SAB Biotherapeutics, Inc

SAB-176-101

A PHASE 1, RANDOMIZED DOUBLE-BLIND, PLACEBO-CONTROLLED, SINGLE ASCENDING DOSE SAFETY, TOLERABILITY, AND PHARMACOKINETICS STUDY OF SAB-176 IN HEALTHY ADULTS

17AUG2020

Table, Listing, and Figure Shells

Version 1.0

Prepared by:

PPD
3900 Paramount Parkway
Morrisville, NC 27560 USA

Document History – Changes compared to previous version of SAP Shells:

Version	Date	Changes

General guidance

Document Headers

The following headers will be used for all tables and figures and listings outlined in this document:

1 mg/kg SAB-176

10 mg/kg SAB-176

25 mg/kg SAB-176

50 mg/kg SAB-176

Pooled placebo (as applicable)

Total (as applicable)

For all Safety tables (from 14.3.1.1 to 14.3.6.4.2) and additional Pooled SAB-176 header will be shown as applicable.

If there are no data for the entire output, then keep all titles/footnotes and column headers, remove subgroup page header where applicable, display “No data to display” as the content of the output.

Document Footnotes

The following programming footnote will be included for all tables, listings, and figures:

<DIRECTORY PATH>PROGRAM NAME Executed: DDMONYYYY hh:mm

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Table 14.1.1
Subject Disposition
All Randomized Subjects

	1 mg/kg SAB-176 (N=xxx) n (%)	10 mg/kg SAB-176 (N=xxx) n (%)	25 mg/kg SAB-176 (N=xxx) n (%)	50 mg/kg SAB-176 (N=xxx) n (%)	Pooled Placebo (N=xxx) n (%)	Total (N=xxx) n (%)
Total Number of Subjects						
Enrolled	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Randomized	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Completed	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Discontinued	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Primary Reason for Discontinuation						
Adverse Event	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to follow-up	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Physician decision	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pregnancy	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Protocol deviation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Site terminated by sponsor	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Study terminated by sponsor	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Withdrawal by subject	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Analysis Populations						
Safety Population[1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PK Population[2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note to Programmer: Percentages with a frequency count of zere in the Total must be suppressed.

Note: [1] The Safety population included all subjects who are randomized and received SAB-176.
[2] The PK population included all subjects in the safety population who have received SAB-176 treatment and have sufficient PK concentration data to calculate reliable estimates of at least one key PK parameters (C_{max} or AUC).
All percentages are based on all randomized subjects within each treatment and overall.
Source Data: Listing 16.2.1 and Listing 16.2.3

Table 14.1.2
Significant Protocol Deviations
All Randomized Subjects

	1 mg/kg SAB-176 (N=xxx) n (%)	10 mg/kg SAB-176 (N=xxx) n (%)	25 mg/kg SAB-176 (N=xxx) n (%)	50 mg/kg SAB-176 (N=xxx) n (%)	Pooled Placebo (N=xxx) n (%)	Total (N=xxx) n (%)
Number of subjects with at least one significant protocol deviation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total number of significant protocol deviation	xx	xx	xx	xx	xx	xx
Deviation 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Deviation 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…						

Note: All percentages are based on Safety population within each treatment and overall.
Source Data: Listing 16.2.2.2

Table 14.1.3
Demographics
Safety Population

	1 mg/kg SAB-176 (N=xxx) n (%)	10 mg/kg SAB-176 (N=xxx) n (%)	25 mg/kg SAB-176 (N=xxx) n (%)	50 mg/kg SAB-176 (N=xxx) n (%)	Pooled Placebo (N=xxx) n (%)	Total (N=xxx) n (%)
Age (Years)						
N	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Sex, n (%)						
Male	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Female	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Race, n (%)						
Black or African american	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Asian	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
American Indian or Alaska native	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Native Hawaiian or Other Pacific Islander	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
White	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Multi-Racial	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ethnicity, n (%)						
Hispanic or Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Hispanic or Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not reported	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Screening Weight (kg)						
n	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Screening Height (cm)						
N	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Screening BMI (kg/m^2)						
N	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Note to programmer: Include all treatment groups. Summarize subjects who report two or more races as "Multi-racial". If there is no such subject, remove "Multi-racial" category. Percentages with a frequency count of zero in the Total must be suppressed

Note: All percentages are based on Safety population within each treatment and overall.
Source Data: Listing 16.2.4.1

Table 14.2.5.1.1
Summary of Serum Concentrations (unit) of SAB-176 Following IV Administration by Treatment
PK Population

Day	Scheduled Time (h)	Summary Statistics	1 mg/kg SAB-176 (N=xx)	10 mg/kg SAB-176 (N=xx)	25 mg/kg SAB-176 (N=xx)	50 mg/kg SAB-176 (N=xx)
0	Pre-dose	n	xx	xx	xx	xx
		Mean	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x
		Geometric Mean	xx.x	xx.x	xx.x	xx.x
		Geometric CV%	xx.x	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x	xx.x
		Minimum	xx.x	xx.x	xx.x	xx.x
		Maximum	xx.x	xx.x	xx.x	xx.x
	1h post EOI	n	xx	xx	xx	xx
		Mean	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x
		Geometric Mean				
		Geometric CV%				
		Median	xx.x	xx.x	xx.x	xx.x
		Minimum	xx.x	xx.x	xx.x	xx.x
		Maximum	xx.xx	xx.x	xx.x	xx.x
…	…	…	…	…	…	…

Note to Programmer:
1. Day includes Pre-dose, 1 h post EOI, 6 h post EOI on Day 0, Day 1 Day 2, Day 3, Day 7, Day 21, Day 42 and Day 90. Note that collections beyond Day 0 will not have a 'scheduled time'.

Note: EOI = end of infusion; SOI = start of infusion
Below the limit of quantitation (BLQ) values were set to the zero for calculation of summary statistics.
Source Data: Listing 16.2.6.1

Table 14.2.5.1.2
Summary of Serum Concentrations (unit) of SAB-176 Following IV Administration by Treatment and ADA Status
PK Population

ADA Status: negative

Day	Scheduled Time (h)	Summary Statistics	1 mg/kg SAB-176 (N=xx)	10 mg/kg SAB-176 (N=xx)	25 mg/kg SAB-176 (N=xx)	50 mg/kg SAB-176 (N=xx)
0	Pre-dose	n	xx	xx	xx	xx
		Mean	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x
		Geometric Mean	xx.x	xx.x	xx.x	xx.x
		Geometric CV%	xx.x	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x	xx.x
		Minimum	xx.x	xx.x	xx.x	xx.x
		Maximum	xx.x	xx.x	xx.x	xx.x
	1h post EOI	N	xx	xx	xx	xx
		Mean	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x
		Geometric Mean				
		Geometric CV%				
		Median	xx.x	xx.x	xx.x	xx.x
		Minimum	xx.x	xx.x	xx.x	xx.x
		Maximum	xx.xx	xx.x	xx.x	xx.x
…	…	…	…	…	…	…

Note to Programmer:

1. *Day includes Pre-dose, 1 h post EOI, 6 h post EOI on Day 0, Day 1, Day 2, Day 3, Day 7, Day 21, Day 42 and Day 90. Note that collections beyond Day 0 will not have a 'scheduled time'.*
2. *ADA Status includes negative, positive and/or missing*

Note: EOI = end of infusion; SOI = start of infusion
Below the limit of quantitation (BLQ) values were set to the zero for calculation of summary statistics.
Source Data: Listing 16.2.6.1

Table 14.2.5.2.1
Summary of Serum Pharmacokinetic Parameters of SAB-176 Following IV Administration by Treatment
PK Population

Parameters	1 mg/kg SAB-176 (N=xx)	10 mg/kg SAB-176 (N=xx)	25 mg/kg SAB-176 (N=xx)	50 mg/kg SAB-176 (N=xx)
Cmax (unit)				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x
CV%	xx.x	xx.x	xx.x	xx.x
Geometric Mean	xx.x	xx.x	xx.x	xx.x
Geometric CV%	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x
Minimum	xx.x	xx.x	xx.x	xx.x
Maximum	xx.x	xx.x	xx.x	xx.x
tmax (unit)				
n	xx	xx	xx	xx
Median	xx.x	xx.x	xx.x	xx.x
Minimum	xx.x	xx.x	xx.x	xx.x
Maximum	xx.x	xx.x	xx.x	xx.x
…	…	…	…	…

Note to programmer:
1. *Additional parameters: AUC0-t (unit), AUC0-0-inf (unit), t1/2 (unit), CL (unit), and Vz(unit).*
2. *Only n, median, minimum and maximum will be presented for tmax.*
3. *Geometric means are set to missing where zero values exist.*

Note: AUCs, t1/2, CL, Vz will not be reported if the number of data points used to calculate λz is less than 3 (not including Cmax), or the calculated coefficient of determination (R2) value for λz is < 0.800
Source Data: Listing 16.2.6.2

Table 14.2.5.2.2
Summary of Serum Pharmacokinetic Parameters of SAB-176 Following IV Administration by Treatment and ADA Status
PK Population

ADA Status: negative

Parameters	1 mg/kg SAB-176 (N=xx)	10 mg/kg SAB-176 (N=xx)	25 mg/kg SAB-176 (N=xx)	50 mg/kg SAB-176 (N=xx)
Cmax (unit)				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x	xx.x
CV%	xx.x	xx.x	xx.x	xx.x
Geometric Mean	xx.x	xx.x	xx.x	xx.x
Geometric CV%	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x
Minimum	xx.x	xx.x	xx.x	xx.x
Maximum	xx.x	xx.x	xx.x	xx.x
tmax (unit)				
n	xx	xx	xx	xx
Median	xx.x	xx.x	xx.x	xx.x
Minimum	xx.x	xx.x	xx.x	xx.x
Maximum	xx.x	xx.x	xx.x	xx.x
…	…	…	…	…

Note to programmer:
1. *Additional parameters: AUC0-t (unit), AUC0-0-inf (unit), t1/2 (unit), CL (unit), and Vz(unit).*
2. *Only n, median, minimum and maximum will be presented for tmax.*
3. *Geometric means are set to missing where zero values exist.*

Note: AUCs, t1/2, CL, Vz will not be reported if the number of data points used to calculate λz is less than 3 (not including Cmax), or the calculated coefficient of determination (R2) value for λz is < 0.800
Source Data: Listing 16.2.6.2

Table 14.2.5.3.1
Statistical Assessment of Dose Proportionality of Serum Pharmacokinetic Parameters for SAB-176
PK Population

Dose Range	Parameter (units)	Intercept Estimate	Slope Estimate	Standard Error of Slope	90% CI of Slope
1 – 50 mg/kg, IV	Cmax (unit)	x.xx	x.xx	x.xx	(x.xx, x.xx)
	AUC0-t(unit)	x.xx	x.xx	x.xx	(x.xx, x.xx)
	AUC0–inf (unit)	x.xx	x.xx	x.xx	(x.xx, x.xx)

CI = confidence interval.
Note: Natural-log transformed pharmacokinetic parameters were analyzed using a power model where ln(parameter)= intercept + beta*ln(dose).
Dose proportionality is concluded if the 90% confidence interval of the slope (beta) lies entirely within (x.xxxx, x.xxxx) for dose range [i.e. (1+ln(0.5)/ln(r),1+ln(2)/ln(r))], where r is the dose range (highest dose/lowest dose).
Source Data: Listing 16.2.6.2.

Table 14.3.1.1
Overall Summary of Adverse Events
Safety Population

	1 mg/kg SAB-176 (N=xxx) n (%)	10 mg/kg SAB-176 (N=xxx) n (%)	25 mg/kg SAB-176 (N=xxx) n (%)	50 mg/kg SAB-176 (N=xxx) n (%)	Pooled SAB-176 (N=xxx) n (%)	Pooled Placebo (N=xxx) n (%)	Total (N=xxx) n (%)
Any TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Treatment-Related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAE by severity							
Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treatment-Related TEAE by severity							
Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Treatment-Related Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Any TEAE Leading to early discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: A TEAE is defined as any event not present before exposure to study drug or any event already present that worsens in intensity or frequency after exposure. At each level of subject summarization, a subject is counted once if the subject reported one or more events. A treatment-related AE is defined as an AE that is evaluated by the investigator as definitely, probably, or possibly related to study drug. If the relationship information is missing, the AE will be considered related. If the severity information is missing, the AE will be considered severe. n represents the number of subjects at each level of summarization. Percentages are based on the number of subjects in the Safety population within each treatment and overall.
Source Data: Listing 16.2.7.1

Table 14.3.1.2
Treatment-Emergent Adverse Events
Safety Population

System Organ Class Preferred Term	1 mg/kg SAB-176 (N=xxx) n (%)	10 mg/kg SAB-176 (N=xxx) n (%)	25 mg/kg SAB-176 (N=xxx) n (%)	50 mg/kg SAB-176 (N=xxx) n (%)	Pooled SAB-176 (N=xxx) n (%)	Pooled Placebo (N=xxx) n (%)	Total (N=xxx) n (%)
All TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term #2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…							
System Organ Class #2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term #2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…							

Note to Programmer: Include all treatment groups. System organ class is displayed in descending order of frequency for "Total" then alphabetically. Preferred term is displayed in descending order of frequency for "Total" then alphabetically within system organ class. If there are no TEAE, then display "No treatment-emergent adverse events were reported.".

Note: A TEAE is defined as any event not present before exposure to study drug or any event already present that worsens in intensity or frequency after exposure. At each level of subject summarization, a subject is counted once if the subject reported one or more events. n represents the number of subjects at each level of summarization. Percentages are based on the number of subjects in the Safety population within each treatment and overall.
Adverse Events were coded using MedDRA, Version xx.x.
Source Data: Listing 16.2.7.1

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

System Organ Class Preferred Term Relationship	1 mg/kg SAB-176 (N=xxx) n (%)	10 mg/kg SAB-176 (N=xxx) n (%)	25 mg/kg SAB-176 (N=xxx) n (%)	50 mg/kg SAB-176 (N=xxx) n (%)	Pooled SAB-176 (N=xxx) n (%)	Pooled Placebo (N=xxx) n (%)	Total (N=xxx) n (%)
All TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unlikely Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Possibly Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Probably Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unlikely Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Possibly Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Probably Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…							

Note to Programmer: Include all treatment groups. System organ class is displayed in descending order of frequency for "Total" then alphabetically. Preferred term is displayed in descending order of frequency for "Total" then alphabetically within system organ class. If there are no TEAEs, then display "No treatment-emergent adverse events were reported.".

Note: A TEAE is defined as any event not present before exposure to study drug or any event already present that worsens in intensity or frequency after exposure. At each level of subject summarization, a subject is counted once for the most related event. A treatment-related AE is defined as an AE that is evaluated by the investigator as definitely, probably, or possibly related to study drug. If the relationship information is missing, the AE will be considered related. n represents the number of subjects at each level of summarization. Percentages are based on the number of subjects in the Safety population within each treatment and overall.
Adverse events were coded using MedDRA version x.x.
Source Data: Listing 16.2.7.1

Table 14.3.1.4
Treatment-Emergent Adverse Events by Severity
Safety Population

System Organ Class Preferred Term Severity	1 mg/kg SAB-176 (N=xxx) n (%)	10 mg/kg SAB-176 (N=xxx) n (%)	25 mg/kg SAB-176 (N=xxx) n (%)	50 mg/kg SAB-176 (N=xxx) n (%)	Pooled SAB-176 (N=xxx) n (%)	Pooled Placebo (N=xxx) n (%)	Total (N=xxx) n (%)
All TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…							

Note to Programmer: Include all treatment groups. System organ class is displayed in descending order of frequency for "Total" then alphabetically. Preferred term is displayed in descending order of frequency for "Total" then alphabetically within system organ class. If there are no TEAEs, then display "No treatment-emergent adverse events were reported.".

Note: A TEAE is defined as any event not present before exposure to study drug or any event already present that worsens in intensity or frequency after exposure. At each level of subject summarization, a subject is counted once if the subject reported one or more events. If the severity information is missing, the AE will be considered severe. n represents the number of subjects at each level of summarization. Percentages are based on the number of subjects in the Safety population within each treatment and overall.
Adverse Events were coded using MedDRA, Version xx.x.
Source Data: Listing 16.2.7.1

Table 14.3.4.1.1
Summary of Actual Value and Change from Baseline in Hematology
Safety Population

Parameter: LAB TEST #1 (UNIT)

	Actual Value						Change From Baseline [1]					
Visit	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Baseline												
1 mg/kg SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx						
10 mg/kg SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx						
25 mg/kg SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx						
50 mg/kg SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx						
Pooled SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx						
Pooled Placebo (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx						
Day 2												
1 mg/kg SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx	xxx	xx.x	xx.xx	xx.x	xx	xx
10 mg/kg SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx	xxx	xx.x	xx.xx	xx.x	xx	xx
25 mg/kg SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx	xxx	xx.x	xx.xx	xx.x	xx	xx
50 mg/kg SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx	xxx	xx.x	xx.xx	xx.x	xx	xx
Pooled SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx	xxx	xx.x	xx.xx	xx.x	xx	xx
Pooled Placebo (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx	xxx	xx.x	xx.xx	xx.x	xx	xx

…

Note to Programmer: Include all treatment groups. Lab test parameters will be displayed in the same order as the lab test listing.
Scheduled visits for hematology include Baseline, Day 2, Day 3, Day 7, Day 42 and Day 90. Start a new page for each parameter.

Note: Baseline is defined as the last non-missing assessment prior to the study drug administration.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.1

Table 14.3.4.1.2
Shift from Baseline in Hematology
Safety Population

Parameter: LAB TEST #1 (UNIT)

	1 mg/kg SAB-176 (N=xx)					…	Pooled Placebo (N=xx)				
	Baseline						Baseline				
Post-Baseline Visit	Low n (%)	Normal n (%)	High n (%)	Total n (%)	Missing n		Low n (%)	Normal n (%)	High n (%)	Total n (%)	Missing n
Day 2											
Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx
Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx
High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx
Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx
Missing	xx	xx	xx	xx	xx		xx	xx	xx	xx	xx
…											

Note to Programmer: Include all treatment groups. Lab test parameters will be displayed in the same order as the lab test listing.
Scheduled visits for hematology include Day 2, Day 3, Day 7, Day 42 and Day 90. Start a new page for each parameter.

Note: Baseline is defined as the last non-missing assessment prior to the study drug administration.
Percentages are based on the number of subjects with non-missing data at both the baseline and the corresponding post-baseline visit.
Source Data: Listing 16.2.8.1

Table 14.3.4.2.1
Summary of Actual Value and Change from Baseline in Serum Chemistry
Safety Population

Use the same shell as Table 14.3.4.1.1.

Note to Programmer: Include all treatment groups. Lab test parameters will be displayed in the same order as the lab test listing.
Scheduled visits for serum chemisty include Baseline, Day 2, Day 3, Day 7 and Day 42. Start a new page for each parameter.

Note: Baseline is defined as the last non-missing assessment prior to the study drug administration.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2

Table 14.3.4.2.2
Shift from Baseline in Serum Chemistry
Safety Population

Use the same shell as Table 14.3.4.1.2.

Note to Programmer: Include all treatment groups. Lab test parameters will be displayed in the same order as the lab test listing.
Scheduled visits for serum chemisty include Day 2, Day 3, Day 7 and Day 42. Start a new page for each parameter.

Note: Baseline is defined as the last non-missing assessment prior to the study drug administration.
Percentages are based on the number of subjects with non-missing data at both the baseline and the corresponding post-baseline visit.
Source Data: Listing 16.2.8.2

Table 14.3.4.3.1
Summary of Actual Value and Change from Baseline in Urianalysis
Safety Population

Use the same shell as Table 14.3.4.1.1.

Note to Programmer: Include all treatment groups. Lab test parameters will be displayed in the same order as the lab test listing.
Scheduled visits for urianalysis include Baseline, Day 2, Day 3, Day 7 and Day 42. Start a new page for each parameter.

Note: Baseline is defined as the last non-missing assessment prior to the study drug administration.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.3

Table 14.3.4.3.2
Shift from Baseline in Urianalysis
Safety Population

Use the same shell as Table 14.3.4.1.2.

Note to Programmer: Include all treatment groups. Lab test parameters will be displayed in the same order as the lab test listing.
Scheduled visits for urianalysis include Day 2, Day 3, Day 7 and Day 42. Start a new page for each parameter.

Note: Baseline is defined as the last non-missing assessment prior to the study drug administration.
Percentages are based on the number of subjects with non-missing data at both the baseline and the corresponding post-baseline visit.
Source Data: Listing 16.2.8.3

Table 14.3.4.4.1
Summary of Actual Value and Change from Baseline in Urine biomarkers
Safety Population

Use the same shell as Table 14.3.4.1.1.

Note to Programmer: Include all treatment groups. Lab test parameters will be displayed in the same order as the lab test listing.
Scheduled visits for urianalysis include Baseline, Day 2, Day 3, Day 7 and Day 42. Start a new page for each parameter.

Note: Baseline is defined as the last non-missing assessment prior to the study drug administration.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.4

Table 14.3.5.1
Summary of Actual Value and Change from Baseline in Vital Signs
Safety Population

Parameter: VITAL SIGN PARAMETER #1 (UNIT)

Visit – Time Point	Actual Value						Change From Baseline [1]					
Treatment	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Baseline												
1 mg/kg SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx						
10 mg/kg SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx						
25 mg/kg SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx						
50 mg/kg SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx						
Pooled SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx						
Pooled Placebo (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx						
Day 1												
1 mg/kg SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx	xxx	xx.x	xx.xx	xx.x	xx	xx
10 mg/kg SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx	xxx	xx.x	xx.xx	xx.x	xx	xx
25 mg/kg SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx	xxx	xx.x	xx.xx	xx.x	xx	xx
50 mg/kg SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx	xxx	xx.x	xx.xx	xx.x	xx	xx
Pooled SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx	xxx	xx.x	xx.xx	xx.x	xx	xx
Pooled Placebo (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx	xxx	xx.x	xx.xx	xx.x	xx	xx
…												

Note to Programmer: Include all treatment groups. Vital sign parameters will be displayed in the same order as the vital sign listing.
Vital Sign parameters include: systolic and diastolic blood pressure, hearth rate, respiratory rate, body temperature and pulse oximetry.
Scheduled visits for vital signs include Baseline, Day 1, Day 2, Day 3, Day 7, Day 21, Day 42 and Day 90. Start a new page for each parameter.

Note: Baseline is defined as the last non-missing assessment prior to the study drug administration.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.6

Table 14.3.6.1.1
Summary of Anti-IgG Antibody Tilter value
Safety Population

Study Day	Summary Statistic	Treatment: 1 mg/kg SAB-176 (N=xx)	10 mg/kg SAB-176 (N=xx)	25 mg/kg SAB-176 (N=xx)	50 mg/kg SAB-176 (N=xx)
Predose	n	x	x	x	x
	Mean	xxx	xxx	xxx	xxx
	SD	xxx	xxx	xxx	xxx
	CV (%)	xxx	xxx	xxx	xxx
	Median	xxx	xxx	xxx	xxx
	Minimum	xxx	xxx	xxx	xxx
	Maximum	xxx	xxx	xxx	xxx
	Geometric Mean	xxx	xxx	xxx	xxx
	Geometric CV (%)	xxx	xxx	xxx	xxx
Day 2	n	x	x	x	x
	Mean	xxx	xxx	xxx	xxx
	SD	xxx	xxx	xxx	xxx
	CV (%)	xxx	xxx	xxx	xxx
	Median	xxx	xxx	xxx	xxx
	Minimum	xxx	xxx	xxx	xxx
	Maximum	xxx	xxx	xxx	xxx
	Geometric Mean	xxx	xxx	xxx	xxx
	Geometric CV (%)	xxx	xxx	xxx	xxx

CV = Coefficient of variation; SD = Standard deviation.
Source Data: Listing 16.2.8.9

Table 14.3.6.1.2
Proportion of Subjects Positive and Negative for Anti-IgG Antibody
Safety Population

Visit Anti-IgG Antibody	1 mg/kg SAB-176 (N=xx)	10 mg/kg SAB-176 (N=xx)	25 mg/kg SAB-176 (N=xx)	50 mg/kg SAB-176 (N=xx)	Pooled SAB-176 (N=xx)	Pooled Placebo (N=xx)
Day 2						
Negative	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Positive	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 3						
Negative	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Positive	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 7						
Negative	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Positive	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 21						
Negative	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Positive	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 42						
Negative	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Positive	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 90						
Negative	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Positive	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: Percentages are based on subjects within the Safety population within each treatment.
Source Data: Listing 16.2.8.9

Table 14.3.6.2.1
Summary of Anti-SAB-176 Antibody Tilter value
Safety Population

Use the same shell as Table 14.3.6.1.1.

CV = Coefficient of variation; SD = Standard deviation.
Source Data: Listing 16.2.8.10

Table 14.3.6.2.2
Proportion of Subjects Positive and Negative for Anti-SAB-176 Antibody
Safety Population

Use the same shell as Table 14.3.6.1.2.

Note: Percentages are based on subjects within the Safety population within each treatment.
Source Data: Listing 16.2.8.10

Table 14.3.6.3.1
Summary of Actual Value and Change from Baseline in Serum parameters HAI assay
Safety Population

Parameter: LAB TEST #1 (UNIT)

	Actual Value						Change From Baseline [1]					
Visit	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Baseline												
1 mg/kg SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx						
10 mg/kg SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx						
25 mg/kg SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx						
50 mg/kg SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx						
Pooled SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx						
Pooled Placebo (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx						
Day 7												
1 mg/kg SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx	xxx	xx.x	xx.xx	xx.x	xx	xx
10 mg/kg SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx	xxx	xx.x	xx.xx	xx.x	xx	xx
25 mg/kg SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx	xxx	xx.x	xx.xx	xx.x	xx	xx
50 mg/kg SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx	xxx	xx.x	xx.xx	xx.x	xx	xx
Pooled SAB-176 (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx	xxx	xx.x	xx.xx	xx.x	xx	xx
Pooled Placebo (N=xxx)	xxx	xx.x	xx.xx	xx.x	xx	xx	xxx	xx.x	xx.xx	xx.x	xx	xx

…

Note to Programmer: Include all treatment groups. Lab test parameters will be displayed in the same order as the lab test listing.
Scheduled visits for hematology include Baseline, Day 7, Day 21, Day 42 and Day 90. Start a new page for each parameter.

Note: Baseline is defined as the last non-missing assessment prior to the study drug administration.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.11

Table 14.3.6.3.2
Shift from Baseline in Serum parameters HAI assay
Safety Population

Parameter: LAB TEST #1 (UNIT)

	1 mg/kg SAB-176 (N=xx)					…	Pooled Placebo (N=xx)				
	Baseline						Baseline				
Post-Baseline Visit	Low n (%)	Normal n (%)	High n (%)	Total n (%)	Missing n		Low n (%)	Normal n (%)	High n (%)	Total n (%)	Missing n
Day 7											
Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx
Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx
High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx
Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx
Missing	xx	xx	xx	xx	xx		xx	xx	xx	xx	xx

…

Note to Programmer: Include all treatment groups. Lab test parameters will be displayed in the same order as the lab test listing.
Scheduled visits for hematology include Day 7, Day 21, Day 42 and Day 90. Start a new page for each parameter.

Note: Baseline is defined as the last non-missing assessment prior to the study drug administration.
Percentages are based on the number of subjects with non-missing data at both the baseline and the corresponding post-baseline visit.
Source Data: Listing 16.2.8.11

Table 14.3.6.4.1
Summary of Actual Value and Change from Baseline in Serum parameters MN assay
Safety Population

Use the same shell as Table 14.3.6.3.1.

Note to Programmer: Include all treatment groups. Lab test parameters will be displayed in the same order as the lab test listing.
Scheduled visits for serum chemisty include Baseline, Day 7, Day 21, Day 42 and Day 90. Start a new page for each parameter.

Note: Baseline is defined as the last non-missing assessment prior to the study drug administration.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.12

Table 14.3.6.4.2
Shift from Baseline in Serum parameters MN assay
Safety Population

Use the same shell as Table 14.3.6.3.2.

Note to Programmer: Include all treatment groups. Lab test parameters will be displayed in the same order as the lab test listing.
Scheduled visits for serum chemisty include Day 7, Day 21, Day 42 and Day 90. Start a new page for each parameter.

Note: Baseline is defined as the last non-missing assessment prior to the study drug administration.
Percentages are based on the number of subjects with non-missing data at both the baseline and the corresponding post-baseline visit.
Source Data: Listing 16.2.8.12

Listing 16.1.7
Randomization

Subject	Cohort	Date/Time of Randomization	Randomization Number	Treatment
xxx	xxxxx	DDMMMYYYY/HH:MM	xxxxx	xxxxxxxxxxxxxxxx
xxx	xxxxx	DDMMMYYYY/HH:MM	xxxxx	xxxxxxxxxxxxxxxx

Note to Programmer: Sort by subject and cohort.

Listing 16.2.1
Discontinued subjects
Enrolled Population

Subject/ Cohort	Date of Last Dose	Date of Final Contact	Completed Study?	Discontinuation		Was Blind Broken?	Date/Time of Unblinding
				Date	Reason		
XXXXXXX/X	DDMMMYYYY	xxxxxx	Yes			No	
XXXXXXX/X	DDMMMYYYY	xxxxxx	No	DDMMMYYYY	XXXXX	Yes	DDMMMYYYY/HH:MM
XXXXXXX/X	DDMMMYYYY	xxxxxx	No	DDMMMYYYY	Adverse Event: XXXX	No	

…

Note to Programmer: Sort by treatment (in the order of dose level), cohort, and subject. If discontinuation occurred due to AE, append the corresponding AE term.

Listing 16.2.2.1
Admission Criteria Deviations
Safety Population

Treatment: xx mg/kg xxxxxxxxx

Subject/ Cohort	Protocol Version	Inclusion Criteria Not Met	Exclusion Criteria Met
XXXXXX/X	AMENDMENT X, VERSION 1.0, DD-MON-YYYY	INxx, INxx, INxx	EXxx, EXxx, EXxx
XXXXXX/X	AMENDMENT X, VERSION 1.0, DD-MON-YYYY		

Note to Programmer: Sort by treatment (in the order of dose level), cohort and subject. If there are no admission criteria deviations, then display "No admission criteria deviations were reported.".

Listing 16.2.2.2
Protocol Deviations

Treatment: xx mg/kg xxxxxxxxx

Subject/ Cohort	Date (Day) [1] of Deviation	Important Deviation	Description
XXXXXX/X	DDMMMYYYY (xx)	Yes	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXX/X	DDMMMYYYY (xx)	No	XXXXXXXXXXXXXX

Note to programmer: Sort by treatment (in the order of dose level), cohort and subject. Start a new page for each treatment. If there are no protocol deviations, then display "No protocol deviations were reported."

[1] Day is calculated relative to the first dose date

Listing 16.2.3
Analysis Population

Treatment: xx mg/kg xxxxxxxxx

Subject/ Cohort	Safety Population [1]	Reason for Exclusion	PK Population [2]	Reason for Exclusion
XXXXXX/X	Yes		Yes	
XXXXXX/X	No	XXXXXXXXX	No	XXXXXXXXX

Note to programmer: Sort by treatment (in the order of dose level), cohort and subject. Start a new page for each treatment.

[1] The Safety population included all subjects who are randomized and received SAB-176.
[2] The PK population included all subjects in the safety population who have received SAB-176 treatment and have sufficient PK concentration data to calculate reliable estimates of at least one key PK parameters (C_{max} or AUC).

Listing 16.2.4.1
Demographics
Safety Population

Treatment: xx mg/kg xxxxxxxxx

Subject/ Cohort	Date of Informed Consent	Date of Birth	Age (years)	Sex	Race	Ethnicity	Screening		
							Height (cm)	Weight (kg)	BMI (kg/m2)
XXXXXX/X	DDMMMYYYY	DDMONYYYY	XX	Male	xxxxxxxxxxxxxx	NOT HISPANIC OR LATINO	XXX.X	XXX.X	XXX.X
XXXXXX/X	DDMMMYYYY	DDMONYYYY	XX	Female	xxxxxxxxx	HISPANIC OR LATINO	XXX.X	XXX.X	XXX.X

Note to Programmer: Sort by treatment (in the order of dose level), cohort and subject. Start a new page for each treatment.

Listing 16.2.4.2
Medical History
Safety Population

Treatment: xx mg/kg xxxxxxxxx

Subject/ Cohort	Condition/Diagnosis	System Organ Class [1] / Preferred Term [1] /	Start Date/Stop Date
XXXXXX/X	XXXXXXXXX	XXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMONYYYY/DDMONYYYY
	XXXXXXXXX	XXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX	DDMONYYYY/Ongoing
XXXXXX/X	XXXXXXXXX	XXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX	DDMONYYYY/DDMONYYYY

Note to Programmer: Sort by treatment (in the order of dose level) cohort, subject, condition/diagnosis, and start/stop date. Start a new page for each treatment. Display "Ongoing" in place of Stop Date if the condition is ongoing. If there are no medical histories, then display "No medical histories were reported."

[1] From MedDRA version xx.x.

Listing 16.2.4.4
Prior and Concomitant Medications
Safety Population

Treatment: xx mg/kg xxxxxxxxx

Subject/ Cohort	Preferred Drug Name [1]/ Drug Name	Prior to Study	Individual Dose/ Total daily dose	Unit	Start Date Time (Day)/ Stop Date Time (Day)	Route/ Freq	Indication (AE ID or MH ID)
XXXXXX/X	XXXXXXXXXXXXXX/ XXXXXXXXXXXXX	YES	XXXX/ XXXX	XXXXXX	DDMONYYYY HH:MM (XX)/ DDMONYYYY HH:MM(XX)	XXX/XXX	XXXXXXXXX (MH: XXXX)
XXXXXX/X	XXXXXXXXXXXXXX/ XXXXXXXXXXXXX	NO	XXXX/ XXX	XXXXXX	DDMONYYYY HH:MM (XX)/ Ongoing	XXX/XXX	XXXXXXXXX (AE: XXXX)

Note to Programmer: Note to Programmer: Sort by treatment, cohort, subject, preferred drug name, and date/time started. Start a new page for each treatment. Display "Ongoing" in place of Stop Date/Time if the medication is ongoing. If there are no prior or concomitant medications, then display "No prior or concomitant medications were reported.".

[1] From WHODrug version xx.x.
Day is calculated relative to the first dose date

Listing 16.2.4.5
Medical/Surgical Treatment Procedures
Safety Population

Treatment: xx mg/kg xxxxxxxxx

Subject/Cohort	Treatment Procedure	Indication	AE ID	Start Date	End Date	Ongoing
XXXXXX/X	XXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXX	XX	DDMONYYYY	DDMONYYYY	No
XXXXXX/X	XXXXXXXXXXXXXXXXXXXXXX	ADVERSE EVENT: xx		DDMONYYYY	DDMONYYYY	No

Note to Programmer: Sort by treatment (in the order of dose level), cohort, subject, procedure, and start/stop date. If procedure is ongoing then display "Ongoing" in the place of Stop Date. If the procedure was for an AE, please attach the corresponding AE ID to Reason. Start a new page for each treatment. If there are no medical or surgical treatment procedures, then display "No medical or surgical treatment procedures were reported."

Day is calculated relative to the first dose date

Listing 16.2.5.1
Study Drug Administration
Safety Population

Subject/ Cohort	Treatment	Planned Timepoint	Treatment Start Date/Time (Day)	Treatment End Date/Time (Day)	Planned Dose (Units)	Frequency/ Route	Dose Adjusted/ Reason	Dose Interrupted/ Duration (Units)	Total amount (Units)	Initial Infusion rate	Treatment Completed
XXXXXX/X	1 mg/kg SAB-176	Day 1	DDMONYYYY HH:MM (XX)	DDMONYYYY HH:MM (XX)	XX(xx)	ONCE/ INTRAVENOUS	YES/ XXXXXXXX	YES/ XXX (xx)	XXX(xx)	XX (mL/kg/hr)	YES
XXXXXX/X	Placebo		DDMONYYYY HH:MM (XX)	DDMONYYYY HH:MM (XX)	XX(xx)		NO	NO	XXX(xx)	XX (mL/kg/hr)	NO

Note to Programmer: Sort by cohort, subject, Start Date and time.

Day is calculated relative to the first dose date

Listing 16.2.6.1
Individual Serum Concentration of SAB-176 Following IV Administration
Safety Population

Treatment	Subject ID	Sex/Age/Race	Day	Scheduled Timepoint	Collection Date/Time	Actual Time (day)	Time Deviation (h)	SAB-176 Conc. (unit)	Comment
xxxx	xxx	x/xxx/xx	0	Pre-dose	DDMMMYYYY/HH:MM	xx.x	x	BLQ	
				1 h post EOI	DDMMMYYYY/HH:MM	xx.x	x	xx.x	HEMOLYZED
				6 h post EOI	DDMMMYYYY/HH:MM	xx.x	x	xx.x	xxxxxxxxx
			1		DDMMMYYYY/HH:MM	xx.x	x	xx.x	
			2		DDMMMYYYY/HH:MM	xx.x	x	xx.x	
			3		DDMMMYYYY/HH:MM	xx.x	x	xx.x	xxxxxxxxx
			7		DDMMMYYYY/HH:MM	xx.x	x	xx.x	
			21		DDMMMYYYY/HH:MM	xx.x	x	xx.x	
			42		DDMMMYYYY/HH:MM	xx.x	x	xx.x	
			90		DDMMMYYYY/HH:MM	xx.x	x	xx.x	
…	…	…	…	…	…	…	….	…	…

Note to Programmer:

1. *Sort by Treatment, Subject ID, Day and Scheduled time point.*
2. *Treatment includes 1 mg/kg SAB-176 IV, 10 mg/kg SAB-176 IV, 25 mg/kg SAB-176 IV and 50 mg/kg SAB-176 IV.*
3. *Time points are: Pre-dose, 1 h post EOI, 6 h post EOI on Day 0, Day 1, Day 2, Day 3, Day 7, Day 21, Day 42 and Day 90. Note that collections beyond Day 0 will not have a 'scheduled time'.*

M = Male, F = Female.
W = White, B = Black or African American, P = Native Hawaiian or other Pacific Islander, A = Asian, N = American Indian or Alaska Native, M = Multiple, O = Other.
EOI = end of infusion; SOI = start of infusion
BLQ: below the lower limit of quantitation (LLOQ); LLOQ for SAB-176 in serum is xx (units).
Source Data: CRF data and concentration data.

Listing 16.2.6.2
Individual Serum Pharmacokinetic Parameters of SAB-176 Following IV Administration
PK Population

Treatment	Subject ID	Cmax (unit)	tmax (unit)	AUC0-t (units)	AUC0-inf (units)	Lambdaz (unit)	t1/2 (unit)	CL (unit)	Vz (unit)
xxxxxx	xxxxxx	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	xxxxxx	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	xxxxxx	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	xxxxxx	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	xxxxxx	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	xxxxxx	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
…	…	…	…	…	…	…	…	…	…

Note to Programmer:

1. *Please sort by Treatment and Subject ID.*
2. *Treatment includes 1 mg/kg SAB-176 IV, 10 mg/kg SAB-176 IV, 25 mg/kg SAB-176 IV and 50 mg/kg SAB-176 IV.*

Source Data: Listing 16.2.6.1.

Listing 16.2.7.1
Adverse Events
Safety Population

Treatment: xx mg/kg xxxxxxxxx

Subject	TEAE	System Organ Class/ Preferred Term/ Adverse Event Term	Start Date/ Time (Day)/ Stop Date/ Time (Day)	Frequency/ Outcome/ Serious/ SAE Criteria	Severity/ Action/ Other Action	Relationship/ Study Disc/ CM/CM ID
XXXXXX	Yes	XXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXX/ XXXXXXXXXXXXXX	DDMONYYYY HH:MM (XX)/ DDMONYYYY HH:MM (XX)	INTERMITTENT/ RECOVERED/ YES\ XXXXXX	MILD/ NOT APPLICABLE/ XXXXXXXX	RELATED/ NO/ YES/##, ##
	No	XXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXX/ XXXXXXXXXXXXXXX	DDMONYYYY HH:MM (XX)/ Ongoing	CONTINOUS/ UNKNOWN/ NO	XXXXXXXXX/ XXXXXXXX/ XXXXXXXXX	XXX/ XXX/ NO

Note to Programmer: Sort by treatment (in the order of dose level), cohort, subject, AE Start Date/Time, and alphabetically by System Organ Class, Preferred Term, and Adverse Event Reported. Display "Ongoing" in place of Stop Date/Time if the AE is ongoing.

Day is calculated relative to the first dose date
CM=Concomitant or Additional Treatment Given?; CM ID=ID of medication/therapy taken for AE
Action=Action taken with study treatment
Relationship=Relationship to study treatment
Study Disc=Caused study discontinuation?
Adverse Events were coded using MedDRA, Version xx.x.

Repeat Listing 16.2.7.1 for the following:

Listing 16.2.7.2
Treatment-Related Adverse Events
Safety Analysis Set

Note to Programmer: Sort by treatment (in the order of dose level), cohort, subject, AE Start Date/Time, and alphabetically by System Organ Class, Preferred Term, and Adverse Event Reported. Remove "Relationship" of Column 7

Day is calculated relative to the first dose date
CM=Concomitant or Additional Treatment Given?; CM ID=ID of medication/therapy taken for AE
Action=Action taken with study treatment
Relationship=Relationship to study treatment
Study Disc=Caused study discontinuation?
Adverse Events were coded using MedDRA, Version xx.x.

Listing 14.3.2.1
Serious Adverse Events
Safety Population

Use the same shell as Listing 16.2.7.1. Omit Serious from column 5.

Day is calculated relative to the first dose date
CM=Concomitant or Additional Treatment Given? ; CM ID=ID of medication/therapy taken for AE
Action=Action taken with study treatment
Relationship=Relationship to study treatment
Study Disc=Caused study discontinuation?
Adverse Events were coded using MedDRA, Version xx.x.

Listing 14.3.2.2
Adverse Events Leading to Early Discontinuation
Safety Population

Use the same shell as Listing 16.2.7.1.

Day is calculated relative to the first dose date
CM=Concomitant or Additional Treatment Given? ; CM ID=ID of medication/therapy taken for AE
Relationship=Relationship to study treatment
Study Disc=Caused study discontinuation?
Adverse Events were coded using MedDRA, Version xx.x.

Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Treatment: xx mg/kg xxxxxxx

Subject/ Cohort	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag	Reference Range	Comments
XXXXXX/X	XXXXXXXX	DDMONYYYY HH:MM (XX)	XXXXXXXXXXXXXXX	XXX.X	XXXXX		XXX.X-XXX.X	
			XXXXXXXXXXXXXXX	XXX.X	XXXXX	H NCS	XXX.X-XXX.X	
			XXXXXXXXXXXXXXX	XXX.X	XXXXX	L NCS	XXX.X-XXX.X	XXXXXXXXX
			XXXXXXXXXXXXXXX	XXX.X	XXXXX			
	XXXXXXX	DDMONYYYY HH:MM (XX) R	XXXXXXXXXXXXXXX	XXX.X	XXXXX	L CS	XXX.X-XXX.X	XXXXXXXXX
			XXXXXXXXXXXXXXX	XXX.X	XXXXX	H NCS	XXX.X-XXX.X	
			XXXXXXXXXXXXXXX	XXX.X	XXXXX	L NCS	XXX.X-XXX.X	
			XXXXXXXXXXXXXXX	XXX.X	XXXXX		XXX.X-XXX.X	

Note to Programmer: Sort by treatment (in the order of dose level), cohort, and subject, Laboratory Test Collection Date/Time, Lab test. For Result and Reference Range, display the number of decimal places where applicable exactly as they are in the data.

R = Repeat.
L = Low; H = High; CS = Clinically Significant; NCS = Not Clinically Significant.
Day is calculated relative to the first dose date

Listing 16.2.8.2
Laboratory Results – Serum Chemistry
Safety Population

Use the same shell as Listing 16.2.8.1.

R = Repeat.
L = Low; H = High; CS = Clinically Significant; NCS = Not Clinically Significant.
Day is calculated relative to the first dose date

Listing 16.2.8.3
Laboratory Results – Urinalysis
Safety Population

Use the same shell as Listing 16.2.8.1.

R = Repeat.
L = Low; H = High; CS = Clinically Significant; NCS = Not Clinically Significant.
Day is calculated relative to the first dose date

Listing 16.2.8.4
Laboratory Results – Urine biomarkers
Safety Population

Use the same shell as Listing 16.2.8.1.

R = Repeat.
L = Low; H = High; CS = Clinically Significant; NCS = Not Clinically Significant.
Day is calculated relative to the first dose date

Listing 16.2.8.5
Laboratory Results – Other
Safety Population

Use the same shell as Listing 16.2.8.1.

Note to Programmer: Omit flag and reference range columns.
R = Repeat.
Day is calculated relative to the first dose date

Listing 16.2.8.6
Vital Sign Results
Safety Population

Treatment: xx mg/kg xxxxxxxxx

Subject/ Cohort	Visit - Timepoint	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)	Pulse Oximetry (%)	Weight (kg)	BMI (kg/m^2)	Comment
XXXXXX/X	Screening	DDMMYYYY HH:MM (XX) R	SITTING	XXX	XX	XXX	XX	XXX	XXX	XXX	XXX	XXXXXXXXX
	XXXXX	DDMMYYYY HH:MM (XX)	SITTING	XXX	XX	XXX	XX	XXX	XXX	XXX		XXXXXXXXX
	XXXXX	DDMMYYYY: HH:MM (XX)		XXX	XX	XXX	XX	XXX	XXX	XXX		XXXXXXXXX

Note to Programmer: Sort by treatment (in the order of dose level), cohort, subject, and Date time. Start a new page for each treatment.

Day is calculated relative to the first dose date
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat

Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Treatment: xx mg/kg xxxxxxxxx

Subject/ Cohort	Position/ Method	Visit/ Date Time (Day)	Heart Rate (beats/min)	PR Interval (msec)	QRS Axis (degrees)	QRS Duration (msec)	QT Interval (msec)	QTcF Interval (msec)	RR Interval (msec)	Interpretation/ Clinically Significant	Abnormal Findings
XXXXXX/X	SUPINE/ XXXXXX	XXXX/ DDMONYYYY HH:MM (XX) R	XXX	XXX	XXX	XXX	XXX	XXX	XXX	AB; NCS	XXXXX
XXXXXX/X	XXXXX/ XXXXXXX	XXXX/ DDMONYYYY HH:MM(XX)	XXX	XXX	XXX	XXX	XXX	XXX	XXX	AB; CS	XXXXX
XXXXXX/X	XXXX/ XXXXXX	XXXX/ DDMONYYYY HH:MM(XX)	XXX	XXX	XXX	XXX	XXX	XXX	XXX	NORMAL	

Note to Programmer: Sort by treatment (in the order of dose level), cohort, subject, and Date Time.

Day is calculated relative to the first dose date
bpm=beats per minute, Int=Interval
R=Repeat, AB=Abnormal, CS=Clinically Significant, NCS=Not clinically significant

Listing 16.2.8.8
Physical Examination
Safety Population

Treatment: xx mg/kg xxxxxxxxx

Subject/ Cohort	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Abnormal Findings
XXXXXX/X	XXXX/ DDMONYYYY (XX)	SKIN	ABNORMAL, CS	XXXXXXXXX
		ABDOMEN	NORMAL	
		…		

Note to Programmer: Sort by treatment, cohort, subject, date/time, and body system (in the order as they appear in CRF). Start a new page for each treatment.

Day is calculated relative to the first dose date
CS=Clinically Significant, NCS=Not clinically significant

Listing 16.2.8.9
Anti-IgG Antibodies using Rheumatoid factor
Safety Population

Treatment: xx mg/kg xxxxxxxxx

Subject/ Cohort	ADA Status	Visit	Sample Collection Date (Day)/Time	ADA Result	Titer	Comment
XXXXXX/X	Positive	Day 2	DDMMMYYYY (xx)/HH:MM	Negative	XXXXX	
		Day 3	DDMMMYYYY (xx)/HH:MM	Negative	XXXXX	XXXXXXXXXXXXXXX
		Day 7	DDMMMYYYY (xx)/HH:MM	Positive	XXXXX	
		Day 21	DDMMMYYYY (xx)/HH:MM	Negative	XXXXX	
		Day 42	DDMMMYYYY (xx)/HH:MM	Negative	XXXXX	
		Day 90	DDMMMYYYY (xx)/HH:MM	Negative	XXXXX	

Note: ADA = Anti-drug Antibody.

Note to programmer: Sort by Treatment, Subject, and Sample Collection Datetime. If titer is not collected, then remove titer column. If additional columns if other information is collected.

Listing 16.2.8.10
Anti-SAB-176 Antibody
Safety Population

Treatment: xx mg/kg xxxxxxxxx

Subject/ Cohort	ADA Status	Visit	Sample Collection Date (Day)/Time	ADA Result	Titer	Comment
XXXXXX/X	Positive	Day 2	DDMMMYYYY (xx)/HH:MM	Negative		
		Day 3	DDMMMYYYY (xx)/HH:MM	Negative		
		Day 7	DDMMMYYYY (xx)/HH:MM	Positive		
		Day 21	DDMMMYYYY (xx)/HH:MM	Negative		
		Day 42	DDMMMYYYY (xx)/HH:MM	Negative		
		Day 90	DDMMMYYYY (xx)/HH:MM	Negative		

Note: ADA = Anti-drug Antibody.

Note to programmer: Sort by Treatment, Subject, and Sample Collection Datetime. If titer is not collected, then remove titer column. If additional columns if other information is collected.

Listing 16.2.8.11
Hemagglutination Inhibition (HAI) Assay
Safety Population

Treatment: xx mg/kg xxxxxxx

Subject/ Cohort	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag	Reference Range	Comments
XXXXXX/X	XXXXXXXX	DDMONYYYY HH:MM (XX)	XXXXXXXXXXXXXXX	XXX.X	XXXXX		XXX.X-XXX.X	
			XXXXXXXXXXXXXXX	XXX.X	XXXXX	H NCS	XXX.X-XXX.X	
			XXXXXXXXXXXXXXX	XXX.X	XXXXX	L NCS	XXX.X-XXX.X	XXXXXXXXX
			XXXXXXXXXXXXXXX	XXX.X	XXXXX			
	XXXXXXX	DDMONYYYY HH:MM (XX) R	XXXXXXXXXXXXXXX	XXX.X	XXXXX	L CS	XXX.X-XXX.X	XXXXXXXXX
			XXXXXXXXXXXXXXX	XXX.X	XXXXX	H NCS	XXX.X-XXX.X	
			XXXXXXXXXXXXXXX	XXX.X	XXXXX	L NCS	XXX.X-XXX.X	
			XXXXXXXXXXXXXXX	XXX.X	XXXXX		XXX.X-XXX.X	

Note to Programmer: Sort by treatment (in the order of dose level), cohort, and subject, Laboratory Test Collection Date/Time, Lab test. For Result and Reference Range, display the number of decimal places where applicable exactly as they are in the data.

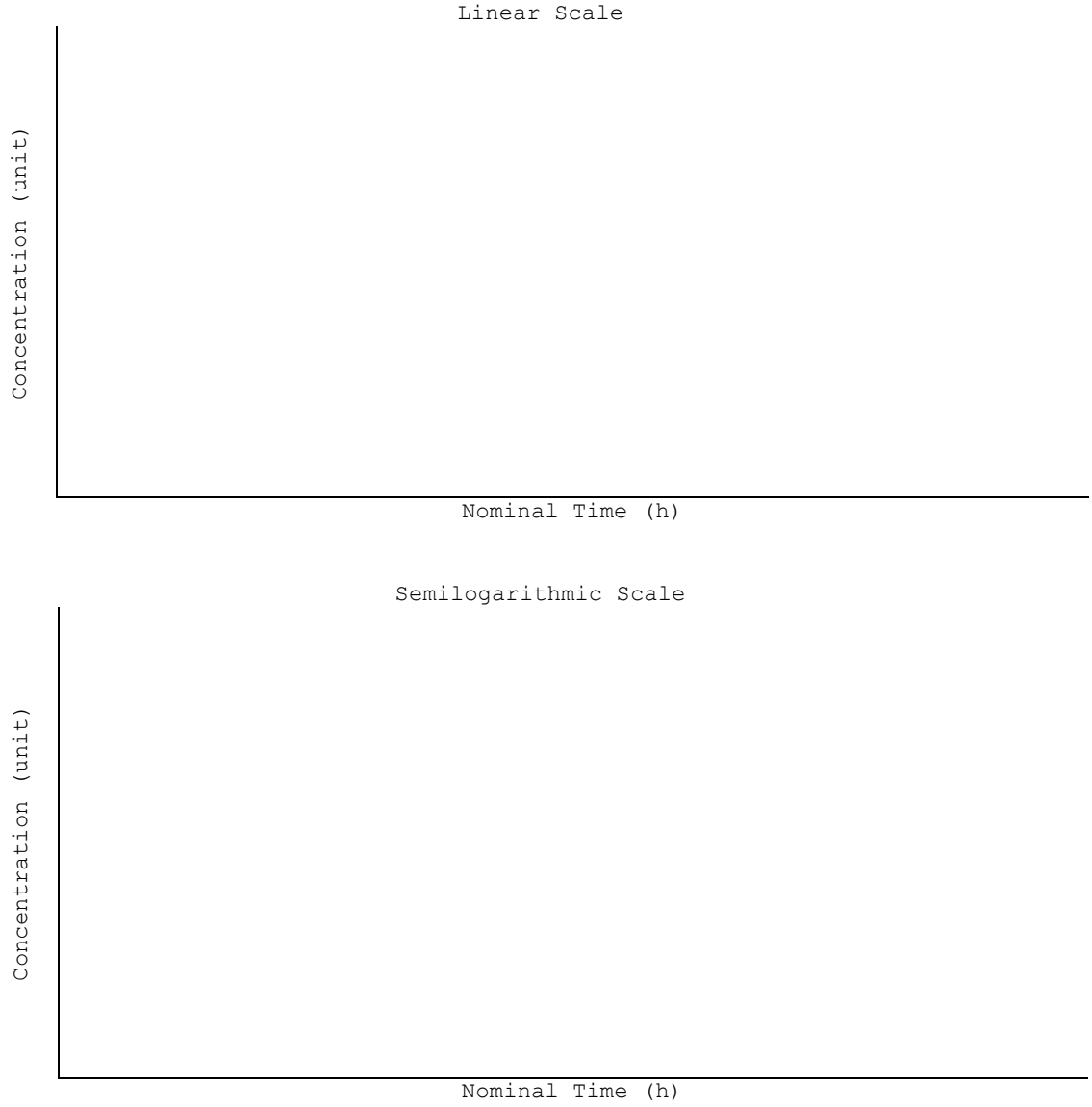
R = Repeat.
L = Low; H = High; CS = Clinically Significant; NCS = Not Clinically Significant.
Day is calculated relative to the first dose date

Listing 16.2.8.12
Microneutralization (MN) Assay
PD Population

Use the same shell as Listing 16.2.8.11.

R = Repeat.
L = Low; H = High; CS = Clinically Significant; NCS = Not Clinically Significant.
Day is calculated relative to the first dose date

Figure 14.2.1.1
Mean (± SD) Serum Concentration versus Time Profiles for SAB-176
PK Population



Note: Time points are relative to the start of infusion.
Source Data: Table 14.2.5.1.1

Note to programmer:
Please plot mean concentration versus nominal time and overlay 4 treatments: 1 mg/kg SAB-176, 10 mg/kg SAB-176, 25 mg/kg SAB-176 and 50 mg/kg SAB-176, display *treatment labels in legend.*

Figure 14.2.1.2
Mean (± SD) Serum Concentration versus Time Profiles for SAB-176 by ADA Status
PK Population

Note: Time points are relative to the start of infusion.
Source Data: Table 14.2.5.1.1

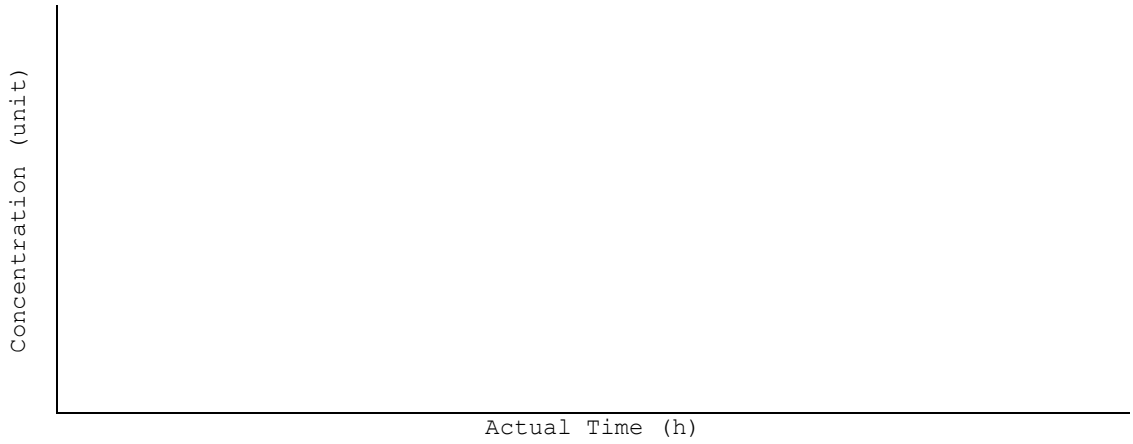
Note to programmer:

1. *Please plot mean concentration versus nominal time and overlay 4 treatments:* 1 mg/kg SAB-176, 10 mg/kg SAB-176, 25 mg/kg SAB-176 and 50 mg/kg SAB-176, display *treatment labels in legend.*
2. *Please continue with ADA Status: positive and/or ADA Status: missing*

Figure 14.2.2.1
Individual Serum Concentration versus Time Profiles for SAB-176
Safety Population

Treatment: XXXXX
Subject ID: xxx
ADA Status: xxx

Linear Scale

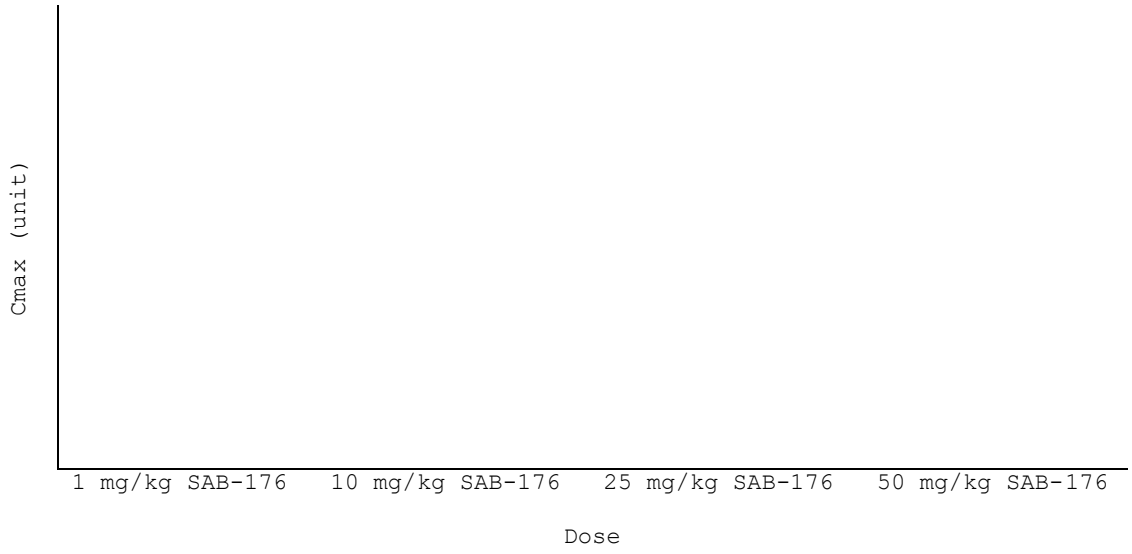


Semilogarithmic Scale

Note: Time points are relative to the start of infusion.
Source Data: Listing 16.2.6.1

Note to Programmer:
1. Please plot individual concentration versus actual time.
2. Present one subject for each plot.
3. Treatment includes 1 mg/kg SAB-176, 10 mg/kg SAB-176, 25 mg/kg SAB-176 and 50 mg/kg SAB-176.

Figure 14.2.3.1
Scatter Plot of Individual and mean Cmax versus Dose for SAB-176 Following IV Administration
PK Population

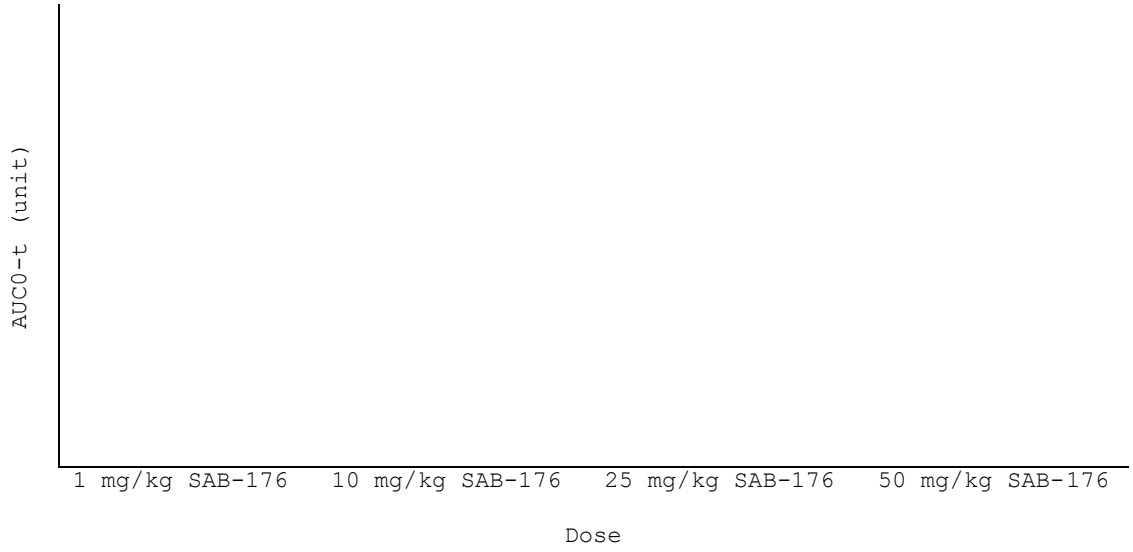


Note: open symbols represent individual data and closed symbols represent mean data.

Source Data: Listing 16.2.6.2 and Table 14.2.5.2.2

Note to Programmer: Use linear scale for both X-axis and Y-axis.

Figure 14.2.3.2
Scatter Plot of Individual and mean AUC0-t versus Dose for SAB-176 Following IV Administration
PK Population

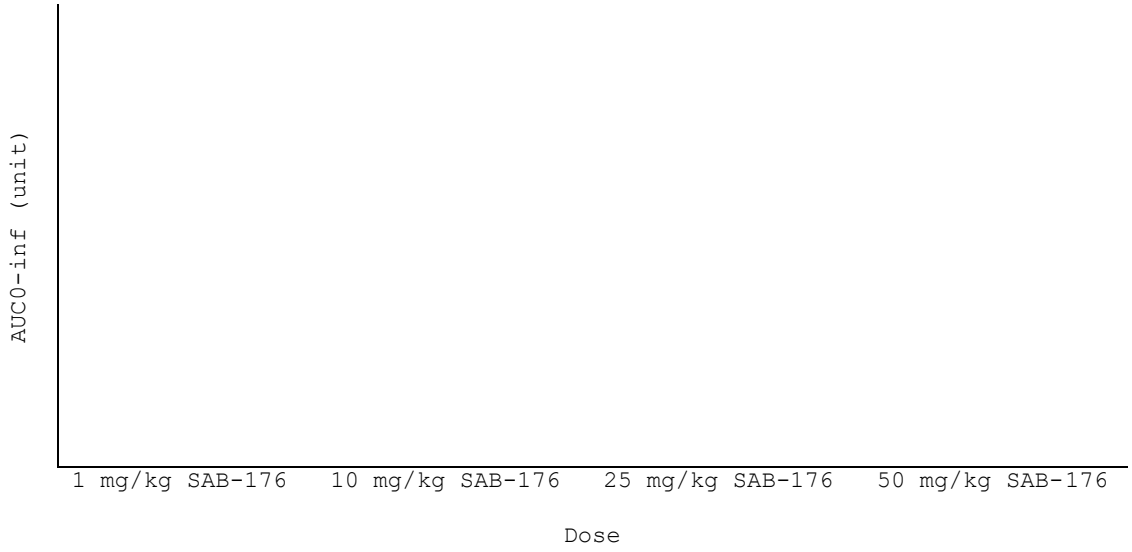


Note: open symbols represent individual data and closed symbols represent mean data.

Source Data: Listing 16.2.6.2 and Table 14.2.5.2.2

Note to Programmer: Use linear scale for both X-axis and Y-axis.

Figure 14.2.3.3
Scatter Plot of Individual and mean AUC0-inf versus Dose for SAB-176 Following IV Administration
PK Population

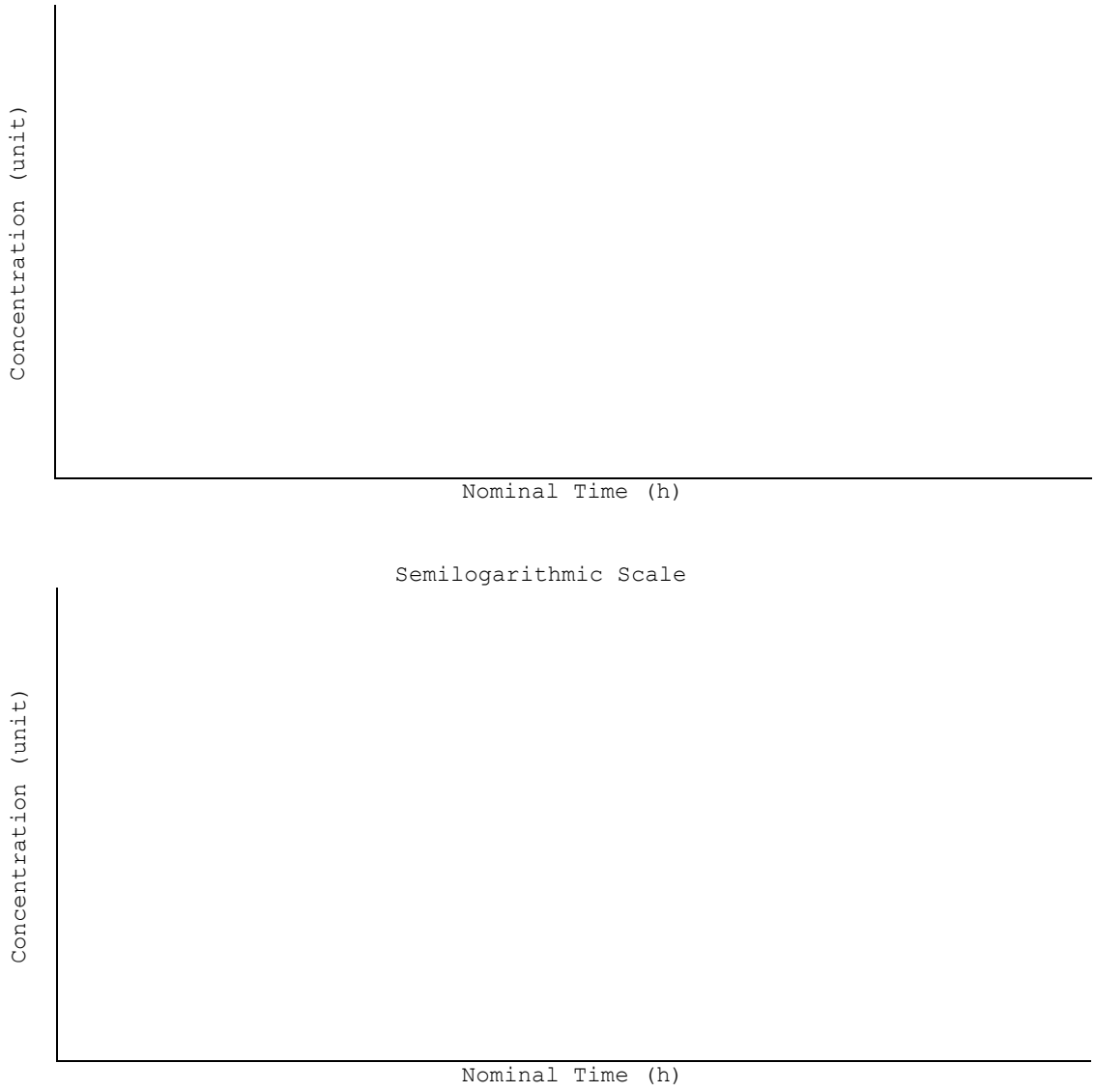


Note: open symbols represent individual data and closed symbols represent mean data.

Source Data: Listing 16.2.6.2 and Table 14.2.5.2.2

Note to Programmer: Use linear scale for both X-axis and Y-axis.

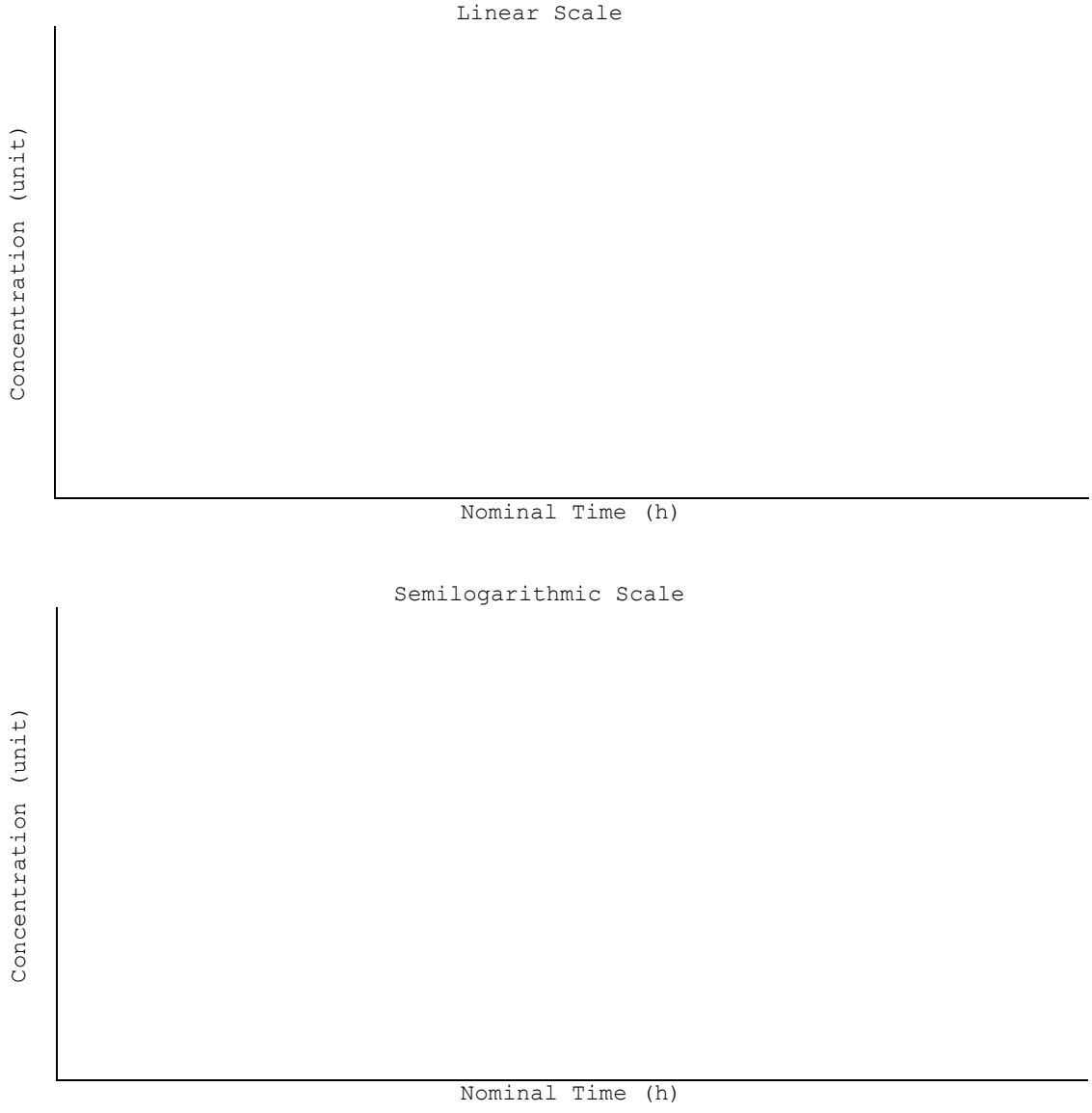
Figure 14.2.4.1
Concentration of Anti-IgG antibodies using rheumatoid factor
Safety Population



Note: Time points are relative to the start of infusion.
Source Data: Table 14.3.6.1.1

Note to programmer:
Please plot mean concentration versus nominal time and overlay 4 treatments: 1 mg/kg SAB-176, 10 mg/kg SAB-176, 25 mg/kg SAB-176 and 50 mg/kg SAB-176, display *treatment labels in legend.*

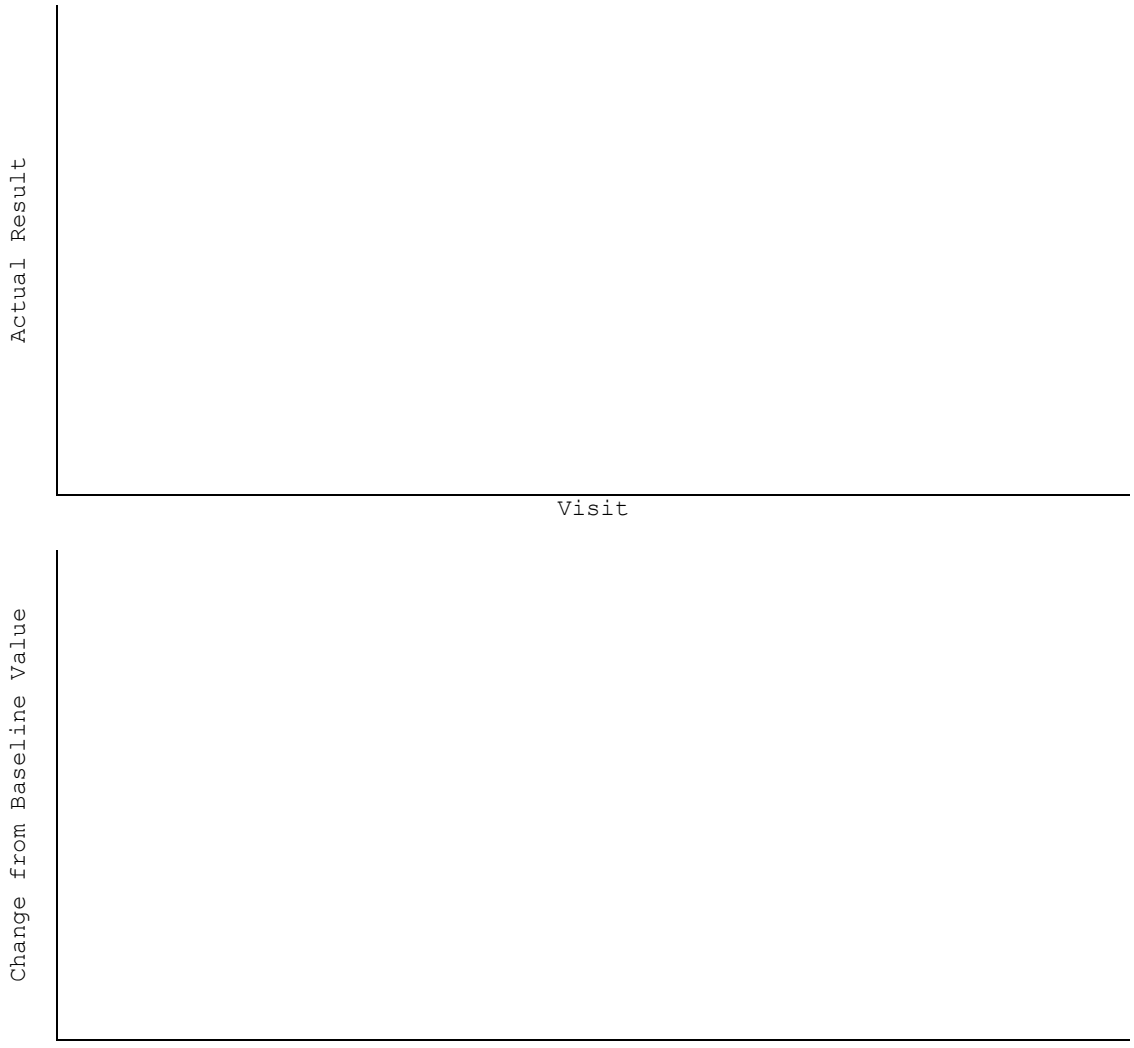
Figure 14.2.5.1
Concentration of Anti-SAB-176 antibody
Safety Population



Note: Time points are relative to the start of infusion.
Source Data: Table 14.3.6.2.1

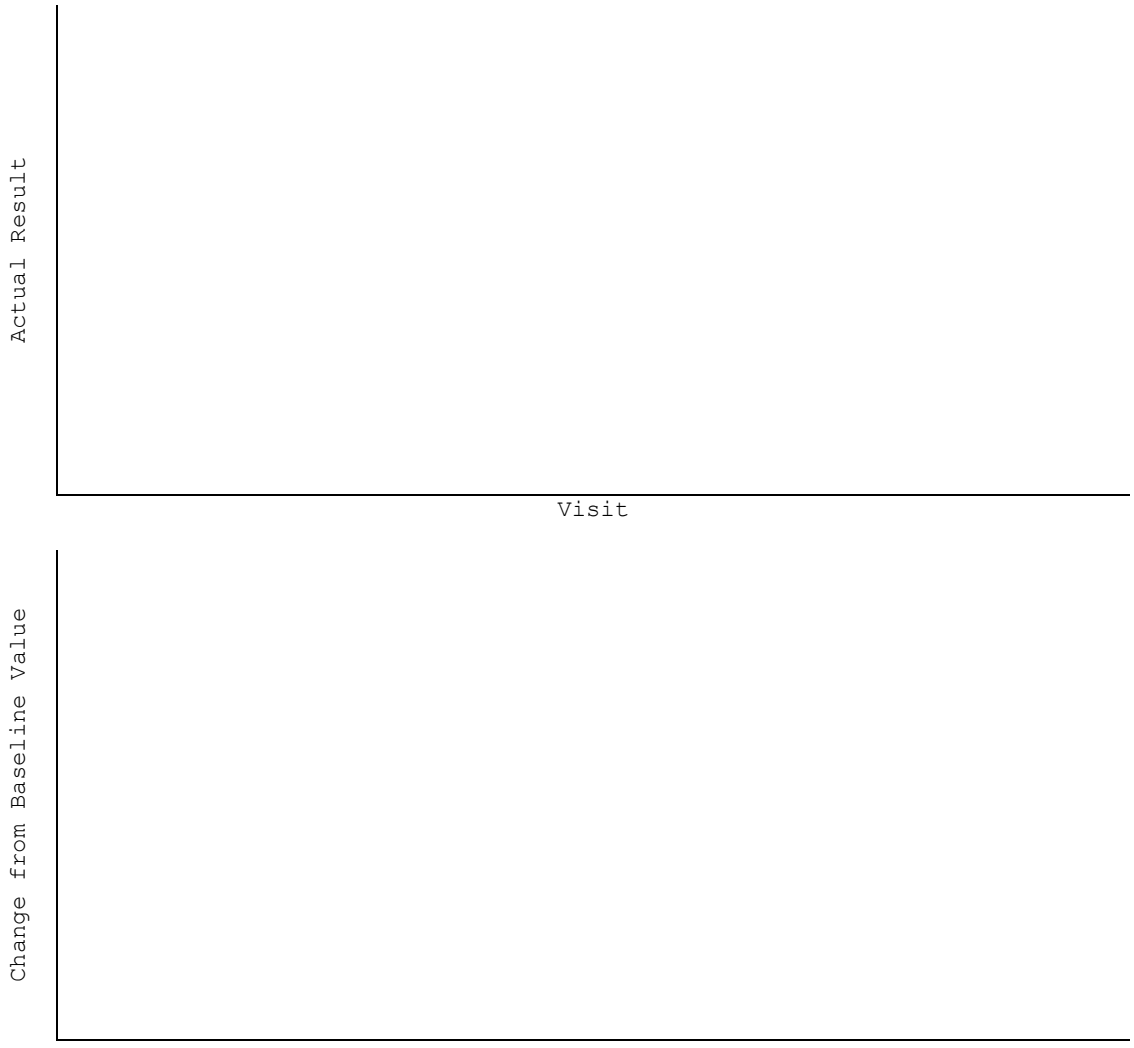
Note to programmer:
Please plot mean concentration versus nominal time and overlay 4 treatments: 1 mg/kg SAB-176, 10 mg/kg SAB-176, 25 mg/kg SAB-176 and 50 mg/kg SAB-176, display *treatment labels in legend.*

Figure 14.2.3.1
Mean (+/-SD) Change from Baseline in Serum Type A HAI Assay
Safety Population



Note to programmer: Present all treatments (exclude total) as overlay on the same plot and provide treatment labels in the legend. Continue with Serum Type B. Start a new page for each parameter. Visits include Baseline; Day 7; Day 21, Day 42 and Day 90.

Figure 14.2.4.1
Mean (+/-SD) Change from Baseline in Serum Type A MN Assay
Safety Population



Note to programmer: Present all treatments (exclude total) as overlay on the same plot and provide treatment labels in the legend. Continue with Serum Type B. Start a new page for each parameter. Visits include Baseline; Day 7; Day 21, Day 42 and Day 90.