(s)
Listing 16.2.6.2 Individual Serum Baseline Corrected Concentration Data of Anti-HAV antibody by Timepoint Following a Single 0.2 mL/kg Intramuscular injection Administration of GamaSTAN in HAV-seronegative healthy subjects (Safety Population)

Listing 16.2.6.3 Individual Serum Baseline Uncorrected PK parameters of Anti-HAV antibody Following a Single 0.2 mL/kg Intramuscular injection Administration of GamaSTAN in HAV-seronegative healthy subjects (PK Population)

Subject	$AUC_{0-\infty}$ (units)	AUC_{0-T} (units)	C_{max} (units)	T_{max} (units)	T_{half} (units)	Cl_{TOT}/F (units)	V_D/F (units)	λz (units)

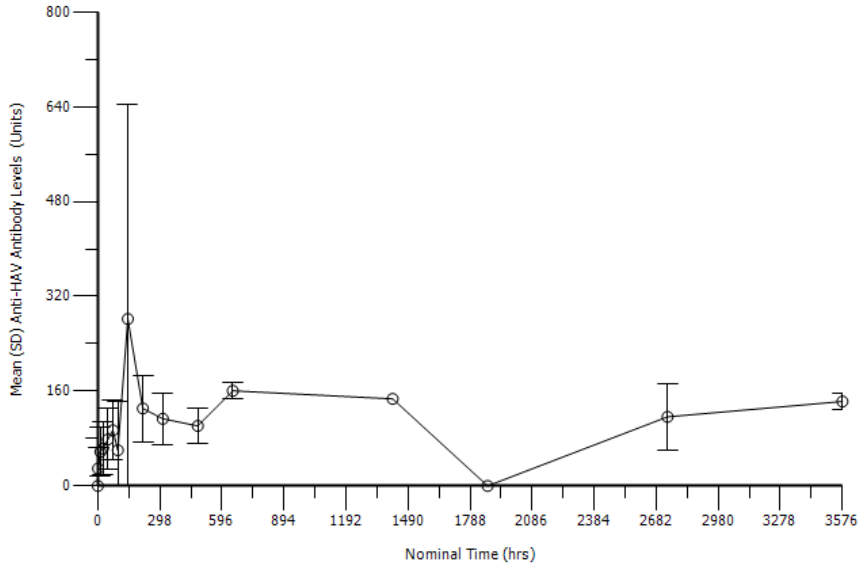
Listing 16.2.6.3 Individual Serum Baseline Uncorrected PK parameters of Anti-HAV antibody Following a Single 0.2 mL/kg Intramuscular injection Administration of GamaSTAN in HAV-seronegative healthy subjects (PK Population) (Cont'd)

Subject	Number of Point	R^2	T_{LIN} (Unit)	T_{LQC} (unit)	$AUC_{\%Extrap}$ (Unit)

Similar Listing(s):
Listing 16.2.6.4 Individual Serum Baseline Corrected PK parameters of Anti-HAV antibody Following a Single 0.2 mL/kg Intramuscular injection Administration of GamaSTAN in HAV-seronegative healthy subjects (PK Population)

Section 14.2.6 Mean PK Figures

Figure 14.2.6.1.1 Mean Serum Baseline Uncorrected Concentration-Time Profile of Anti-HAV antibody Following a Single 0.2 mL/kg Intramuscular injection Administration of GamaSTAN in HAV-seronegative healthy subjects (PK Population) - Linear Scale



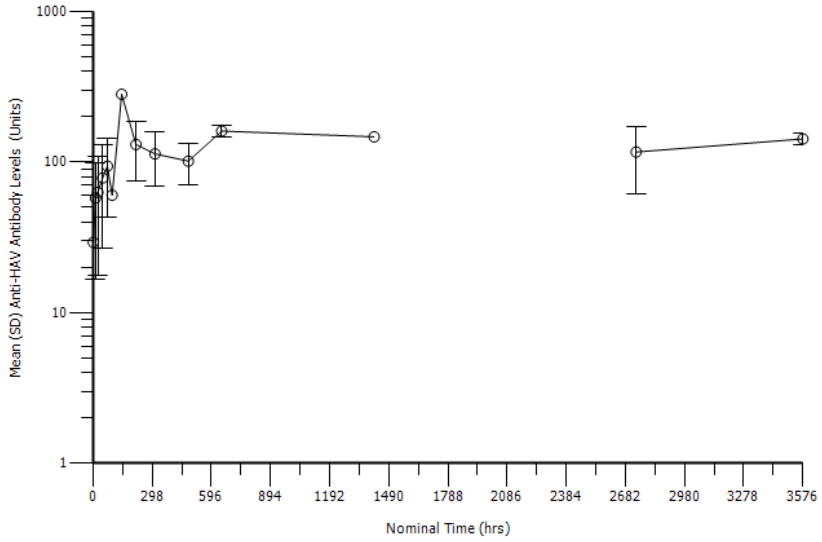
Similar Figure(s):

Figure 14.2.6.1.3 Mean Serum Baseline Corrected Concentration-Time Profile of Anti-HAV antibody Following a Single 0.2 mL/kg Intramuscular injection Administration of GamaSTAN in HAV-seronegative healthy subjects (PK Population) – Linear Scale

Figure 14.2.6.2.1 Median Serum Baseline Uncorrected Concentration-Time Profile of Anti-HAV antibody Following a Single 0.2 mL/kg Intramuscular injection Administration of GamaSTAN in HAV-seronegative healthy subjects (PK Population) – Linear Scale

Figure 14.2.6.2.3 Median Serum Baseline Corrected Concentration-Time Profile of Anti-HAV antibody Following a Single 0.2 mL/kg Intramuscular injection Administration of GamaSTAN in HAV-seronegative healthy subjects (PK Population) – Linear Scale

Figure 14.2.6.1.2 Mean Serum Baseline Uncorrected Concentration-Time Profile of Anti-HAV antibody Following a Single 0.2 mL/kg Intramuscular injection Administration of GamaSTAN in HAV-seronegative healthy subjects (PK Population) – Semi-Log Scale



Note: The figures do not reflect the actual data of the study.

Similar Figure(s):

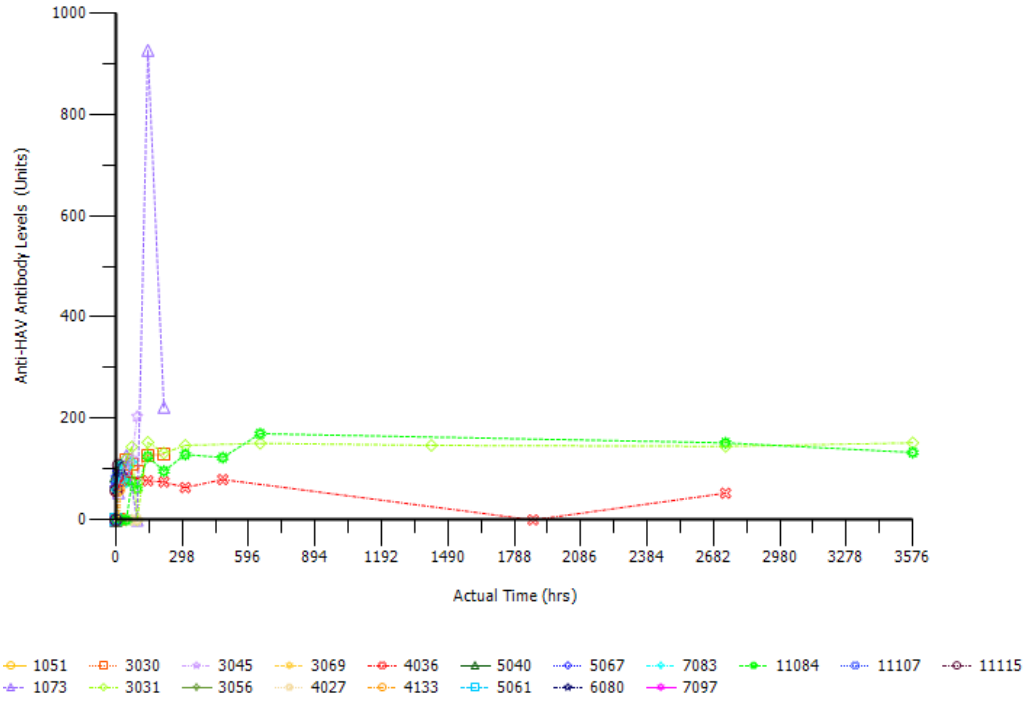
Figure 14.2.6.1.4 Mean Serum Baseline Corrected Concentration-Time Profile of Anti-HAV antibody Following a Single 0.2 mL/kg Intramuscular injection Administration of GamaSTAN in HAV-seronegative healthy subjects (PK Population) – Semi-Log Scale

Figure 14.2.6.2.2 Median Serum Baseline Uncorrected Concentration-Time Profile of Anti-HAV antibody Following a Single 0.2 mL/kg Intramuscular injection Administration of GamaSTAN in HAV-seronegative healthy subjects (PK Population) – Semi-Log Scale

Figure 14.2.6.2.4 Median Serum Baseline Corrected Concentration-Time Profile of Anti-HAV antibody Following a Single 0.2 mL/kg Intramuscular injection Administration of GamaSTAN in HAV-seronegative healthy subjects (PK Population) – Semi-Log Scale

[redacted]

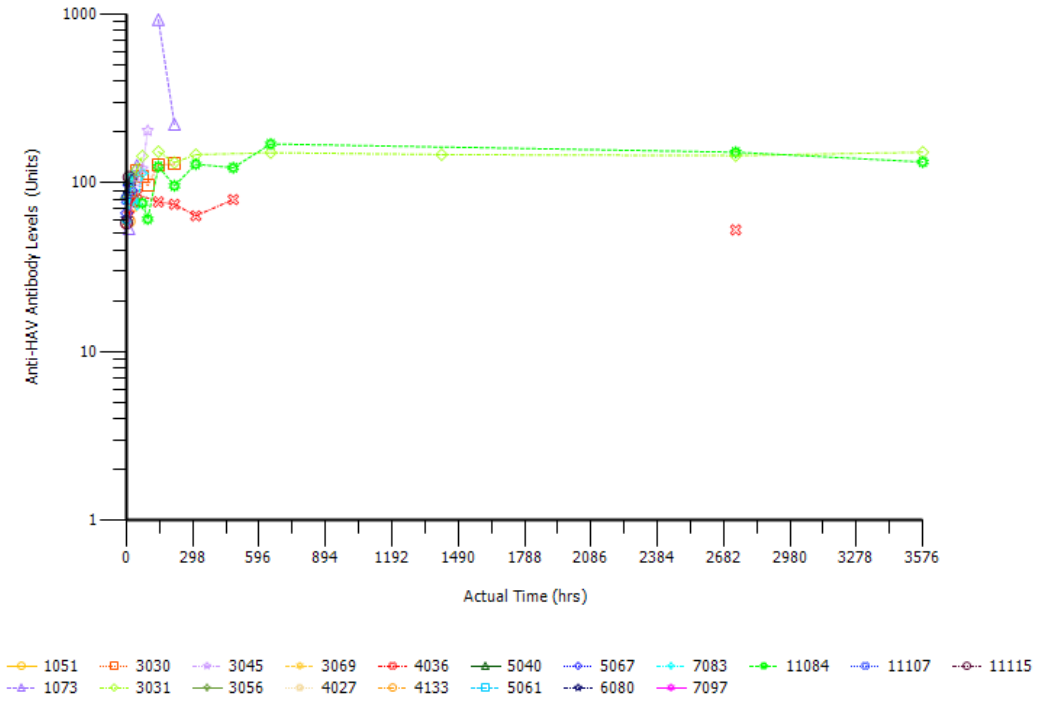
Figure 14.2.6.3.1 Individual Serum Baseline Uncorrected Concentration-Time Profile of Anti-HAV antibody Following a Single 0.2 mL/kg Intramuscular injection Administration of GamaSTAN in HAV-seronegative healthy subjects (PK Population) – Linear Scale



Similar Figure(s):

Figure 14.2.6.3.3 Individual Serum Baseline Corrected Concentration-Time Profile of Anti-HAV antibody Following a Single 0.2 mL/kg Intramuscular injection Administration of GamaSTAN in HAV-seronegative healthy subjects (PK Population) – Linear Scale

Figure 14.2.6.3.2 Individual Serum Baseline Uncorrected Concentration-Time Profile of Anti-HAV antibody Following a Single 0.2 mL/kg Intramuscular injection Administration of GamaSTAN in HAV-seronegative healthy subjects (PK Population) – Semi-Log Scale



Similar Figure(s):

Figure 14.2.6.3.4 Individual Serum Baseline Corrected Concentration-Time Profile of Anti-HAV antibody Following a Single 0.2 mL/kg Intramuscular injection Administration of GamaSTAN in HAV-seronegative healthy subjects (PK Population) – Semi-Log Scale

16.1.9.2 Statistical Output

Not applicable.