16.1.9 Documentation of statistical methods

Document	Date
Statistical Analysis Plan, Version 1.0	07 February 2018
Table Shells, Version 1.0	07 February 2018
Figure Shells, Version 1.0	07 February 2018
Listing Shells, Version 1.0	07 February 2018

Statistical Analysis Plan

Study Number: ANB020-003

Placebo-Controlled Proof of Concept Study to Investigate ANB020 Activity in Adult Patients with Peanut Allergy

Author: [redacted]
Version Number: Final 1.0
Date: 07 Feb 2018

Statistical Analysis Plan Signature Page

Statistical Analysis Plan Draft 2.0 (Dated 25Jul2017) for Protocol ANB020-003.

	Name	Signature	Date
Author:	[redacted]	[redacted]	MMMYYYY
Position:			
Company:	IQVIA™		

Upon review of this document, the undersigned approves this version of the Statistical Analysis Plan, authorizing that the content is acceptable for the reporting of this study.

	Name	Signature	Date
Reviewed and Approved By:	[redacted]		DDMMMYYYY
Position:			
Company:	IQVIA™		
Reviewed and Approved By:	[redacted]		DDMMMYYYY 11 Apr 2018
Position:			
Company:	IQVIA™		
Reviewed and Approved By:	[redacted]		DDMMMYYYY 11APR2018

Document: \\eedc-nas01a\biosdata\AnaptysBio\ANB020\CYA74303\Biostatistics\Documentation\SAP\Final2018-02-07
Author: [redacted]
Version Number: Final 1.0
Version Date: 07Feb2018

Template No: CS_TP_BS016 Revision 4
Effective Date: 01Apr2016

Reference: CS_WI_BS005

Position:	Medical Writer 1	
Company:	IQVIA™	
Reviewed and Approved By:	[redacted]	DDMMMYYYY 12 APR 2018
Position:		
Company:	IQVIA™	
Reviewed and Approved By:	[redacted]	DDMMMYYYY 17APR2018
Position:		
Company:	AnaptysBio, Inc	

Document: \\eedc-nas01a\biosdata\AnaptysBio\ANB020\CYA74393\Biostatistics\Documentation\SAP\Final2018-02-07
Author: Preenan Sarkar
Version Number: Final 1.0
Version Date: 07Feb2018

Template No: CS_TP_BS016 Revision 4
Effective Date: 01Apr2016
Reference: CS_WI_BS005

Statistical Analysis Plan Signature Page

Statistical Analysis Plan Draft 2.0 (Dated 25Jul2017) for Protocol ANB020-003.

	Name	Signature	Date
Author:	[redacted]		DDMMMYYYY
Position:			
Company:	IQVIA™		

Upon review of this document, the undersigned approves this version of the Statistical Analysis Plan, authorizing that the content is acceptable for the reporting of this study.

	Name	Signature	Date
Reviewed and Approved By:	[redacted]		DDMMMYYYY 11-4-18
Position:			
Company:	IQVIA™		
Reviewed and Approved By:	[redacted]		DDMMMYYYY
Position:			
Company:	IQVIA™		
Reviewed and Approved By:	[redacted]		DDMMMYYYY 11APR2018

List of Reviewers

Reviewer Name	Position/ Role	Company
[redacted]		IQVIA™
		IQVIA™
		IQVIA™
		IQVIA™
		AnaptysBio, Inc.

Modification History

Unique Identifier for this Version	Date of the Document Version	Author	Significant Changes from Previous Authorized Version
Draft 1.0	08 Mar 2017	[redacted]	Not Applicable – First Version
Version 1.0	16 Mar 2017		Addressed client comments
Draft 2.0	05 Jun 2017		Applied changes based on protocol amendment 2.0 dated 30May2017
Draft 2.0	13 Jun 2017		Implemented SBR comments
Draft 2.0	28 Jun 2017		Implemented PK comments
Draft 2.0	25 Jul 2017		Implemented MW comments, changes based on protocol amendment 3.0 dated 30Jun2017
Draft 3.0	07 Feb 2018		Implemented PK comments
Final Draft	10 Apr 2018		Prepared the document for Sign off before DBL

Table of Contents

List of Abbreviations and Definitions of Terms

Abbreviation	Definition
AE	Adverse event
ANCOVA	Analysis of covariance
$\%AUC_{ex}$	Percentage of $AUC_{(0\text{-inf})}$ obtained by extrapolation
$AUC_{(0\text{-inf})}$	Area under the concentration-time curve from time zero (predose) extrapolated to infinite time
$AUC_{(0\text{-last})}$	Area under the concentration-time curve from time zero (predose) to time of last quantifiable concentration
BLQ	Below the lower limit of quantitation
BMI	Body mass index
BP	Blood pressure
BPCFC	Blind placebo-controlled food challenge
CI	Confidence interval
CL	Systemic clearance following intravenous dosing
C_{max}	Maximum observed concentration
CV	Coefficient of variation
ECG	Electrocardiogram
eCRF	Electronic case report form

EOS	End of Study
ET	Early Termination
gCV	Geometric coefficient of variation
Gmean	Geometric mean
HR	Heart rate
ICH	International Council for Harmonisation
IP	Investigational product
IV	Intravenous(ly)
λ_z	Apparent terminal rate constant
LLOQ	Lower limit of quantitation
LS	Least-squares
MedDRA	Medical Dictionary for Regulatory Activities
n	Sample size or number of observations
OFC	Oral Food Challenge
PD	Pharmacodynamic(s)
PK	Pharmacokinetic(s)
R_{sq}	Coefficient of determination
SAE	Serious adverse event

SAP	Statistical analysis plan
SAS	Statistical analysis system
SD	Standard deviation
SI	System International
TEAE	Treatment emergent adverse event
$t_{1/2}$	Apparent terminal half-life
t_{max}	Time to maximum observed concentration
V_{ss}	Volume of distribution at steady state following intravenous dosing
V_Z	Volume of distribution
WBC	White blood cell
WHO DD	World Health Organization Drug Dictionary

1. INTRODUCTION

This document describes the statistical analyses to be performed and data presentations to be produced for this phase II, randomized, double-blind, placebo-controlled, study to evaluate the safety, tolerability and efficacy of single IV infusion of 300 mg ANB020 in 20 Adult Patients with Peanut Allergy.

The purpose of this statistical analysis plan (SAP) is to ensure the credibility of the study findings by specifying the statistical approaches to the analysis of the double-blind data prior to database lock. This SAP was developed based on the International Conference on Harmonization (ICH) E3 and E9 Guidelines and in reference to the following document:

Protocol AnaptysBio ANB020-003 amendment 3 dated 30Jun2017.

Any deviations during the analysis and reporting process from the current SAP will be described and justified in the final report. Analysis issues that suggest changes to the principal features stated in the protocol will be documented in a protocol amendment. Otherwise, the SAP will be updated through an amendment with the changes in the analysis documented in the amendment.

2. STUDY OBJECTIVES

2.1. PRIMARY OBJECTIVES

To assess the safety and tolerability of single dose administration of ANB020 in adult patients with peanut allergy

To measure the response of adult patients with peanut allergy on Day 14 following an oral blind placebo-controlled food challenge (BPCFC) threshold and total cumulative peanut dose tolerated after administration of ANB020 or placebo compared to cumulative baseline peanut BPCFC

2.2. SECONDARY OBJECTIVES

To compare the symptoms to peanut antigen challenge on Day 14 using the Oral Food Challenge (OFC) Symptoms Scoring Assessment Tool after administration of ANB020 or placebo compared to baseline peanut BPCFC symptoms

To describe the limited pharmacokinetics (PK) of ANB020 following a single, intravenous (IV) dose

2.3. EXPLORATORY OBJECTIVES

To assess the effect of ANB020 on circulating serum cytokines

To assess the effect of ANB020 on leukocytes within whole blood

To compare the immune response of ANB020 to placebo dosed patients in the ex vivo peanut antigen challenge

To measure the response of adult patients with peanut allergy on Day 45 following an oral BPCFC threshold and cumulative peanut dose tolerated after administration of ANB020 or placebo compared to cumulative baseline peanut BPCFC

To compare the symptoms to peanut antigen challenge on Day 45 using the OFC Symptoms Scoring Assessment Tool after administration of ANB020 or placebo compared to baseline peanut BPCFC symptoms

3. STUDY DESIGN

3.1. GENERAL DESCRIPTION

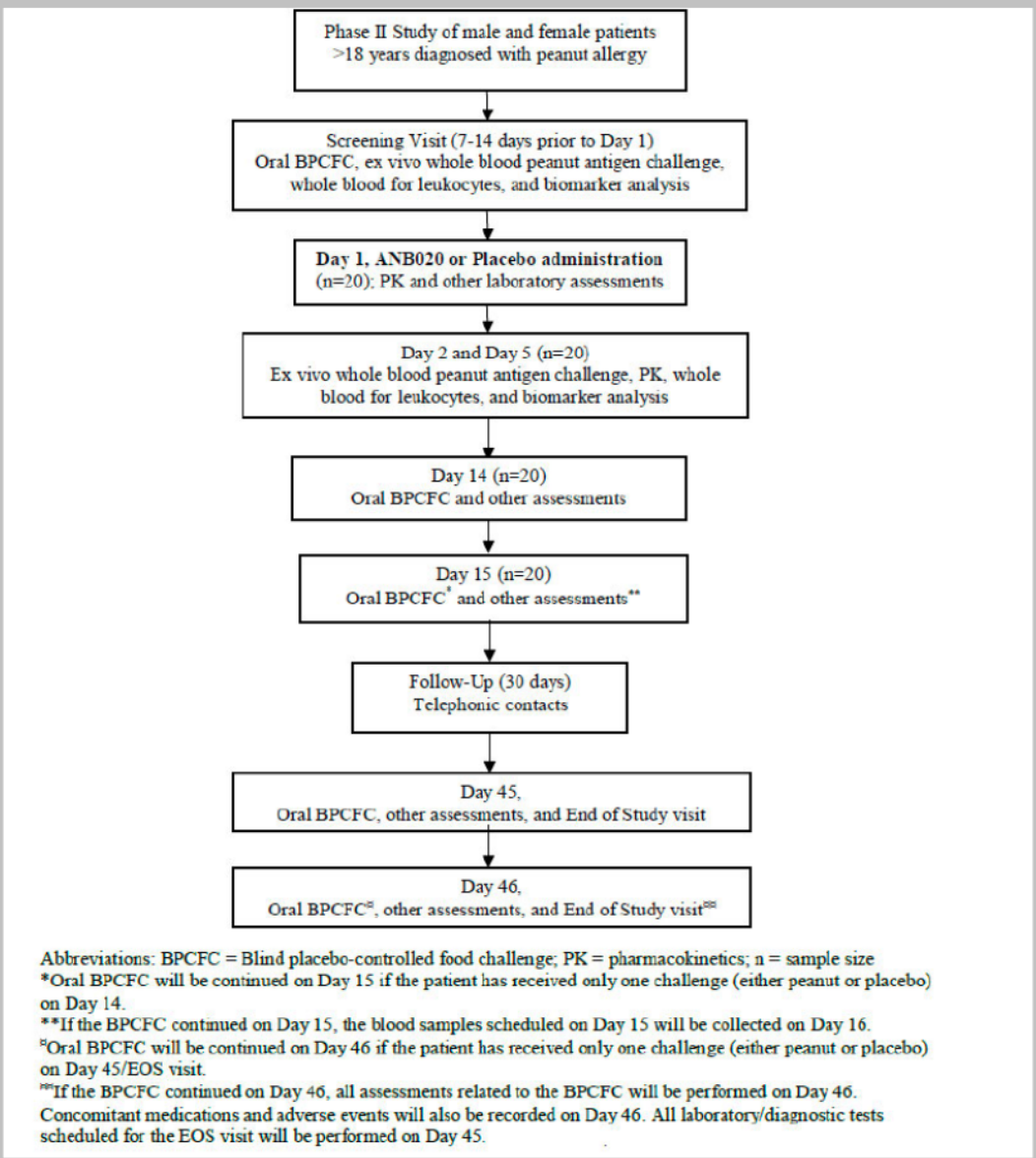
This is a Phase II, double-blind, placebo-controlled, proof of concept study to assess the safety and tolerability of ANB020 in adult patients with peanut allergy. This study will also investigate the effects of ANB020 or placebo in adult peanut allergic patients following an oral BPCFC at 2 and 6 weeks post ANB020 or placebo administration. The effects of ANB020 on the immune response to peanut upon ex vivo peanut antigen challenge will be evaluated.

No formal statistical calculation has been performed for sample size. Approximately 20 patients will be enrolled in the study.

Patients will be randomized in a 3:1 ratio to receive ANB020 (300 mg/100 mL) or matching 100 mL placebo (0.9% sodium chloride) administered through intravenous route.

A schematic of the study design is included as Figure 1:

Figure 1: Schematic of Study Design



Abbreviations: BPCFC = Blind placebo-controlled food challenge; PK = pharmacokinetics; n = sample size
*Oral BPCFC will be continued on Day 15 if the patient has received only one challenge (either peanut or placebo) on Day 14.
**If the BPCFC continued on Day 15, the blood samples scheduled on Day 15 will be collected on Day 16.
[S]Oral BPCFC will be continued on Day 46 if the patient has received only one challenge (either peanut or placebo) on Day 45/EOS visit.
[SS]If the BPCFC continued on Day 46, all assessments related to the BPCFC will be performed on Day 46. Concomitant medications and adverse events will also be recorded on Day 46. All laboratory/diagnostic tests scheduled for the EOS visit will be performed on Day 45.

3.2. SCHEDULE OF EVENTS

The schedule of events can be found in Section 4.1, Table 4.1 of the protocol

3.3. CHANGES TO ANALYSIS FROM PROTOCOL

No changes from the analysis planned in the protocol were made.

4. PLANNED ANALYSIS

This SAP describes the methodology for final analysis.

4.1. DATA MONITORING COMMITTEE (DMC)

No DMC is planned of this study.

4.2. INTERIM ANALYSIS

No interim analysis is planned for this study.

4.3. FINAL ANALYSIS

All final, planned statistical analyses identified in this SAP will be performed by the IQVIA Biostatistics department.

Analysis of the PK and pharmacodynamics (PD) of ANB020 and the associated figures, will be the responsibility of the clinical pharmacokineticist (PK analyst) at IQVIA. The PK/PD summaries and data listings will be the responsibility of the ECD biostatistician at IQVIA.

5. ANALYSIS SETS

Summaries will be presented by treatment and overall as appropriate.

Listings will be presented for all patients available in the data transfer received from data management.

The following analysis sets will be used:

5.1. ALL PATIENTS SCREENED [SCR]

Patients who have signed the informed consent form and have been screened.

5.2. RANDOMIZED ANALYSIS SET [RND]

All patients who have been allocated to a randomized treatment arm, regardless of whether they received the planned treatment or not. Patients will be considered according to their randomized

treatment.

5.3. Full Analysis Set [FAS]

All patients who have received ANB020 or placebo and were present in the study until Day 14 with post baseline BPCFC and OFC results present. The full analysis set will be used for all efficacy analyses. Patients will be considered according to their randomized treatment.

5.4. Safety Analysis Set [SAF]

All patients who have received any portion of ANB020 or placebo infusion. The safety analysis set will be used for all safety analyses. Patients will be considered according to their actual treatment received.

5.5. Pharmacokinetic Analysis Set [PK]

All patients who have received ANB020 and have at least one post dose serum concentration data value available for ANB020 without any events or protocol deviation deemed to affect PK assessments. The PK analysis set will be used for all PK analyses.

5.6. Pharmacodynamic Analysis Set [PD]

All patients who have received at least one dose of ANB020 or placebo and provide at least one evaluable post dose PD measurement without any events or protocol deviation deemed to affect PD assessment. The PD analysis set will be used for all PD analyses.

6. General Considerations

The following descriptive statistics will be presented in summary tables:

Continuous variables: will be summarized by treatment group using number of valid cases (n), mean, median, standard deviation (SD), minimum, and maximum.

Categorical variables: will be summarized by treatment group using frequency tables [frequencies (n) and percentages (%)]. Percentages are routinely based on the total category count excluding the missing category if not otherwise mentioned. Missing category with zero count will not be presented.

In general, for non-PK/PD data, the number of decimal places displayed for each statistic will be determined as follows:

Mean and median: 1 more than the number of decimal places allotted in the raw data received from data management.

Standard deviation: 2 more than the number of decimal places allotted in the raw data.

Minimum and maximum: equal to the number of decimal places allotted in the raw data.

Percentages: All percentages between 0 and 100 will be rounded to one decimal unless there is a need to report more than one decimal for percentages.

Ranges will be reported to the same number of decimal places displayed by the laboratory.

P-values, if any, shall be reported to four decimal places or as <0.0001.

Pharmacokinetic parameters will be rounded for reporting purposes both in the summary tables and by-subject listings. For the calculation of descriptive statistics and the statistical analysis, rounded values as presented in the data listings will be used. All data will be reported and analyzed with the same precision as the source data regardless of how many significant figures or decimals the data carry. For most derived PK parameters, 3 significant digits will be used as the standard rounding procedure, with the following exceptions:

Parameters directly derived from source data [e.g., maximum observed concentration (C_{max})] will be reported and analyzed with the same precision as the source data.

Parameters derived from actual elapsed sample collection times [e.g., time to maximum observed concentration (t_{max})] will be reported in hours with 2 decimal places.

Apparent terminal rate constant (λ_z) will be reported with 4 decimal places.

For PK data, reporting of mean (arithmetic and geometric), SD, and median will carry 1 more significant figure than the source data. Minimum and maximum will carry the same number of significant figures as the source data. The bounds of any confidence intervals (CIs) will be reported with 2 decimals, and coefficient of variation (CV) will be reported as a percentage to 1 decimal place.

Extra measurements (such as unscheduled or repeat assessments) will not be included in the descriptive statistics, but will be included in subject listings. Pharmacokinetic summaries will be presented for all subjects in the PK analysis set as defined in Section 5.5. Similarly, PD summaries will be presented for all subjects in the PD analysis set as defined in Section 5.6. Data from subjects excluded from an analysis set will be included in the data listings, but not in the summaries.

6.1. Reference Start Date and Study Day

The reference start date is defined as the day of the first dose of study medication (Day 1 is the day of the first dose of study medication), and will appear in every listing where an assessment date or event date appears.

The study day will be calculated from the reference start date, and will be used to show start/stop day of assessments and events.

If the date of the event is on or after the reference date then:

Study Day = (date of event – reference date) + 1

If the date of the event is prior to the reference date then:

Study Day = (date of event – reference date)

If the event date is partial or missing, Study Day, and any corresponding durations will appear partial or missing in the listings.

Refer to Appendix 1 for more details.

6.2. Baseline

The nearest non-missing measurements taken prior to ANB020 or placebo administration, i.e., reference start date, will be considered as baseline. If the last non-missing measurement and the reference start date coincide, that measurement will be considered baseline, but Adverse Events (AEs) and medications commencing on the reference start date will be considered post-baseline.

6.3. Retests, Unscheduled Visits and Early Termination Data

Listings will include scheduled, unscheduled, retest, and early discontinuation data.

6.4. Windowing Conventions

Not applicable.

6.5. Statistical Tests

All tests of treatment effects will be conducted at a 2-sided alpha level of 0.05, or with 2-sided 95% CIs.

6.6. COMMON CALCULATIONS

For quantitative measurements, change from baseline will be calculated as:

Test Value at Visit X – Baseline Value

6.7. SOFTWARE VERSION

All analyses will be conducted using SAS System® Version 9.2 or higher.

The non-compartmental PK analysis will be conducted using SAS System® and/or Phoenix WinNonlin® 6.4 or higher, and PK graphics will be prepared using SigmaPlot® 12.5, or higher.

7. STATISTICAL CONSIDERATIONS

7.1. ADJUSTMENTS FOR COVARIATES AND FACTORS TO BE INCLUDED IN ANALYSES

The change from baseline on Day 14 of tolerated peanut dose will be compared between ANB020 and placebo using an analysis of covariance (ANCOVA) with treatment as fixed effect and baseline results as a covariate. Similarly, the mixed model for repeated measures for analysis of exploratory endpoints will include baseline and baseline by visit terms as covariates.

7.2. MULTICENTER STUDIES

Not applicable as this is a single center study.

7.3. MISSING DATA

No imputations will be performed on missing data.

7.4. MULTIPLE COMPARISONS/ MULTIPLICITY

Not applicable.

7.5. EXAMINATION OF SUBGROUPS

No subgroups analysis will be performed for this study.

8. Output Presentations

The templates provided with this SAP describe the presentations for this study and the format and content of the summary tables, figures, and listings are to be provided by IQVIA Biostatistics.

All visit assessments will be presented according to the nominal visit name.

9. Disposition and Withdrawals

All patients who provide informed consent will be accounted.

Data collected in Early Termination (ET) and End of Study (EOS) pages in the electronic Case Report Form (eCRF) will be used to present disposition and withdrawal results. Frequency table will be provided for:

number of patients in the All Patients Screened Set (provided informed consent and demographic details available)

number of patients eligible at screening

number of patients eligible at Day 1

number of screen failures

number of patients in the Randomized Analysis Set

number of patients administered the treatment

number of patients in the Full Analysis Set

number of patients in the Safety Analysis Set

number of patients in the Pharmacokinetic Analysis Set

number of patients in the Pharmacodynamic Analysis Set

number of patients who discontinued the study

primary reason for discontinuation

number of patients who completed the study

A listing will be presented with the following details.

screening date

assigned treatment

screen failure (Yes/No)?

completed study (Yes/No)?

If not completed the study, then reason for discontinuation

A separate listing will be presented of eligibility criteria deviations for which the all patient screened population will used.

10. Demographic and other Baseline Characteristics

Demographic data and other baseline characteristics will be presented for the Randomized Analysis Set. No statistical testing will be carried out for demographic or other baseline characteristics.

Summary statistics will be provided for:

Age (years) - calculated relative to date of consent

Weight (kg)

Height (cm)

BMI (kg/m^2)

Frequency tables will be provided for:

Gender

Ethnicity

Race

A listing for patient demographic data and other baseline characteristics will be presented.

10.1. Derivations

BMI (kg/ m^2) = weight (kg)/ height $(m)^2$

11. Protocol Deviations

All protocol deviations observed during study conduct will be captured in Clinical Trial Management System (CTMS).

The Investigator and Sponsor will review the protocol violation records from CTMS and provide confirmation on the categorization of violations as major or other.

Major protocol deviations or events include changes to the procedures that may impact the quality of the data or any circumstances that can alter the evaluation of the PK data. Examples include, but may not be limited to, sample processing errors that lead to inaccurate bioanalytical results, incomplete dose administered, incomplete PK profile collected, use of disallowed concomitant medication thought to affect PK. In the case of a major protocol deviation or event, affected PK data collected will be excluded from the summaries and statistical analyses, but will still be reported in the study result listings.

A frequency table for major protocol violations will be provided for Randomized Analysis Set. Major protocol deviations or events that impact the quality of the PK and/or PD data will be listed only.

A list of major protocol deviations that involve eligibility criteria or could significantly affect study assessments will be provided. The incidence of each protocol violation will be listed.

12. Surgical and Medical History

Frequency tables will be provided for medical history findings summarized by body system for the Randomized Analysis Set. Version 19.1 of Medical Dictionary for Regulatory Activities (MedDRA) will be used.

AEs due to BPCFC at screening visit will be captured as medical history.

A listing of medical history diagnoses with all details will be presented.

13. Concomitant Illnesses

Not applicable.

14. Concomitant Medications

A frequency table will be provided for concomitant medications and will be summarized by Anatomic, therapeutic and chemical classification (ATC) Level 1 and 3 for Safety Analysis Set. Concomitant medication will be coded using WHO drug dictionary Version Dec 2016.

See Appendix 1 for handling of partial dates for medications. If it is not possible to define a medication as prior, concomitant, or post treatment, the medication will be classified by the worst case; i.e.,

concomitant.

'Prior' medications are medications which started and stopped prior to the first dose of study medication.

'Concomitant' medications are medications which:

- started prior to, on or after the first dose of study medication,
- AND ended on or after the date of first dose of study medication or were ongoing at the end of the study.

A listing for medication with all details will be presented and safety analysis set will be used for the same.

15. Study Medication Exposure

A listing of exposure to Investigational Product will be presented, with details of start and end time of infusion, interruptions, and total volume administered. IP Administration data will be used to generate the listing.

16. Study Medication Compliance

Overall compliance is expected as the study medication is being administered at the clinic, however no summary will be provided for compliance.

17. Efficacy Outcomes

17.1. Primary Efficacy

17.1.1. Primary Efficacy Endpoint

The difference in total cumulative tolerated peanut dose during BPCFC between post-treatment and baseline, following treatment with ANB020 or placebo on Day 14.

17.1.2. Analysis of Primary Efficacy Endpoint

The null hypothesis for the primary efficacy analysis is:

H0: There is no difference in change from baseline on day 14 for total cumulative tolerated peanut dose during BPCFC between ANB020 and placebo.

Vs the alternative:

H1: There is a difference in change from baseline on day 14 for total cumulative tolerated peanut dose during BPCFC between ANB020 and placebo

The primary efficacy analysis will be carried out for the FAS population.

The actual and change from baseline values of primary efficacy endpoints will be summarized using appropriate descriptive statistics by treatment at all time points where assessment is done. Change from baseline will be evaluated where possible.

Regarding the primary efficacy endpoint, change from baseline on day 14 of tolerated dose will be compared between ANB020 and placebo using an ANCOVA with treatment as fixed effect and baseline results as a covariate.

The following statistics will be presented:

- Treatment difference
- Standard error of treatment difference
- 95% CI
- p-value

The treatment difference and 95% CI will also be presented graphically.

Patient-wise data listings will be provided.

17.2. SECONDARY EFFICACY

17.2.1. SECONDARY EFFICACY ENDPOINT

Clinical scores of OFC Symptom Scoring Assessment Tool on Day 14

17.2.2. SECONDARY PHARMACOKINETIC ENDPOINT

Maximum observed concentration (Cmax)

Time to maximum observed concentration (t_{max})

17.2.3. ANALYSIS OF SECONDARY EFFICACY ENDPOINT

The analysis of the secondary efficacy endpoint will be carried out in the similar way as of primary efficacy endpoint for FAS population.

For analysis of secondary PK endpoints, refer to Section 19 for details.

17.3. EXPLORATORY EFFICACY

17.3.1. EXPLORATORY EFFICACY ENDPOINTS

The difference in total cumulative tolerated peanut dose during BPCFC between post-treatment and baseline, following treatment with ANB020 or placebo on Day 45

Clinical scores of OFC Symptom Scoring Assessment Tool on Day 45

17.3.2. EXPLORATORY PHARMACODYNAMICS ENDPOINTS

Serum cytokines will be evaluated including, but not be limited to, IL-4, IL-5, IL-9, IL-13, IL-33, and sST2

Differential white blood cell counts (WBC) in the whole blood will be measured to monitor circulating leukocyte populations

For the ex vivo peanut antigen challenge, the whole blood peanut response assay will measure the cytokine levels released from pathogenic T cells

17.3.3. ANALYSIS OF EXPLORATORY EFFICACY ENDPOINTS

The Full Analysis Set will be used for the efficacy analysis.

The actual and change from baseline values of all the exploratory endpoints will be summarized using appropriate descriptive statistics by treatment at all time points where assessment is done. Change from baseline will be evaluated where possible.

Change from baseline on day 45 for tolerated dose and OFC symptom scores will be compared between ANB020 and placebo using a mixed model for repeated measures with treatment, visit, and treatment by visit interaction as fixed effect, and baseline and baseline by visit terms as covariates. The data collected at baseline, day 14, and day 45 will be used in the model.

The following statistics will be presented:

- Treatment differences
- Standard error of treatment difference
- 95% CI
- p-value

An appropriate covariance matrix (e.g., unstructured [UN]) will be used in the model.

The treatment difference and 95% CI will also be presented graphically.

Patient-wise data listings will be provided.

For analysis of exploratory PD endpoints, refer Section 20 for details.

18. SAFETY OUTCOMES

Safety outcomes will be based on the Safety Analysis Set defined in Section 6.

There will be no statistical comparisons between the treatment groups for safety data.

18.1. ADVERSE EVENTS

Adverse Events (AEs) will be coded using MedDRA Version 19.1.

Treatment emergent adverse events (TEAEs) are defined as AEs that started or worsened in severity on or after the date and time of the IP infusion or if the event represents an exacerbation of a condition observed pre-treatment. This excludes AEs due to BPCFC. AEs due to BPCFC during screening visit will be captured in medical history events.

Non treatment emergent adverse event (Non-TEAE) will be defined as any AE that started after the informed consent form has been signed and before the first dose of study medication and did not qualify for TEAE in terms of severity.

Adverse events with missing start dates will be considered treatment-emergent. AEs with missing stop dates or with stop dates after the end of the study date will be considered to have been ongoing at the end of the study.

The relationship to investigational product will be presented as “Related” versus “Not Related”. Here the relationship categories “Unrelated” and “Unlikely” collected in the eCRF will be mapped to “Not Related”, while the categories “Possible”, “Probable” and “Unknown” will be mapped to “Related”.

For each treatment, numbers of events, patients experiencing adverse events and percentage will be tabulated. The following summary tables will be provided by system organ class and preferred term for each treatment group:

- number of patients with at least one TEAE
- number of patients with at least one serious TEAE

- number of patients with at least one TEAE by severity
- number of patients with at least one TEAE by relationship to IP
- number of patients with at least one TEAE leading to discontinuation from the study
- number of patients with at least one TEAE leading to interruption of IP
- number of patients with at least one TEAE leading to death
- number of patients with non-TEAE
- number of patients with AEs due BPCFC

When calculating the number of patients who experience an AE, an event that occurred one or more times on treatment will contribute one observation to the numerator and denominator for all safety patients exposed to ANB020 or placebo for the respective treatment, i.e., the event will be counted only once per SOC and per PT with highest severity and worst relationship with IP.

Listings will be provided for TEAEs, Serious TEAEs, TEAEs leading to discontinuation from study or of IP, and TEAEs leading to deaths for safety analysis set.

18.2. DEATHS

The number of patients with at least one TEAE leading to death will be summarized and listed as described above.

18.3. LABORATORY EVALUATIONS

Results from both the central and local laboratory will be included in the reporting. Central laboratory results will be reported for hematology, clinical chemistry and urinalysis. Local urine pregnancy test results will be reported as well. The actual and change from baseline values for each laboratory parameter will be summarized using descriptive statistics (n, mean, SD, median, and range) by treatment and all available visits.

The following summaries will be provided for laboratory data:

- Incidence of abnormal values according to normal range criteria
- Potential clinical significance of clinical laboratory assessments

A shift table will be presented of the potential shifts from baseline to the final measurement of values that are clinically relevantly high or low.

A listing of patients with abnormal values or clinically significant changes will be presented.

Hematology and clinical laboratory data will be reported in System International (SI) units.

18.4. ECG EVALUATIONS

The following ECG parameters will be summarized:

- Heart Rate (bpm)
- PR Interval (msec)
- QRS Interval (msec)
- QT Interval (msec)
- QTcB (msec) *{based on Bazett formula}*
- QTcF (msec) *{based on Fridericia formula}*

The actual and change from baseline values for the above parameters will be summarized using descriptive statistics (n, mean, SD, median, and range) by treatment and all available visits.

The overall assessment of ECG will be summarized using frequency and percentage of the following indications:

- Normal
- Abnormal, Not Clinically Significant (ANCS)
- Abnormal, Clinically Significant (ACS)

A listing of ECG parameters and of the overall assessment will be provided.

18.4.1. ECG SPECIFIC DERIVATION

Bazett's Correction (msec)

$$QTcB\ (\text{msec}) = \frac{QT\ (ms)}{\sqrt{RR\ (ms)/1000}}$$

Fridericia's Correction (msec)

$$QTcF\ (\text{msec}) = \frac{QT\ (ms)}{\sqrt[3]{RR\ (ms)/1000}}$$

18.4.2. ECG MARKEDLY ABNORMAL CRITERIA

Absolute values of the QT interval will be classified as:

- >=450 msec
- >=480 msec
- >=500 msec

The change from Baseline of QT interval will be classified as:

- >30 msec increase from baseline
- >60 msec increase from baseline

18.5. VITAL SIGNS

The following Vital Signs measurements will be reported for this study:

- Blood Pressure (mmHg)
- Respiratory Rate (resp/min)
- Pulse Rate (breaths/min)
- Temperature (°C or °F)

The actual and change from baseline values for the above parameters will be summarized using descriptive statistics (n, mean, SD, median, and range) by treatment and all available visits.

A listing of the above parameters will be provided.

18.6. PHYSICAL EXAMINATION

The frequency and percentage of patients with physical examination assessments will be summarized by body system and treatment group at each available visit.

A listings of physical examination findings will be provided.

18.7. OTHER SAFETY ASSESSMENTS (SPIROMETRY)

For patients with a history of asthma, the following spirometry or peak flow parameters will be summarized for observed and change from baseline values by treatment group at each available visit:

Actual FEV1

Predicted FEV1

Percent Predicted

A detailed listing will be presented for spirometry.

19. PHARMACOKINETIC OUTCOMES

Pharmacokinetic analysis of the plasma concentration data for ANB020 will be performed at IQVIA, Overland Park, Kansas, United States. The actual sampling times will be used in the PK parameter calculations, and PK parameters will be derived using standard non-compartmental methods using Phoenix WinNonlin® 6.4 or higher (Pharsight Corp., Certara Company, Princeton, New Jersey, United States); and/or SAS® Version 9.2 or higher. Graphics may be prepared with SAS® Version 9.2, or higher; SigmaPlot® 12.5, or higher (Systat Software, Inc., San Jose, California, United States); or Phoenix WinNonlin® 6.4, or higher.

A listing of PK blood sample collection times as well as derived sampling time deviations will be provided. A subject listing of all concentration-time data for ANB020 will be provided.

Concentration data of ANB020 will be summarized by treatment and nominal time point using the number of observations (n), and number of observations ≥ lower limit of quantitation (LLOQ), arithmetic mean, SD, CV, minimum, median, and maximum. Concentrations below the lower limit of quantitation (BLQ) will be treated as zero for calculation of descriptive statistics. If the calculated mean concentration is BLQ, the mean value will be reported as BLQ and the SD and CV will be reported as not applicable (NA). Missing data will not be interpolated. If 1 or more concentrations at a given time point are missing, they will be reported as missing and will be omitted from the calculation of descriptive statistics.

Plots of the mean plasma concentration-time profile for ANB020 will be presented by nominal sampling time on linear and semi-logarithmic scales. Individual concentration-time data will be listed and plotted by actual sampling times on linear and semi-logarithmic scales.

For the calculation of PK parameters, concentrations that are BLQ will be assigned a value of zero if they precede quantifiable samples prior to t_{max}. Any anomalous concentration values observed at pre-dose will be identified in the study report and will be used for the computation of PK parameters if the anomalous value is not greater than 5% of C_{max}. If the anomalous value is greater than 5% of C_{max}, the PK parameters for the given subject will be included in listings but excluded from summary presentations and analyses. Following C_{max}, BLQ values embedded between 2 quantifiable data points will be treated

as missing. Trailing BLQ values (BLQ values after the last quantifiable concentration) will be set to zero. If consecutive BLQ concentrations are followed by quantifiable concentrations in the terminal portion of the concentration curve, these quantified values will be excluded from the PK analysis by setting them to missing.

The following PK parameters will be computed for ANB020, if data permits:

C_{max}	Maximum concentration in serum (µg/mL), obtained directly from the observed concentration versus time data.
t_{max}	Time of maximum concentration (h), obtained directly from the observed concentration versus time data.
$AUC_{(0\text{-}inf)}$	Area under the concentration-time curve in serum from time zero (predose) extrapolated to infinite time (h·µg/mL), calculated by linear up/log down trapezoidal summation and extrapolated to infinity by addition of the last quantifiable concentration divided by the apparent terminal rate constant: $AUC_{(0\text{-}last)} + C_{last}/\lambda_z$.
$AUC_{(0\text{-}last)}$	Area under the serum concentration-time curve from time zero to the time of the last quantifiable concentration (h·µg/mL), calculated by linear up/log down trapezoidal summation.
CL	Systemic clearance (L/h), calculated as dose/ $AUC_{(0\text{-}inf)}$.
λ_z	Apparent terminal rate constant (1/h), determined by linear regression of the terminal points of the log-linear concentration-time curve.
$t_{1/2}$	Apparent terminal half-life (h), determined as ($\ln 2/\lambda_z$).
V_{ss}	Volume of distribution at steady state following intravenous dosing (L), calculated as mean residence time (extrapolated to infinity) multiplied by systemic clearance.
V_z	Volume of distribution (L), estimated by dividing the systemic clearance by

λ_z.

The following ANB020 PK parameters will be calculated for diagnostic purposes and listed, but will not summarized:

λ_z_lower	Start time (h) of the log-linear regression to determine λ_z and $t_{1/2}$.
λ_z_upper	End time (h) of the log-linear regression to determine λ_z and $t_{1/2}$.
$t_{1/2}$, Interval	The time interval (h) of the log-linear regression to determine λ_z and $t_{1/2}$, calculated as λ_z_upper − λ_z_lower,
$t_{1/2}$, N	Number of data points included in the log-linear regression analysis used to calculate λ_z and $t_{1/2}$. A minimum of 3 data points is required.
R_{sq}	Coefficient of determination for calculation of λ_z. A minimum of 3 data points (excluding C_{max}) will be used for determination of the terminal linear phase of the concentration-time profile. If the Rsq is less than 0.800 then λ_z, $t_{1/2}$, $AUC_{(0\text{-inf})}$, CL, V_{ss}, and V_Z will be listed but not included in summary presentations or analyses.
$\%AUC_{ex}$	Percentage of $AUC_{(0\text{-inf})}$ obtained by extrapolation, calculated as $[(C_{last}/\lambda z)/AUC_{(0\text{-inf})}\times 100]$. If the extrapolated area is greater than 20.0% of $AUC_{(0\text{-inf})}$, then $AUC_{(0\text{-inf})}$ will listed but not included in summary presentations or analyses.

The PK parameters, with the exception of t_{max}, will be summarized by treatment using n, arithmetic mean, SD, CV, minimum, median, maximum, geometric mean (Gmean), and geometric CV (gCV). The PK parameter t_{max} will be reported with n, minimum, median, and maximum only.

20. PHARMACODYNAMIC OUTCOMES

The PD analysis set will be used for PD analysis.

Observed values, change from baseline and relative change from baseline for circulating cytokines,

differential WBC counts (circulating leukocytes), and cytokine levels released from pathogenic T-cells (ex vivo whole blood peanut response assay) will be summarized with descriptive statistics including 95% CIs for the mean by nominal time point and treatment. Relative change from baseline is calculated as (actual-baseline)/baseline and will be reported as percentage.

Comparison between ANB020 and placebo will be performed using a repeated measures ANCOVA model on observed values with treatment, time point of measurement, and treatment by time point interaction as fixed effects, and baseline value as a covariate. An unstructured covariance matrix will be used. If the model fails to converge, then appropriate covariance matrix (e.g., compound symmetric) will be selected based on Akaike Information Criteria (AIC). All tests of treatment effects will be conducted at a 2-sided alpha level of 0.05 or with 2-sided 95% CIs. The following statistics will be presented:

- Least-squares (LS) mean for treatment difference
- Standard error of LS mean of difference
- 95% CI for LS mean treatment difference
- p-value for comparison of ANB020 versus placebo

Log or other transformation may be applied upon specific parameters as appropriate to meet the analysis assumptions.

A listing of PD blood sample collection date and times will be provided. A subject listing of all PD data (serum cytokines IL-4, IL-5, IL-9, IL-13, IL-33 and sST2, leukocytes in whole blood, and cytokine levels released from pathogenic T-cells following the ex vivo whole blood peanut response assay) will be provided. All PD parameters will be summarized as described in Section 6, General Considerations, and observed values will be presented graphically in scatter plots of individual, mean, and median values by treatment and study day.

21. GENETIC ANALYSIS

Not applicable.

22. DATA NOT SUMMARIZED OR PRESENTED

The unscheduled visits will not be summarized, but listed.

23. REFERENCES

Protocol amendment dated 30May2017

Annotated study book Version 2 dated 26Dec2016

APPENDIX 1. **PARTIAL DATE CONVENTIONS**

Imputed dates will NOT be presented in the listings.

Algorithm for Treatment Emergence of Adverse Events:

START DATE	STOP DATE	ACTION
Known	Known	If start date < study med start date, then not TEAE If start date >= study med start date, then TEAE
	Partial	If start date < study med start date, then not TEAE If start date >= study med start date, then TEAE
	Missing	If start date < study med start date, then not TEAE If start date >= study med start date, then TEAE
Partial, but known components show that it cannot be on or after study med start date	Known	Not TEAE
	Partial	Not TEAE
	Missing	Not TEAE

START DATE	STOP DATE	ACTION
Partial, could be on or after study med start date	Known	If stop date < study med start date, then not TEAE If stop date >= study med start date, then TEAE
	Partial	Impute stop date as latest possible date (i.e., last day of month if day unknown or 31st December if day and month are unknown), then: If stop date < study med start date, then not TEAE If stop date >= study med start date, then TEAE
	Missing	Assumed TEAE
Missing	Known	If stop date < study med start date, then not TEAE If stop date >= study med start date, then TEAE
	Partial	Impute stop date as latest possible date (i.e., last day of month if day unknown or 31st December if day and month are unknown), then: If stop date < study med start date, then not TEAE If stop date >= study med start date, then TEAE
	Missing	Assumed TEAE

Algorithm for Prior / Concomitant Medications:

START DATE	STOP DATE	ACTION

START DATE	STOP DATE	ACTION
Known	Known	If stop date < study med start date, assign as prior If stop date >= study med start date assign as concomitant
	Partial	Impute stop date as latest possible date (i.e., last day of month if day unknown or 31st December if day and month are unknown), then: If stop date < study med start date, assign as prior If stop date >= study med start date, assign as concomitant
	Missing	If stop date is missing, it could never be assumed a prior medication, assign as concomitant
Partial	Known	Impute start date as earliest possible date (i.e., first day of month if day unknown or 1st January if day and month are unknown), then: If stop date < study med start date, assign as prior If stop date >= study med start date, assign as concomitant

START DATE	STOP DATE	ACTION
	Partial	Impute start date as earliest possible date (i.e., first day of month if day unknown or 1st January if day and month are unknown) and impute stop date as latest possible date (i.e., last day of month if day unknown or 31st December if day and month are unknown), then: If stop date < study med start date, assign as prior If stop date >= study med start date, assign as concomitant
	Missing	If stop date is missing, it could never be assumed a prior medication, assign as concomitant
Missing	Known	If stop date < study med start date, assign as prior If stop date >= study med start date, assign as concomitant
	Partial	Impute stop date as latest possible date (i.e., last day of month if day unknown or 31st December if day and month are unknown), then: If stop date < study med start date, assign as prior If stop date >= study med start date, assign as concomitant
	Missing	Assumed concomitant

TABLE SHELLS

Placebo-Controlled Proof of Concept Study to Investigate ANB020 Activity in Adult Patients with Peanut Allergy

Study No. ANB020-003

Output Templates Signature Page

Table Shells Draft 3.0 (Dated 07Feb2018) for Protocol ANB020-003.

	Name	Signature	Date
Author:	[redacted]	[redacted]	
Position:			
Company:	IQVIA™		

Upon review of this document, the undersigned approves this version of the Output Templates, authorizing that the content is acceptable for the reporting of this study.

	Name	Signature	Date
Reviewed and Approved By:	[redacted]		
Position:			11-4-18
Company:	IQVIA™		
Reviewed and Approved By:	[redacted]		
Position:			
Company:	IQVIA™		
Reviewed and Approved By:	[redacted]		11 APR 2018
Position:			

Company:	IQVIA™
Reviewed and Approved By:	[redacted] 12 APR 2018
Position:	
Company:	IQVIA™
Reviewed and Approved By:	[redacted] 11 APR 2018
Position:	
Company:	AnaptysBio, Inc.

Output Templates Signature Page
Table Shells Draft 3.0 (Dated 07Feb2018) for Protocol ANB020-003.

	Name	Signature	Date
Author:	[redacted]	[redacted]	
Position:			
Company:	IQVIA™		

Upon review of this document, the undersigned approves this version of the Output Templates, authorizing that the content is acceptable for the reporting of this study.

	Name	Signature	Date
Reviewed and Approved By:	[redacted]		
Position:			
Company:	IQVIA™		
Reviewed and Approved By:	[redacted]		11 Apr 2018
Position:			
Company:	IQVIA™		
Reviewed and Approved By:	[redacted]		11 APR 2018
Position:			

List of Reviewers

Reviewer Name	Position/ Role	Company
[redacted]		IQVIA™
		IQVIA™
		IQVIA™
		IQVIA™
		AnaptysBio, Inc

Modification History

Unique Identifier for this Version	Date of the Document Version	Author	Significant Changes from Previous Authorized Version
Draft 1 0	08 Mar 2017	[redacted]	Not Applicable-First Draft
Version 1 0	16 Mar 2017		Addressed client comments
Draft 2 0	05 Jun 2017		Revision based on protocol amendment 2 0 dated 30May2017
Draft 2 0	13 Jun 2017		Implemented SBR comments
Draft 2 0	28 Jun 2017		Implemented PK comments
Draft 2 0	25 Jul 2017		Implemented MW comments, changes based on protocol amendment 3 0 dated 30Jun2017
Draft 3 0	07Feb2018		Implemented PK comments
Final Copy	10 Apr 2018		Prepared the Final copy for sign off

Table of Contents

Table 14 1 1 1
Patient Disposition – All Patients Screened Set

Category	ANB020 (N=XX) n (%)	Placebo (N=XX) n (%)	Total (N=xx) n (%)
Patients in Randomized Analysis Set	xx	xx	xx
Patients Administered the Treatment	xx (xx x)	xx (xx x)	xx (xx x)
Patients in FAS Population	xx (xx x)	xx (xx x)	xx (xx x)
Patients in SAF Population	xx (xx x)	xx (xx x)	xx (xx x)
Patients in PK Analysis Set	xx (xx x)	xx (xx x)	xx (xx x)
Patients in PD Analysis Set	xx (xx x)	xx (xx x)	xx (xx x)
Patients who Completed the Study	xx (xx x)	xx (xx x)	xx (xx x)
Patients who Completed the Study till Day 14	xx (xx x)	xx (xx x)	xx (xx x)
Patients who Completed the Study till Day 45	xx (xx x)	xx (xx x)	xx (xx x)
Patients who Discontinued the Study	xx (xx x)	xx (xx x)	xx (xx x)
Reason for Discontinuation			
Adverse Event	xx (xx x)	xx (xx x)	xx (xx x)
Death	xx (xx x)	xx (xx x)	xx (xx x)
----------	----------		
Lack of compliance of protocol	xx (xx x)	xx (xx x)	xx (xx x)
Other	xx (xx x)	xx (xx x)	xx (xx x)

Source: Listing 16 1 2 1, 16 1 2 2
Note:
- N is the number of patients within each treatment group in the Randomized Analysis Set
- Percentages are based on the number of randomized patients in the respective treatment arm (N)
- Percentage for reason for discontinuation is based on number of patients who discontinued the study

Programming Note (not part of table): Add missing row where necessary Percentage for reason for discontinuation shall be taken from discontinued patients

Table 14 1 2 1
Protocol Deviations – Randomized Analysis Set

Deviations/Violations	ANB020 (N=XX) n (%)	Placebo (N=XX) n (%)	Total (N=XX) n (%)
Patients with major protocol deviations	xx (xx x)	xx (xx x)	xx (xx x)
Patients with category 1 deviation	xx (xx x)	xx (xx x)	xx (xx x)
Patients with category 2 deviation	xx (xx x)	xx (xx x)	xx (xx x)

Source: Listing 16 1 11 1
Note:
- N is the number of patients within each treatment group in the Randomized Analysis Set
- Percentages are based on the number of randomized patients in the respective treatment arm (N)
- Patients with multiple protocol deviations within the same category are counted only once under that category

Table 14 1 3 1
Demographic Characteristics – Randomized Analysis Set

Characteristic	Statistics	ANB020 (N=XX)	Placebo (N=XX)	Total (N=XX)
Age (years)	n	xx	xx	xx
	Mean (SD)	xx x (xx xx)	xx x (xx xx)	xx x (xx xx)
	Median	xx x	xx x	xx x
	Min, Max	xx, xx	xx, xx	xx, xx
Gender	n (%)			
Male		xx (xx x)	xx (xx x)	xx (xx x)
Female		xx (xx x)	xx (xx x)	xx (xx x)
Child Bearing Potential Females	n (%)			
Yes		xx (xx x)	xx (xx x)	xx (xx x)
No		xx (xx x)	xx (xx x)	xx (xx x)
If Not Child Bearing Potential, <Categories>	n (%)	xx (xx x)	xx (xx x)	xx (xx x)
Race	n (%)			
<Categories>		xx (xx x)	xx (xx x)	xx (xx x)
Ethnicity	n (%)			
<Categories>		xx (xx x)	xx (xx x)	xx (xx x)
Weight (Kg)	.....			
Height (m)	.....			
BMI(kg/m^2)	.....			

Source: Listing 16 1 1 1
Note:
- N is the number of patients within each treatment group in the Randomized Analysis Set Percentages are based on the number of randomized patients in the respective treatment arm (N)

Programming Note (not part of table): Add missing row where applicable Present descriptive statistics similar to age for weight, height and BMI (present n, mean, SD, min, max, median)

Table 14 1 3 2
Other Baseline Characteristics – Randomized Analysis Set

Characteristic	Statistics	ANB020 (N=XX)	Placebo (N=XX)	Total (N=XX)
Skin Prick Test and ImmunoCAP Testing				
Performed Within 8 Weeks of Screening?	n (%)			
Yes		xx (xx x)	xx (xx x)	xx (xx x)
No		xx (xx x)	xx (xx x)	xx (xx x)
Peanut Extract				
Done	n (%)	xx (xx x)	xx (xx x)	xx (xx x)
Longest Wheal Diameter (mm)	n	xx	xx	xx
	Mean (SD)	xx x (xx xx)	xx x (xx xx)	xx x (xx xx)
	Median	xx x	xx x	xx x
	Min, Max	xx, xx	xx, xx	xx, xx
Orthogonal Diameter at the Mid-Point of Longest Axis (mm)	.....			
Not Done	n (%)	xx (xx x)	xx (xx x)	xx (xx x)
Positive Control				
Done	n (%)	xx (xx x)	xx (xx x)	xx (xx x)
Longest Wheal Diameter (mm)	.....			
Orthogonal Diameter at the Mid-Point of Longest Axis (mm)	.....			
Not Done	n (%)	xx (xx x)	xx (xx x)	xx (xx x)
Negative Control				
Done	n (%)	xx (xx x)	xx (xx x)	xx (xx x)
Longest Wheal Diameter (mm)	.....			
Orthogonal Diameter at the Mid-Point of Longest Axis (mm)	.....			

Table 14 1 3 2
Other Baseline Characteristics – Randomized Analysis Set

Characteristic	Statistics	ANB020 (N=XX)	Placebo (N=XX)	Total (N=XX)
Not Done	n (%)	xx (xx x)	xx (xx x)	xx (xx x)
Drugs of Abuse				
Sample Collected?	n (%)			
Yes		xx (xx x)	xx (xx x)	xx (xx x)
Positive		xx (xx x)	xx (xx x)	xx (xx x)
Negative		xx (xx x)	xx (xx x)	xx (xx x)
No		xx (xx x)	xx (xx x)	xx (xx x)

Source: Listing 16 1 6 1, 16 1 8 1
Note:
- N is the number of patients within each treatment group in the Randomized Analysis Set
- Percentages are based on the number of randomized patients in the respective treatment arm (N)

Programming Note (not part of table):
- Add missing row where applicable
- Longest Wheal Diameter (mm) and Orthogonal Diameter at the Mid-Point of Longest Axis (mm) will be summariuzed using n, mean, SD, min, max, median

Table 14 1 3 3
Baseline Disease Characteristics – Randomized Analysis Set

Characteristic	Statistics	ANB020 (N=XX)	Placebo (N=XX)	Total (N=XX)
Quantiferon Gold Test [1]				
Blood Sample Collected?	n (%)			
Yes		xx (xx x)	xx (xx x)	xx (xx x)
Positive		xx (xx x)	xx (xx x)	xx (xx x)
Negative		xx (xx x)	xx (xx x)	xx (xx x)
No		xx (xx x)	xx (xx x)	xx (xx x)
Virology				
Blood Sample Collected?	n (%)			
Yes		xx (xx x)	xx (xx x)	xx (xx x)
No		xx (xx x)	xx (xx x)	xx (xx x)
If Yes,				
Hepatitis B Surface Antigen	n (%)			
<Categories>		xx (xx x)	xx (xx x)	xx (xx x)
Hepatitis C Antibody	n (%)			
<Categories>		xx (xx x)	xx (xx x)	xx (xx x)
HIV Antibody	n (%)			
<Categories>		xx (xx x)	xx (xx x)	xx (xx x)

Table 14 1 3 3
Baseline Disease Characteristics – Randomized Analysis Set

Characteristic	Statistics	ANB020 (N=XX)	Placebo (N=XX)	Total (N=XX)

Source: Listing 16 1 9 1, 16 1 10 1
Note:
- N is the number of patients within each treatment group in the Randomized Analysis Set
- Percentages are based on the number of randomized patients in the respective treatment arm (N)
- [1] – Test for Tuberculosis

Programming Note (not part of table): Add missing row where applicable *This table can be modified as per the data requirement.*

Table 14 1 3 4
Serum Pregnancy Test – Randomized Analysis Set

	Visit	Characteristic	Result	Statistics	ANB020 (N=XX)	Placebo (N=XX)	Total (N=XX)
Serum Pregnancy Test [1]	Baseline	Test Performed	Yes	n (%)	xx (xx x)	xx (xx x)	xx (xx x)
			No		xx (xx x)	xx (xx x)	xx (xx x)
		Outcome	Positive	n (%)	xx (xx x)	xx (xx x)	xx (xx x)
			Negative		xx (xx x)	xx (xx x)	xx (xx x)
	< Visits >	----------					

Source: Listing 16 1 5 1
Note:
- N is the number of female patients within each treatment group in the Randomized Analysis Set
- Percentages are based on the number of randomized female patients in respective treatment arm (N)
- [1] – Only for women of child bearing potential

Programming Note (not part of table): Add missing row where applicable *This table can be modified as per the data requirement.*

Table 14 1 4 1
Medical History – Randomized Analysis Set

System Organ Class Preferred Term	ANB020 (N=XX) n (%)	Placebo (N=XX) n (%)	Total (N=XX) n (%)
System Organ Class 1			
Preferred Term1	xx (xx x)	xx (xx x)	xx (xx x)
Preferred Term2	xx (xx x)	xx (xx x)	xx (xx x)
----------	xx (xx x)	xx (xx x)	xx (xx x)
System Organ Class 2			
Preferred Term1	xx (xx x)	xx (xx x)	xx (xx x)
Preferred Term2	xx (xx x)	xx (xx x)	xx (xx x)
----------	xx (xx x)	xx (xx x)	xx (xx x)

Source: Listing 16 1 3 1
Note:
- N is the number of patients within each treatment group in the Randomized Analysis Set
- Patients experiencing multiple events within the same SOC or preferred term are counted only once under those categories
- Percentages are based on the number of randomized patients in the respective treatment arm (N)

Programming Note (not part of table): Number and percentage (%) of patients with Medical History, sorted by decreasing frequency of system organ class and preferred term in total column. Mention "Uncoded" if there are any terms which are not coded yet

Table 14 1 5 1
Prior Medications by ATC Level – Safety Analysis Set

ATC Level 1 ATC Level 3	ANB020 (N=XX) n (%)	Placebo (N=XX) n (%)	Total (N=XX) n (%)
Number of Patients with at least one Prior Medication	xx (xx x)	xx (xx x)	xx (xx x)
ATC Level 1	xx (xx x)	xx (xx x)	xx (xx x)
ATC Level 3	xx (xx x)	xx (xx x)	xx (xx x)
ATC Level 3	xx (xx x)	xx (xx x)	xx (xx x)
----------			
	xx (xx x)	xx (xx x)	xx (xx x)
ATC Level 1	xx (xx x)	xx (xx x)	xx (xx x)
ATC Level 3	xx (xx x)	xx (xx x)	xx (xx x)
ATC Level 3			

Source: Listing 16 1 12 1
Note:
- N is the number of patients within each treatment group under Safety Analysis Set
- Medications are coded using WHO Drug Dictionary Dec 2016
- Patients with multiple usage of the same medication within the same ATC level 3 term are counted only once
- Percentages are based on number of patients within each treatment group under Safety Analysis Set(N)
- Only the patients with prior medications are summarized

Programming Note (not part of table): Number and percentage (%) of patients with prior medications, sorted by descending order of frequency in total column Add"Uncoded" if any events are not coded yet
If ATC level is not present or received from the DM, present this table for only PT's
Programming Note (not part of table): Similar table will be generated as follows:

Table 14 1 6 1 Concomitant Medications by ATC Level – Safety Analysis Set

Tables 14.1.6.1 will be summarized only for patients having atleast one concomitant medication.

Table 14 1 7 1
Study Medication Exposure – Safety Analysis Set

Charateristic	Statistics	ANB020 (N=XX) n (%)	Placebo (N=XX) n (%)	Total (N=XX) n (%)
Total Volume Administered	n	xx	xx	xx
	Mean (SD)	xx x (xx xx)	xx x (xx xx)	xx x (xx xx)
	Median	xx x	xx x	xx x
	Min, Max	xx, xx	xx, xx	xx, xx

Source: Listing 16 1 13 1Note:
- N is the number of patients within each treatment group under Safety Analysis Set
- Percentages are based on number of patients within each treatment group under Safety Analysis Set(N)
- IV = Intravenous

Table 14 2 1 1
Cumulative Tolerated Peanut Dose (Unit) During BPCFC – Full Analysis Set

Visit	Statistics	ANB020 (N=XX)	Placebo (N=XX)
Baseline	n	xx	xx
	Mean (SD)	xx x (xx xx)	xx x (xx xx)
	Median	xx x	xx x
	Min, Max	xx, xx	xx, xx
Day 14	n	xx	xx
	Mean (SD)	xx x (xx xx)	xx x (xx xx)
	Median	xx x	xx x
	Min, Max	xx, xx	xx, xx
Change from Baseline to Day 14	n	xx	xx
	Mean (SD)	xx x (xx xx)	xx x (xx xx)
	Median	xx x	xx x
	Min, Max	xx, xx	xx, xx

Day 45	n	xx	xx
	Mean (SD)	xx x (xx xx)	xx x (xx xx)
	Median	xx x	xx x
	Min, Max	xx, xx	xx, xx
Change from Baseline to Day 45	n	xx	xx
	Mean (SD)	xx x (xx xx)	xx x (xx xx)
	Median	xx x	xx x
	Min, Max	xx, xx	xx, xx

Source: Listing 16 2 1 1
Note:
- N is the number of patients within each treatment group under Full Analysis Set
- Baseline is defined as the nearest non-missing value before first dose of study medication

Programming Note: Continue this table for all available visits and respective change from baseline

Table 14 2 1 2
Primary Efficacy: Change from Baseline in Total Cumulative Tolerated Peanut Dose (Unit) During BPCFC at Day 14 – Full Analysis Set

Treatment LSMEANS (SE)		Treatment Difference ANB020 vs Placebo (Standard Error)	95% CI for Difference	p-value
ANB020	Placebo			
xxxx xxx (xxxx xxx)	xxxx xxx (xxxx xxx)	xxx xx (xxx xxx)	(xxx xx, xxx xx)	0 xxx

Note:
- P-value is obtained using ANCOVA model with treatment as fixed effect and baseline value as covariate

Programming Note: Refer SAP for Model

Table 14 2 2 1
OFC Symptom Score – Full Analysis Set

Visit	Statistics	ANB020 (N=XX)	Placebo (N=XX)
Baseline (Prior to challenge 1)	n	xx	xx
	Mean (SD)	xx x (xx xx)	xx x (xx xx)
	Median	xx x	xx x
	Min, Max	xx, xx	xx, xx
Prior to challenge 2	----		
After completion of challenge 1	----		
After completion of challenge 2	----		
2 hours after the challenge completion	----		
Unscheduled time point	----		
Day 14			
Prior to challenge 1	n	xx	xx
	Mean (SD)	xx x (xx xx)	xx x (xx xx)
	Median	xx x	xx x
	Min, Max	xx, xx	xx, xx
Change from Baseline to Prior to challenge 1 of Day 14	n	xx	xx
	Mean (SD)	xx x (xx xx)	xx x (xx xx)
	Median	xx x	xx x
	Min, Max	xx, xx	xx, xx

Day 45			
Prior to challenge 1	n	xx	xx
	Mean (SD)	xx x (xx xx)	xx x (xx xx)
	Median	xx x	xx x

Table 14 2 2 1
OFC Symptom Score – Full Analysis Set

Visit	Statistics	ANB020 (N=XX)	Placebo (N=XX)
	Min, Max	xx, xx	xx, xx

Change from Baseline to time point of Day 45	n	xx	xx
	Mean (SD)	xx x (xx xx)	xx x (xx xx)
	Median	xx x	xx x
	Min, Max	xx, xx	xx, xx

Source: Listing 16 2 2 1
Note:
- N is the number of patients within each treatment group under Full Analysis Set
- Baseline is defined as the nearest non-missing value before first dose of study medication

Programming Note: Continue this table for all available visits and respective change from baseline

Table 14 2 2 2
Secondary Efficacy: Chane from Baseline in OFC Symptom Score at Day 14 – Full Analysis Set

Treatment LSMEANS (SE)		Treatment Difference ANB020 vs Placebo (Standard Error)	95% CI for Difference	p-value
ANB020	Placebo			
xxxx xxx (xxxx xxx)	xxxx xxx (xxxx xxx)	xxx xx (xxx xxx)	(xxx xx, xxx xx)	0 xxx

Note:
- P-value is obtained using ANCOVA model with treatment as fixed effect and baseline value as covariate

Programming Note: Refer SAP for Model

Table 14 2 3 1
Change from Baseline in Total Cumulative Tolerated Peanut Dose (Unit) During BPCFC and OFC Symptom Score at Day 45 – Full Analysis Set

Endpoint	Treatment LSMEANS (SE)		Treatment Difference ANB020 vs Placebo (Standard Error)	95% CI for Difference	p-value
	ANB020	Placebo			
Total Cumulative Tolerated Peanut Dose During BPCFC	xxxx xxx (xxxx xxx)	xxxx xxx (xxxx xxx)	xxx xx (xxx xxx)	(xxx xx, xxx xx)	0 xxx
OFC Symptom Score	xxxx xxx (xxxx xxx)	xxxx xxx (xxxx xxx)	xxx xx (xxx xxx)	(xxx xx, xxx xx)	0 xxx

Note:
- P-value is obtained using MMRM model with treatment, visit, treatment*visit as fixed effects and baseline and baseline*visit as covariates

Programming Note: Refer SAP for Model

Table 14 3 1 1
Overview of Adverse Events – Safety Analysis Set

Characteristic	ANB020 (N=XX) n (%)	Placebo (N=XX) n (%)	Total (N=XX) n (%)
Overall number of TEAEs	xx	xx	xx
Overall number of Non-TEAEs	xx	xx	xx
Overall number of AE due to BPCFC	xx	xx	xx
Number of Patients with at least one			
TEAE	xx (xx x)	xx (xx x)	xx (xx x)
Serious TEAE	xx (xx x)	xx (xx x)	xx (xx x)
Severe TEAE	xx (xx x)	xx (xx x)	xx (xx x)
Related TEAE	xx (xx x)	xx (xx x)	xx (xx x)
Non-TEAE	xx (xx x)	xx (xx x)	xx (xx x)
AE due to BPCFC	xx (xx x)	xx (xx x)	xx (xx x)
Patients with TEAE by Severity			
Mild	xx (xx x)	xx (xx x)	xx (xx x)
Moderate	xx (xx x)	xx (xx x)	xx (xx x)
Severe	xx (xx x)	xx (xx x)	xx (xx x)
Patients with TEAE by Final Outcome			
Recovered	xx (xx x)	xx (xx x)	xx (xx x)
Recovering	xx (xx x)	xx (xx x)	xx (xx x)
Not Recovered	xx (xx x)	xx (xx x)	xx (xx x)
Recovered with Sequelae	xx (xx x)	xx (xx x)	xx (xx x)
Fatal	xx (xx x)	xx (xx x)	xx (xx x)
Lost to Follow-Up	xx (xx x)	xx (xx x)	xx (xx x)
Action Taken with the Study Drug for Patients with TEAE			
Drug Permanently Discontinued	xx (xx x)	xx (xx x)	xx (xx x)
Dose Reduced	xx (xx x)	xx (xx x)	xx (xx x)
Dose Interrupted	xx (xx x)	xx (xx x)	xx (xx x)
Dose Not Changed	xx (xx x)	xx (xx x)	xx (xx x)
None	xx (xx x)	xx (xx x)	xx (xx x)
Patients with TEAE with Relationship to Study Drug			
Unrelated	xx (xx x)	xx (xx x)	xx (xx x)
Unlikely	xx (xx x)	xx (xx x)	xx (xx x)

Table 14 3 1 1
Overview of Adverse Events – Safety Analysis Set

Characteristic	ANB020 (N=XX) n (%)	Placebo (N=XX) n (%)	Total (N=XX) n (%)
Possible	xx (xx x)	xx (xx x)	xx (xx x)
Probable	xx (xx x)	xx (xx x)	xx (xx x)
Unknown	xx (xx x)	xx (xx x)	xx (xx x)
Patients with TEAE with Seriousness Criteria			
Death	xx (xx x)	xx (xx x)	xx (xx x)
Life-Threatening	xx (xx x)	xx (xx x)	xx (xx x)
Inpatient Hospitalization or Prolongation of Existing Hospitalization	xx (xx x)	xx (xx x)	xx (xx x)
Persistent or Significant Disability/ Incapacity	xx (xx x)	xx (xx x)	xx (xx x)
Congenital Abnormality/ Birth Defect	xx (xx x)	xx (xx x)	xx (xx x)
Other Medically Significant Events	xx (xx x)	xx (xx x)	xx (xx x)
Patients who Discontinued from the Study Due to TEAE	xx (xx x)	xx (xx x)	xx (xx x)

Source: Listing 16 3 1 1, 16 3 2 1, 16 3 3 1, 16 3 4 1
Note:
- N is the number of patients within each treatment group under Safety Analysis Set
- Adverse Event terms are coded using latest version of MedDRA
- Patients experiencing multiple events are counted only once within the treatment group
- Percentages are based on number of patients within each treatment group under Safety Analysis Set (N)
- AE- Adverse Event, TEAE- Treatment Emergent Adverse Events

Programming Note (not part of table): For count of TEAEs, use the coded term (preferred term)

Table 14 3 1 2
TEAE by System Organ Class and Preferred Term – Safety Analysis Set

System Organ Class Preferred Term	ANB020 (N=XX)	Placebo (N=XX)	Total (N=XX)
Number of Patients with at least one TEAE	xx (xx x)	xx (xx x)	xx (xx x)
System Organ Class 1	xx (xx x)	xx (xx x)	xx (xx x)
Preferred Term 1	xx (xx x)	xx (xx x)	xx (xx x)
Preferred Term 2	xx (xx x)	xx (xx x)	xx (xx x)

System Organ Class 2	xx (xx x)	xx (xx x)	xx (xx x)
Preferred Term 1	xx (xx x)	xx (xx x)	xx (xx x)

Source: Listing 16 3 1 1, 16 3 2 1, 16 3 3 1, 16 3 4 1
Note:
- N is the number of patients within each treatment group under Safety Analysis Set
- Adverse Event terms are coded using System Organ Class and Preferred term using using latest version of MedDRA
- Patients experiencing multiple events within the same SOC or PT are counted only once under those categories
- Percentages are based on number of patients within each treatment group under Safety Analysis Set (N)

Programming Note (not part of table):
- Table will be sorted in decreasing frequency of system organ class and preferred term of total column Include "Uncoded" if events are not coded
  A subject can have one or more preferred terms reported under a given system organ class
- Similar tables will be generated for Safety Analysis Set as follows:

Table 14 3 1 2 1 TEAEs by Preferred Term – Safety Analysis Set

Table 14 3 1 3 Serious TEAEs by System Organ Class and Preferred Term – Safety Analysis Set

Table 14 3 1 4 TEAEs Leading to Discontinuation from the Study by System Organ Class and Preferred Term – Safety Analysis Set

Table 14 3 1 5 TEAEs Leading to Interruption of Study Drug by System Organ Class and Preferred Term – Safety Analysis Set

Table 14 3 1 6 TEAEs Leading to Death by System Organ Class and Preferred Term – Safety Analysis Set

Table 14 3 1 7 Non TEAEs by System Organ Class and Preferred Term – Safety Analysis Set

Table 14 3 1 8 Adverse Events due to BPCFC by System Organ Class and Preferred Term – Safety Analysis Set

Table 14 3 2 1
TEAEs by Severity, System Organ Class and Preferred Term – Safety Analysis Set

System Organ Class Preferred Term	ANB020 (N=XX)			Placebo (N=XX)		
	Mild	Moderate	Severe	Mild	Moderate	Severe
Number of Patients with at least one TEAE by Severity	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)
System Organ Class 1	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)
Preferred Term 1	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)
Preferred Term 2	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)
System Organ Class 2	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)
Preferred Term 1	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)

Source: Listing 16 3 1 1, 16 3 2 1, 16 3 3 1, 16 3 4 1
Note:
- N is the number of patients within each treatment group under Safety Analysis Set
- Adverse Event terms are coded using System Organ Class and Preferred term using using latest version of MedDRA
- Patients experiencing multiple events within the same SOC or preferred term are counted only once under those categories
- Percentages are based on number of patients within each treatment group under Safety Analysis Set (N)
- Patients experiencing the same event with different severity level are counted under the most severe occurrence

Programming Note (not part of table):
- Table will be sorted in decreasing frequency of system organ class and preferred term of total column Include "Uncoded" if events are not coded
- A subject can have one or more preferred terms reported under a given system organ class

Table 14 3 2 1
TEAEs by Severity, System Organ Class and Preferred Term – Safety Analysis Set

System Organ Class Preferred Term	Total (N=XX)		
	Mild	Moderate	Severe
Number of Patients with at least one TEAE by Severity	xx (xx x)	xx (xx x)	xx (xx x)
System Organ Class 1	xx (xx x)	xx (xx x)	xx (xx x)
Preferred Term 1	xx (xx x)	xx (xx x)	xx (xx x)
Preferred Term 2	xx (xx x)	xx (xx x)	xx (xx x)
System Organ Class 2	xx (xx x)	xx (xx x)	xx (xx x)
Preferred Term 1	xx (xx x)	xx (xx x)	xx (xx x)

Source: Listing 16 3 1 1, 16 3 2 1, 16 3 3 1, 16 3 4 1
Note:
- N is the number of patients within each treatment group under Safety Analysis Set
- Adverse Event terms are coded using System Organ Class and Preferred term using using latest version of MedDRA
- Patients experiencing multiple events within the same SOC or preferred term are counted only once under those categories
- Percentages are based on number of patients within each treatment group under Safety Analysis Set (N)
- Patients experiencing the same event with different severity level are counted under the most severe occurrence

Programming Note (not part of table):
- Table will be sorted in decreasing frequency of system organ class and preferred term of total column Include "Uncoded" if events are not coded
- A subject can have one or more preferred terms reported under a given system organ class

Table 14 3 3 1
TEAEs by Relationship to Study Drug, System Organ Class and Preferred Term – Safety Analysis Set

System Organ Class Preferred Term	ANB020 (N=XX)		Placebo (N=XX)		Total (N=XX)	
	Related	Not Related	Related	Not Related	Related	Not Related
Number of Patients with at least one TEAE by Relationship	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)
System Organ Class 1	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)
Preferred Term 1	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)
Preferred Term 2	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)
System Organ Class 2	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)
Preferred Term 1	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)	xx (xx x)

Source: Listing 16 3 1 1, 16 3 2 1, 16 3 3 1, 16 3 4 1
Note:
- N is the number of patients within each treatment group under Safety Analysis Set
- Adverse Event terms are coded using System Organ Class and Preferred term using using latest version of MedDRA
- Patients experiencing multiple events within the same SOC or preferred term are counted only once under those categories
- Percentages are based on number of patients within each treatment group under Safety Analysis Set (N)
- Patients experiencing the same event with different relationship level are counted under the worst degree of relationship
- AEs with relationship in ("Possible", "Probable" and "Unknown") are mapped to "Related", else to "Unrelated"

Programming Note (not part of table):
- Table will be sorted in decreasing frequency of system organ class and preferred term of total column Include "Uncoded" if events are not coded
- A subject can have one or more preferred terms reported under a given system organ class

Table 14 3 4 1
Markably Abnormal Laboratory Criteria (Local Lab) – Safety Analysis Set

Laboratory Category Parameter	Visit	Markably Abnormality Criteria	Indication Low/High	ANB020 (N=XX)	Placebo (N=XX)	Total (N=XX)
Hematology						
Parameter 1	<Visits>	Criteria xx	Low	xx (xx x)	xx (xx x)	xx (xx x)
		Criteria xx	Low	xx (xx x)	xx (xx x)	xx (xx x)
Parameter 2	<Visits>	Criteria xx	High	xx (xx x)	xx (xx x)	xx (xx x)
----------		Criteria xx	High	xx (xx x)	xx (xx x)	xx (xx x)
Clinical Chemistry						
Parameter 1	<Visits>	Criteria xx	Low	xx (xx x)	xx (xx x)	xx (xx x)
Parameter 2	<Visits>	Criteria xx	High	xx (xx x)	xx (xx x)	xx (xx x)

Urinalysis						
Parameter 1	<Visits>	Criteria xx	High	xx (xx x)	xx (xx x)	xx (xx x)
Parameter 2	<Visits>	Criteria xx	Low	xx (xx x)	xx (xx x)	xx (xx x)

Source: Listing 16 3 5 1
Note:
- N is the number of patients within each treatment group under Safety Analysis Set
- Percentages are based on number of patients within each treatment group under Safety Analysis Set (N)
- Only the incidences of abnormal values according to normal range criteria are summarized

Programming Note (not part of table): Continue this table for

Table 14 3 4 2
Potential Clinically Significant Laboratory Assessments – Safety Analysis Set

Laboratory Category Parameter	Visit	Potential Clinical Significance Status	ANB020 (N=XX)	Placebo (N=XX)	Total (N=XX)
Hematology					
Parameter 1	<Visits>	Normal	xx (xx x)	xx (xx x)	xx (xx x)
		Abnormal NCS	xx (xx x)	xx (xx x)	xx (xx x)
		Abnormal CS	xx (xx x)	xx (xx x)	xx (xx x)
		Missing	xx (xx x)	xx (xx x)	xx (xx x)
Parameter 2	<Visits>	Normal	xx (xx x)	xx (xx x)	xx (xx x)
		Abnormal NCS	xx (xx x)	xx (xx x)	xx (xx x)
----------		Abnormal CS	xx (xx x)	xx (xx x)	xx (xx x)
		Missing	xx (xx x)	xx (xx x)	xx (xx x)
Clinical Chemistry					
Parameter 1	<Visits>				
----------	----------	----------			
Urinalysis					
Parameter 1	<Visits>				
----------	----------	----------			

Urinalysis
Source: Listing 16 3 5 1
Note:
- N is the number of patients within each treatment group under Safety Analysis Set
- Percentages are based on number of patients within each treatment group under Safety Analysis Set (N)
- NCS – Not Clinically Significant, CS – Clinically Significant

Programming Note (not part of table): Use all relevant visits and parameters

Table 14 3 4 3
Laboratory Parameters – Safety Analysis Set

			ANB020 (N=XX)		Placebo (N=XX)		Total (N = XX)	
Laboratory Category Parameter	Visit	Statistics	Actual	Change from Baseline	Actual	Change from Baseline	Actual	Change from Baseline
Hematology								
Parameter 1	Baseline	n	xx	-	xx	-	xx	-
		Mean (SD)	xx x (xx xx)	-	xx x (xx xx)	-	xx x (xx xx)	-
		Median	xx x	-	xx x	-	xx x	-
		Min, Max	xx, xx	-	xx, xx	-	xx, xx	-
	Day 1	n	xx	xx	xx	xx	xx	xx
		Mean (SD)	xx x (xx xx)	xx x (xx xx)	xx x (xx xx)	xx x (xx xx)	xx x (xx xx)	xx x (xx 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

	Day 45							
Parameter 2	----------							

Source: Listing 16 3 5 1
Note:
- N is the number of patients within each treatment group under Safety Analysis Set
- Baseline is defined as the last non-missing value before first dose of study medication

Programming Note (not part of table): Present all the parameters in Hematology, Clinical Chemistry, and Urinalysis
Provide appropriate discreptives for urinalysis Use all relevant visits

Table 14 3 4 4
Shifts from Baseline in Clinical Laboratory Results – Safety Analysis Set

Laboratory Category Parameter	Visit	Baseline Assessment	Post Baseline Assessments ANB020 (N=XX) Low	Normal	High	Missing	Total	Placebo (N=XX) Low	Normal	High	Missing	Total
Hematology												
Parameter 1	Day 1	Low	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
		Normal	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
		High	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
		Missing	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
		Total	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Day 2											

Parameter 2	------											

Source: Listing 16 3 5 1
Note:
- N is the number of patients within each treatment group under Safety Analysis Set
- Baseline is defined as the last non-missing value before first dose of study medication

Programming Note (not part of table): Present all the parameters in Hematology, Clinical Chemistry and Urinalysis Use all relevant visits

Table 14 3 5 1
12-Lead ECG – Safety Analysis Set

			ANB020 (N=XX)		Placebo (N=XX)		Total (N=XX)	
Parameter (Unit)	Visit	Statistics	Actual	Change from Baseline	Actual	Change from Baseline	Actual	Change from Baseline
Heart Rate (bpm)	Baseline	n	xx	-	xx	-	xx	-
		Mean (SD)	xx x (xx xx)	-	xx x (xx xx)	-	xx x (xx xx)	-
		Median	xx x	-	xx x	-	xx x	-
		Min, Max	xx, xx	-	xx, xx	-	xx, xx	-
	Day 45	n	xx	xx	xx	xx	xx	xx
		Mean (SD)	xx x (xx xx)	xx x (xx xx)	xx x (xx xx)	xx x (xx xx)	xx x (xx xx)	xx x (xx 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
PR Interval (msec)	----------							
QRS Interval (msec)	----------							
QT Interval (msec)	----------							
QTc Interval (msec)	----------							
QTcB (msec)	----------							
QTcF (msec)	----------							

Source: Listing 16 3 6 1
Note:
- N is the number of patients within each treatment group under Safety Analysis Set
- Baseline is defined as the nearest non-missing value before first dose of study medication

Programming Note (not part of table): Continue the table for all parameters and all available visits

Table 14 3 5 2
Overall ECG and QT Changes from Baseline – Safety Analysis Set

Category	Visit	Indication	ANB020 (N=XX)	Placebo (N=XX)	Total (N=XX)
Overall Assessment of ECG	Baseline	Nomal	xx (xx x)	xx (xx x)	xx (xx x)
		Abnormal NCS	xx (xx x)	xx (xx x)	xx (xx x)
		Abnormal CS	xx (xx x)	xx (xx x)	xx (xx x)
		Missing	xx (xx x)	xx (xx x)	xx (xx x)
	Day 45	Nomal	xx (xx x)	xx (xx x)	xx (xx x)
		Abnormal NCS	xx (xx x)	xx (xx x)	xx (xx x)
		Abnormal CS	xx (xx x)	xx (xx x)	xx (xx x)
		Missing	xx (xx x)	xx (xx x)	xx (xx x)
Patients reaching a value in QT Interval (msec) at any time during treatment above or equal to [1]		>= 450 (msec)			
		>= 480 (msec)			
		>= 500 (msec)			
Patients Experiencing an increase in QT Interval (msec) at any Time During Treatment by more than [1] [2]		>30 (msec)			
		>60 (msec)			
Patients Experiencing a decrease in QT Interval (msec) at any Time During Treatment by more than [1] [2]		>30 (msec)			
		>60 (msec)			

Source: Listing 16 3 6
Note:
- N is the number of patients within each treatment group under Safety Analysis Set
- Percentages are based on number of patients within each treatment group under Safety Analysis Set (N)
- NCS – Not Clinically Significant, CS – Clinically Significant
- [1] Cumulative counts, [2] Change from baseline to any observation on treatment

Programming Note (not part of table): Use all relevant visits and parameters

Table 14 3 6 1
Vital Signs – Safety Analysis Set

Parameter (Unit)	Visit	Time Point	Statistics	ANB020 (N=XX) Actual	ANB020 (N=XX) Change from Baseline	Placebo (N=XX) Actual	Placebo (N=XX) Change from Baseline	Total (N=XX) Actual	Total (N=XX) Change from Baseline
Pulse Rate (bpm)	<Visits>	<Time Point>	n	xx	-	xx	-	xx	-
			Mean (SD)	xx x (xx xx)	-	xx x (xx xx)	-	xx x (xx xx)	-
			Median	xx x	-	xx x	-	xx x	-
			Min, Max	xx, xx	-	xx, xx	-	xx, xx	-
Respiratory Rate (resp/min)	<Visits>								
Body Temperature (°C)	<Visits>								
Body Temperature (°F)	<Visits>								
Systolic Blood Pressure (mmHg)	<Visits>								
Diastolic Blood Pressure (mmHg)	<Visits>								

Source: Listing 16 3 7 1
Note:
- N is the number of patients within each treatment group under Safety Analysis Set
- Baseline is defined as the nearest non-missing value before first dose of study medication

Programming Note (not part of table): Continue the table for all parameters and all available visits

Table 14 3 7 1
Spirometry – Safety Analysis Set

			ANB020 (N=XX)		Placebo (N=XX)		Total (N=XX)	
Parameter (Unit)	Visit	Statistics	Actual	Change from Baseline	Actual	Change from Baseline	Actual	Change from Baseline
Actual FEV_1 (L)	<Visits>	n	xx	-	xx	-	xx	-
		Mean (SD)	xx x (xx xx)	-	xx x (xx xx)	-	xx x (xx xx)	-
		Median	xx x	-	xx x	-	xx x	-
		Min, Max	xx, xx	-	xx, xx	-	xx, xx	-
Predicted FEV_1 (L)	<Visits>							
Percent of Predicted (%)	<Visits>							

Source: Listing 16 3 8 1
Note:
- N is the number of patients within each treatment group under Safety Analysis Set
- Baseline is defined as the nearest non-missing value before first dose of study medication

Programming Note (not part of table): Continue the table for all parameters and all available visits

Table 14 3 7 2
Ashtma Assessment of Symptom Control – Safety Analysis Set

Category	Visit	Indication	ANB020 (N=XX)	Placebo (N=XX)	Total (N=XX)
Patients with Asthma Symptoms More than Twice a Week	Baseline	Yes	xx (xx x)	xx (xx x)	xx (xx x)
		No	xx (xx x)	xx (xx x)	xx (xx x)
	Day 14	Yes	xx (xx x)	xx (xx x)	xx (xx x)
		No			
Patients Who Woke in Night due to Asthma	<Visits>	Yes	xx (xx x)	xx (xx x)	xx (xx x)
		No	xx (xx x)	xx (xx x)	xx (xx x)
Patients Needed Reliever for Symptoms More than Twice a Week	<Visits>				
Patients with Acitivity Limitation due to Asthma	<Visits>				
Level of Asthma Symptom Control	<Visits>	Well Controlled	xx (xx x)	xx (xx x)	xx (xx x)
		Partially Controlled	xx (xx x)	xx (xx x)	xx (xx x)
		Uncontrolled	xx (xx x)	xx (xx x)	xx (xx x)

Source: Listing 16 1 7 1
Note:
- N is the number of patients within each treatment group under Safety Analysis Set
- Percentages are based on number of patients within each treatment group under Safety Analysis Set (N)

Programming Note (not part of table): Use all relevant visits and parameters *Table can be modified as per the data requirement*

Table 14 3 8 1
Physical Examination – Safety Analysis Set

Parameter	Visit	Category	ANB020 (N=XX) n (%)	Placebo (N=XX) n (%)	Total (N=XX) n (%)
General appearance	Baseline	Normal	xx (xx x)	xx (xx x)	xx (xx x)
		Abnormal, NCS	xx (xx x)	xx (xx x)	xx (xx x)
		Abnormal, CS	xx (xx x)	xx (xx x)	xx (xx x)
		Not Done	xx (xx x)	xx (xx x)	xx (xx x)
	Day 14	Normal	xx (xx x)	xx (xx x)	xx (xx x)
		Abnormal, NCS	xx (xx x)	xx (xx x)	xx (xx x)
		Abnormal, CS	xx (xx x)	xx (xx x)	xx (xx x)
		Not Done	xx (xx x)	xx (xx x)	xx (xx x)
	Day 45	----------			

Source: Listing 16 3 9 1
Note:
- N is the number of patients within each treatment group under Safety Analysis Set
- Percentages are based on number of patients within each treatment group under Safety Analysis Set (N)
- NCS – Not Clinically Significant, CS – Clinically Significant

Programming Note (not part of table): Continue the table for all other parameters and all available visits May need to add "Missing" row if response is not available for some patients

Table 14 4 1 1
Summary of Serum Concentration of ANB020 – Pharmacokinetic Analysis Set

Visit	Nominal Time Point	Statistics	ANB020 (N=XX)
Day 1	Pre-Dose	n, LLOQ(n) Mean (SD) CV Median (Min, Max)	xx, xx xx x (xx xx) xx x xx x (xx, xx)
	0 50 hours post SOI	n, LLOQ (n) Mean (SD) CV Median (Min, Max)	xx, xx xx x (xx xx) xx x xx x (xx, xx)
	EOI	----------	
	EOI+3 hours	----------	
Day 2	24 hours post SOI	----------	
Day 5	96 hours post SOI	----------	
Day 15	336 hours post SOI	----------	
Day 45	1056 hours post SOI	----------	

Source: Listing 16 4 1 1
Note:
- CV = coefficient of variation; EOI = End of Infusion; LLOQ(n) = number of observations ≥lower limit of quantitation; Max = maximum; Min = minimum; n = number of observations; SD = standard deviation; SOI = Start of Infusion

Programming Note (not part of table): Use all relevant visits and time points

Table 14 4 1 2
Summary of Pharmacokinetic Parameters of ANB020 – Pharmacokinetic Analysis Set

Parameter	Statistics	ANB020 (N=XX)
C_{max}	n	xx, xx
	Mean (SD)	xx x (xx xx)
	CV	xx x
	Median (Min, Max)	xx x (xx, xx)
	Gmean (gCV)	xx x (xx xx)
t_{max}	n	xx
	Median	xx xx
	Min, Max	xx, xx

Source: Listing 16 4 1 2
Note:
- CV = coefficient of variation; gCV = geometric coefficient of variation; Gmean = geometric mean; Max = maximum; Min = minimum; n = number of observations; SD = standard deviation

Programming Note (not part of table): Continue this for all other summarized parameters, if any

Table 14 5 1 1
Summary of Pharmacodynamic Endpoints – Pharmacodynamic Analysis Set

				ANB020 (N=XX)			Placebo (N=XX)		
Analyte (unit)	Visit	Nominal Time Point	Statistics	Observed	Change from Baseline	Relative Change from Baseline (%)	Observed	Change from Baseline	Relative Change from Baseline (%)
Serum Cytokines IL-33 (unit)	Baseline	-	n	xx			xx		
			Mean (SD)	xx x (xx xx)			xx x (xx xx)		
			Median	xx x			xx x		
			Min, Max	xx, xx			xx, xx		
			95% CI	(xx xx, xx xx)			(xx xx, xx xx)		
	Day 2	24 hours post SOI	n	xx	xx	xx	xx	xx	xx
			Mean (SD)	xx x (xx xx)	xx x (xx xx)	xx x (xx xx)	xx x (xx xx)	xx x (xx xx)	xx x (xx 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
			95% CI	(xx xx, xx xx)	(xx xx, xx xx)	(xx xx, xx xx)	(xx xx, xx xx)	(xx xx, xx xx)	(xx xx, xx xx)
	Day 5	96 hours post SOI	--------						
	Day 15	336 hours post SOI							

Leukocytes (unit)									

Ex Vivo Cytokines <analyte> (unit)									

Source: Listing 16 5 1 1, 16 2 5 2, 16 2 5 3
Note:
- CI = confidence interval; EOI = End of Infusion; Max = maximum; Min = minimum; n = number of observations; SD = standard deviation; SOI = Start of Infusion
- Relative change from baseline = (actual-baseline)/baseline
- Baseline is defined as the last non-missing value before first dose of study medication

Programming Note (not part of table): Continue the table for all other analytes of Serum Cytokines, Leukocytes, and Ex Vivo peanut antigen challenge cytokines in whole blood at all available visits and respective time points

Table 14 5 1 2
Statistical Analysis of Pharmacodynamic Endpoints – Pharmacodynamic Analysis Set

Comparison	Parameter	Treatment Difference (Standard Error)	95% CI	p-value
ANB020 vs Placebo	Serum Cytokines IL-33	xxx xx (xxx xxx)	(xxx xx, xxx xx)	0 xxx
	Serum Cytokines IL-4			

Note:
- CI = confidence interval P-value is obtained using Mixed Effect ANCOVA model with treatment, visit, treatment*visit as fixed effects and baseline value as covariate

Programming Note (not part of table): Continue the table for all other analytes of Serum Cytokines, Leukocytes, and Ex Vivo peanut antigen challenge cytokines in whole blood at all available visits and respective time points

FIGURE SHELLS

Placebo-Controlled Proof of Concept Study to Investigate ANB020 Activity in Adult Patients with Peanut Allergy

Study No. ANB020-003

IQVIA

Figure Shells

Output Templates Signature Page

Figure Shells Draft 3.0 (Dated 07Feb2018) for Protocol ANB020-003.

	Name	Signature	Date
Author:	[redacted]		DDMMMYYYY
Position:			
Company:	IQVIA™		

Upon review of this document, the undersigned approves this version of the Output Templates, authorizing that the content is acceptable for the reporting of this study.

	Name	Signature	Date
Reviewed and Approved By:	[redacted]		DDMMMYYYY
Position:			
Company:	IQVIA™		
Reviewed and Approved By:	[redacted]		DDMMMYYYY
Position:			
Company:	IQVIA™		
Reviewed and Approved By:	[redacted]		DDMMMYYYY 11 APR 2018
Position:			
Company:	IQVIA™		
Reviewed and Approved By:	[redacted]		DDMMMYYYY 12 APR 2018
Position:			
Company:	IQVIA™		
Reviewed and Approved By:	[redacted]		DDMMMYYYY 11 APR 2018

Document: \\eedc-nas01a\biosdata\AnaptysBio\ANB020\CYA74393\Biostatistics\Documentation\SAP\Final\2017-06-28

Author: [redacted]

Version Number: Final 1.0

Version Date: 28JUN2017

IQVIA

Figure Shells

Output Templates Signature Page

Figure Shells Draft 3.0 (Dated 07Feb2018) for Protocol ANB020-003.

	Name	Signature	Date
Author:	[redacted]		DDMMMYYYY
Position:			
Company:	IQVIA™		

Upon review of this document, the undersigned approves this version of the Output Templates, authorizing that the content is acceptable for the reporting of this study.

	Name	Signature	Date
Reviewed and Approved By:	[redacted]		DDMMMYYYY
Position:			11-4-18
Company:	IQVIA™		
Reviewed and Approved By:	[redacted]		DDMMMYYYY
Position:			
Company:	IQVIA™		
Reviewed and Approved By:	[redacted]		DDMMMYYYY 11 APR 2018
Position:			
Company:	IQVIA™		
Reviewed and Approved By:	[redacted]		DDMMMYYYY
Position:			
Company:	IQVIA™		
Reviewed and Approved By:	[redacted]		DDMMMYYYY 11 APR 2018

Document: \\eedc-nas01a\biosdata\AnaptysBio\ANB020\CYA74393\Biostatistics\Documentation\SAP\Final\2017-06-28

Author: [redacted]

Version Number: Final 1.0

Version Date: 28JUN2017

IQVIA

Figure Shells

Output Templates Signature Page

Figure Shells Draft 3.0 (Dated 07Feb2018) for Protocol ANB020-003.

	Name	Signature	Date
Author:	[redacted]		DDMMMYYYY
Position:			
Company:	IQVIA™		

Upon review of this document, the undersigned approves this version of the Output Templates, authorizing that the content is acceptable for the reporting of this study.

	Name	Signature	Date
Reviewed and Approved By:	[redacted]		DDMMMYYYY
Position:			
Company:	IQVIA™		
Reviewed and Approved By:	[redacted]		DDMMMYYYY 11 Apr 2018
Position:			
Company:	IQVIA™		
Reviewed and Approved By:	[redacted]		DDMMMYYYY 11 APR 2018
Position:			
Company:	IQVIA™		
Reviewed and Approved By:	[redacted]		DDMMMYYYY
Position:			
Company:	IQVIA™		
Reviewed and Approved By:	[redacted]		DDMMMYYYY 11 APR 2018

Document: \\eedc-nas01a\biosdata\AnaptysBio\ANB020\CYA74393\Biostatistics\Documentation\SAP\Final\2017-06-28

Author: [redacted]

Version Number: Final 1.0

Version Date: 28JUN2017

List of Reviewers

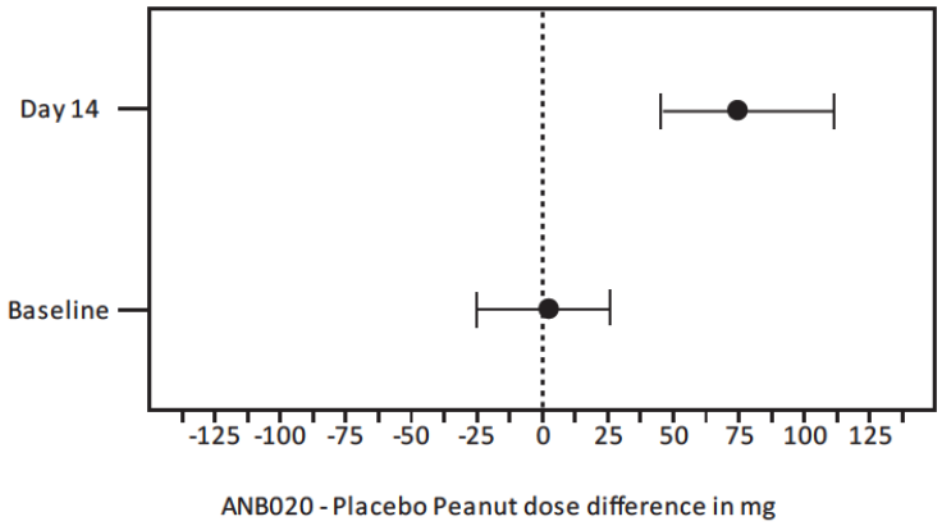
Reviewer Name	Position/ Role	Company
[redacted]		IQVIA™
		IQVIA™
		IQVIA™
		IQVIA™
		AnaptysBio, Inc

Modification History

Unique Identifier for this Version	Date of the Document Version	Author	Significant Changes from Previous Authorized Version
Draft 1 0	08 Mar 2017	[redacted]	Not Applicable-First Draft
Version 1 0	16 Mar 2017		Addressed client comments
Draft 2 0	08 Jun 2017		Revision based on protocol amendment 2 0 dated 30May2017
Draft 2 0	13 Jun 2017		Implemented SBR comments
Draft 2 0	28 Jun 2017		Implemented PK comments
Draft 2 0	25 Jul 2017		Implemented MW comments, changes based on protocol amendment 3 0 dated 30Jun2017
Draft 3 0	07 Feb 2018		Implemented PK comments

Table of Contents

Figure 16 1 7 1
Mean and 95% CI for Between-Treatment Difference in Peanut Dose– Full Analysis Set

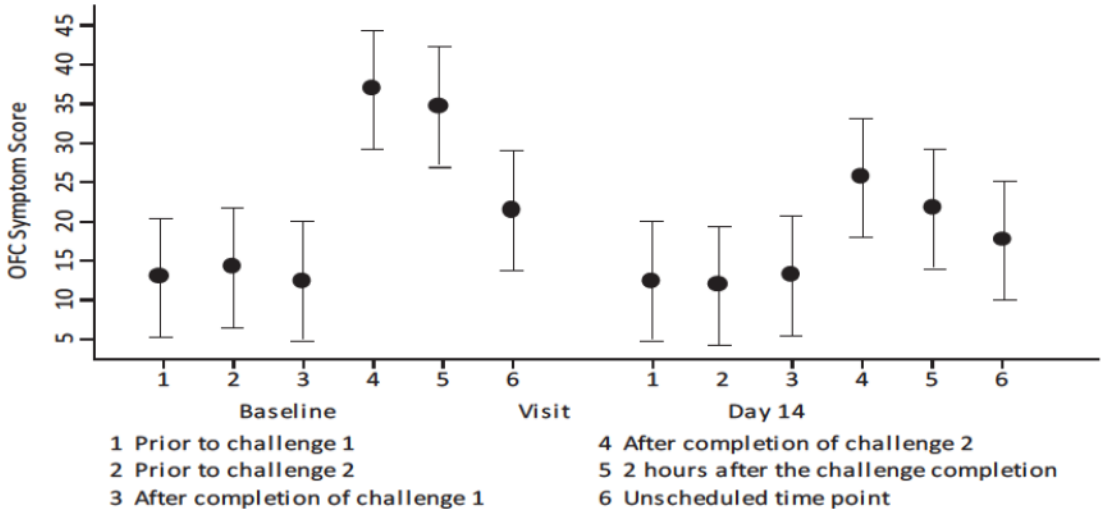


Source: Table 14 2 1 2, 14 2 3 1

Note: CI = confidence interval Mean difference and 95% CI at Day 14 has been obtained through ANCOVA model with treatment as fixed effect and baseline results as a covariate; and mean difference and 95% CI at Day 45 has been obtained through MMRM ANCOVA model with treatment, visit, treatment*visit as fixed effects and baseline and baseline*visit as covariates

Programmer's Note: Include all possible visits (Baseline, Day 14, Day 45)

Figure 16 1 7 2
Mean and 95% CI for OFC Symptom Score by Treatment and Mean Peanut Dose – Full Analysis Set

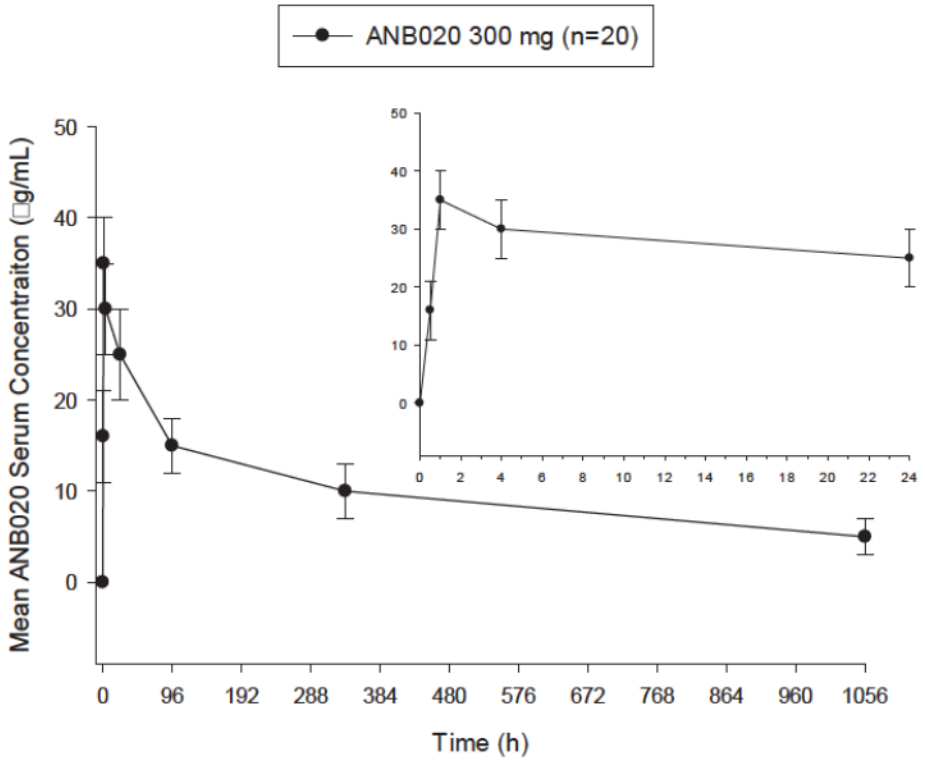


Source: Table 14 2 2 2, 14 2 3 1

Note: CI = confidence interval Mean at Day 14 has been obtained through ANCOVA model with treatment as fixed effect and baseline results as a covariate; and mean at Day 45 has been obtained through MMRM ANCOVA model with treatment, visit, treatment*visit as fixed effects and baseline and baseline*visit as covariates

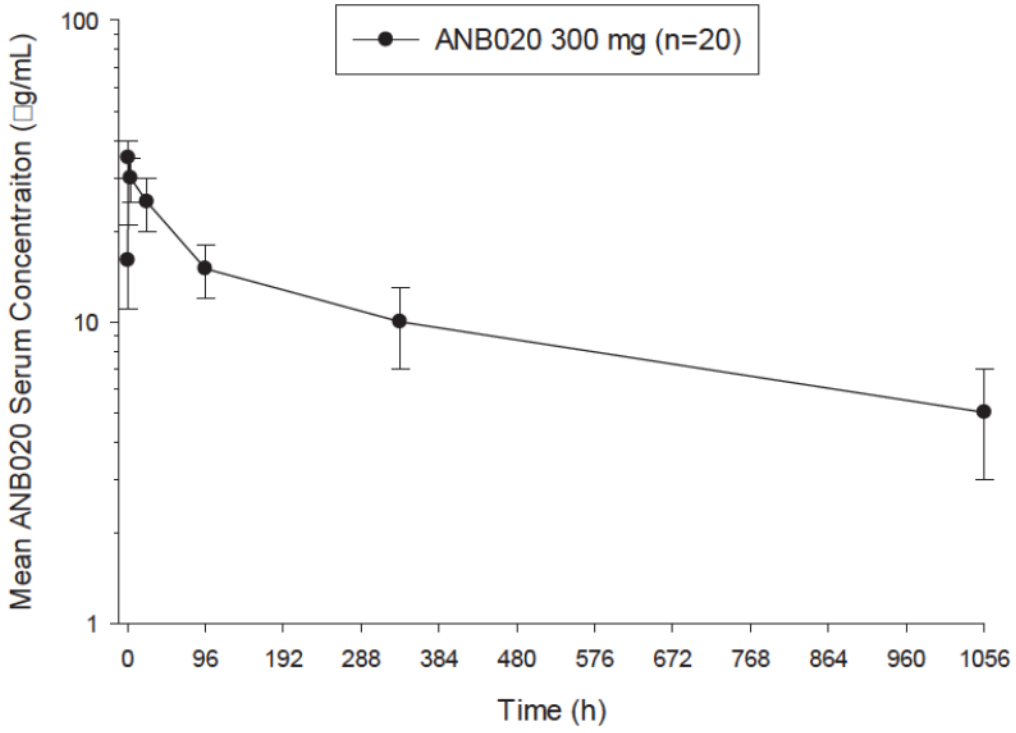
Programmer's Note: Include all possible visits (Baseline, Day 14, Day 45)
Programmer's Note: Similar plots to be presented for the following parameters

Figure 16 1 7 3 1
Mean (±SD) Serum Concentration Time Profile of ANB020 After IV infusion – Pharmacokinetic Analysis Set
Linear Scale



Source: Table xxx
Note: SD = standard deviation
End of infusion (EOI) was approximately 1 hour after the start of infusion (SOI)

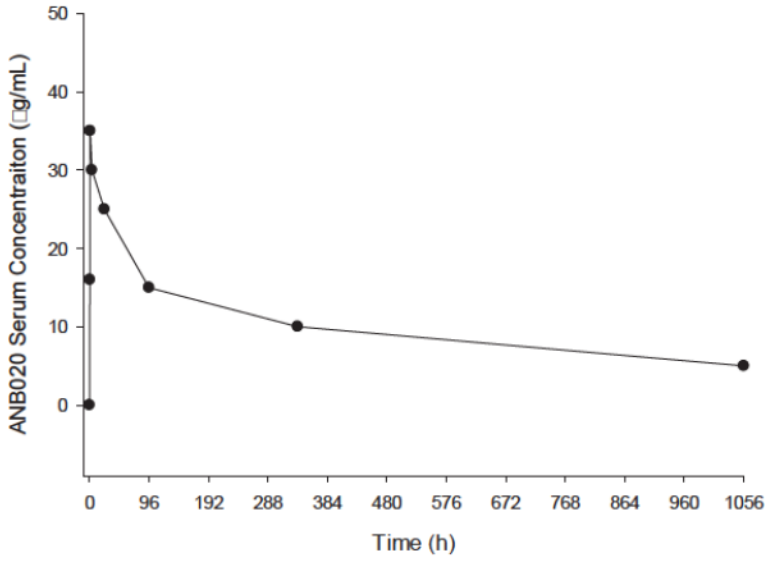
Figure 16 1 7 3 2
Mean (±SD) Serum Concentration Time Profile of ANB020 After IV infusion – Pharmacokinetic Analysis Set
Semi-logarithmic scale



Source: Table xxx
Note: SD = standard deviation
End of infusion (EOI) was approximately 1 hour after the start of infusion (SOI)

Figure 16 1 7 5 1 X
Individual ANB020 Serum Concentration Time Profiles After IV infusion – Safety Analysis Set
Patient 1

Linear Scale



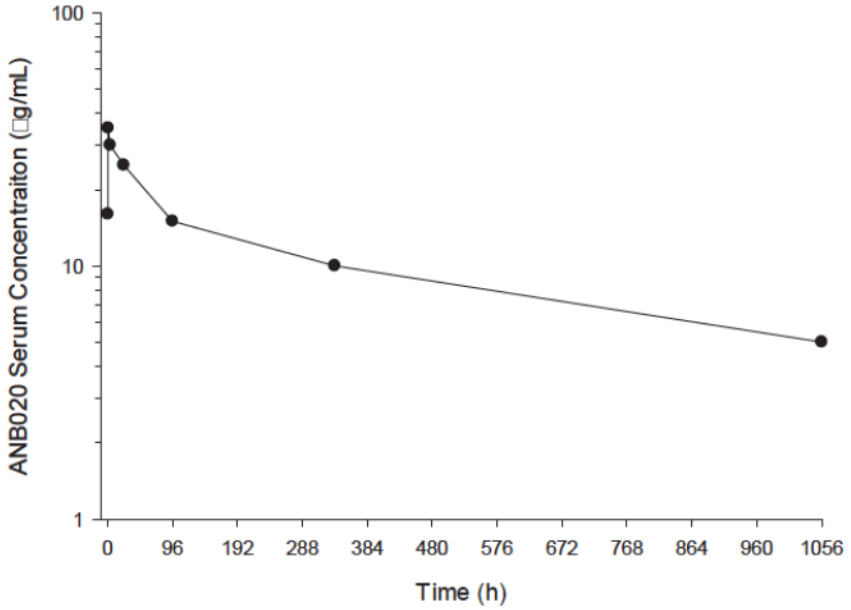
Source: Listing xxx

Programming Note: (not part of table): This plot will be prepared for each subject
X will take values from 1 – 20

Figure 16 1 7 5 2 X
Individual ANB020 Serum Concentration Time Profile After IV infusion – Safety Analysis Set

Patient 1

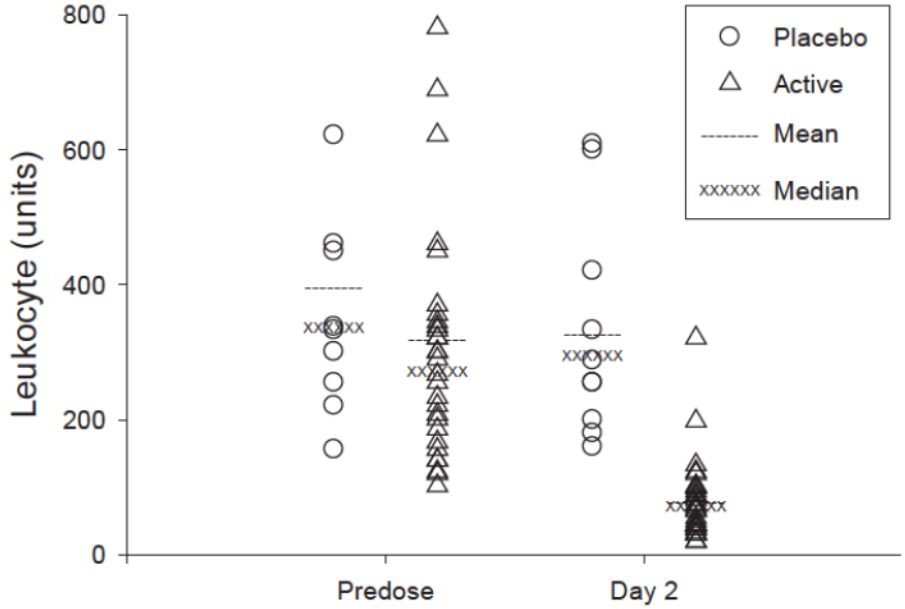
Semi-logarithmic scale



Source: Listing xxx

Programming Note: (not part of table): This plot will be prepared for each subject
X will take values from 1 – 20

Figure 16 1 7 6
Individual, Median, and Mean Plot of Pharmacodynamic Endpoints – Pharmacodynamic Analysis Set



Programming Note (not part of table): Present the analytes (by page): Serum Sampling for Biomarkers Serum Cytokines, Leukocytes, Cytokine levels released from pathogenic T cells in the ex vivo whole blood Peanut Challenge Assay Each plot would include a separate postdose presentation (similar to Day 2) for each day an assessment is made per protocol

LISTING SHELLS

Placebo-Controlled Proof of Concept Study to Investigate ANB020 Activity in Adult Patients with Peanut Allergy

Study No. ANB020-003

Output Templates Signature Page

Listing Shells Draft 3.0 (Dated 07Feb2018) for Protocol ANB020-003.

	Name	Signature	Date
Author:	[redacted]		DDMMMYYYY
Position:			
Company:	IQVIA™		

Upon review of this document, the undersigned approves this version of the Output Templates, authorizing that the content is acceptable for the reporting of this study.

	Name	Signature	Date
Reviewed and Approved By:	[redacted]		DDMMMYYYY
Position:			1-4-18
Company:	IQVIA™		
Reviewed and Approved By:	[redacted]		DDMMMYYYY
Position:			
Company:	IQVIA™		

Output Templates Signature Page

Listing Shells Draft 3.0 (Dated 07Feb2018) for Protocol ANB020-003.

	Name	Signature	Date
Author:	[redacted]	[redacted]	DDMMMYYYY
Position:			
Company:	IQVIA™		

Upon review of this document, the undersigned approves this version of the Output Templates, authorizing that the content is acceptable for the reporting of this study.

	Name	Signature	Date
Reviewed and Approved By:	[redacted]		DDMMMYYYY
Position:			
Company:	IQVIA™		
Reviewed and Approved By:	[redacted]		DDMMMYYYY 11 Apr 2018
Position:			
Company:	IQVIA™		

Reviewed and Approved By:	[redacted]	DDMMMYYYY 11APR 2018
Position:		
Company:	IQVIA™	
Reviewed and Approved By:	[redacted]	DDMMMYYYY 12 APR 2018
Position:		
Company:	IQVIA™	
Reviewed and Approved By:	[redacted]	DDMMMYYYY 11APR2018
Position:		
Company:	AnaptysBio, Inc.	

List of Reviewers

Reviewer Name	Position/ Role	Company
[redacted]		IQVIA™
		IQVIA™
		IQVIA™
		IQVIA™
		AnaptysBio, Inc

Modification History

Unique Identifier for this Version	Date of the Document Version	Author	Significant Changes from Previous Authorized Version
Draft 1 0	08 Mar 2017	[redacted]	Not Applicable-First Draft
Version 1 0	16 Mar 2017		Addressed client comments
Draft 2 0	05 Jun 2017		Revision based on protocol amendment 2 0 dated 30May2017
Draft 2 0	13 Jun 2017		Implemented SBR comments
Draft 2 0	28 Jun 2017		Implemented PK comments
Draft 2 0	25 Jul 2017		Implemented MW comments, changes based on protocol amendment 3 0 dated 30Jun2017
Draft 3 0	07 Feb 2018		Implemented PK comments
Final 1 0	10 Apr 2018		Finalized the documemt for sign off

Table of Contents

Listing 16 2 1 1
Patient Screening Summary - All Patients Screened

	Patient No	Treatment	Age/Gender	Date and Time of ICF	Confirmed Informed Consent at Day 1/If No, Specify	Completed study?	If No, Reason for Discontinuation
	XXX	XXX	32/Male	DDMMMYYYY YTHH:MM	Yes	Yes	-
	XXX	XXX	31/Female	DDMMMYYYY YTHH:MM	Yes	No	Screen Failure
	XXX	XXX	28/Female	DDMMMYYYY YTHH:MM	No: xxxx	No	Subject Withdrew Consent
	...						

Programming Note (not part of table): Sort by patient number, date and time of ICF

Listing 16 2 1 2
Patient Disposition - All Patients Screened

Patient No	Treatment	Age/Gender	Administered the Treatment	Included in Randomized Analysis Set	Included in FAS	Included in SAF	Included in PK Analysis Set	Included in PD Analysis Set
XXX	XXX	32/Male	Yes	Yes	Yes	Yes	Yes	Yes
XXX	XXX	31/Female						
XXX	XXX	28/Female						
...								

1. All patients who have received at least one dose of ANB020 or placebo and provide at least one evaluable post dose PD measurement without any events or protocol deviation deemed to affect PD assessment.
2. All patients who have received ANB020 and have at least one post dose serum concentration data value available for ANB020 without any events or protocol deviation deemed to affect PK assessments.

Listing 16 2 2
Protocol Deviation - All Patients Screened

Patient No	Treatment	Age/Gender	Significance	Deviation Date	Deviation Category	Deviation Description	Lead to Patient Exclusion from PK Population	Lead to Patient Exclusion from PD Population
XXX	XXX	32/Male	Major	DDMMMYYYY	xxxxxxx	xxxxxxxxxxxxx	Yes	No
XXX	XXX	31/Female	Major	DDMMMYYYY	xxxxxxx	xxxxxxxxxxxxx	xx	xx
XXX	XXX	28/Female						
.....								

Listing 16 2 3 1
Study Eligibility Criteria - All Patients Screened

Patient No	Age/ Gender	Did the patientt meet the eligibility criteria for the study?	If No, Specify criteria
XXX	32/ Male	Yes	
XXX	31/ Female	Yes	
XXX	28/ Female	No	INCD7
.....			

Programming Note (not part of table): Sort by patient number

Listing 16 2 4 1
Demographic Characteristics - Randomized Analysis Set

Patient No / Treatment	Age/Gender	Ethnicity	Race	Weight (Kg)	Height (Kg)	BMI(kg/m^2)	If Female, then WOCBP	If Not WOCBP, then Method Used
XXX/ XXX	32/Male	xxxxxx	xxxxxx	xx xx	xx xx	xx xx	-	-
XXX/ XXX	31/Female	xxxxxx	xxxxxx	xx xx	xx xx	xx xx	Yes	-
XXX/ XXX	28/Female	xxxxxx	Xxxxxx	xx xx	xx xx	xx xx	No	Other: xxxx
…								

Note:
WOCBP: Women of Child Bearing Potential

Programming Note (not part of table): Sort by patient number; USUBJID may be modified later

Listing 16 2 4 2
Medical History Diagnosis - Randomized Analysis Set

Patient No / Treatment	Age/Gender	Medical History Number	Medical History Diagnosis	Primary System Organ Class	Preferred Term	Start Date/ End Date	Currently taking medication?
XXX/ XXX	32/Male	XXXX	XXXX	xxxxx	xxxx	DDMMMYYYY/ DDMMMYYYY	No
XXX/ XXX	31/Female	XXXX	XXXX			DDMMMYYYY/ Ongoing	Yes
XXX/ XXX	28/Female	XXXX	XXXX			DDMMMYYYY/ Ongoing	Yes
...							

Note: Only patients with relevant medical history have been listed
Programming Note (not part of table): Sort by patient number, medication history number, start date

Listing 16 2 4 3
Serum Pregnancy Test - Randomized Analysis Set

Patient No / Treatment	Age/ Gender	Visit	Was the serum pregnancy test performed?	If No, Specify reason	Date of serum pregnancy test	Result
XXX/ XXX	32/ Female	Baseline	Yes	-	DDMMMYYYY	Negative
		Day 14	Yes	-	----------	
		Day 15	Yes	-		
XXX/ XXX	31/ Female	---------	No	Xxxx		
XXX/ XXX	28/ Female		Yes		DDMMMYYYY	Positvie
...						

Note: The listings consists only female patients in RND population
Programming Note (not part of table): Sort by patient number, date

Listing 16 2 4 4
Skin Prick Test and ImmunoCAP Testing - Randomized Analysis Set

Patient No / Treatment	Age/ Gender	Was Skin prick test and ImmunoCAP testing performed within 8 weeks before screening?	If No, Specify reason	Date and time of test	Peanut extract	Longest wheal diameter (mm)	Orthogonal diameter at the mid-point of the longest axis (mm)	If Not Done, Specify reason	Positive control	Longest wheal diameter (mm)	Orthogonal diameter at the mid-point of the longest axis (mm)	If Not Done, Specify reason	Negative control	Longest wheal diameter (mm)	Orthogonal diameter at the mid-point of the longest axis (mm)	If Not Done, Specify reason
XXX/ XXX	32/ Male	Yes		DDMMMYYYY/ hh:mm	Done	xxx	xxx		Done	xxx	xxx		Done	xxx	xxx	
XXX/ XXX	31/ Female	No	xxxx		Not Done			xxx	Not Done			xxx	Not Done			xxx
XXX/ XXX	28/ Female	Yes		DDMMMYYYY/ hh:mm	Done	xxx	xxx		Done	xxx	xxx		Done	xxx	xxx	
…																

Programming Note (not part of table): Sort by patient number

Listing 16 2 4 5
Global Initiative for Asthma Assessment of Symptom Control - Randomized Analysis Set

Patient No / Treatment	Age/ Gender	Daytime asthma symptoms more than twice a week?	Any night waking due to asthma?	Reliever needed for symptoms more than twice a week?	Any activity limitation due to asthma?	Level of Asthma Symptom Control
XXX/XXX	32/ Male	No	No	No	No	Well-controlled (None of these)
XXX/XXX	31/ Female	Yes	Yes	No	No	Partially controlled (1-2 of these)
XXX/XXX	28/ Female	No	No	Yes	Yes	Uncontrolled (3-4 of these)
…						

Programming Note (not part of table): Sort by patient number

Listing 16 2 4 6
Drug Abuse - Randomized Analysis Set

Patient No / Treatment	Age/ Gender	Visit	Was a sample collected for drugs of abuse?	If No, Specify reason	Date of sample collection	Result	If positive , Specify
XXX/XXX	32/ Male	Baseline	Yes		DDMMMYYYY	Negative	
		Day 14	Yes		DDMMMYYYY	Negative	
		Day 15	Yes		DDMMMYYYY	Negative	
XXX/XXX	31/ Female		No	xxxx			

XXX/XXX	28/ Female		Yes		DDMMMYYYY	Positvie	xxxx
...							

Programming Note (not part of table): Sort by patient number Continue for all other available visits This listing can be modified as per the data requirement

Listing 16 2 4 7
Virology - Randomized Analysis Set

Patient No / Treatment	Age/ Gender	Was the sample collected?	If No, Specify reason	Date of sample collection	Hepatitis B Surface Antigen	If Not Done , Specify reason	Hepatitis C Antibody	If Not Done , Specify reason	HIV Antibody	If Not Done , Specify reason
XXX/XXX	32/ Male	Yes		DDMMMYYYY/ hh:mm	Negative		Positvie		Positvie	
XXX/XXX	31/ Female	No	xxxx							
XXX/XXX	28/ Female	Yes		DDMMMYYYY	Positvie		Negative		Negative	
...										

Programming Note (not part of table): Sort by patient number

Listing 16 2 4 8
TB screening - Randomized Analysis Set

Patient No / Treatment	Age/ Gender	Was a blood sample collected for quantiferon gold test?	If No, Specify reason	Date of sample collection	Result
XXX/XXX	32/ Male	Yes		DDMMMYYYY	Negative
XXX/XXX	31/ Female	No	xxxx		
XXX/XXX	28/ Female	Yes		DDMMMYYYY	Positvie
...					

Programming Note (not part of table): Sort by patient number

Listing 16 2 4 9
Prior and Concomitant Medications - Safety Analysis Set

Patient No / Treatment	Age/ Gender	Medication Number	Medication Name Reported/ Preferred Term	Start Date/ End Date/ Ongoing	Dose (Unit)/ Frequency/ Route	Indication	Prior or Concomitant
XXX/XXX	32/ Male	1	XXXX	DDMMMYYYY/ DDMMMYYYY	XXX mg	XXXX	Concomitant
XXX/XXX	31/ Female	2	XXXX	DDMMMYYYY/ DDMMMYYYY	XXX mcg	XXXX	Prior
XXX/XXX	28/ Female	3	XXXX	DDMMMYYYY/ DDMMMYYYY	XXX ml	XXXX	Prior
...							

Programming Note (not part of table): Sort by patient number, medication number, start date

Listing 16 2 5 1
Exposure to Investigational Product – Safety Analysis Set

Patient No / Treatment	Age/Gender	IP administered via IV/ If No, reason	Start Date and Start Time	End Date and End Time	Total Volume Administered (mL)	If Total volume administered <100 ml, Reason
XXX/XXX	32/Male	Yes	DDMMMYYYYThh:mm	DDMMMYYYYThh:mm	XXXX	xxxx
XXX/XXX	31/Female	Yes	DDMMMYYYYThh:mm	DDMMMYYYYThh:mm	XXXX	-
XXX/XXX	28/Female	No/ xxxx				
…						

Note:
IP – Investigational Product
IV – Intravenous

Programming Note (not part of table): Sort by patient number, start date, start time

Listing 16 2 6 1
Oral Peanut Food Challenge (BPCFC) - Full Analysis Set

Patient No / Treatment	Age/ Gender	Visit	Was oral BPCFC performed?	Cumulative Ingested 1 (Unit)	Start Date/ Start Time of dose challenge 1	End Date / End Time of dose challenge 1	Cumulative Ingested 2 (Unit)	Start Date/ Start Time of dose challenge 2	End Date / End Time of dose challenge 2
XXX/XXX	32/ Male	Baseline	Yes	XX	DDMMMYYYYTh h:mm	DDMMMYYY YThh:mm	XX	DDMMMYYYYT hh:mm	DDMMMY YYYThh:m m
		Day 14	----------						
		Day 45							
XXX/XXX	31/ Female	-------	No	XX	DDMMMYYYYTh h:mm	DDMMMYYY YThh:mm	XX	DDMMMYYYYT hh:mm	DDMMMY YYYThh:m m
XXX/XXX	28/ Female	---------	No	-	-				
...									

Note: BPCFC=Blind Placebo-Controlled Food Challenge
Programming Note (not part of table): Sort by patient number, start date, start time

Listing 16 2 6 2
Oral Food Challenge Symptom Scoring - Full Analysis Set

Patient No / Treatment	Age/ Gender	Visit	Time point	Date/ Time of Assessment	Skin Rash/ Pruritus/ Urticaria/ Angioedema (Grade)	Nasal Sneezing/ Itching/ Congestion/ Rhinorrhea/ Airway obstruction (Grade)	Chest Wheezing (Grade)	Abdomen Nausea/ Abdominal pain/ Emesis/ Diarrhea (Grade)
XXX/XXX	32/ Male	Baseline	Prior to challenge 1	DDMMMYYYY/ hh:mm	3/ 2/ 0/ 3f	3/ 2/ 0/ 1/ 3	3	3/ 2/ 0/ 3
		Day 14		----------				3/ 2/ 0/ 3
		Day 45						3/ 2/ 0/ 3
XXX/XXX	31/ Female	----	Prior to challenge 2	DDMMMYYYY/ hh:mm	3/ 2/ 0/ 3	3/ 2/ 0/ 1/ 3	0	3/ 2/ 0/ 3

XXX/XXX	28/ Female	-----	After completion of challenge 2	DDMMMYYYY/ hh:mm	3/ 2/ 0/ 3	3/ 2/ 0/ 1/ 3	3	3/ 2/ 0/ 3
...								

Programming Note (not part of table): Sort by patient number, start date, start time Continue for all other available visits

Listing 16 2 7 1
Treatment Emergent Adverse Events - Safety Analysis Set

Patient No / Treatment	Age/ Gender/ Race	AE Number	System Organ Class/Preferred term/Verbatim Text	Start Date/ End Date	Did AE occur prior to the start of IP infusion?	AE Severity	Final Outcome	Action taken with the study drug	Relationship to study drug	Serious/ Criteria [1]	Did the AE cause the subject to discontinue from the study?	Was subject treated for AE?
XXX/XXX	32/ Male/ Race	xxxx	xx/xx/xx	DDMMMYYYY/ DDMMMYYYY	No	Severe	Recovered	Dose interrupted	Unlikely	Yes/ XXX	Yes	No
XXX/XXX	31/ Female/ Race	xxxx	xx/xx/xx	DDMMMYYYY/ DDMMMYYYY	Yes	Mild	Fatal	Drug permanently discontinued	Possible	Yes/ XXX	Yes	Yes
XXX/XXX	28/ Female/ Race	xxxx	xx/xx/xx	DDMMMYYYY/ DDMMMYYYY	Yes	Moderate	Lost to follow-up	Dose reduced	Probable	No	No	No
…												

Note:
[1] – If SAE led to death, then date of death and primary/ secondary cause of death are provided; if required hospitalization, then date of admission and date of discharge are provided

Programming Note (not part of table): Sort by patient number, AE number, start date

Listing 16 2 7 2
Treatment Emergent Adverse Events Leading to Discontinuation of Study Drug - Safety Analysis Set

Patient No / Treatment	Age/ Gender/ Race	AE Number	System Organ Class/Preferred term/Verbatim Text	Start Date/ End Date	Did AE occur prior to the start of IP infusion?	AE Severity	Final Outcome	Action taken with the study drug	Relationship to study drug	Serious/ Criteria[1]	Was subject treated for AE?
XXX/XXX	32/ Male/ Race	XXXX	XX/xx/xx	DDMMMYYYY / DDMMMYYYY	No	Severe	Recovered	Dose interrupted	Unlikely	Yes/ XXX	No
XXX/XXX	31/ Female/ Race	XXXX	XX/xx/xx	DDMMMYYYY / DDMMMYYYY	Yes	Mild	Fatal	Drug permanently discontinued	Possible	Yes/ XXX	Yes
XXX/XXX	28/ Female/ Race	XXXX	XX/xx/xx	DDMMMYYYY / DDMMMYYYY	Yes	Moderate	Lost to follow-up	Dose reduced	Probable	No	Yes
...											

Note:
[1] – If SAE led to death, then date of death and primary/ secondary cause of death are provided; if required hospitalization, then date of admission and date of discharge are provided

Programming Note (not part of table): Sort by patient number, AE number, start date

Listing 16 2 7 3
Serious Treatment Emergent Adverse Events - Safety Analysis Set

Patient No / Treatment	Age/ Gender/ Race	AE Number	System Organ Class/Preferred term/Verbatim Text	Start Date/ End Date	Did AE occur prior to the start of IP infusion?	AE Severity	Final Outcome	Action taken with the study drug	Relationship to study drug	Seriousness Criteria[1]	Did the AE cause the subject to discontinue from the study?	Was subject treated for AE?
XXX/XXX	32/ Male/ Race	XXXX	XX/xx/xx	DDMMMYYYY / DDMMMYYYY	No	Severe	Recovered	Dose interrupted	Unlikely	XXX	Yes	No
XXX/XXX	31/ Female/ Race	XXXX	XX/xx/xx	DDMMMYYYY / DDMMMYYYY	Yes	Mild	Fatal	Drug permanently discontinued	Possible	XXX	Yes	Yes
XXX/XXX	28/ Female/ Race	XXXX	XX/xx/xx	DDMMMYYYY / DDMMMYYYY	Yes	Moderate	Lost to follow-up	Dose reduced	Probable	XXX	No	Yes
...												

Note:
[1] – If SAE led to death, then date of death and primary/ secondary cause of death are provided; if required hospitalization, then date of admission and date of discharge are provided

Programming Note (not part of table): Sort by patient number, AE number, start date

Listing 16 2 7 4
Treatment Emergent Adverse Events Leading to Death - Safety Analysis Set

Patient No / Treatment	Age/ Gender/ Race	AE Number	System Organ Class/Preferred term/Verbatim Text	Start Date/ End Date	Did AE occur prior to the start of IP infusion?	AE Severity	Action taken with the study drug	Relationship to study drug	Cause and Date of Death	Did the AE cause the subject to discontinue from the study?	Was subject treated for AE?
XXX/XXX	32/ Male/ Race	XXXX	XX/xx/xx	DDMMMYYYY / DDMMMYYYY	No	Severe	Dose interrupted	Unlikely	XXX/ DDMMMYYYY	Yes	No
XXX/XXX	31/ Female/ Race	XXXX	XX/xx/xx	DDMMMYYYY / DDMMMYYYY	Yes	Mild	Drug permanently discontinued	Possible	XXX/ DDMMMYYYY	Yes	Yes
XXX/XXX	28/ Female/ Race	XXXX	XX/xx/xx	DDMMMYYYY / DDMMMYYYY	Yes	Moderate	Dose reduced	Probable	XXX/ DDMMMYYYY	No	Yes
…											

Programming Note (not part of table): Sort by patient number, AE number, start date

Listing 16 2 7 5
Adverse Events Due to BPCFC - Safety Analysis Set

Patient No / Treatment	Age/ Gender/ Race	AE Number	System Organ Class/Preferred term/Verbatim Text	Start Date/ End Date	Did AE occur prior to the start of IP infusion?	AE Severity	Final Outcome	Action taken with the study drug	Relationship to study drug	Seriousness Criteria[1]	Did the AE cause the subject to discontinue from the study?	Was subject treated for AE?
XXX/XXX	32/ Male/ Race	XXXX	XX/xx/xx	DDMMMYYYY / DDMMMYYYY	No	Severe	Recovered	Dose interrupted	Unlikely	XXX	Yes	No
XXX/XXX	31/ Female/ Race	XXXX	XX/xx/xx	DDMMMYYYY / DDMMMYYYY	Yes	Mild	Fatal	Drug permanently discontinued	Possible	XXX	Yes	Yes
XXX/XXX	28/ Female/ Race	XXXX	XX/xx/xx	DDMMMYYYY / DDMMMYYYY	Yes	Moderate	Lost to follow-up	Dose reduced	Probable	XXX	No	Yes
...												

Listing 16 2 8 1
Clinically Significant Laboratory Results - Safety Analysis Set

Patient No / Treatment	Age/ Gender/ Race	Test	Visit	Date	Reference Range	Value[a]	Unit	Change from baseline
XXX/XXX	32/ Male/ Race	Hemoglobin	Sreening	DDMMMYYYY	(XX-YY)	xxxx	xx	xxxx
XXX/XXX	31/ Female/ Race	XXXX	xx	DDMMMYYYY	(XX-YY)	xxxx[H]	xx	xxxx
XXX/XXX	28/ Female/ Race	XXXX	xx	DDMMMYYYY	(XX-YY)	xxxx[L]	xx	xxxx
...								

[a] The high (H) or low (L) values are only flagged
Programming Note (not part of table): Sort by patient number, test, visit, date Present all the parameters

Listing 16 2 8 2
ECG - Safety Analysis Set

Patient No / Treatment	Age/ Gender/ Race	12-Lead ECF Performed?	Date	Visit	Test (Unit)	Value	Change from baseline
XXX/XXX	32/ Male/ Race	Yes	DDMMMYYYY	Baseline	Heart Rate (bpm)	xxxx	
				Day 45		xxxx	xxxx
				Baseline	PR Interval (msec)	xxxx	xxxx
				Day 45			
					QRS Interval (msec)		
				----------	----------		
					QTcF (msec)		
XXX/XXX	31/ Female/ Race	No/ xxxx					

Programming Note (not part of table): Sort by patient number, test, visit, date Present all the parameters for all available visits

Listing 16 2 8 3
Vital Signs - Safety Analysis Set

Patient No / Treatment	Age/ Gender/ Race	Vital Signs Collected?	Visit	Test (Unit)	Date and Time	Time Point	Value	Change from baseline
XXX/XXX	32/ Male/ Race	Yes	<Visits>	Blood Pressure (msec)	DDMMMYYYYTHH:MM	Prior to challenge 1	xxx/xx	-
							Not Done	
XXX/XXX	31/ Female/ Race	No/ xxxx						

Programming Note (not part of table): Sort by patient number, test, visit, date, time Present all the parameters for all available visits

Listing 16 2 8 4
Spirometry - Safety Analysis Set

Patient No / Treatment	Age/ Gender/ Race	Visit	Date	Does subject have a history of asthma?	Predicted FEV1 (Unit)	Actual FEV1 Measurement (Unit)	Percent of Predicted
XXX/XXX	32/ Male/ Race	Baseline	DDMMMYYYY	No/ xxxx			
		Day 14					
		Day 15					
		Day 45					
XXX/XXX	31/ Female/ Race	xx	DDMMMYYYY	Yes	xxxx	xxxx	xxxx

Programming Note (not part of table): Sort by patient number, test, visit, date

Listing 16 2 8 5
Physical Examination Results - Safety Analysis Set

Patient No / Treatment	Age/ Gender/ Race	Visit	Body System	Time point	Date/ Time of Assessment	Result	If Abnormal, clinically significant, specify
XXX/XXX	32/ Male/ Race	Baseline	General appearance	Prior to start of BPCFC	DDMMMYYYYThh:mm	Normal	
		Day 14		----------			
		Day 45					
			Head, Eyes, Ears, Nose and Throat ----------				
XXX/XXX	31/ Female/ Race		----------	Early termination	DDMMMYYYYThh:mm	Abnormal, clinically significant	xxxx
XXX/XXX	28/ Female/ Race			Unscheduled time point	DDMMMYYYYThh:mm	Not Done	
...							

Programming Note (not part of table): Sort by patient number, date, time Present all the Body Systems

Listing 16 2 8 6
Individual ANB020 Serum Concentrations - Safety Analysis Set

Patient No / Treatment	Visit	Nominal Time Point	Blood Sample Collected? If No, Reason	Date and Time	Concentration (Unit)
XXX/XXX	Day 1	Pre-Dose	Yes	DDMMMYYYYThh:mm	xxxx
		0 5 hours post SOI	Yes	DDMMMYYYYThh:mm	xxxx
		EOI	Yes	DDMMMYYYYThh:mm	xxxx
		EOI+3 hours	No: xxxx	-	-
XXX/XXX	Day 2	24 hours post SOI			

XXX/XXX	Day 15			DDMMMYYYY/ hh:mm	xxxx
...					

Note:
SOI – Start of Infusion, EOI – End of Infusion
Programming Note (not part of table): Sort by patient number, visit, date, time Present all the visits

Listing 16 2 8 7 1
Individual ANB020 Serum Pharmacokinetic Parameters - Safety Analysis Set

Patient No / Treatment	Cmax (ug/mL)	tmax (h)	AUC(0-last) (h*ug/mL)	AUC(0-inf) (h*ug/mL)	t1/2 (h)	Lambda-z (1/h)	CL (L/h)	Vss (L)	Vz (L)
XXX/XXX	xxxx	xxxx							
XXX/XXX	xxxx	xxxx							
XXX/XXX	xxxx	xxxx							
...									

Programming Note (not part of table): Sort by patient number, visit All subjects and parameters will be listed

Listing 16 2 8 7 2
Individual Lambda-z Related Parameters for ANB020 - Safety Analysis Set

Patient No / Treatment	Lambda-z_lower (h)	Lambda-z_upper (h)	t1/2, Interval (h)	t1/2, N	Rsq	%AUCex (%)
XXX/XXX						
XXX/XXX						
XXX/XXX						
...						

Note(s): Lambda-z_lower = start time (h) of the log-linear regression to determine λz and t1/2; Lambda-z_upper = End time (h) of the log-linear regression to determine λz and t1/2; t1/2, Interval = the time interval in the terminal phase used to determine lambda_z; t1/2, N = number of observations included in calculation of lambda_z; ND not determined; Rsq = coefficient of determination for calculation of lambda-z; %AUCex = percentage of AUC(0-inf) extrapolated

Programming Note (not part of table): Sort by patient number, visit All subjects and parameters will be listed

Listing 16 2 8 8
Circulating Serum Cytokines - Safety Analysis Set

Patient No / Treatment	Visit	Blood Sample Collected? If No, Reason	Date and Time	Cytokine Analyte (Unit)	Value	Change from Baseline	Relative Change from Baseline
XXX/XXX	<Visits>	Yes	DDMMMYYYYT/hh:mm	IL-33 (unit)	xxxx		
	<Visits>						
	<Visits>						
	<Visits>						

Programming Note (not part of table): Sort by patient number, analyte, visit, date, time Present all the visits where assessment done Present the endpoints Cytokines IL-33, IL-4, IL-5, IL-9, IL-13, sST2

Listing 16 2 8 9
Leukocytes (Whole Blood) - Safety Analysis Set

Patient No / Treatment	Visit	Blood Sample Collected? If No, Reason	Date and Time of Collection	Date and Time of Sample Run	Value (10E3/uL)	Result	Change from Baseline	Relative Change from Baseline
XXX/XXX	Baseline	Yes	DDMMMYYYYT hh:mm	DDMMMYYYYT hh:mm	xxxx	Normal		
	Day 2	Yes	DDMMMYYYYT hh:mm	DDMMMYYYYT hh:mm	xxxx	Abnormal NCS		
	-----	-------						
	Day 45	No: xxxx	-	-				

Note:
NCS – Not Clinically Significant, CS – Clinically Significant
Programming Note (not part of table): Sort by patient number, visit, date and time of collection Present all the visits where assessment done

Listing 16 2 8 10
Ex vivo Peanut Challenge Assay for Cytokines Released from T-cells (Whole Blood) - Safety Analysis Set

Patient No / Treatment	Visit	Blood Sample Collected? If No, Reason	Date and Time of Collection	Time Stimulated (Hours)	Date and Time of Sample Run	Analyte (Unit)	Value	Change from Baseline	Relative Change from Baseline
XXX/XXX	Baseline	Yes	DDMMMYYYYT hh:mm	Hh:mm	DDMMMYYYYT hh:mm	xxx (unit)	xxxx		
	Day 2								

	Day 5								
	Baseline					xxx (unit)			

	Day 5								
						----------			
						xxx (unit)			

Programming Note (not part of table): Sort by patient number, analyte, visit, date and time of collection Present all the visits where assessment done Present all analytes

Listing 16 2 8 11 1
Subjects Excluded from the Pharmacokinetic Analysis Set

Patient No / Treatment	Reason(s) for exclusion

Listing 16 2 8 11 2
Data Excluded from the Pharmacokinetic Analysis Set

Patient No / Treatment	Data excluded	Reason(s) for exclusion