Table/Figure/Listing Shells

A RANDOMIZED, DOUBLE-BLIND, SINGLE-DOSE, THREE-ARM, PARALLEL-GROUP, PHASE 1 STUDY TO COMPARE PHARMACOKINETIC AND SAFETY OF TRS003 TO CHINA-APPROVED BEVACIZUMAB AND US-LICENSED AVASTIN, WHEN ADMINISTERED INTRAVENOUSLY TO HEALTHY MALE SUBJECTS

Sponsor Study No. TRS00301001
inVentiv Health Clinique Inc. Project No. 182013

Final Version: 1.0

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SIGNATURES

Sponsor Study No.: TRS00301001

inVentiv Project No.: 182013

Study Title: A Randomized, Double-Blind, Single-Dose, Three-Arm, Parallel-Group, Phase 1 Study to Compare Pharmacokinetic and Safety of TRS003 to China-Approved Bevacizumab and US-Licensed Avastin, When Administered Intravenously to Healthy Male Subjects.

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TABLE OF CONTENTS

1. Tables, Figures and Data Listings Formatting

The table, figure, and data listing (TFL) shells are presented in order to provide a framework for displaying the study data. The shells may change due to unforeseen circumstances. The shells may not be truly representative of every aspect of the study (e.g., sampling time points, assessed laboratory parameters, calculated parameters, units), but are intended to illustrate the general layout of the tables, figures, and data listings that will be included in the final report.

The default tables, listings, and figures layout will be as presented in Table 1-1:

Table 1-1 Layout Specifications

Orientation	Portrait	Landscape
Paper Size	Letter	Letter
Margins	Top: 3.05 cm Bottom: 2.54 cm Left: 2.54 cm Right: 2.54 cm	Top: 3.05 cm Bottom: 2.2 cm Left: 1.9 cm Right: 1.9 cm
Font	Table text: Times new Roman 9 or 10 pts Table title: Times new Roman 12 pts Table legend: Times new Roman 10 pts	

The font size may be reduced as necessary to allow additional columns to be presented, but not at the expense of clarity. Also the orientation may be changed to portrait if appropriate.

Except for pharmacokinetic (PK) tables, descriptive statistics for minimum and maximum will be presented with the same decimal digits as the original values, and with one more decimal place than the original data for mean, standard Deviation, and median. For PK tables, the data presentation will be as per the appropriate inVentiv SOP.

2. Summary TFLs

Table 2-1 List of Table Shells

Table Number	Title
	In-Text Table
10.1-1	Subject Disposition
11.4.2.3-1	Summary of Pharmacokinetic Parameters– PK Population
11.4.2.3-2	Ratios (A/B and C/B), 90% Geometric Confidence Intervals, Inter-Subjects CV (%) and P-value – PK Population
11.4.2.3-3	Ratios (A/C), 90% Geometric Confidence Intervals, Inter-Subjects CV (%) and P-value – PK Population
	Demographic Data Summary Tables
14.1-1	Summary of Demographic Characteristics of Subjects Included in the Safety Population
14.1-2	Summary of Demographic Characteristics of Subjects Included in the Pharmacokinetic Population
	Pharmacokinetic Tables
14.2.1-1	Descriptive Statistics of Bevacizumab Plasma Concentration over Nominal Time by Treatment - PK Population
14.2.1-2	Descriptive Statistics of Bevacizumab Pharmacokinetic Parameters by Treatment - PK Population
14.2.1-3	Ratios (A/B, A/C and C/B), 90% Geometric Confidence Intervals, Inter-Subjects CV (%) and P-value – PK Population
	Safety Data Summary Tables
14.3.1-1	Frequency of Subjects Experiencing Treatment-Emergent Adverse Events and Number of Events Summarized per Treatment – Safety Population
14.3.1-2	Frequency of Subjects Experiencing Treatment-Emergent Adverse Events Summarized per Treatment and Severity – Safety Population
14.3.1-3	Number of Treatment-Emergent Adverse Events Summarized per Treatment and Severity – Safety Population
14.3.1-4	Frequency of Subjects Experiencing Treatment-Emergent Adverse Events Summarized per Treatment and Relationship – Safety Population
14.3.1-5	Number of Treatment-Emergent Adverse Events Summarized per Treatment and Relationship – Safety Population
14.3.4-1	Biochemistry Summary Descriptive Statistics – Safety Population
14.3.4-2	Frequency of Subjects – Biochemistry Shifts from Baseline – Safety Population
14.3.4-3	Hematology Summary Descriptive Statistics – Safety Population
14.3.4-4	Frequency of Subjects – Hematology Shifts from Baseline – Safety Population
14.3.4-5	Urinalysis (pH and Specific Gravity) Summary Descriptive Statistics – Safety Population

Table 2-2 List of Figures Shells

Figure Number*	Title
14.2.2-1a to 14.2.2-114a**	Plasma Concentrations for Subject XX - Linear Scale
14.2.2-1b to 14.2.2-114b**	Plasma Concentrations for Subject XX - Semi-Log Scale
14.2.2-115a	Mean (± SD) Plasma Concentrations - Linear Scale
14.2.2-115b	Mean (± SD) Plasma Concentrations - Semi-Log Scale
14.2.2-116a	Overlay of Individual and Mean Plasma Concentrations by Treatment - Linear Scale
14.2.2-116b	Overlay of Individual and Mean Plasma Concentrations by Treatment - Semi-Log Scale

* Depending on the number of subjects included in the PK population, the figure numbering presented here may change in the report.

** Similar figures will be presented for each subject who received study medication

Table 2-3 List of Data Listings Shells

Listing Number	Title
	Documentation of Statistical Methods
16.1.9-1	ANOVA for Treatment Comparisons (A/B, A/C and B/C) – PK Population
16.1.9-2	Wilcoxon Rank Sum Test for T_{max} for Treatment Comparisons (A/B, A/C and B/C) – PK Population
	Subject Characteristics Listings
16.2.1-1	Subjects Completion and Discontinuation Information
16.2.2-1	Protocol Deviations
16.2.4-1	Demographics
16.2.4-2	Medical History Findings at Screening
16.2.4-3	Prior and Concomitant Medications
16.2.4-4	Study Drug Administration
	PK Data Listings
16.2.6-1	Listing of Individual Actual Sampling Times and Pharmacokinetic Concentrations
16.2.6-2	Listing of Individual Pharmacokinetic Parameters
	Safety Data Listings
16.2.7-1	Treatment-Emergent Adverse Events
16.2.7-2	Serious Adverse Events
16.2.8-1	Clinical Laboratory – Biochemistry
16.2.8-2	Clinical Laboratory – Hematology
16.2.8-3	Clinical Laboratory – Urinalysis
16.2.8-4	Vital Signs Result
16.2.8-5	Electrocardiogram Result
16.2.8-6	Immunogenicity Assessment

3. CSR In-text Tables

Table 10.1-1 Subject Disposition

Category	TRS003, 3 mg/kg IV Infusion Dose (A)	China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose (B)	US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose (C)	Overall
Screened	-	-	-	xx
Screening Failures[1,2]	-	-	-	x (xx.x)
Not Enrolled[1,3]	-	-	-	x (xx.x)
Enrolled[1,4]	-	-	-	x (xx.x)
Dosed	xx	xx	xx	xx
Not Dosed	xx	xx	xx	xx
Completed[5]	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
Number of Subjects Discontinued[7]	xx	xx	xx	xx
Primary Reason for Discontinuation[7, 8]				
Adverse Event	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
Death	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
Pregnancy	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
Protocol Deviation	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
Lost to Follow-up	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
Study Terminated by Sponsor	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
Non-Compliance with Study Drug	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
Withdrawal by Subject	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
Physician Decision	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
Other	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)

[1] Percentage based on the number of screened subjects.
[2] Screening failures include volunteers who did not meet project criteria.
[3] Not enrolled include volunteers who were judged eligible but decided not to participate on study or who were not selected to participate in the study since there was already a sufficient number of subjects.
[4] Enrolled include volunteers who were judged eligible and accepted to participate in the trial after having signed the approved final version of the study informed consent

form and also those identified as standby who may replace subjects who withdraw from the study before dosing.
[5] Percentage based on the number of dosed subjects for a given treatment.
[6] Percentage based on the overall number of subjects dosed (safety population).
[7] Overall, each subject could only contribute once to each reason for discontinuation, regardless of the number of occurrences.
[8] Percentage based on the number of discontinued subjects per treatment group or overall, as appropriate.

Data source: Listings 16.2.1-1 and 16.2.4-4.

Table 11.4.2.3-1 Summary of Pharmacokinetic Parameters – PK Population

Parameter (unit)	TRS003, 3 mg/kg IV Infusion Dose (A)				China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose (B)				US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose (C)			
	N	Mean	SD	CV%	N	Mean	SD	CV%	N	Mean	SD	CV%
AUC_{0-t} (h*pg/mL) AUC_{0-inf} (h*pg/mL) Residual area (%) C_{max} (pg/mL) $T_{½\ el}$ (h) K_{el} (/h) Cl (L/h) V_d (L)												
Parameter (unit)	TRS003, 3 mg/kg IV Infusion Dose (A)				China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose (B)				US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose (C)			
	N	Median	Min	Max	N	Median	Min	Max	N	Median	Min	Max
T_{max} (h)												

N: Number of observations; SD: Standard Deviation; CV%: Coefficient of Variation; Min: Minimum; Max: Maximum; '-': Not calculated.

Table 11.4.2.3-2 Ratios (A/B and C/B), 90% Geometric Confidence Intervals, Inter-Subjects CV (%) and p-value – PK Population

Comparison (Trt1 vs Trt2)	Parameter (unit)	Geometric LSM		Ratio[1]	90% Geometric C.I.[2]		Inter-Subject CV (%)[3]	p-value
		Trt1	Trt2	Trt1/Trt2 (%)	Lower (%)	Upper (%)		Treatment
A vs B	AUC_{0-t} (h*pg/mL)							
	AUC_{0-inf} (h*pg/mL)							
	C_{max} (pg/mL)							
…								

[1] Calculated using least-squares means according to the formula: $\exp^{(DIFFERENCE)} * 100$.
[2] 90% Geometric Confidence Interval calculated according to the formula: $\exp^{(DIFFERENCE \pm t_{(dfResidual)} * SE_{DIFFERENCE})} * 100$.
[3] Calculated according to formula: SQRT ($\exp^{(MSE)}$ - 1) * 100.
LSM: Least Square Mean; Trt: Treatment.
Probability (p) values are derived from Type III sums of squares; p-value for the treatment effect is tested against the residual mean square error.
Treatment A: TRS003, 3 mg/kg IV Infusion Dose; Treatment B: China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose;
Treatment C: US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose.

Note: This table will be repeated for Table 11.4.2.3-3. Please adapt title and treatment footnotes accordingly.

4. Summary Tables

Table 14.1-1 Summary of Demographic Characteristics of Subjects Included in the Safety Population

Category	Statistic	TRS003, 3 mg/kg IV Infusion Dose (A)	China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose (B)	US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose (C)
Age (years)	N	xx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Min, Max	xx-xx	xx-xx	xx-xx
Age Groups				
<18	n (%)	x (xx.x)	x (xx.x)	x (xx.x)
18-40	n (%)	x (xx.x)	x (xx.x)	x (xx.x)
> 40	n (%)	x (xx.x)	x (xx.x)	x (xx.x)
Ethnicity				
Not Hispanic or Latino	n (%)	x (xx.x)	x (xx.x)	x (xx.x)
Hispanic or Latino	n (%)	x (xx.x)	x (xx.x)	x (xx.x)
Race				
White	n (%)	x (xx.x)	x (xx.x)	x (xx.x)
Black	n (%)	x (xx.x)	x (xx.x)	x (xx.x)
Asian	n (%)	x (xx.x)	x (xx.x)	x (xx.x)
Am Indian	n (%)	x (xx.x)	x (xx.x)	x (xx.x)
Hawaiian	n (%)	x (xx.x)	x (xx.x)	x (xx.x)
Multi-racial	n (%)	x (xx.x)	x (xx.x)	x (xx.x)
Other	n (%)	x (xx.x)	x (xx.x)	x (xx.x)
Height (cm)	N	xx	xx	xx
	Mean	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx
	Min, Max	xx.xx-xx.xx	xx.xx-xx.xx	xx.xx-xx.xx

Weight (kg)	N	xx	xx	xx
	Mean	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx
	Min, Max	xx.xx-xx.xx	xx.xx-xx.xx	xx.xx-xx.xx
BMI (kg/m^2)	N	xx	xx	xx
	Mean	xx.xxx	xx.xxx	xx.xxx
	SD	xx.xxx	xx.xxx	xx.xxx
	Median	xx.xxx	xx.xxx	xx.xxx
	Min, Max	xx.xx-xx.xx	xx.xx-xx.xx	xx.xx-xx.xx

Programming Note:
1) Refer to the note below for additional instructions

N: Number of subjects dosed; n (%): Number and percent of subjects; SD: Standard Deviation.
Am Indian: American Indian or Alaskan Native; Black: Black or African American; Hawaiian: Native Hawaiian or Pacific Islander;
BMI: Body Mass Index.
Last results (scheduled or unscheduled) obtained at screening were used to generate this table.
Data source: Listing 16.2.4-1

Note: This table will be repeated for Table 14.1-2. Please adapt title and treatment footnotes accordingly.

Table 14.2.1-1 Descriptive Statistics for Bevacizumab Plasma Concentration over Nominal Time by Treatment – PK Population

Treatment	Nominal Time	Time Unit	N	Mean	SD	CV%	Min	Median	Max	Geometric Mean	Concentration Unit
A	Pre-dose	h									
	0.000 (at EOI)	h									
	0.500	h									
	4.00	h									
	8.00	h									
	24.0	h									
	48.0	h									
	96.0	h									
	168	h									
	336	h									
	672	h									
	1008	h									
	1344	h									
	1680	h									
	2016	h									

…

N: Number of observations; SD: Standard Deviation; CV%: Coefficient of Variation; Min: Minimum; Max: Maximum; '-': Not Calculated; EOI: End of infusion.
Treatment A: TRS003, 3 mg/kg IV Infusion Dose; Treatment B: China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose;
Treatment C: US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose.
Data source: Listing 16.2.6-1

Table 14.2.1-2 Descriptive Statistics of Pharmacokinetic Parameters by Treatment – PK Population

Treatment	Parameter(unit)	N	Mean	SD	CV%	Min	Median	Max	Geometric Mean
A	AUC_{0-t} (pg*h/mL)								
	AUC_{0-inf} (pg*h/mL)								
	Residual Area (%)								
	C_{max} (pg/mL)								
	T_{max} (h)								
	$T_{1/2\ el}$ (h)								
	K_{el} (/h)								
	$K_{el\ Lower}$ (/h)								
	$K_{el\ Upper}$ (/h)								
	Cl (L/h)								
	V_d (L)								
	…								
…									

N: Number of observations; SD: Standard Deviation; CV%: Coefficient of Variation; Min: Minimum, Max: Maximum; '-': Not calculated.
Treatment A: TRS003, 3 mg/kg IV Infusion Dose; Treatment B: China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose;
Treatment C: US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose.
Data source: Listing 16.2.6-2

Table 14.2.1-3 Ratios (A/B, A/C and C/B), 90% Geometric Confidence Intervals, Inter-Subjects CV (%) and P-value – PK Population

Comparison (Trt1 vs.Trt2)	Parameter(unit)	Geometric LSM		Ratio[1] (Trt1/Trt2) (%)	90% Geometric C.I.[2]		Inter-Subject CV (%)[3]	p-value
		Trt1	Trt2		Lower (%)	Upper (%)		Treatment
A vs B	AUC_{0-t} (h*pg/mL)							
	AUC_{0-inf} (h*pg/mL)							
	C_{max} (pg/mL)							
A vs C	AUC_{0-t} (h*pg/mL)							
	AUC_{0-inf} (h*pg/mL)							
	C_{max} (pg/mL)							
C vs B	AUC_{0-t} (h*pg/mL)							
	AUC_{0-inf} (h*pg/mL)							
	C_{max} (pg/mL)							

[1] Calculated using least-squares means according to the formula: $\exp^{(DIFFERENCE)} * 100$.
[2] 90% Geometric Confidence Interval calculated according to the formula: $\exp^{(DIFFERENCE \pm t_{(dfResidual)} * SE_{DIFFERENCE})} * 100$.
[3] Calculated according to formula: SQRT ($\exp^{(MSE)}$ - 1) * 100.
LSM: Least Square Mean; Trt: Treatment.
Treatment A: TRS003, 3 mg/kg IV Infusion Dose; Treatment B: China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose;
Treatment C: US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose.
Data Source: Listing 16.1.9-1

Table 14.3.1-1 Frequency of Subjects Experiencing Treatment-Emergent Adverse Events and Number of Events Summarized per Treatment – Safety Population

MedDRA® System Organ Class MedDRA® Preferred Term	Statistic	TRS003, 3 mg/kg IV Infusion Dose (N=XX)	China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose (N=XX)	US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose (N=XX)	Overall (N=XX)
Number of TEAEs	E	xx	xx	xx	xx
Number of Subjects with TEAEs	n (%)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
MedDRA® System Organ Class 1	n(%) E	x (xx.x) x	x (xx.x) x	x (xx.x) x	x (xx.x) x
MedDRA® Preferred Term 1	n(%) E	x (xx.x) x	x (xx.x) x	x (xx.x) x	x (xx.x) x
MedDRA® Preferred Term 2	n(%) E	x (xx.x) x	x (xx.x) x	x (xx.x) x	x (xx.x) x
MedDRA® System Organ Class 2	n(%) E	x (xx.x) x	x (xx.x) x	x (xx.x) x	x (xx.x) x
MedDRA® Preferred Term 1	n(%) E	x (xx.x) x	x (xx.x) x	x (xx.x) x	x (xx.x) x
MedDRA® Preferred Term 2	n(%) E	x (xx.x) x	x (xx.x) x	x (xx.x) x	x (xx.x) x
MedDRA® System Organ Class 3	n(%) E	x (xx.x) x	x (xx.x) x	x (xx.x) x	x (xx.x) x
MedDRA® Preferred Term 1	n(%) E	x (xx.x) x	x (xx.x) x	x (xx.x) x	x (xx.x) x
MedDRA® Preferred Term 2	n(%) E	x (xx.x) x	x (xx.x) x	x (xx.x) x	x (xx.x) x

Programming Notes:
1) SOC will be presented in descending order of overall incidence rate in terms of frequency of subjects and then in frequency of events (alphabetical order will be used in case of equal rates). For each SOC, PT will be presented the same way.
2) Refer to footnotes for additional instructions.

E: Number of TEAEs; N: Number of subjects dosed; n (%): Number and percent of subjects with TEAE; MedDRA®: Medical Dictionary for Regulatory Activities, version 21.0; TEAEs: Treatment-Emergent Adverse Events.
Each subject could only contribute once to each of the incidence rates, regardless of the number of occurrences.
Overall: Included results from all treatment groups.
Data source: Listing 16.2.7-1

Table 14.3.1-2 Frequency of Subjects Experiencing Treatment-Emergent Adverse Events Summarized per Treatment and Severity – Safety Population

MedDRA® System Organ Class MedDRA® Preferred Term	TRS003, 3 mg/kg IV Infusion Dose (N=XX)					China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose (N=XX)				
n (%)	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
MedDRA® System Organ Class 1	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
MedDRA® Preferred Term 1	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
MedDRA® Preferred Term 2	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
MedDRA® System Organ Class 2	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
MedDRA® Preferred Term 1	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
MedDRA® Preferred Term 2	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)

Programming Notes:

1) *SOC will be presented in descending order of overall incidence rate in terms of frequency of subjects and then in frequency of events (alphabetical order will be used in case of equal rates). For each SOC, PT will be presented the same way.*
2) *If the distribution of treatments is presented on more than one page, preserve the order of the SOC and PT as defined in the generation of the global table without severity.*
3) *Refer to footnotes for additional instructions.*

N: Number of subjects dosed; n (%): Number and percent of subjects with treatment-emergent adverse events; MedDRA®: Medical Dictionary for Regulatory Activities, version 21.0.

Each subject could only contribute once to each of the incidence rates, regardless of the number of occurrence; the highest severity is presented.

Grade 1: Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated; Grade 2: Moderate; minimal, local or non-invasive intervention indicated; limiting age-appropriate instrumental activities of daily; Grade 3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care activities of daily living; Grade 4: Life-threatening consequences; urgent intervention indicated; Grade 5: Death related to AE.

Overall: Included results from all treatment groups.

Data source: Listing 16.2.7-1

Table 14.3.1-2 Frequency of Subjects Experiencing Treatment-Emergent Adverse Events Summarized per Treatment and Severity – Safety Population

MedDRA® System Organ Class MedDRA® Preferred Term	US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose (N=XX)					Overall (N=XX)				
n (%)	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
MedDRA® System Organ Class 1	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
MedDRA® Preferred Term 1	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
MedDRA® Preferred Term 2	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
MedDRA® System Organ Class 2	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
MedDRA® Preferred Term 1	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
MedDRA® Preferred Term 2	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)

Programming Notes:

1) *SOC will be presented in descending order of overall incidence rate in terms of frequency of subjects and then in frequency of events (alphabetical order will be used in case of equal rates). For each SOC, PT will be presented the same way.*
2) *If the distribution of treatments is presented on more than one page, preserve the order of the SOC and PT as defined in the generation of the global table without severity.*
3) *Refer to footnotes for additional instructions.*

N: Number of subjects dosed; n (%): Number and percent of subjects with treatment-emergent adverse events; MedDRA®: Medical Dictionary for Regulatory Activities, version 21.0.

Each subject could only contribute once to each of the incidence rates, regardless of the number of occurrence; the highest severity is presented.

Grade 1: Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated; Grade 2: Moderate; minimal, local or non-invasive intervention indicated; limiting age-appropriate instrumental activities of daily; Grade 3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care activities of daily living; Grade 4: Life-threatening consequences; urgent intervention indicated; Grade 5: Death related to AE.

Overall: Included results from all treatment groups.

Data source: Listing 16.2.7-1

Table 14.3.1-3 Number of Treatment-Emergent Adverse Events Summarized per Treatment and Severity – Safety Population

MedDRA® System Organ Class MedDRA® Preferred Term	TRS003, 3 mg/kg IV Infusion Dose (N=XX)					China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose (N=XX)				
E	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
MedDRA® System Organ Class 1	x	x	x	x	x	x	x	x	x	x
MedDRA® Preferred Term 1	x	x	x	x	x	x	x	x	x	x
MedDRA® Preferred Term 2	x	x	x	x	x	x	x	x	x	x
MedDRA® System Organ Class 2	x	x	x	x	x	x	x	x	x	x
MedDRA® Preferred Term 1	x	x	x	x	x	x	x	x	x	x
MedDRA® Preferred Term 2	x	x	x	x	x	x	x	x	x	x

Programming Notes:

1) *SOC will be presented in descending order of overall incidence rate in terms of frequency of subjects and then in frequency of events (alphabetical order will be used in case of equal rates). For each SOC, PT will be presented the same way.*
2) *If the distribution of treatments is presented on more than one page, preserve the order of the SOC and PT as defined in the generation of the global table without severity.*

E: Number of treatment-emergent adverse event; N: Number of subjects dosed; MedDRA®: Medical Dictionary for Regulatory Activities, version 21.0.

Grade 1: Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated; Grade 2: Moderate; minimal, local or non-invasive intervention indicated; limiting age-appropriate instrumental activities of daily; Grade 3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care activities of daily living; Grade 4: Life-threatening consequences; urgent intervention indicated; Grade 5: Death related to AE.

Overall: Included results from all treatment groups.

Data source: Listing 16.2.7-1

Table 14.3.1-3 Number of Treatment-Emergent Adverse Events Summarized per Treatment and Severity – Safety Population

MedDRA® System Organ Class MedDRA® Preferred Term	US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose (N=XX)					Overall (N=XX)				
E	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
MedDRA® System Organ Class 1	x	x	x	x	x	x	x	x	x	x
MedDRA® Preferred Term 1	x	x	x	x	x	x	x	x	x	x
MedDRA® Preferred Term 2	x	x	x	x	x	x	x	x	x	x
MedDRA® System Organ Class 2	x	x	x	x	x	x	x	x	x	x
MedDRA® Preferred Term 1	x	x	x	x	x	x	x	x	x	x
MedDRA® Preferred Term 2	x	x	x	x	x	x	x	x	x	x

Programming Notes:

1) *SOC will be presented in descending order of overall incidence rate in terms of frequency of subjects and then in frequency of events (alphabetical order will be used in case of equal rates). For each SOC, PT will be presented the same way.*
2) *If the distribution of treatments is presented on more than one page, preserve the order of the SOC and PT as defined in the generation of the global table without severity.*

E: Number of treatment-emergent adverse event; N: Number of subjects dosed; MedDRA®: Medical Dictionary for Regulatory Activities, version 21.0.

Grade 1: Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated; Grade 2: Moderate; minimal, local or non-invasive intervention indicated; limiting age-appropriate instrumental activities of daily; Grade 3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care activities of daily living; Grade 4: Life-threatening consequences; urgent intervention indicated; Grade 5: Death related to AE.

Overall: Included results from all treatment groups.

Data source: Listing 16.2.7-1

Table 14.3.1-4 Frequency of Subjects Experiencing Treatment-Emergent Adverse Events Summarized per Treatment and Relationship – Safety Population

MedDRA® System Organ Class MedDRA® Preferred Term	TRS003, 3 mg/kg IV Infusion Dose (N=XX)		China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose (N=XX)		US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose (N=XX)		Overall (N=XX)	
n (%)	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
MedDRA® System Organ Class 1	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
MedDRA® Preferred Term 1	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
MedDRA® Preferred Term 2	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
MedDRA® System Organ Class 2	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
MedDRA® Preferred Term 1	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
MedDRA® Preferred Term 2	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)

Programming Notes:

1) *SOC will be presented in descending order of overall incidence rate in terms of frequency of subjects and then in frequency of events (alphabetical order will be used in case of equal rates). For each SOC, PT will be presented the same way.*
2) *If the distribution of treatments is presented on more than one page, preserve the order of the SOC and PT as defined in the generation of the global table without relationship.*
3) *Refer to footnotes for additional instructions.*

N: Number of subjects dosed; n (%): Number and percent of subjects with treatment-emergent adverse event; MedDRA®: Medical Dictionary for Regulatory Activities, version 21.0.

Each subject could only contribute once to each of the incidence rates, regardless of the number of occurrence; the highest relationship is presented.

Overall: Included results from all treatment groups.

Data source: Listing 16.2.7-1

Table 14.3.1-5 Number of Treatment-Emergent Adverse Events Summarized per Treatment and Relationship – Safety Population

MedDRA® System Organ Class MedDRA® Preferred Term	TRS003, 3 mg/kg IV Infusion Dose (N=XX)		China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose (N=XX)		US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose (N=XX)		Overall (N=XX)	
E	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
MedDRA® System Organ Class 1	x	x	x	x	x	x	x	x
MedDRA® Preferred Term 1	x	x	x	x	x	x	x	x
MedDRA® Preferred Term 2	x	x	x	x	x	x	x	x
MedDRA® System Organ Class 2	x	x	x	x	x	x	x	x
MedDRA® Preferred Term 1	x	x	x	x	x	x	x	x
MedDRA® Preferred Term 2	x	x	x	x	x	x	x	x

Programming Notes:

1) *SOC will be presented in descending order of overall incidence rate in terms of frequency of subjects and then in frequency of events (alphabetical order will be used in case of equal rates). For each SOC, PT will be presented the same way.*
2) *If the distribution of treatments is presented on more than one page, preserve the order of the SOC and PT as defined in the generation of the global table without relationship.*

E: Number of treatment-emergent adverse event; N: Number of subjects dosed; MedDRA®: Medical Dictionary for Regulatory Activities, version 21.0.
Overall: Included results from all treatment groups.
Data source: Listing 16.2.7-1

Table 14.3.4-1 Biochemistry Summary Descriptive Statistics – Safety Population

Parameter (unit) Normal Range	Visit	Statistic	TRS003, 3 mg/kg IV Infusion Dose (N=XX)	China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose (N=XX)	US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose (N=XX)
Parameter 1 (unit)	Screening	n	xx	xx	xx
xx-xx		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	Day -1	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	Baseline	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	Day 2	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	Day 2 - CFB	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	Day 8	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx

Table 14.3.4-1 Biochemistry Summary Descriptive Statistics – Safety Population

Parameter (unit) Normal Range	Visit	Statistic	TRS003, 3 mg/kg IV Infusion Dose (N=XX)	China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose (N=XX)	US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose (N=XX)
	Day 8 - CFB	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	Day 29	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	Day 29 - CFB	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	Day 57	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	Day 57 - CFB	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	Day 85 (EOS)	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx

Table 14.3.4-1 Biochemistry Summary Descriptive Statistics – Safety Population

Parameter (unit) Normal Range	Visit	Statistic	TRS003, 3 mg/kg IV Infusion Dose (N=XX)	China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose (N=XX)	US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose (N=XX)
	Day 85 (EOS) - CFB	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx

CFB: Change from baseline; N: Number of subjects dosed; n: Number of subjects; SD: Standard Deviation; EOS: End of study.
Baseline is defined as the last results (scheduled or unscheduled) obtained prior to infusion.
Data source: Listing 16.2.8-1

Note: This table will be repeated for Tables 14.3.4-3, and 14.3.4-5. Please adapt title and footnotes accordingly.

Table 14.3.4-2 Frequency of Subjects – Biochemistry Shifts from Baseline – Safety Population

Treatment Parameter (unit)	Baseline Flag: Post-Baseline Flag: Visit	Low Low n (%)	Low Normal n (%)	Low High n (%)	Normal Low n (%)	Normal Normal n (%)	Normal High n (%)	High Low n (%)	High Normal n (%)	High High n (%)
TRS003, 3 mg/kg IV Infusion Dose (N=XX)										
Parameter 1	Day 2	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	Day 8	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	Day 29	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	Day 57	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	Day 85 (EOS)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
Parameter 2	Day 2	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	Day 8	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	Day 29	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	Day 57	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	Day 85 (EOS)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
… Add for all other Treatments and Parameters										

Programming Notes:

1) *Preserve parameters, scheduled visits and sorting defined in Summary Descriptive Statistics Table*
2) *Refer to footnotes for additional instructions.*
3) *Adapt Data Source to the appropriate laboratory category listing.*

N: Number of subjects dosed; n: Number and percent of subjects; EOS: End of study.
Baseline is defined as the last results (scheduled or unscheduled) obtained prior to infusion.
Percentage based on the number of subjects having available results at baseline and at the specific post-baseline visit.
Data source: Listing 16.2.8-1

Note: This table will be repeated for Tables 14.3.4-4, and 14.3.4-6. Please adapt title and footnotes accordingly.

Table 14.3.4-7 Urinalysis Frequency Summary – Categorical Results – Safety Population

Parameter (unit) Normal Range	Visit	Result	n (%)	TRS003, 3 mg/kg IV Infusion Dose (N=XX)	China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose (N=XX)	US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose (N=XX)
Parameter 1(unit) XX-XX	Screening	Negative		x (xx.x)	x (xx.x)	x (xx.x)
		Trace		x (xx.x)	x (xx.x)	x (xx.x)
	Day -1	Negative		x (xx.x)	x (xx.x)	x (xx.x)
		Trace		x (xx.x)	x (xx.x)	x (xx.x)
	Baseline	Negative		x (xx.x)	x (xx.x)	x (xx.x)
		Trace		x (xx.x)	x (xx.x)	x (xx.x)
	Day 2	Negative		x (xx.x)	x (xx.x)	x (xx.x)
		Trace		x (xx.x)	x (xx.x)	x (xx.x)
	Day 8	Negative		x (xx.x)	x (xx.x)	x (xx.x)
		Trace		x (xx.x)	x (xx.x)	x (xx.x)
	Day 29	Negative		x (xx.x)	x (xx.x)	x (xx.x)
		Trace		x (xx.x)	x (xx.x)	x (xx.x)
	Day 57	Negative		x (xx.x)	x (xx.x)	x (xx.x)
		Trace		x (xx.x)	x (xx.x)	x (xx.x)
	Day 85 (EOS)	Negative		x (xx.x)	x (xx.x)	x (xx.x)
		Trace		x (xx.x)	x (xx.x)	x (xx.x)

…

Programming Notes:

1) *Urine Microscopy parameters will not presented in this table.*
2) *Evaluate if the units must be added to parameter name if a numeric result was observed. Remove (units) from column header if no numeric results were observed.*
3) *For each parameter provide normal range of primary facility and, for gender specific parameters, use the same sorting of gender from demographic table.*
4) *Independently for each parameter, sort results by gradation.*
5) *Refer to footnotes for additional instructions.*

N: Number of subjects dosed; n (%): Number and percent of subjects; EOS: End of study.

Percentage based on the number of subjects having available result at each visit, independently for each parameter.

Data source: Listing 16.2.8-3

Table 14.3.4-8 Frequency of Subjects – Urinalysis Shifts from Screening – Categorical Results – Safety Population

Treatment Parameter (unit)	Visit	Baseline Flag: Post-Baseline Flag:	Normal		Abnormal	
			Normal n (%)	Abnormal n (%)	Normal n (%)	Abnormal n (%)
TRS003, 3 mg/kg IV Infusion Dose (N=XX)						
Parameter 1	Day 2		x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	Day 8		x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	Day 29		x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	Day 57		x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	Day 85 (EOS)		x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
Parameter 2	Day 2		x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	Day 8		x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	Day 29		x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	Day 57		x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
	Day 85 (EOS)		x (xx.x)	x (xx.x)	x (xx.x)	x (xx.x)
…						
Add for all other Treatments and Parameters						

Programming Notes:

1) *Preserve parameters, scheduled visits and sorting defined in Summary Descriptive Statistics Table*
2) *Refer to footnotes for additional instructions.*
3) *Adapt Data Source to the appropriate laboratory category listing.*

N: Number of subjects dosed; n: Number and percent of subjects; EOS: End of study.

Baseline is defined as the last results (scheduled or unscheduled) obtained prior to Infusion.

Percentage based on the number of subjects having available results at baseline and at the specific post-baseline visit.

Data source: Listing 16.2.8-3

Table 14.3.4-9 Vital Signs Summary Descriptive Statistics – Safety Population

Parameter (unit) Normal Range	Timepoint	Statistic	TRS003, 3 mg/kg IV Infusion Dose (N=XX)	China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose (N=XX)	US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose (N=XX)
Parameter 1 (unit)	Screening	n	xx	xx	xx
xx-xx		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	Day -1	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	Day 1, Pre-dose	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	Baseline	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	0H Infusion	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	0H Infusion - CFB	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx

Table 14.3.4-9 Vital Signs Summary Descriptive Statistics – Safety Population

Parameter (unit) Normal Range	Timepoint	Statistic	TRS003, 3 mg/kg IV Infusion Dose (N=XX)	China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose (N=XX)	US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose (N=XX)
	0H (Post EOI)	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	0H (Post EOI) - CFB	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	0.5H (Post EOI)	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	0.5H (Post EOI) - CFB	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	4H, Day 1	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	4H, Day 1 - CFB	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx

Table 14.3.4-9 Vital Signs Summary Descriptive Statistics – Safety Population

Parameter (unit) Normal Range	Timepoint	Statistic	TRS003, 3 mg/kg IV Infusion Dose (N=XX)	China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose (N=XX)	US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose (N=XX)
	8H, Day 1	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	8H Day 1 - CFB	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	Day 2	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	Day 2 - CFB	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	Day 3	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	Day 3 - CFB	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx

Table 14.3.4-9 Vital Signs Summary Descriptive Statistics – Safety Population

Parameter (unit) Normal Range	Timepoint	Statistic	TRS003, 3 mg/kg IV Infusion Dose (N=XX)	China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose (N=XX)	US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose (N=XX)
	Day 8	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	Day 8 - CFB	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	Day 29	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	Day 29 - CFB	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	Day 57	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	Day 57 - CFB	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx

Table 14.3.4-9 Vital Signs Summary Descriptive Statistics – Safety Population

Parameter (unit) Normal Range	Timepoint	Statistic	TRS003, 3 mg/kg IV Infusion Dose (N=XX)	China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose (N=XX)	US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose (N=XX)
	Day 85 (EOS)	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	Day 85 (EOS) - CFB	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx

CFB: Change from baseline; N: Number of subjects dosed; n: Number of subjects; SD: Standard Deviation; EOS: End of study; EOI: End of infusion.
Baseline is defined as the last results (scheduled or unscheduled) obtained prior to infusion.
Data source: Listing 16.2.8-4

Table 14.3.4-10 Electrocardiogram Summary Descriptive Statistics – Safety Population

Parameter (unit) Normal Range	Timepoint	Statistic	TRS003, 3 mg/kg IV Infusion Dose (N=XX)	China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose (N=XX)	US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose (N=XX)
Parameter 1 (unit)	Screening	n	xx	xx	xx
xx-xx		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	0.5H (Post EOI)	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	0.5H (Post EOI) - CFS	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	Day 85 (EOS)	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx
	Day 85 (EOS) - CFS	n	xx	xx	xx
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x
		Min, Max	xx-xx	xx-xx	xx-xx

CFS: Change from screening; N: Number of subjects dosed; n: Number of subjects; SD: Standard Deviation; EOS: End of study; EOI: End of infusion.
Screening is defined as the last screened results (scheduled or unscheduled).
Data source: Listing 16.2.8-5

Table 14.3.4-11 Descriptive Statistics of Immunogenicity - Safety Population

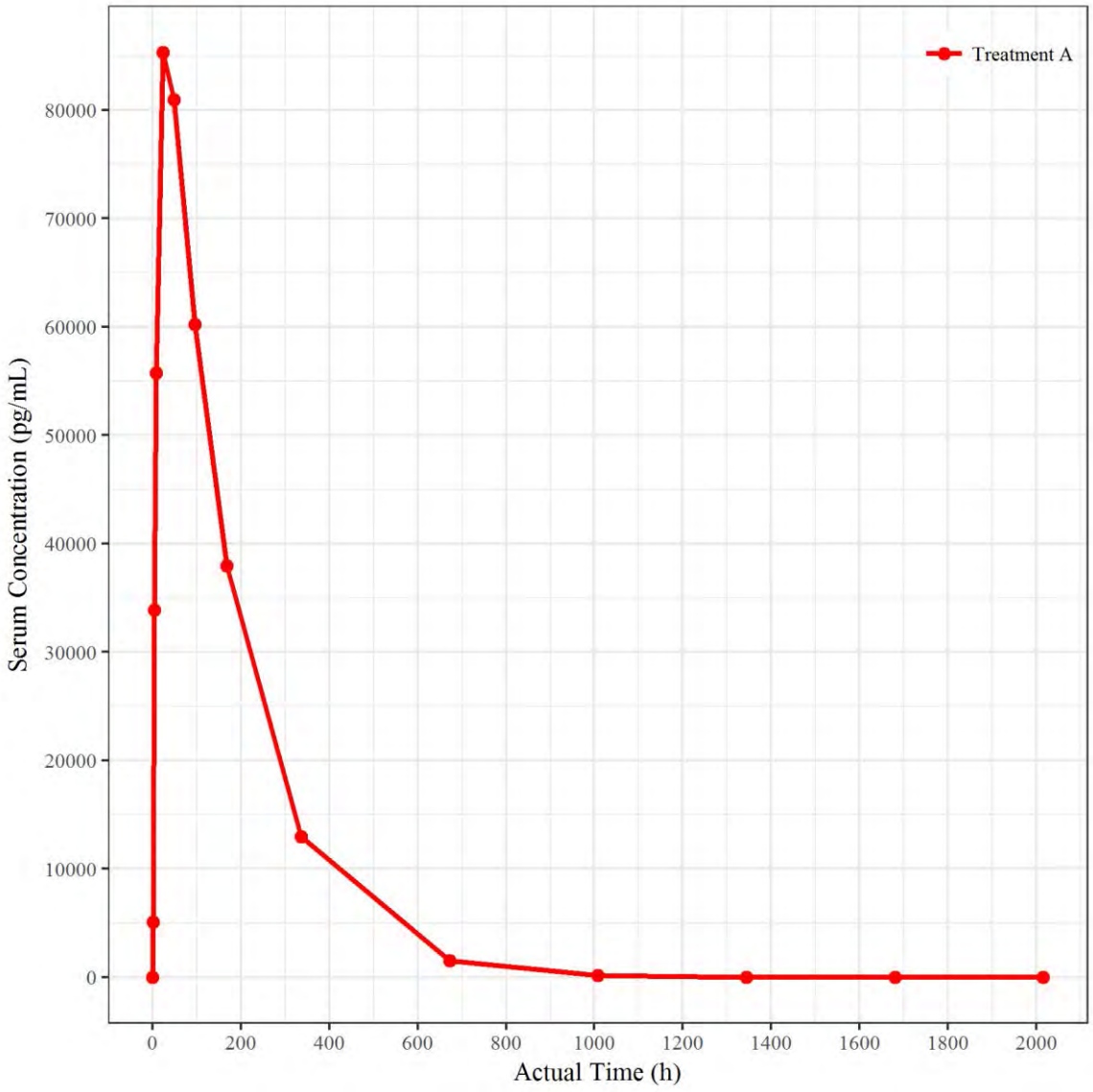
Treatment	Nominal Time	Time Unit	N	Mean	SD	CV%	Min	Median	Max	Result Unit
A	0.000	h								
	336	h								
	672	h								
	1344	h								
	2016	h								

…

N: Number of observations; SD: Standard Deviation; CV%: Coefficient of Variation; Min: Minimum, Max: Maximum.
Treatment A: TRS003, 3 mg/kg IV Infusion Dose; Treatment B: China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose;
Treatment C: US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose.
Data source: Listing 16.2.8-6

5. Figures

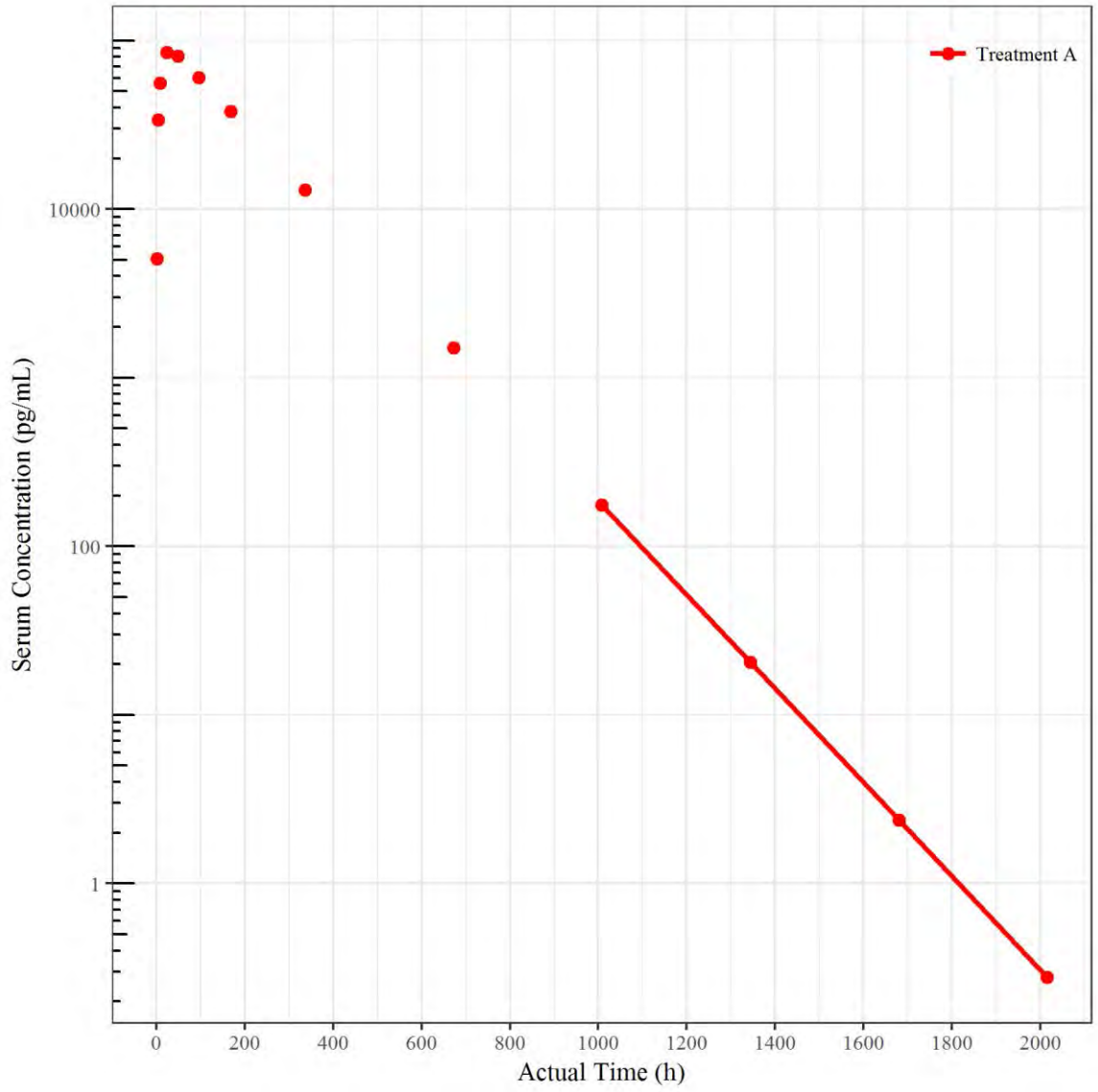
Figure 14.2.2-1a: Plasma Concentrations for Subject XX - Linear Scale



Treatment A: TRS003, 3 mg/kg IV Infusion Dose; Treatment B: China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose; Treatment C: US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose.

Note: This figure will be repeated for each subject included in the PK population.

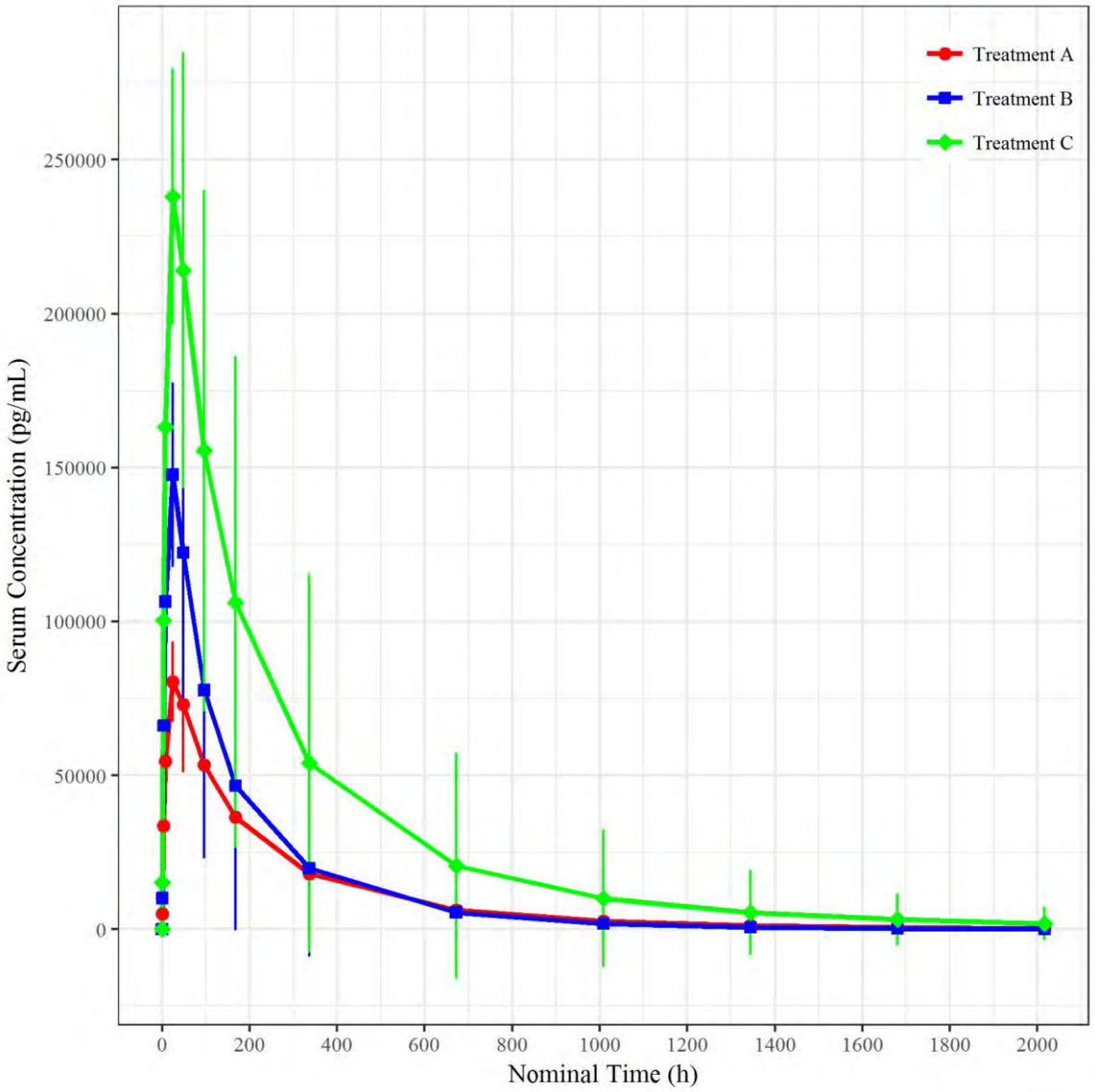
Figure 14.2.2-1b: Plasma Concentrations for Subject XX – Semi-Log Scale



Treatment A: TRS003, 3 mg/kg IV Infusion Dose; Treatment B: China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose; Treatment C: US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose.

Note: This figure will be repeated for each subject included in the PK population.

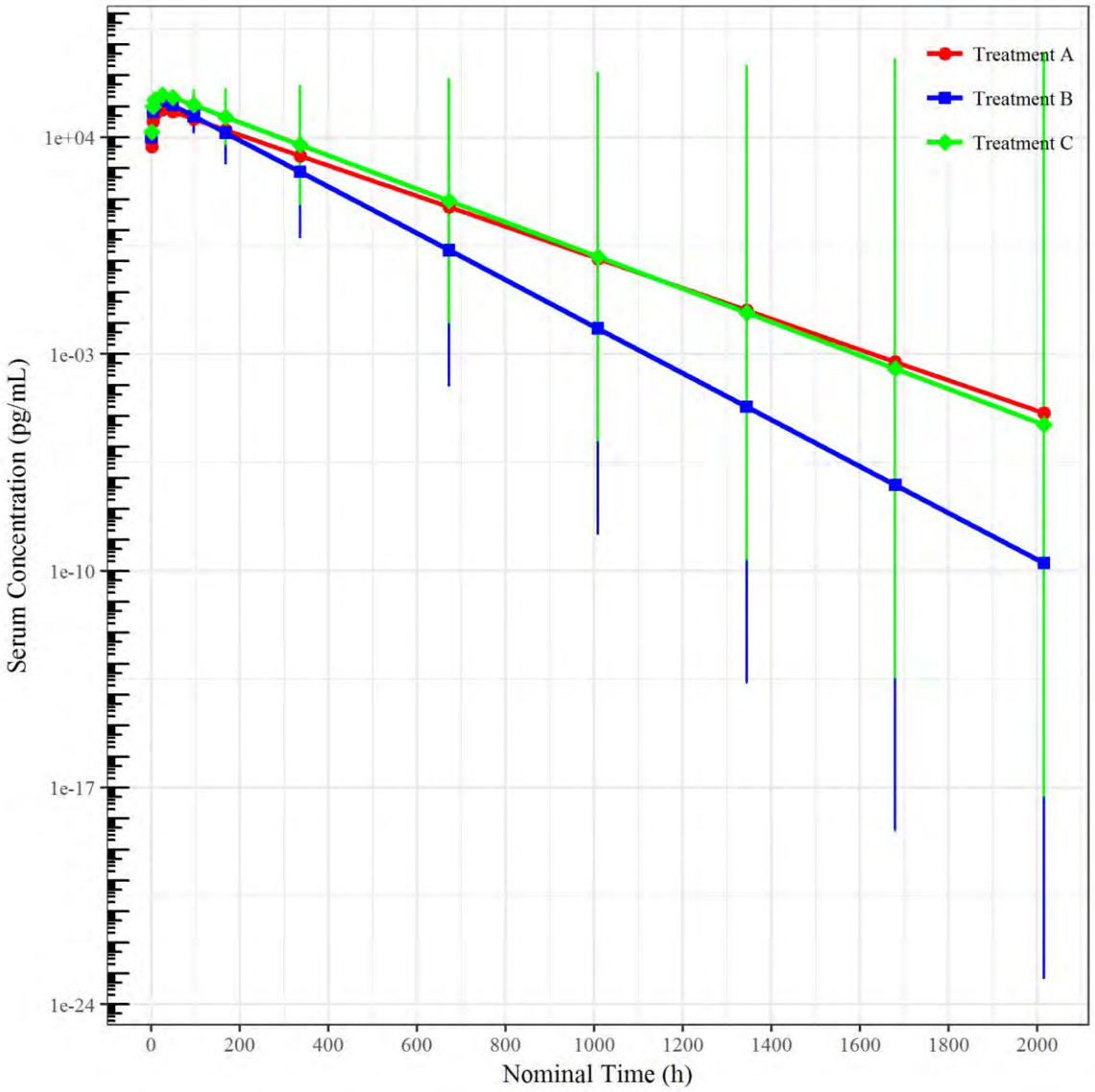
Figure 14.2.2-115a: Mean (± SD) Plasma Concentrations - Linear Scale



Treatment A: TRS003, 3 mg/kg IV Infusion Dose; Treatment B: China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose; Treatment C: US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose.

Note: This figure will be repeated for each subject included in the PK population.

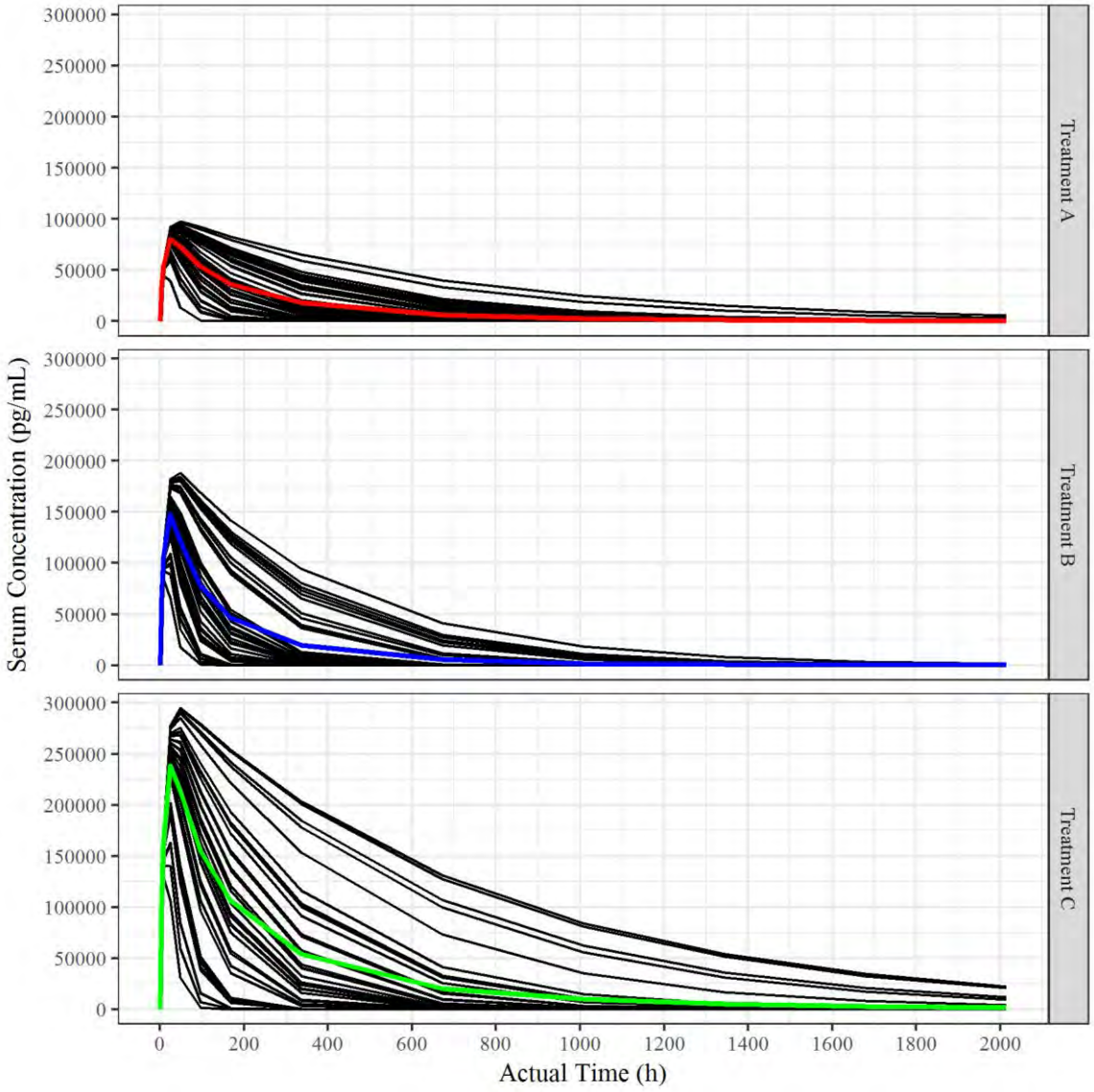
Figure 14.2.2-115b: Mean (± SD) Plasma Concentrations - Semi-Log Scale



Treatment A: TRS003, 3 mg/kg IV Infusion Dose; Treatment B: China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose; Treatment C: US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose.

Note: This figure will be repeated for each subject included in the PK population.

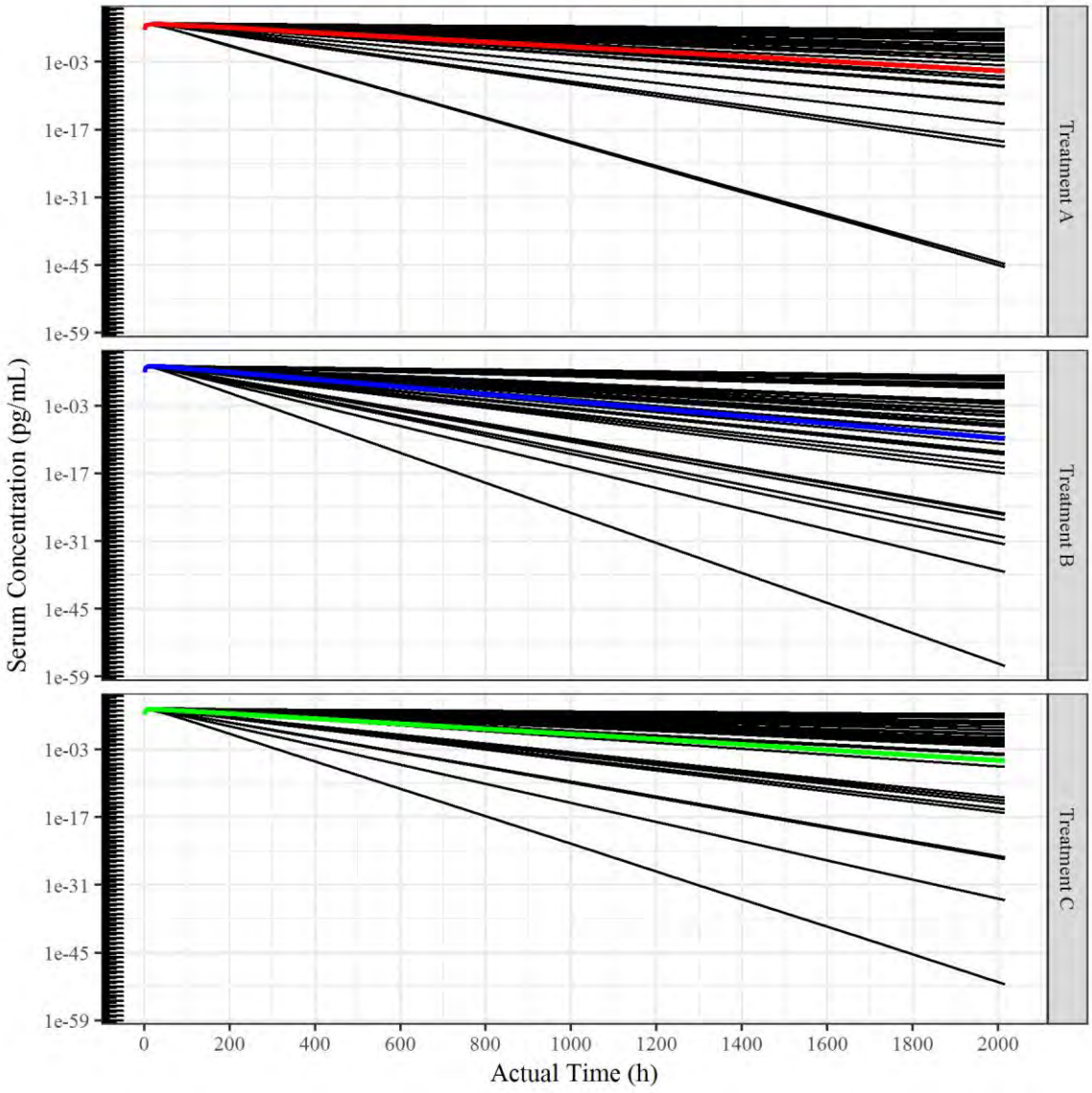
Figure 14.2.2-116a: Overlay of Individual and Mean Plasma Concentrations by Treatment - Linear Scale



Treatment A: TRS003, 3 mg/kg IV Infusion Dose; Treatment B: China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose; Treatment C: US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose.

Note: This figure will be repeated for each subject included in the PK population.

Figure 14.2.2-116b: Overlay of Individual and Mean Plasma Concentrations by Treatment - Semi-Log Scale



Treatment A: TRS003, 3 mg/kg IV Infusion Dose; Treatment B: China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose; Treatment C: US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose.

Note: This figure will be repeated for each subject included in the PK population.

6. Listings

Listing 16.1.9-1 ANOVA for Treatment Comparisons (A/B, A/C and B/C) – PK Population

The GLM Procedure

Comparison: A vs B; Parameter: xxxx (unit).

Class Level Information		
Class	Levels	Values
TRT		

Number of Observations Read	
Number of Observations Used	

The GLM Procedure
Dependent Variable: LN_AUCLST

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model					
Error					
Corrected Total					

R-Square	Coeff Var	Root MSE	VAR Mean

Source	DF	Type III SS	Mean Square	F Value	Pr > F
TRT					

The GLM Procedure

Source	Type III Expected Mean Square
TRT	Var(Error) + 2 Var(subject)

The GLM Procedure

Tests of Hypotheses for Mixed Model Analysis of Variance
Dependent Variable: LN_AUCLST

Source	DF	Type III SS	Mean Square	F Value	Pr > F

Source	DF	Type III SS	Mean Square	F Value	Pr > F
TRT					
Error: MS(Error)					

Least Squares Means

		H0:LSMean1=LSMean2
TRTVAR	LSMEAN	Pr > |t|
A		
B		

TRT	VAR	LSMEAN	90% Confidence Limits
A			
B			

Least Squares Means for Effect Treatment

i	j	Difference Between Means	90% Confidence Limits for LSMean(i)-LSMean(j)
1	2		

Dependent Variable: LN_AUCLST

Parameter	Estimate	Standard Error	t Value	Pr > |t|	90% Confidence Limits
A-B					

Treatment A: TRS003, 3 mg/kg IV Infusion Dose; Treatment B: China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose; Treatment C: US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose.

Note: All ANOVA results for ln-transformed AUC_{0-t}, AUC_{0-inf}, and C_{max} and untransformed T_{max}, K_{el}, and $T_{1/2\ el}$ will be presented for treatment A vs treatment C and treatment B vs treatment C comparisons in this listing.

Listing 16.1.9-2 Wilcoxon Rank Sum Test for T_{max} for Treatment Comparison (A/B, A/C and B/C) – PK Population

Difference	Statistic	Value
A – B	n	
	Mean	
	Median	
	SD	
	Min	
	Max	
Wilcoxon Rank-Sum Test	S	
	p-value	

n: Number of subjects; SD: Standard Deviation; Min: Minimum; Max: Maximum.
Treatment A: TRS003, 3 mg/kg IV Infusion Dose; Treatment B: China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose; Treatment C: US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose.

Note: Wilcoxon Rank sum test for T_{max} will be also presented for treatment A vs treatment C and treatment B vs treatment C comparisons in this listing.

Listing 16.2.1-1 Subjects Completion and Discontinuation Information

Subject	Treatment	Completion/ Discontinuation Date and Time	Primary Reason for Discontinuation	Comment
001	A	DD-MM-YYYYTHH:MM	XXX	XXX

Treatment A: TRS003, 3 mg/kg IV Infusion Dose; Treatment B: China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose; Treatment C: US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose.

Listing 16.2.2-1 Protocol Deviations

Subject	Treatment	Category	Deviation

Treatment A: TRS003, 3 mg/kg IV Infusion Dose; Treatment B: China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose; Treatment C: US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose.

Listing 16.2.4-1 Demographics

Subject	Treatment	Age (years)	Race	Ethnicity	BMI (kg/m^2)	Height (cm)	Weight (kg)
001	A						

BMI: Body Mass Index.
Last results (scheduled or unscheduled) obtained at screening were used to generate this table.
Treatment A: TRS003, 3 mg/kg IV Infusion Dose; Treatment B: China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose;
Treatment C: US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose.

Listing 16.2.4-2 Medical History Findings at Screening

Subject	Treatment	Finding	MedDRA® Preferred Term	MedDRA® System Organ Class	Onset Date	Resolution Date (or Ongoing)
		FINDING 1	Preferred Term 1	SOC 1	YYYY-MM-DDTHH:MM	YYYY-MM-DDTHH:MM
		FINDING 2	Preferred Term 2	SOC 2	YYYY-MM-DDTHH:MM	ONGOING

Programming Notes:

1) SOC and Finding will be presented in uppercase. The Preferred Term will be presented in "propcase". The SAS coding "/~n" between terms will generate the break line.
2) The SAS coding "/~n" between dates will generate the break line.
3) If finding is ongoing, replace missing resolution date per ONGOING.
4) Sort events per Subject, Start Date, Stop Date, SOC and PT.
5) For incomplete date display, refer to CDISC SDTM Implementation Guide according to ISO 8601 format.

MedDRA®: Medical Dictionary for Regulatory Activities; MedDRA® Version 21.0.
Treatment A: TRS003, 3 mg/kg IV Infusion Dose; Treatment B: China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose;
Treatment C: US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose.

Listing 16.2.4-3 Prior and Concomitant Medications

Subject	Treatment	Prior/ Concomitant	WHO DDE ATC / WHO DDE Preferred Term / Medication	Dose (unit)/ Frequency	Route	Onset Date and Time/ Resolution Date and Time (or Ongoing)	Indication (Condition or AE No.)
	A	Prior	ATC 1/ Preferred Term 1/ MEDICATION 1/	20 (mg) QID	ORAL	YYYY-MM-DDTHH:MM/ YYYY-MM-DDTHH:MM	
	B	Concomitant	ATC 2/ Preferred Term 2/ MEDICATION 2/			YYYY-MM-DDTHH:MM/ ONGOING	

Programming Notes:

1) ATC and Medication will be presented in uppercase. The Preferred Term will be presented in "propcase". The SAS coding "/~n" between terms will generate the break line.

2) The SAS coding "/~n" will generate the break line between treatment sequence and treatment, dose with units and frequency. In the same way apply a break line between dates.

3) If medication is ongoing, replace missing resolution date per ONGOING.

4) Sort events per Subject, Onset Date, Resolution Date, ATC and PT.

5) For incomplete date display, refer to CDISC SDTM Implementation Guide according to ISO 8601 format.

ATC: Anatomic Therapeutic Chemical; WHO DDE: World Health Organization Drug Dictionary Enhanced Version Mar2018, format B.
Treatment A: TRS003, 3 mg/kg IV Infusion Dose; Treatment B: China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose;
Treatment C: US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose.

Listing 16.2.4-4 Study Drug Administration

Subject	Treatment	Infusion Start Date and Time	Infusion End Date and Time	Total Dose
		YYYY-MM-DDTHH:MM:SS	YYYY-MM-DDTHH:MM:SS	

Treatment A: TRS003, 3 mg/kg IV Infusion Dose; Treatment B: China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose;
Treatment C: US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose.

Listing 16.2.6-1 Listing of Individual Actual Sampling Times and Pharmacokinetic Concentrations

Subject	Treatment	Nominal Time	Time Unit	Actual Time	Concentration	Concentration Unit	Excluded Flag	Reason	Dose Date and Time	PK Sampling Date and Time
001	A	Pre-dose	h	0.005		pg/mL	N		DDMMMYYYYT HH:MM:SS	DDMMMYYYYT HH:MM:SS
		0.000 (at EOI)	h	0.001		pg/mL	N			
		0.500	h	0.489		pg/mL	Y	inconclusive		
		4.00	h	4.001						
		…		…						
002	B	Pre-dose	h	0.005		pg/mL	N			
		0.000 (at EOI)	h	0.001		pg/mL	N			
		0.500	h	0.489		pg/mL	Y	inconclusive		
		4.00	h	4.001						

EOI: End of infusion.
Treatment A: TRS003, 3 mg/kg IV Infusion Dose; Treatment B: China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose;
Treatment C: US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose.

Listing 16.2.6-2 Listing of Individual Pharmacokinetic Parameters

Subject	Treatment	Parameter	Results	Unit	Excluded Flag	Reason
001	A	AUC_{0-t}			N	
		AUC_{0-inf}			N	
		C_{max}			Y	Not Estimable
		Residual area			Y	Not Estimable
		…				
002	B	AUC_{0-t}			N	
		AUC_{0-inf}			N	
		C_{max}			Y	Not Estimable
		Residual area			Y	Not Estimable
		…				

Treatment A: TRS003, 3 mg/kg IV Infusion Dose; Treatment B: China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose;
Treatment C: US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose.

Listing 16.2.7-1 Treatment-Emergent Adverse Events

Subject	Treatment	AE Number	MedDRA® System Organ Class/ MedDRA® Preferred Term/ Adverse Event Description	Onset Date and Time/ Resolution Date and Time (or Ongoing)	Severity/ Relationship	Serious (Yes/No)	Action taken		Outcome
							Study Drug	Other	
001			SOC 1/ Preferred Term 1/ DESCRIPTION 1	YYYY-MM-DDTHH:MM/ YYYY-MM-DDTHH:MM	Grade 1/ Related	Yes			
			SOC 2/ Preferred Term 2/ DESCRIPTION 2	YYYY-MM-DDTHH:MM/ ONGOING	Grade 2/ Not Related	No			

Programming Notes:

1) SOC and AE Description will be presented in uppercase. The Preferred Term will be presented in "propcase". The SAS coding "/~n" between terms will generate the break line.
2) The SAS coding "/~n" will generate the break line between dates and between Severity and Relationship.
3) If needed, hardcode OUTCOME and ACTIONS in order to introduce break line (~n) between answer elements.
4) If medication is ongoing, replace missing resolution date per ONGOING.
5) Sort events per Subject, Onset Date/time, Resolution Date/time, SOC and PT.
6) For incomplete date display, refer to CDISC SDTM Implementation Guide according to ISO 8601 format.
7) Please update' MedDRA® System Organ Class' footnote by keeping only those SOC terms referred in table.

MedDRA®: Medical Dictionary for Regulatory Activities (MedDRA®); MedDRA® Version 21.0.
MedDRA® System Organ Class (SOC): Cardiac disorders (Card); Eye disorders (Eye); Gastrointestinal disorders (Gastr); General disorders and administration site conditions (Genrl); Infections and infestations (Infec); Injury, poisoning and procedural complications (Inj&P); Investigations (Inv); Musculoskeletal and connective tissue disorders (Musc); Nervous system disorders (Nerv); Psychiatric disorders (Psych); Respiratory, thoracic and mediastinal disorders (Resp); Skin and subcutaneous tissue disorders (Skin) Vascular disorders (Vasc).
Treatment A: TRS003, 3 mg/kg IV Infusion Dose; Treatment B: China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose;
Treatment C: US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose.

Note: The list of MedDRA® SOC will be updated according to the AEs observed for the study.

Note: Similar layout will be used for Listing 16.2.7-2, please adapt title and footnotes accordingly.

Listing 16.2.8-1 Clinical Laboratory - Biochemistry

Subject	Treatment	Laboratory	Visit	Collection Date and Time	Parameter(unit)	Result	Flag	Normal Range
001				YYYY-MM-DDTHH:MM			H	XX.X-XX.X

Programming Notes:

1) *Sort assessments per Subject, Visit/Date and parameters. Sorting for parameter should be as defined in Summary Descriptive Statistics Table.*
2) *For each parameter provide normal range of primary facility and, for gender specific parameters, use the same sorting of gender from demographic table.*
3) *If multiple laboratories involved, display standard and normalised results. Display the ranges in the same way. The SAS coding "/~n" between results or ranges will generate the break line.*
   Take care to use the same precision of both, standard and normalised results/ranges.
4) *Adapt flag footnote for Urinalysis listing per*
   N: Normal result; A: Abnormal result; H: Above normal range; L: Below normal range.
5) *Laboratory facilities could be abbreviated with appropriation description on footnote (iHC: inVentiv Health Clinical Laboratory; BML: Biron Medical Laboratory).*

H: Above normal range; L: Below normal range; N: Normal Range.
Treatment A: TRS003, 3 mg/kg IV Infusion Dose; Treatment B: China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose;
Treatment C: US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose.

Note: Similar layout will be used for Listings 16.2.8-2, 16.2.8-3 and 16.2.8-6. Please adapt title and footnotes accordingly.

Listing 16.2.8-4 Vital Signs Result

Subject	Treatment	Timepoint	Measurement Date and Time	Parameter(unit)	Result
001	A	Screening	YYYY-MM-DDTHH:MM		

Programming Notes:

1) Sort assessments per Subject, Timepoint/Date and parameter. Parameters for each subject to be sorted as defined in Summary Descriptive Statistics Table.

EOS: End of study; EOI: End of infusion.
Treatment A: TRS003, 3 mg/kg IV Infusion Dose; Treatment B: China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose;
Treatment C: US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose.

Listing 16.2.8-5 Electrocardiogram Result

Subject	Treatment	Timepoint	Assessment Date and Time	Parameter(unit)	Result/ Interpretation*	Normal range
			YYYY-MM-DDTHH:MM			XX.X-XX.X

Programming Notes:

1) *Sort assessments per Subject, Timepoint/Date and parameter. Parameters for each subject to be sorted as defined in Summary Descriptive Statistics Table.*

*The medical judgement for abnormal ECG interpretation is also presented in this column as CS: Clinically significant or NCS: Not clinically significant.
EOS: End of study; EOI: End of infusion.
Treatment A: TRS003, 3 mg/kg IV Infusion Dose; Treatment B: China-Approved Bevacizumab, 3 mg/kg IV Infusion Dose;
Treatment C: US Licensed Avastin® (Bevacizumab), 3 mg/kg IV Infusion Dose.