STATISTICAL ANALYSIS PLAN

TITLE PAGE

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of RDX-002 on Postprandial Triglycerides in Patients Discontinuing the Glucagon-like Peptide-1 (GLP-1) Agonists, Semaglutide or Tirzepatide, for the Treatment of Obesity

Final Version 2.0: JUN 12, 2025

Confidentiality Statement

The information contained in this document is privileged and confidential. Do not copy, circulate, or otherwise distribute without written authorization from Response Pharmaceuticals, Inc.

TABLE OF CONTENTS

Contents

TITLE PAGE ..... 1 TABLE OF CONTENTS ..... 2 DECLARATION ..... 4 REVISION HISTORY..... 5 LIST OF ABBREVIATIONS ..... 6 1 INTRODUCTION ..... 9 2 STUDY DETAILS..... 9

2.1 Study Objectives..... 9 2.1.1 Study Design 10

2.2 Determination of Sample Size ..... 15 2.3 Randomization..... 15 2.4 Blinding ..... 15 3 DATA ANALYSIS CONSIDERATION ..... 15 3.1 General Data Considerations..... 15

3.2 Handling of Missing Data ..... 17 3.2.1 Missing data handling for safety data: ..... 17 3.2.2 For Missing AE Relationship/Severity: ..... 17 3.2.3 Missing data handling for PK data: ..... 18 3.2.4 Missing data handling for Efficacy data: 18

4 DEFINITIONS AND DERIVATIONS..... 18 5 PRIMARY AND SECONDARY ENDPOINTS ..... 18 5.1 Primary Efficacy Endpoint ..... 18 5.2 Secondary Efficacy Endpoints ..... 18 5.3 Exploratory Efficacy Endpoints ..... 19 5.4 Pharmacokinetic Endpoints ..... 20 5.5 Safety Endpoints..... 20 6 ANALYSIS POPULATION AND TREATMENT GROUPS ..... 21 6.1 Analysis Population ..... 21 6.2 Treatment Groups ..... 21 7 ANALYSES METHODS AND REPORTING DESCRIPTIONS 21

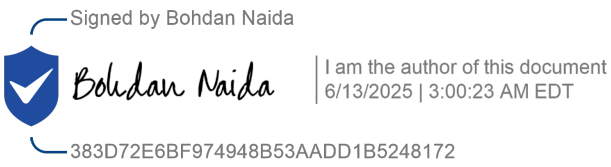
7.1 Patient Disposition 21

7.2 Demography and Baseline Characteristics 22 7.3
Medical History 22 7.4
Prior and Concomitant Medications 22 7.5
Protocol Deviation 23 7.6
Study Drug Exposure and Treatment Compliance 23
7.7 Efficacy Analysis 23 7.7.1
Analysis of Primary Efficacy Endpoint 23 7.7.2
Analysis of Secondary Efficacy Endpoints 25 7.7.3
Analysis of Exploratory Efficacy Endpoints 27
7.8 Safety Analysis 35 7.8.1
Adverse Events 36 7.8.2
Clinical Laboratory Data 36 7.8.3
Vital Signs 38 7.8.4
Electrocardiograms 38 7.8.5
Physical Examination 39 7.8.6
Stool Questionnaire 39
7.9 PK Analysis 39 7.10
Pooled Analyses 39 7.11
Subgroup Analyses 39 7.12
Interim Analysis 39 7.13
Changes to Analyses Specified in Protocol 39 8
REFERENCE 40 9
APPENDIX 40
9.1 APPENDIX I: BLOOD PRESSURE, BODY WEIGHT, WAIST CIRCUMFERENCE AND TOTAL BODY FAT MASS MEASUREMENTS ... 40 9.1.1
Blood Pressure Measurements 40 9.1.2
Body Weight and Waist Circumference Measurements 41 9.1.3
Total Body Fat Mass 42
9.2 Appendix II: Pharmacokinetic and Postprandial Blood Sampling Schedule 42 9.3
Appendix III: Composition of a High-Fat Meal 44 9.4
Appendix IV: Patient Diary 45 9.5
Appendix V: Bristol Stool Form Scale 47
9.6 Appendix VI: Management Plan for Diarrhea 48

DECLARATION

I, the undersigned, declare that I have prepared the statistical analysis plan along with TLF mock shells and that to the best of my knowledge this document is internally consistent with protocol and scientifically rational.

Prepared by:



Name: Bohdan Naida Designation\Role:
Project Biostatistician

Sign & Date (MMM DD, YYYY)

I, the undersigned declare that I have reviewed the statistical analysis plan along with TLF mock shells and that to the best of my knowledge the document is internally consistent with protocol and scientifically rational.

Reviewed by:



Name: Saniya Goon
Designation\Role: Lead Biostatistician

Sign & Date (MMM DD, YYYY)

AUTHORIZATION: I, the undersigned, declare that I have reviewed the statistical analysis plan along with TLF mock shells and that to the best of my knowledge the document accurately reflects the protocol objectives.

Authorized by:



Sponsor representative(s) name: William J Sasiela, PhD
Designation\Role: Chief Medical Officer

Sign & Date (MMM DD, YYYY)

REVISION HISTORY

Version	Date	Author	Reasons
1.0	02APR2025	Prasanth Palanisamy	Initial Version
2.0	12JUN2025	Bohdan Naida	Change of title of Exploratory analysis

LIST OF ABBREVIATIONS

Abbreviation or special term	Definition
AE	adverse events
ANCOVA	analysis of covariance anatomical
ATC AUC	therapeutic chemical area under
	the curve
AUC_{0-24}	area under the concentration-time curve from time zero to 24-hours
$AUC_{0-\infty}$	area under the concentration-time curve from time zero to infinity
AUC_{0-t}	area under the concentration-time curve from time zero until the last measurable concentration or last sampling time t, whichever occurs first.
BID	twice daily
BLQ	below the limit of quantification
BMI	body mass index
BP	blood pressure blood
BUN	urea nitrogen
CI	confidence interval
CKD-EPI	chronic kidney disease epidemiology collaboration
CL/F	apparent total plasma clearance
cm C_{max}	centimeter
CV DBP	maximum measured plasma concentration
ECG	coefficient of variation
eCRF EOS	diastolic blood pressure
FSH GLP-	electrocardiogram electronic
1 GM CV	case report form end of
HbA1c	study
HDL-C	follicle-stimulating hormone
HOMA-IR	glucagon-like peptide-1
hs-CRP	geometric mean coefficient of variation
iAUC	glycated hemoglobin
ICF	high-density lipoprotein cholesterol
	homeostatic model assessment for insulin resistance high
Confidential	sensitivity C-reactive protein
	incremental area under the curve
	informed consent form

Abbreviation or special term	Definition
ICH	international council for harmonisation of technical requirements for pharmaceuticals for human use
ITT	intent-to-treat
kg	kilograms
λ	terminal elimination rate constant
LDH	lactate dehydrogenase
LDL-C	low-density lipoprotein cholesterol
LLOQ	lower limit of quantification
LS	least squares
m MCH	meters
MCHC	mean corpuscular hemoglobin
MCV	mean corpuscular hemoglobin concentration
MedDRA	mean corpuscular volume
mITT NC	medical dictionary for regulatory activities
OT	modified intent-to-treat
PK	not calculable
PP	off-treatment
PT	pharmacokinetic
Q1	per-protocol
Q3	preferred term
r	first quartile
RBC	third quartile
SAE	pearson's correlation coefficients
SAP	red blood cell
SAS	serious adverse event
SBP	statistical analysis plan
SD SE	statistical analysis system
SoA	systolic blood pressure
SOC	standard deviation standard
SUSAR t½	error
TEAE TG	schedule of activities
TLF	system organ class
	suspected unexpected serious adverse reaction terminal
Confidential	elimination half-life, calculated as ln(2)/λz
	treatment-emergent adverse event
	triglyceride
	tables, listings and figures

Abbreviation or special term	Definition
T_{max}	time of the maximum measured plasma concentration.
TSH	thyroid stimulating hormone
US	united states
Vz/F	apparent volume of distribution
WBC	white blood cell
WHODD	world health organization drug dictionary

1 INTRODUCTION

This Statistical Analysis Plan (SAP) describes the statistical methods and data handling procedures to be followed during the final reporting and analyses of data collected for the study protocol RDX-002-024-011.

This SAP should be read in conjunction with the study protocol and electronic case report form (eCRF). This version of SAP has been developed using the protocol (RDX-002-024-011 Amendment 2, dated DEC 13, 2024) and eCRF (version 6.0 dated FEB 10, 2025).

This Phase 2, proof-of-concept study (RDX-002-024-011) has been planned to evaluate the effect of 12 weeks of treatment with RDX-002 on postprandial TGs and body weight among patients who have recently discontinued treatment with the GLP-1 agonists, semaglutide or tirzepatide, for obesity.

2 STUDY DETAILS

2.1 Study Objectives

The primary objective of the study is:

- To assess the efficacy of 12 weeks of treatment with 200 mg BID RDX-002 on the mean percentage change from baseline on postprandial TGs among patients who have recently discontinued treatment with semaglutide or tirzepatide for obesity

The secondary objectives of the study are:

- To evaluate the effect of 12 weeks of treatment with RDX-002 on mean percent change from baseline in body weight in patients who have recently discontinued semaglutide or tirzepatide obesity therapies
- To evaluate the effect of 12 weeks of treatment with RDX-002 on LDL-C in patients who have recently discontinued semaglutide or tirzepatide obesity therapies

The exploratory objectives of the study are:

- To explore the treatment effect of RDX 002 at Week 6 on body weight and LDL-C in patients who have recently discontinued GLP 1 treatment for weight loss
- To explore the treatment effect of RDX 002 at Weeks 6 and 12 on other fasting lipids (total cholesterol, non-high density lipoprotein cholesterol [non-HDL-C]) and TGs in patients who have recently discontinued GLP-1 treatment for weight loss
- To explore the treatment effect of RDX 002 at Weeks 6 and 12 on other obesity linked risk factors; waist circumference, total body fat mass, HbA1c, homeostatic model assessment for insulin resistance (HOMA-IR), high sensitivity C reactive protein (hs-CRP), and fasting

and postprandial glucose and insulin in patients who have recently discontinued GLP-1 treatment for weight loss

- To explore the effect of 12 weeks of treatment with RDX-002 on systolic blood pressure (SBP) and diastolic blood pressure (DBP) in patients who have recently discontinued GLP 1 treatment for weight loss
- To evaluate the effect of discontinuation of the GLP-1 agonists semaglutide or tirzepatide on changes in postprandial TGs

The pharmacokinetic objective of the study is:

- To evaluate the pharmacokinetics (PK) of RDX-002 in patients who have recently discontinued GLP-1 treatment for weight loss

The safety objective of the study is:

- To evaluate the safety of RDX-002 in patients who have recently discontinued semaglutide or tirzepatide obesity therapies

2.1.1 Study Design

This is a Phase 2, randomized, double-blind, placebo-controlled, parallel-group study that will be conducted at a single study site in the US. Patients who have planned discontinuation of semaglutide or tirzepatide treatment for obesity, have lost ≥10% or 10 kg of their original body weight and are aged 18 to 65 years will be eligible for Screening.

The study will be conducted as follows:

Visit S1 - Screening Visit (Day -42 to Day -14): The Screening Visit (Visit S1) will occur no more than 42 to 14 days prior to the Baseline and Randomization Visit (Visit T1) while patients are still on their current GLP-1 therapy.

Visit G1 - GLP-1 Therapy Assessments (Day -42 to Day -14): After completing all screening assessments, patients who meet the screening requirements will return to the clinic for the GLP-1 therapy assessment visit (Visit G1). This visit will be conducted prior to Timepoint G2, while patients are still on their current GLP-1 treatment. To allow for flexibility with patient scheduling and planning for the discontinuation of GLP-1 therapy, Visit S1 and Visit G1 should occur during the 28 days prior to Timepoint G2. At Visit G1, patients will undergo an assessment of postprandial TG levels. Patients will consume a standardized high-fat test meal (Appendix III) and TG levels will be measured 30 minutes prior to the initiation of the test meal and at 1-, 2-, 3-, 4-, 6-, and 8-hours after the initiation of the test meal.

Timepoint G2 – Discontinuation of GLP-1 (Day -14 to Day -7): Patients will be instructed to commence the planned discontinuation of their current GLP-1 agonist treatment (semaglutide or tirzepatide) after Visit G1 and within 7 to 14 days prior to randomization to RDX-002 or matching placebo.

Visit T1 – Baseline and Randomization (Day 1): Eligible patients will be randomly assigned to receive RDX-002 or matching placebo for a 12-week treatment period. Randomization is 1:1.

Only patients with recent discontinuation (7 to 14 days prior to randomization) of semaglutide or tirzepatide who lost ≥10% or 10 kg of body weight during their treatment with the above drugs and continue to satisfy the screening period study entrance criteria at Visit T1 (Day 1) will be randomized to treatment with RDX-002 or matching placebo. Patients will consume the standardized high-fat test meal at Visit T1 (Day 1). The TG levels will be measured 30 minutes prior to initiation of the test meal and at 1-, 2-, 3-, 4-, 6-, and 8-hours after the initiation of the test meal. Following the 8-hour blood draw, patients will take their first dose of either RDX-002 or placebo 30 minutes prior to dinner.

Patients will take RDX-002 everyday BID; approximately 30 minutes prior to breakfast (or the first meal of the day) and approximately 30 minutes prior to dinner.

Visit T2 - Clinic Visit (Day 43): Patients will return to the clinic at Visit T2 (Day 43) for designated blood draws and study procedures. The TG levels will be measured 30 minutes prior to receiving their dose of either RDX-002 or placebo. Following the study procedures, patients will receive the dose of either RDX-002 or placebo 30 minutes prior to a standard clinic meal.

Visit T3 - Clinic Visit (Day 85) - End of Study (EOS): Patients will return to the clinic at Visit T3 (Day 85) for designated blood draws and study procedures. Following the study procedures, patients will receive their dose of either RDX-002 or placebo 30 minutes prior to beginning their standardized high-fat test meal. The TG levels will be measured 30 minutes prior to receiving the dose of either RDX-002 or placebo (and within 60 minutes prior to beginning of the standardized high-fat test meal) and post-dose at 1-, 2-, 3-, 4-, 6-, and 8-hours after the initiation of the test meal. End of study procedures will be conducted during this visit.

Note: A follow-up telephone monitoring call will be conducted by the site staff every 2 weeks (±2 days) from the date of randomization up to Visit T3 (Day 85) to assess patient reported compliance to study treatment. During this telephone call, adherence to recording of dosing and bowel movement in patient diary, any adverse events (AEs) that occurred, and concomitant medications will be reviewed.

Visit OT - Off-treatment Follow-up Phone Call (Day 99): Patients will receive an off-treatment follow-up phone call approximately 2 weeks after the last dose of RDX-002 or placebo for review of any AEs.

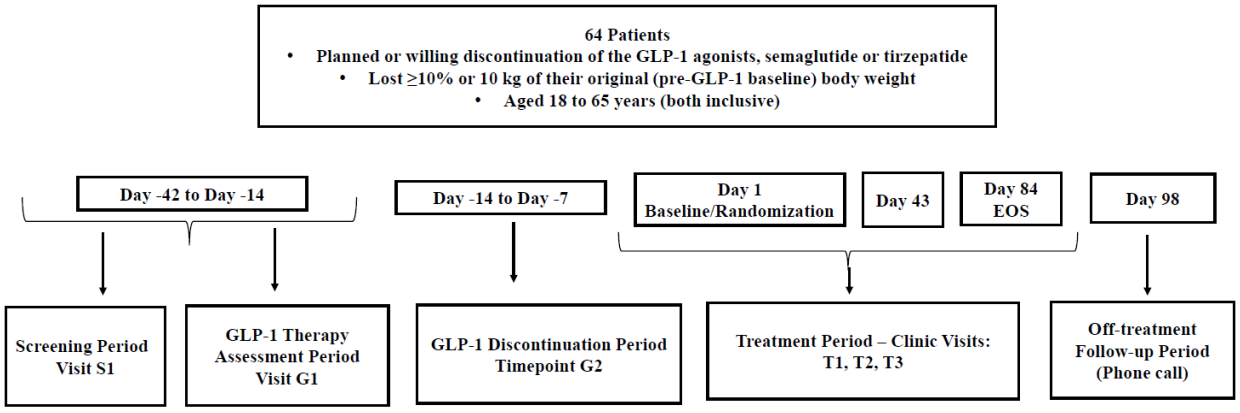
Notes:

1. At Visit G1, Visit T1 and Visit T3, patients will be instructed to consume the standardized high-fattest meal (Appendix III) entirely within 15 minutes. For patients who have difficulty consuming the meal within the initial allowable time, an additional window of up to 15 minutes will be provided to complete the meal.
2. For Visit T1, Visit T2 and Visit T3, patients will be instructed to come for clinic visits without taking their scheduled doses of RDX-002 or placebo.

The study design is illustrated in

Figure 1

Figure 1: Study Design Schematic



Abbreviations: GLP-1 = glucagon-like peptide-1; EOS = end of study.

Table 1: Schedule of Activities (SoA)

	Screening Period	GLP-1 Therapy Assessment Period	GLP-1 Discontinuation Period	Treatment Period – Clinic Visit			Off-treatment Follow-up Period (Phone call)
Study Visits/Days	Visit S1 (Day -42 to Day -14)	Visit G1 (Day -42 to Day -14)	Timepoint G2 (14 to Day -7)	Visit T1 (Day 1) Baseline and Randomization	Visit T2 (Day 43)	Visit T3 (Day -(Day 85) End of Study	Visit OT (Day 99)
Informed consent	X						
Assignment of patient identification (screening) number	X						
Inclusion and exclusion criteria	X			X			
Demographics	X						
Medical history	X						
Prior medications	X						
Physical examination	X	X		X	X	X	
Height	X						

	Screening Period	GLP-1 Therapy Assessment Period	GLP-1 Discontinuation Period	Treatment Period – Clinic Visit			Off-treatment Follow-up Period (Phone call)
Study Visits/Days	Visit S1 (Day -42 to Day -14)	Visit G1 (Day -42 to Day -14)	Timepoint G2 (Day -14 to Day -7)	Visit T1 (Day 1) Baseline and Randomization	Visit T2 (Day 43)	Visit T3 (Day - (Day 85) End of Study	Visit OT (Day 99)
Vital signs	X	X		X	X	X	
12-Lead ECG	X			X	X		
Hematology	X	X		X	X	X	
Clinical chemistry, including fasting glucose	X	X		X	X	X	
Urinalysis (microscopic)	X	X		X	X	X	
Serology test	X						
Breath alcohol test	X			X			
Urine drug test	X			X			
Serum pregnancy test	X						
Urine pregnancy test				X			
eGFR using CKD-EPI formula	X	X		X	X	X	
Instruction for discontinuing current GLP-1 agonist treatment			X				
Randomization				X			
High-fat test meal		X		X		X	
Standard clinic meal					X		
RDX-002 or matching placebo dosing (BID)				X	X	X	
Body weight and BMI	X	X		X	X	X	
Total body fat mass	X	X					

	Screening Period	GLP-1 Therapy Assessment Period	GLP-1 Discontinuation Period	Treatment Period – Clinic Visit			Off-treatment Follow-up Period (Phone call)
Study Visits/Days	Visit S1 (Day -42 to Day -14)	Visit G1 (Day -42 to Day -14)	Timepoint G2 14 to Day -7)	Visit T1 (Day 1) Baseline and Randomization	Visit T2 (Day 43)	Visit T3 (Day -85) Study End of	Visit OT (Day 99)
Waist circumference	X	X		X	X	X	
Fasting TGs		X		X	X	X	
Fasting lipid panel	X	X		X	X	X	
Fasting insulin		X		X	X	X	
Postprandial glucose, insulin, TGs		X		X		X	
HbA1c	X	X		X	X	X	
hs-CRP	X	X		X	X	X	
HOMA-IR-sampling	X	PK		X	X	X	
Dispensing of patient diary				X	X		
Collection and review of patient diary					X	X	
Dispensing of study drug				X	X		
Collection and review of used and unused study drug					X	X	
AE monitoring and recording		X	X	X	X	X	X
Concomitant medications		X	X	X	X	X	X
Stool questionnaire				X	X	X	
Telephonic follow-up monitoring call				X (every 2 weeks ±2 days)			

Abbreviations: AE = adverse event; BID = twice daily; BMI = body mass index; CKD-EPI = Chronic Kidney Disease Epidemiology Collaboration; ECG = electrocardiogram; eGFR = estimated glomerular filtration rate; GLP- 1 = glucagon-like peptide-1; HbA1C = glycated hemoglobin; HOMA IR = homeostatic model assessment for insulin resistance; hs-CRP = high sensitivity C-reactive protein; OT = off treatment; PK = pharmacokinetic; TG = triglycerides.

2.2 Determination of Sample Size

Approximately 64 patients will be enrolled targeting 58 completers in this study, while accounting for 10% drop-out rate. This sample size was estimated based on primary efficacy endpoint and one of the secondary efficacy endpoints (difference in the mean percent change from baseline in body weight in patients treated with RDX-002 as compared with placebo at Week 12).

Primary efficacy endpoint with assumption of 60% difference in the mean percentage change in incremental postprandial TG AUC from baseline between RDX-002 and placebo and a pooled standard deviation (SD) of 50% observed in the previous clinical study, using two-sided test with 5% level of significance.

Secondary efficacy endpoint with assumption of 3% absolute difference in the mean percent change in body weight between RDX-002 and placebo with a pooled SD of 4% using two-sided test with 5% level of significance.

A sample of 64 patients results in at least 80% power (calculated using TWOSAMPLEMEANS in PROC POWER in SAS®) and is considered to be sufficient to satisfy the above study objectives.

2.3 Randomization

Patients will be randomized into 1:1 allocation ratio (i.e., 32 patients in RDX 002 group and 32 patients in placebo group).

2.4 Blinding

This is a randomized, double-blind, study. Patients and investigator (or designee) will remain blinded to the study treatment assignment during the study.

In case of an emergency, only SUSARs may require unblinding or in cases when knowledge of the study treatment assignment is needed in order to make treatment decisions, the investigator (or designee) may unblind the patient's study treatment assignment. The investigator (or designee) should make every attempt to contact the Sponsor prior to initiating any unblinding procedures.

When a blind is broken for safety reasons, the patient will be withdrawn from the study treatment and the event will be recorded on the eCRF. The patient will be encouraged to continue safety follow up per study schedule. The circumstances leading to the breaking of the treatment code should be fully documented in the investigator's study files and in the patient's source documentation. Assignment of study treatment should not be recorded in any study documents or source document.

3 DATA ANALYSIS CONSIDERATION

3.1 General Data Considerations

The statistical analyses will be performed by Veranex, using SAS Version 9.4 (or higher). All Tables, Listings and Figures (TLFs) will be produced in landscape format. In general, all data will

be listed by patient, treatment group, assessment date, visit/timepoint, and parameter as appropriate. The total number of patients in the study group (N) under the stated population will be displayed in the group header of summary tables. Data will be summarized using descriptive statistics.

Unless otherwise stated, descriptive statistics for continuous variables will include number of patients with non-missing value of a variable/parameter (n), mean, coefficient of variation (CV%), geometric mean and geometric coefficient of variation (GM CV%) [for PK parameters only, as appropriate], standard deviation (SD), median, first quartile (Q1) and third quartile (Q3), minimum, and maximum. In case of n<2, where n indicates the number of evaluable patients at the particular visit or timepoint, only n, minimum and maximum will be displayed. The statistic "Missing" will also be evaluated by enumerating the number of missing entries/patients, if any at that visit, and presented as a summary statistic only for the resulting timepoints and will only be displayed if it is non-zero.

In summary tables of categorical variables, counts and percentages will be presented. The count (n) indicates the actual number of patients with a particular value of a variable or event, which should always be less than or equal to the total number of patients in the respective treatment group (N). Percentage will be calculated as (n/N) *100. The number and percentage of patients will always be presented in the form XX (XX.X). Counts of zero in any category will be presented as "0" with no percentage displayed. Percentages of 100 in any category will be presented as "100" with no decimal places.

Decimal Precision Convention: The minimum and maximum statistics will be presented to the same number of decimal places as the raw data. The mean, median, first quartile (Q1), third quartile (Q3) and confidence interval (CI) will be presented to one more decimal place than the raw data, whereas the standard deviation (SD) and standard error (SE) will be presented to two more decimal places than the raw data. For a raw data with >2 decimals, a maximum of three decimal places will apply to all summary statistics.

For PK parameters except parameters related to time, values will be rounded to three significant digits in the listings. Mean, median and geometric mean will be displayed to four significant digits, the SD to five significant digits, minimum and maximum to three significant digits, and CV% and geometric CV% to one decimal place. For PK parameters except parameters related to time, CV% and geometric CV% will be displayed to one decimal place. For PK parameters related to time (Eg. Tmax, Kel Lower etc.,), geometric mean, CV% and geometric CV% will not be calculated.

P-values will generally be presented three decimal places. P-values less than 0.001 will be presented as "<0.001", and p-values greater than 0.999 will be presented as ">0.999".

The following conventions will be applied to analyses/data presentation: All dates will be displayed in DDMMMYYYY format.
Unscheduled visit data will be presented in Listings, but not in Tables and Figures.

3.2 Handling of Missing Data

3.2.1 Missing data handling for safety data:

To handle missing or partial AEs and concomitant medication dates, the following rules will be applied.

For Partial Start Dates: 1.
If the year is unknown, then do not impute the date. 2. If
the month is unknown, then:

i. If the year matches the year of the first dose date, then impute the month of the dose date. ii. Otherwise, assign "January."

3. If the day is unknown, then:
   i. If the month and year match the month and year of the first dose date, then impute the day of the dose date.
   ii. Otherwise, assign "01."

For Partial End Dates:

1. If the year is unknown, then do not impute the date but assign a missing value.

2. If the month and day is unknown and the year is earlier than the year in EOS visit, then assign "31 December". Else assign the EOS date.
3. If the day is unknown and the month and year indicate it is occurring before EOS visit, then assign the last day of the month. Else assign the EOS date.

After implementing the rules above, to determine whether AEs (or medications) with missing start or stop dates are pre-treatment or on/after treatment, the following strategy will be used:

1. If the start date and stop date are both missing, then the most conservative approach will be taken and the AE (or medication) will be considered to be treatment emergent (or concomitant medication).
2. If the start date is missing but the stop date is not missing and is on or after the day of study dose administration, then the most conservative approach will be taken and the AE (or medication) will be considered to be treatment emergent (or concomitant medication).
3. If the start date is missing but the stop date is not missing and is before the day of study dose and after the date of signed informed consent, then the AE (or medication) will be considered before treatment (or prior medication).
4. If the start date is not missing but the stop date is missing, then the most conservative approach is taken, and medication will be considered to be concomitant while the AE is defined by start date.

3.2.2 For Missing AE Relationship/Severity:

If the Adverse Event Relationship flag is missing, the relationship for adverse event will be imputed and will be considered as "Related". If the Adverse Event Severity grade is missing, the severity will be imputed and will be considered as "Severe".

3.2.3 Missing data handling for PK data:

PK parameters will be estimated based on the reported drug concentrations. No imputation will be used for missing concentration data.

3.2.4 Missing data handling for Efficacy data: No

imputation will be used for missing Efficacy data.

4 DEFINITIONS AND DERIVATIONS

Baseline: Baseline is defined as the last non-missing value (either scheduled or unscheduled) prior to the first dose administration of the study drug, unless otherwise stated. If the assessment occurs on the same day as the first study drug administration, then the time of assessment should be compared to the time of first dose administration.

Change from Baseline: The change from baseline values will be calculated as post-baseline value minus the baseline value.

Change from Baseline = Post baseline value - Baseline value
Percent change from Baseline = [(Post baseline value - Baseline value) / (Baseline value)]*100

Treatment-Emergent Adverse Event (TEAE): A TEAE is defined as any new AE that is reported on/after initiation of study treatment or any pre-existing AE/condition that worsened in severity following initiation of study treatment.

5 PRIMARY AND SECONDARY ENDPOINTS

5.1 Primary Efficacy Endpoint

The primary efficacy endpoint of study is:

- Difference in the mean percent change in the incremental postprandial TG area under the curve (AUC) in patients treated with RDX-002 as compared with placebo at Week 12

Note: Incremental postprandial TG AUC sets the pre-test meal (fasting) TG levels at zero and calculates the increased levels of TG that occur with and following the consumption of the test meal. It is an attempt to measure only the incremental increase in TGs as the postprandial TGs and exclude the fasting, hepatic TGs.

5.2 Secondary Efficacy Endpoints

Following are the secondary efficacy endpoints of the study:

- Difference in the mean percent change in the total postprandial TG AUC in patients treated with RDX-002 as compared with placebo at Week 12

Note: The total or absolute postprandial TG AUC measures the entire area under the curve that includes both the fasting (hepatic) TGs as well as the postprandial TGs.

- Difference in the mean percent change from baseline in body weight in patients treated with RDX- 002 as compared with placebo at Week 12

- Difference in the proportion of patients treated with RDX-002 exhibiting at least a 5% increase from baseline in body weight as compared with placebo at Week 12

- Difference in the mean percent change from baseline in LDL-C in patients treated with RDX-002 as compared with placebo at Week 12

5.3 Exploratory Efficacy Endpoints

Following are the exploratory efficacy endpoints of the study:

- Difference in the percent change from baseline in body weight in patients treated with RDX-002 as compared with placebo at Week 6

- Difference in the percent change from baseline in LDL-C in patients treated with RDX-002 as compared with placebo at Week 6

- Difference in the percent change from baseline in fasting TGs in patients treated with RDX-002 as compared with placebo at Weeks 6 and 12

- Difference in the percent change from baseline in total cholesterol and non-HDL C in patients treated with RDX-002 as compared with placebo at Weeks 6 and 12

- Relationship between changes in incremental postprandial TGs AUC and change in body weight for patients by both RDX 002 and placebo treatment group separately from baseline to Week 12

- Relationship between changes in incremental postprandial TGs AUC and change in body weight in patients pre- and post-discontinuation of GLP-1 treatment:

    - Relationship between change in incremental postprandial TGs AUC at baseline compared to Visit G1 (pre GLP 1 agonist discontinuation) and change in body weight from baseline to Week 12 in patients treated with placebo.

- Difference in the change from baseline in waist circumference in patients treated with RDX-002 as compared with placebo at Weeks 6 and 12

- Difference in the percent change from baseline in total body fat mass as measured by Inbody H20N scale in patients treated with RDX 002 as compared to placebo at Weeks 6 and 12

- Difference in the change from baseline in HbA1c in patients treated with RDX 002 as compared with placebo at Weeks 6 and 12

- Difference in the change from baseline in HOMA-IR index in patients treated with RDX 002 as compared with placebo at Weeks 6 and 12

- Difference in the percent change from baseline in hs-CRP levels in patients treated with RDX 002 as compared with placebo at Weeks 6 and 12

- Difference in the change from baseline in fasting glucose and insulin in patients treated with RDX-002 as compared with placebo at Weeks 6 and 12

- Difference in the change from baseline in postprandial glucose and insulin in patients treated with RDX-002 as compared with placebo at Weeks 6 and 12

- Difference in change from baseline in SBP and DBP in patients treated with RDX-002 as compared with placebo at Week 12

- Difference in the percent change in incremental and absolute postprandial TGs AUCs from pre-GLP-1 discontinuation i.e, Visit G1 to baseline (12 weeks post-GLP-1 discontinuation) i.e., Visit T1 (Day 1)

5.4 Pharmacokinetic Endpoints

- PK parameters of RDX-002 and its main inactive metabolite at Week 12 in patients treated with RDX-002.

5.5 Safety Endpoints

- Incidence of treatment-emergent adverse events (TEAEs) including determination of serious adverse events (SAEs) and TEAEs leading to discontinuation and laboratory abnormalities as characterized by type, frequency, timing, severity (mild, moderate, severe), seriousness and relationship to RDX 002

- Concomitant medications

- Clinical laboratory tests (hematology, chemistry, and urinalysis)

- Vital sign measurements

- Electrocardiogram (ECG)

- Physical examination findings

- Stool questionnaire

6 ANALYSIS POPULATION AND TREATMENT GROUPS

6.1 Analysis Population

Enrolled Analysis Set: All patients who have signed the Informed Consent Form (ICF) and met all eligibility criteria.

Intent-to-Treat (ITT) Set: The ITT Set will include all randomized patients. It will be the primary analysis set for the efficacy analyses.

Safety Analysis Set: The Safety Analysis Set will include all patients who receive at least one dose of RDX-002 or placebo.

Modified Intent-to-Treat (mITT) Set: The mITT Set will include all randomized patients who have all key measurements (postprandial TGs, body weight and LDL-C) performed at Visit T1 (Day 1), Visit T2 (Day 43) and Visit T3 (Day 85). This population will be used for analysis of primary and secondary efficacy endpoints.

Per-Protocol (PP) Set: The PP Set will include all patients who completed the study without major protocol deviations and satisfy any additional indication-specific requirements of the analysis population. The PP Set will be used for the primary and secondary efficacy analyses.

Pharmacokinetic (PK) Analysis Set: The PK Analysis set will consist of patients included in the Safety population who have at least one post-dose quantifiable plasma concentration for RDX-002. A quantifiable concentration is defined as a measurable value without any events or deviations that would compromise the integrity of the plasma concentration. It should be noted that due to the properties of RDX-002, which stays within the intestinal enterocyte with little to no absorption into the blood, some patients who correctly take the drug and have a PK blood sample taken may not show blood levels of RDX-002 or its main inactive metabolite.

6.2 Treatment Groups

In this study there are two treatment groups which are "RDX-002" and "Placebo". For the display purpose, the header will be labelled as "RDX-002" and "Placebo".

7 ANALYSES METHODS AND REPORTING DESCRIPTIONS

7.1 Patient Disposition

Patient disposition will be summarized by the number and percentage of number of patients screened, number of screen failure patients, patients in enrolled analysis set, safety analysis set, intent-to-treat (ITT) set, modified intent-to-treat (mITT) set, per-protocol (PP) set and pharmacokinetic (PK) analysis set. Number of patients who completed the treatment, number of patient who discontinued from the treatment along with the reasons for discontinuation from the treatment, number of patients who completed the study, and number of patient who discontinued

from the study along with the reasons for discontinuation from the study by treatment group and overall.

An individual patient data on disposition will be presented in listing.

7.2 Demography and Baseline Characteristics

The demographic and baseline characteristics will include age (years), sex, childbearing potential (yes/no), reason for non-childbearing potential (surgically sterile/ postmenopausal), ethnicity, race and baseline body measurements height (cm), weight (kg), and BMI (kg/m2) will be summarized by treatment group and overall, for Safety Analysis Set. Continuous variables will be summarized using descriptive statistics (n, mean, SD, Q1, Q3, minimum, median and maximum) and for categorical variables, the number and percentage of patient in each category will be summarized.

An individual patient data listing for demographic and baseline characteristics will be presented.

7.3 Medical History

Medical history events will be classified by system organ class (SOC) and preferred term (PT), according to Medical Dictionary for Regulatory Activities (MedDRA). Medical history events will be summarized by SOC and PT by treatment group and overall for patients in the Safety Analysis Set. The summaries will display the number and percentage of patients experiencing any medical history event as well as the number and percentage of patients with at least one medical history event in each SOC and PT. Medical history will be coded using Medical Dictionary for Regulatory Activities (MedDRA) version 27.0 or higher.

Medical history data will also be listed for the Safety Analysis Set.

7.4 Prior and Concomitant Medications

Prior Medications:
For a patient in the Safety Population, prior medications will include any medication taken prior to patient's first dose of study drug.

Concomitant Medications:
Concomitant medications are medications taken by patient on/after the start of first study drug administration.

Prior and concomitant medications will be classified according to the World Health Organization Drug Dictionary (WHODD) version Global B3 MAR 01, 2024, or higher.

Prior and concomitant medications will be summarized by Anatomical Therapeutic Chemical (ATC) classification level 3 and Preferred Term (PT) using number and percentages for Safety Analysis Set by treatment group.

Patients taking multiple prior/concomitant medication will be counted only once in summary table. If the patient is taking medication prior to study drug administration and continues the same drug after study drug administration, then such Patients will be summarized in both prior and concomitant medication summary tables.

An individual patient data listing will be presented for Safety Analysis Set. Also, an individual patient data listing for GLP-1 agonist Discontinuation will be presented for Safety Analysis Set

7.5 Protocol Deviation

Protocol deviations will be summarized descriptively with counts and percentages in treatment group and overall, by classification, and by category for the Safety Analysis Set.

An individual patient data listing for protocol deviations will be presented for Safety Analysis Set.

7.6 Study Drug Exposure and Treatment Compliance

Study drug exposure and treatment compliance data will be summarized treatment overall using the Safety Analysis Set.

Duration of Drug exposure = Date of last use of study drug – Date of first use of study drug + 1.
Treatment compliance = (Total number of doses taken by patients during the study / Number of planned doses) *100.

Study drug exposure individual patient data listing will be provided for the Safety Analysis Set

7.7 Efficacy Analysis

7.7.1 Analysis of Primary Efficacy Endpoint

- Difference in the mean percent change in the incremental postprandial TG area under the curve (AUC) in patients treated with RDX-002 as compared with placebo at Week 12: The primary efficacy endpoint will be analyzed by an analysis of covariance (ANCOVA) model with terms mean percent change in the incremental postprandial TG area under the curve value as dependent variable, for treatment group as fixed categorical effect and baseline incremental postprandial TG area under the curve value as continuous fixed covariate in the model. Summaries will include least squares (LS) means and associated standard errors (SEs) estimated from the ANCOVA. Differences in LS means and associated standard errors (SEs) and 95% confidence interval (CI) will be presented along with the p-value from the test of no difference in mean percent change from baseline between treatment groups. The primary analysis will be performed on the ITT Analysis Set with supportive analyses performed on the mITT Analysis Set and PP Analysis Set.

Postprandial TG incremental area under the curve (iAUC) calculation:

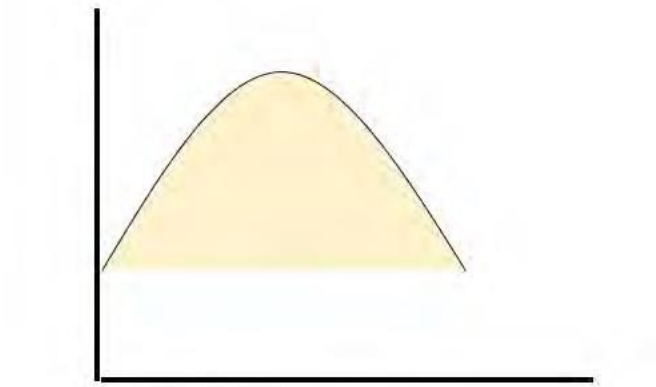
Incremental area under curve (iAUC) of postprandial TG will be calculated using linear trapezoidal linear interpolation rule from the zero time point to the last quantifiable postprandial TG value.

$$iAUC = \int_a^b f(x)dx \approx \sum\left((b-a) * \frac{f(a)+f(b)}{2}\right)$$

a and b are the fixed timepoints. f(a) and f(b) are the postprandial TG values of the respective timepoints of increased levels of TG that occur with consumption of the test meal from the pre-test meal (fasting) TG.

The pre-meal blood sample will be averaged and used for the summary and analysis purpose.

The method for quantitating incremental AUC sets the T = 0 values at zero in an attempt to isolate only the postprandial TG levels derived from the consumed meal. Incremental postprandial TG AUC sets the pre-test meal (fasting) TG levels at zero and calculates the increased levels of TG that occur with consumption of the test meal. It is an attempt to measure only the incremental increase in TGs as the postprandial TGs and exclude the fasting, hepatic TGs.



Incremental AUC

Also, analysis of primary efficacy endpoint will be summarized using descriptive statistics (n, Mean, SD, Q1,Q3, Median, Minimum and Maximum) to summarized by treatment group for mITT Analysis Set.
An individual patient data will be presented in Listing for ITT Analysis Set. The
following plot will be presented for ITT Analysis Set.

- Box-plot for postprandial TG Incremental AUC presented by treatment group •

Line Plot of Mean Incremental Postprandial TG by treatment group

7.7.2 Analysis of Secondary Efficacy Endpoints

- Difference in the mean percent change in the total postprandial TG AUC in patients treated with RDX-002 as compared with placebo at Week 12:

  This secondary efficacy endpoint will be analyzed by an analysis of covariance (ANCOVA) model with terms mean percent change in the total or absolute postprandial TG area under the curve value as dependent variable, for treatment group as fixed categorical effect and baseline total or absolute postprandial TG area under the curve value as continuous fixed covariate in the model. Summaries will include least squares (LS) means and associated standard errors (SEs) estimated from the ANCOVA. Differences in LS means and associated standard errors (SEs) and 95% confidence interval (CI) will be presented along with the p-value from the test of no difference in mean percent change from baseline between treatment groups. This analysis will be performed on the mITT Analysis Set.

Postprandial TG total or absolute area under the curve (tAUC) calculation:

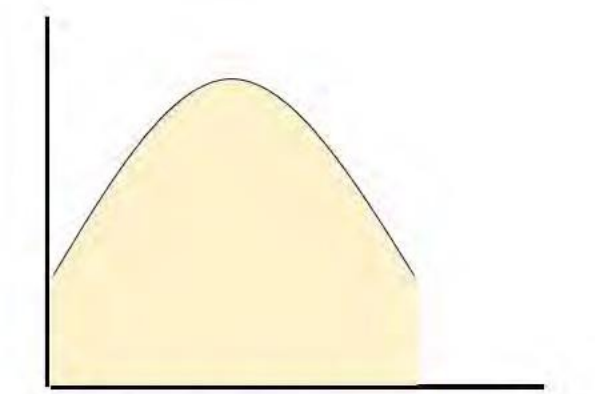
Total or absolute area under curve (AUC) of postprandial TG will be calculated using linear trapezoidal linear interpolation rule from the zero time point to the last quantifiable postprandial TG value.

$$AUC = \int_a^b f\left(x\right)dx \approx \sum\left(\left(b-a\right) * \frac{f\left(a\right)+f\left(b\right)}{2}\right)$$

a and b are the fixed timepoints. f(a) and f(b) are the postprandial TG values of the respective timepoints of total or absolute postprandial TG that occur with consumption of the test meal measures the entire area under the curve that includes both the fasting (hepatic) TGs as well as the postprandial TGs.

The pre-meal blood sample will be averaged and used for the summary and analysis purpose.

The total or absolute postprandial TG AUC measures the entire area under the curve that includes both the fasting (hepatic) TGs as well as the postprandial TGs.



The following plot will be presented for mITT Analysis Set.

- Box-plot for postprandial TG total/absolute AUC presented by treatment group
- Line Plot of Mean total/absolute Postprandial TG by treatment group

- Difference in the mean percent change from baseline in body weight in patients treated with RDX- 002 as compared with placebo at Week 12:

  This secondary efficacy endpoint will be analyzed by an analysis of covariance (ANCOVA) model with terms mean percent change from baseline in body weight value as dependent variable, for treatment group as fixed categorical effect and baseline body weight value as continuous fixed covariate in the model. Summaries will include least squares (LS) means and associated standard errors (SEs) estimated from the ANCOVA. Differences in LS means and associated standard errors (SEs) and 95% confidence interval (CI) will be presented along with the p-value from the test of no difference in mean percent change from baseline between treatment groups. This analysis will be performed on the mITT Analysis Set.

- Difference in the proportion of patients treated with RDX-002 exhibiting at least a 5% increase from baseline in body weight as compared with placebo at Week 12:

  The proportions of patients exhibiting a weight gain of at least 5% will be presented along with exact (Clopper-Pearson) 95% CIs for both treatment group. The difference between treatment groups in the proportion of patients exceeding this weight gain threshold will be presented along with exact (unconditional) 95% CIs for the difference. The difference in proportions will be calculated as RDX-002 minus placebo, such that a negative value favors RDX-002, i.e., a negative value indicates a reduction in the proportion of patients exceeding the weight gain threshold for patients randomized to RDX-002. Fisher's exact test will be used to compare the proportions between treatment groups. This analysis will be performed on the mITT Analysis Set.

- Difference in the mean percent change from baseline in LDL-C in patients treated with RDX 002 as compared with placebo at Week 12:

This secondary efficacy endpoint will be analyzed by an analysis of covariance (ANCOVA) model with terms mean percent change from baseline in LDL-C value as dependent variable, for treatment group as fixed categorical effect and baseline LDL-C value as continuous fixed covariate in the model. Summaries will include least squares (LS) means and associated standard errors (SEs) estimated from the ANCOVA. Differences in LS means and associated standard errors (SEs) and 95% confidence interval (CI) will be presented along with the p-value from the test of no difference in mean percent change from baseline between treatment groups. This analysis will be performed on the mITT Analysis Set.

Also, analysis of secondary efficacy endpoints will be summarized using frequency counts and percentage by treatment groups for categorical variables and descriptive statistics (n, Mean, SD, Q1,Q3, Median, Minimum and Maximum) will be used to summarized by treatment group for continuous variables using mITT Analysis Set.

An individual patient data will be presented for secondary efficacy endpoints in Listing for mITT Analysis Set.

7.7.3 Analysis of Exploratory Efficacy Endpoints

These below mentioned exploratory endpoints will be summarized using descriptive statistics (n, Mean, SD, Q1, Q3, Median, Minimum and Maximum) by treatment group and overall (if required) for continuous variables using mITT Analysis Set.

- Difference in the percent change from baseline in body weight in patients treated with RDX-002 as compared with placebo at Week 6. Along with, line graph of mean percent change in body weight by visits (at Baseline, Week 6 and Week 12) and Waterfall plot of individual weight change from baseline at Week 12 placebo and RDX-002 separately.

- Difference in the percent change from baseline in LDL-C in patients treated with RDX-002 as compared with placebo at Week 6

- Difference in the percent change from baseline in fasting TGs in patients treated with RDX-002 as compared with placebo at Weeks 6 and 12

- Difference in the percent change from baseline in total cholesterol and non-HDL-C in patients treated with RDX-002 as compared with placebo at Weeks 6 and 12

- Difference in the change from baseline in waist circumference in patients treated with RDX-002 as compared with placebo at Weeks 6 and 12

- Difference in the percent change from baseline in total body fat mass as measured by Inbody H20N scale in patients treated with RDX-002 as compared to placebo at Weeks 6 and 12

- Difference in the change from baseline in HbA1c in patients treated with RDX-002 as compared with placebo at Weeks 6 and 12. Also, a summary of shifts will compare the baseline HbA1c test to the post-baseline by Weeks 6 and 12 and the categories of HbA1c values are "<5.7%", ">=5.7% to <6.5%" and ">=6.5%".

- Difference in the change from baseline in HOMA-IR index in patients treated with RDX-002 as compared with placebo at Weeks 6 and 12.

- Difference in the percent change from baseline in hs-CRP levels in patients treated with RDX-002 as compared with placebo at Weeks 6 and 12. Also, the same summary will be provided for using subgroups baseline hs-CRP levels >=2 mg/L and <2 mg/L.

- Difference in the change from baseline in fasting glucose and insulin in patients treated with RDX-002 as compared with placebo at Weeks 6 and 12

- Difference in the change from baseline in the incremental postprandial glucose and insulin AUC and total postprandial glucose and insulin AUC will be summarized descriptively in patients treated with RDX-002 as compared with placebo at Weeks 6 and 12. Line Plot of Mean Incremental Postprandial glucose and insulin by treatment group and Line Plot of Mean Total/Absolute Postprandial glucose and insulin by treatment group

- Difference in change from baseline in SBP and DBP in patients treated with RDX-002 as compared with placebo at Week 12. Also, a summary of shifts will compare the baseline SBP and DBP test to the post-baseline by Weeks 6 and 12 and the categories for SBP <130 and >=130 mm Hg and DPB of <80 and >=80 mm Hg.

- Difference in the percent change in incremental and absolute postprandial TGs AUCs from pre-GLP-1 discontinuation i.e., Visit G1 to baseline (1-2 weeks post-GLP-1 discontinuation) i.e., Visit T1 (Day 1)

Also, these below mentioned exploratory efficacy endpoints will be analyzed descriptively. Pearson's correlation coefficients [r] will be employed to analyze the relationship between respective endpoints variables. A Scatter plot will be plotted with x-axis and y-axis of respective endpoints variables. A regression line will be included considering below respective independent and dependent variables. The Pearson's correlation coefficient [r] and the corresponding p-value will be displayed. This analysis will be performed on the mITT Analysis Set .

- Relationship between changes in incremental postprandial TGs AUC and change in body weight for patients by both RDX 002 and placebo treatment group separately from baseline to Week 12

- Relationship between change in incremental postprandial TGs AUC at baseline compared to Visit G1 (pre-GLP-1 agonist discontinuation) and change in body weight from baseline to Week 12 in patients treated with placebo

An individual patient data will be presented for exploratory efficacy endpoints in Listing for mITT Analysis Set.

Table 2: Summary of Efficacy Endpoint(s) Analysis Strategy

Endpoint	Statistical Method / Test	Analysis Set	Missing Data Imputation Approach	Parameters/Variables in the analysis test/Model)	Analysis Time (Stat. point
Primary Endpoint					
Difference in the mean percent change in the incremental postprandial TG area under the curve (AUC) in patients treated with RDX-002 as compared with placebo at Week 12	Descriptive statistics and ANCOVA	ITT Analysis Set, mITT Analysis Set and PP Analysis Set	No imputation	mean percent change in the incremental postprandial TG area under the curve as dependent variable, treatment group as categorical fixed effect and baseline incremental postprandial TG area under the curve as continuous covariate.	Week 12
Secondary Endpoints					
Difference in the mean percent change in the total postprandial TG AUC in patients treated with RDX-002 as compared with placebo at	Descriptive statistics and ANCOVA	mITT Analysis Set and PP Analysis Set	No imputation	mean percent change in the total postprandial TG AUC as dependent variable, treatment group as categorical fixed effect and baseline mean percent change in the total postprandial TG	Week 12

Endpoint	Statistical Method / Test	Analysis Set	Missing Data Imputation Approach	Parameters/Variables in the analysis test/Model)	Analysis Time (Stat. point AUC as
Week 12				continuous covariate.	
Difference in the mean percent change from baseline in body weight in patients treated with RDX-002 as compared with placebo at Week 12	Descriptive statistics and ANCOVA	mITT Analysis Set	No imputation	mean percent change from baseline in body weight as dependent variable, treatment group as categorical fixed effect and baseline body weight as continuous covariate.	Week 12
Difference in the proportion of patients treated with RDX-002 exhibiting at least a 5% increase from baseline in body weight as compared with placebo at Week 12	Descriptive statistics, exact (Clopper-Pearson), exact (unconditional) 95% CIs and Fisher's exact	mITT Analysis Set	No imputation	at least a 5% increase from baseline in body weight and treatment group	Week 12
Difference in the mean percent change from baseline in LDL-C in patients treated with RDX-002 as compared with placebo at Week 12	Descriptive statistics and ANCOVA	mITT Analysis Set	No imputation	mean percent change from baseline in LDL-C as dependent variable, treatment group as categorical fixed effect and baseline in LDL-C as continuous covariate.	Week 12
Exploratory Endpoints					
Difference in the percent	Descriptive statistics	mITT Analysis Set	No imputation		Week 6

Endpoint	Statistical Method / Test	Analysis Set	Missing Data Imputation Approach	Parameters/Variables in the analysis test/Model)	Analysis Time (Stat. point
change from baseline in body weight in patients treated with RDX-002 as compared with placebo at Week 6					
Difference in the percent change from baseline in LDL-C in patients treated with RDX-002 as compared with placebo at Week 6	Descriptive statistics	mITT Analysis Set	No imputation		Week 6
Difference in the percent change from baseline in fasting TGs in patients treated with RDX-002 as compared with placebo at Weeks 6 and 12	Descriptive statistics	mITT Analysis Set	No imputation		Week 6 and Week 12
Difference in the percent change from baseline in total cholesterol and non-HDL-C in patients	Descriptive statistics	mITT Analysis Set	No imputation		Week 6 and Week 12

Endpoint	Statistical Method / Test	Analysis Set	Missing Data Imputation Approach	Parameters/Variables in the analysis test/Model)	Analysis Time point (Stat.
treated with RDX-002 as compared with placebo at Weeks 6 and 12					
Relationship between changes in incremental postprandial TGs AUC and change in body weight for patients by both RDX 002 and placebo treatment group separately from baseline to Week 12	Pearson's correlation coefficients [r]	mITT Set	No Analysis imputation	changes incremental postprandial TGs AUC and change in body weight at Week 12 by treatment groups	Week 12 from Baseline
Relationship between change in incremental postprandial TGs AUC at baseline compared to Visit G1 (pre GLP 1 agonist discontinuation) and change in body weight from baseline to Week 12 in patients treated with placebo	Pearson's correlation coefficients [r]	mITT Set	No Analysis imputation	Change in incremental postprandial TGs AUC and change in weight from baseline	Visit G1 and Week 12 from Baseline body

Endpoint	Statistical Method / Test	Analysis Set	Missing Data Imputation Approach	Parameters/Variables in the analysis test/Model)	Analysis Time (Stat. point
Difference in the change from baseline in waist circumference in patients treated with RDX-002 as compared with placebo at Weeks 6 and 12	Descriptive statistics	mITT Set	No Analysis imputation		Week 6 and Week 12
Difference in the percent change from baseline in total body fat mass as measured by Inbody H20N scale in patients treated with RDX 002 as compared to placebo at Weeks 6 and 12	Descriptive statistics	mITT Set	No Analysis imputation		Week 6 and Week 12
Difference in the change from baseline in HbA1c in patients treated with RDX 002 as compared with placebo at Weeks 6 and 12	Descriptive statistics	mITT Set	No Analysis imputation	Shift table - HbA1c	Week 6 and Week 12

Endpoint	Statistical Method / Test	Analysis Set	Missing Data Imputation Approach	Parameters/Variables in the analysis test/Model)	Analysis Time (Stat. point
Difference in the change from baseline in HOMA-IR index in patients treated with RDX 002 as compared with placebo at Weeks 6 and 12	Descriptive statistics	mITT Set	No Analysis imputation		Week 6 and Week 12
Difference in the percent change from baseline in hs CRP levels in patients treated with RDX 002 as compared with placebo at Weeks 6 and 12	Descriptive statistics	mITT Set	No Analysis imputation	Baseline hs-CRP	Week 6 and Week 12
Difference in the change from baseline in fasting glucose and insulin in patients treated with RDX-002 as compared with placebo at Weeks 6 and 12	Descriptive statistics	mITT Set	No Analysis imputation		Week 6 and Week 12
Difference in the change from baseline	Descriptive statistics	mITT Analysis Set	No imputation		Week 12

Endpoint	Statistical Method / Test	Analysis Set	Missing Data Imputation Approach	Parameters/Variables in the analysis test/Model)	Analysis Time (Stat. point
in postprandial glucose and insulin in patients treated with RDX-002 as compared with placebo at Weeks 6 and 12					
Difference in change from baseline in SBP and DBP in patients treated with RDX-002 as compared with placebo at Week 12	Descriptive statistics	mITT Analysis Set	No imputation	Shift table - SBP and DBP	Week 12
Difference in the percent change in incremental and absolute postprandial TGs AUCs from pre- GLP-1 discontinuation i.e., Visit G1 to baseline (12 weeks post-GLP-1 discontinuation) i.e., Visit T1 (Day 1)	Descriptive statistics	mITT Analysis Set	No imputation		Visit G1 and Visit T1 (Day 1)

7.8 Safety Analysis

The safety analysis will be based on the Safety Analysis Set. Safety will be evaluated by presenting summaries of Adverse Events(AEs), clinical laboratory assessments, vital signs, ECG results, and

physical examination findings by treatment group and overall. Data listings of individual patient safety data will be presented by treatment groups.

7.8.1 Adverse Events

AEs will be coded using MedDRA version 27.0 or higher. A patient experiencing the same AE more than once will be counted only once for that preferred term, assuming the worse severity and worse relatedness to study drug. If severity is missing then the worst severity should be considered and if relationship is missing, then the worst relationship should be considered.

The AEs will be summarized overall by treatment group for with the number and percentage of patients in the following categories:

- Number of Patients with AEs
- Number of Patients with Serious AEs •

Number of Patients with TEAEs

- Number of Patients with Serious TEAEs
- Number of Patients with Treatment related TEAEs
- Number of Patients with Treatment related Serious TEAEs
- Number of Patients with TEAEs Leading to Discontinued from Study Drug •

Number of Patients with TEAEs Leading to Withdrawal from Study

- Number of Patients with TEAEs Leading to Death •

Severity

- Action Taken
- Outcome of AE

A summary of TEAEs, including the number of events reported, the number and percentage of patients with event, will be presented by SOC and PT by treatment group, in the following categories.

- Summary of TEAEs by SOC and PT
- Summary of TEAEs by Severity, SOC and PT
- Summary of TEAEs by Relationship to study treatment, SOC and PT

These above summaries will include cumulative incidence (percent of patients experiencing at least 1 AE), and exposure-adjusted incidence rates (in 100 patient-years).

- Summary of TEAEs by Leading to withdrawal from study, SOC and PT

Deaths, SAEs, withdrawal from study treatment due to TEAEs, and withdrawal from the study due to TEAEs will each be summarized by treatment group and provided in by patient data listings.

7.8.2 Clinical Laboratory Data

The Clinical Laboratory test categories will include assessments of Hematology, Clinical Chemistry, Standard Fasting Lipid Panel and Urinalysis. Categorical parameters will be summarized using frequency count and percentage; and continuous laboratory parameters will be

summarized using descriptive statistics (n, Mean, SD, Q1, Q3, Median, Minimum and Maximum) for the Safety Analysis Set. Summaries of reported (both continuous and categorical) and change from baseline values will be presented by treatment group and overall.
Additional laboratory evaluations include Serum and urine pregnancy testing, Serology and Urine drug test and breath alcohol test these results will be presented an individual data listing.

An individual data listings of laboratory results will be presented for hematology, clinical chemistry and urinalysis test categories.

Table 3: Laboratory Analytes for Safety Evaluations

Hematology:

Hematocrit	White blood cell (WBC) count with differential
Hemoglobin	Platelet count
Red blood cell (RBC) count	Mean corpuscular hemoglobin (MCH)
Mean corpuscular hemoglobin concentration (MCHC)	Mean corpuscular volume (MCV)
Glycated hemoglobin (HbA1c)	

Clinical Chemistry:

Blood urea nitrogen (BUN)	AST (SGOT)	Alkaline phosphatase
Serum creatinine	ALT (SGPT)	Bilirubin (total, direct and indirect)
Uric acid	Amylase	Creatinine
Calcium	Albumin	Lactate dehydrogenase (LDH)
Glucose	Sodium	Total Protein
Magnesium	Chloride	Carbon dioxide
FSH (as needed)	Potassium	TSH (at Screening only)
Creatine Kinase	Phosphorus	Uric Acid

Insulin and HOMA-IR will be collected at time points indicated in the schedule of events (Table 1).

The eGFR will be calculated using the CKD-EPI formula.

Standard Fasting Lipid Panel:

Low-density lipoprotein cholesterol (LDL-C)
High-density lipoprotein cholesterol (HDL-C)
Total cholesterol
Non-high density lipoprotein cholesterol (non-HDL-C)

Triglycerides

Urinalysis:

Specific gravity	Blood ketones
pH	Bilirubin
Glucose	Urobilinogen
Protein	Leukocyte
Esterase	Nitrite

7.8.3 Vital Signs

Vital signs measurements will include Systolic blood pressure (mmHg), Diastolic blood pressure (mmHg), Mean value of systolic blood pressure (mmHg), Mean value of diastolic blood pressure (mmHg), Heart Rate (beats/min), Respiratory rate (breaths/minute) and Body Temperature (Celsius).

Patients must be in a supine position for at least 5 minutes before each measurement. Standardized procedure for measuring blood pressure for all patients is provided in Appendix I.

The reported and change from baseline values will be summarized using descriptive statistics (n, Mean, SD, Q1, Q3, Median, Minimum and Maximum) by treatment group and overall, for Safety Analysis Set.

An individual patient data listing for vital signs data will be presented.

7.8.4 Electrocardiograms

The 12-lead ECG measurements will include Heart Rate (bpm), PR Interval (msec), QRS duration (msec), QT Interval (msec), QTc Interval (msec) and RR Interval(msec) as well as an overall interpretation.

Actual and change from baseline values of quantitative ECG parameters will be summarized by treatment and overall, visit and timepoint using descriptive statistics for the Safety Analysis Set. Overall assessment of safety ECGs (Normal, Abnormal – NCS, Abnormal CS) will be summarized using frequency counts and percentage by treatment, visit and timepoint for the Safety Analysis Set.

An individual patient data listing for ECG results will be presented for Safety Analysis Set.

7.8.5 Physical Examination

A complete physical examination will include assessments of the general appearance, extremities, eyes, nose, mouth/throat/neck, thyroid, dermatologic, lymphatic, respiratory, cardiovascular, gastrointestinal, musculoskeletal, neurologic and other.

Physical examination results will be summarized using frequency counts and percentage by treatment group and overall, visit for the overall for Safety Analysis Set.

An individual patient data listing for physical examination findings data will be presented for Safety Analysis Set.

7.8.6 Stool Questionnaire

Number of bowel movements per day and Bristol stool form scale will be summarized using descriptive statistics (n, Mean, SD, Q1, Q3, Median, Minimum and Maximum) by treatment group, for Safety Analysis Set.

Line plot of mean daily bowel movements from Day 1 to Day 85 and line plot of mean daily stool score from Day 1 to Day 85 will be provided separately for RDX-002 and placebo for Safety Analysis Set.

An individual patient data listing for stool questionnaire data will be presented for Safety Analysis Set.

7.9 PK Analysis

Pharmacokinetic analyses will be described in detail and summarized in a separate report and is Outside the scope of this SAP.

7.10 Pooled Analyses

No pooled analyses will be conducted in this study.

7.11 Subgroup Analyses

No Subgroup analyses will be conducted in this study.

7.12 Interim Analysis

No Interim analyses will be conducted in this study.

7.13 Changes to Analyses Specified in Protocol

1. Study patients were termed as “subjects” or “patients” in the protocol. However, it has been changed it to “patients” to maintain consistency across the sections in the SAP.

2. Enrolled Analysis Set definition defined in this SAP for analysis purposes.

3. In the protocol, the exploratory endpoint - "Difference in the mean change from baseline in postprandial glucose and insulin in patients treated with RDX-002 as compared with placebo at Weeks 6 and 12" is there. Whereas, In the SAP, to be more appropriate, "Incremental AUC and Absolute/Total AUC for glucose and insulin" has been suggested to analyse.

4. In the protocol, the exploratory endpoint-"Relationship between changes in incremental postprandial TGs AUC and change in body weight for patients treated with RDX-002 as compared with placebo from baseline to Week 12" will be analyzed by treatment group which is mentioned in the SAP.

5. In the protocol, the given exploratory endpoint "The Relationship between percent change in incremental postprandial TGs AUC at Week 12 as compared to baseline and change in body weight at Week 12 as compared to baseline in patients treated with RDX-002" will not be analyzed.

6. In the protocol, since the exploratory endpoints are summarized descriptively, the title of exploratory endpoints wherever it is mentioned "mean/ median change" needs to rephrased to "change from baseline".

8 REFERENCE

- ICH E3: Structure and Content of Clinical Study Reports. •

ICH E9: Statistical Principles for Clinical Trials

- Clinical Study Protocol (RDX-002-024-011 Amendment 2, dated DEC 13, 2024) • eCRF

Version and Date: version 6.0 dated FEB 10, 2025

9 APPENDIX

9.1 APPENDIX I: BLOOD PRESSURE, BODY WEIGHT, WAIST CIRCUMFERENCE AND TOTAL BODY FAT MASS MEASUREMENTS

9.1.1 Blood Pressure Measurements

Blood pressure (BP) will be collected pre-dose at the time points indicated in the schedule of events (Table 1). Patients should not exercise, smoke or consume caffeine 30 minutes prior to BP measurement. Blood pressure measurements should be done prior to ECG recordings.

Below listed standardized procedure for measuring BP should be followed:

- Patient should be in supine position for at least 5 minutes and the measurement arm supported so that the midpoint of the BP cuff is at heart level;
- A BP monitor (preferably of the same make and model) should be used for all patient measurements;
- An appropriate-sized cuff should be used with the bladder centered over the brachial artery;
- The arm used for BP measurement should be recorded and maintained for all measurements;
- All BP measurements should be preferably at approximately the same time of day unless not possible;
- At each visit, 3 BP measurements (each measurement 1 - 2 minutes apart at supine position) should be obtained using the same arm. Mean supine BP is defined as the average of 3 supine BP measurements for any single clinic visit;
- If the lowest and highest SBP measurements are >15 mm Hg apart, additional readings should be performed to achieve 3 readings within 15 mm Hg SBP are obtained. Up to six readings may be obtained, if needed. The visit BP measurement will be determined from the 3 readings with SBP within 15 mm Hg.

9.1.2 Body Weight and Waist Circumference Measurements

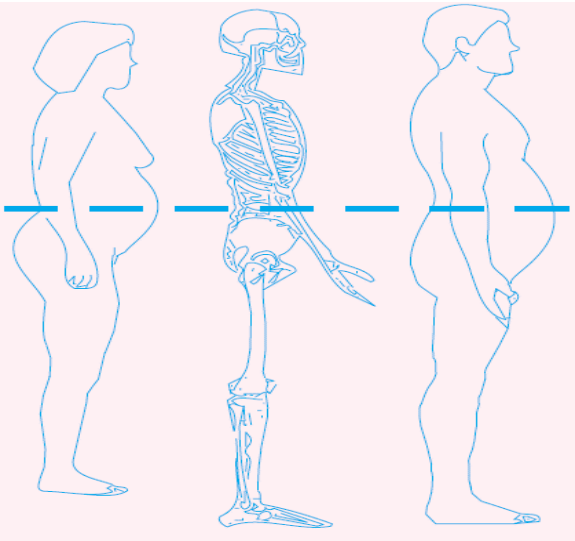
Body weight and waist circumference will be taken for all patients according to the schedule of events (Table 1). The BMI will be calculated based on the patients' height measurement taken at Visit S1.

To obtain the most valid and reliable measurement, patients will be encouraged to weigh first thing in the morning, while wearing minimal clothing (e.g., hospital gown), before eating/drinking and after voiding their bladder/bowels.

To measure waist circumference, study site staff should follow the following steps:

Locate the upper hip bone and the top of the right iliac crest; Place a measuring tape in a horizontal plane around the abdomen at the level of the iliac crest; Before reading the tape measure, ensure that the tape is snug, but does not compress the skin, and is parallel to the floor; Measure at the end of a normal expiration.

Measuring – Tape Position for Waist Circumference in Adults



9.1.3 Total Body Fat Mass

InBody H20N device will be used to obtain total body fat mass for all patients according to the schedule of events (Table 1).

InBody H20N device is a smart weight analyzer that measures whole-body composition with advanced technology and ease of use. It comes with handlebar electrodes as well as footplate electrodes, so the entire body composition is measured, not estimated. The device has an auto-calibration functionality that is completed each time the device is turned on.

Below is an image of the InBody H20N Scale:



9.2 Appendix II: Pharmacokinetic and Postprandial Blood Sampling Schedule

Visit	Analyte	Onboard Drug	# Patients	# Timepoints	Timepoints	Total Samples
Visit G1	TG, glucose, insulin	RDX-002:Placebo	32:32	8	0 (×2), 1, 2, 3, 4, 6, 8	512
Visit T1	TG, glucose, insulin	RDX-002:Placebo	32:32	8	0 (×2), 1, 2, 3, 4, 6, 8	512

Visit T3	TG, glucose, insulin	RDX-002:Placebo	32:32	8	0 (×2), 1, 2, 3, 4, 6, 8	512	
Visit T3	RDX-002, main inactive metabolite	RDX-002:Placebo	32:32	7	0, 1, 2, 3, 4, 6, 8	448	
						TOTAL	1,984
						TOTAL TGs	1,536

Abbreviations: PK = pharmacokinetic, TG(s) = triglycerides.
Notes:
1. The PK samples at Visit T3 will be collected at same timepoints as postprandial TGs.
2. Postprandial samples for TGs, glucose and insulin and PK samples will be collected with a ±5 minutes collection window.

9.3 Appendix III: Composition of a High-Fat Meal

An example of a high-fat meal	• Two eggs fried in butter • Two strips of bacon • Two slices of toast with butter • Four ounces of hash brown potatoes • Eight ounces of whole milk
Total calories Calories	800-1000
from protein	150 250
Calories from carbohydrates	500-600
Calories from fat	≥50
Percent calories from fat	

Note: 50 percent of calories are derived from fat. Substitutions can be made to this meal if the total and fat calorie content, volume, and viscosity are maintained.
Source: Assessing the Effects of Food on Drugs in INDs and NDAs — Clinical Pharmacology Considerations Guidance for Industry. US Department of Health and Human Services, Food and Drug Administration Center for Drug Evaluation and Research (CDER), Clinical Pharmacology, June 2022.

Picture of a High-Fat Meal



9.4 Appendix IV: Patient Diary

To be Completed by Clinic Staff			
Patient Initials:		Date Diary Provided to Patient	
Patient ID:		Date Diary Returned to Clinic:	

Instructions: This diary is used to collect information that will help us better understand the results of this study. Please complete this diary each day starting with the day and date you first received your study medication. Enter the information in each column by hand. Starting with the day/date you first received your study medication, write the time you took your first dose of the study medication, the time you ate your first meal of the day, the time you took your second (evening) dose of study medication, and the time you ate your evening meal. If you missed a dose of your study medication, please put an X in the shaded box "I did not take my study medication" for that day/time.

The clinic staff will call you every 2 weeks to talk with you briefly about the information you enter on this diary.

Please bring this completed diary to your next clinic visit, for clinic staff to review.

To be Completed by Clinic Staff						
Patient Initials:			Date Diary Provided to Patient			
Patient ID:			Date Diary Returned to Clinic:			
Date (DD/MMM/YYYY i.e. 25 Dec 2024)	First Dose of Study Medication TIME (hh:mm) AM/PM-circle one	I did not take my study medication	First Meal of the Day TIME (hh:mm) AM/PM-circle one	Second Dose of Study Medication TIME (hh:mm) AM/PM-circle one	I did not take my study medication	Dinner/Evening Meal TIME (hh:mm) AM/PM-circle one
	AM/PM		AM/PM	AM/PM		AM/PM
	AM/PM		AM/PM	AM/PM		AM/PM
	AM/PM		AM/PM	AM/PM		AM/PM
	AM/PM		AM/PM	AM/PM		AM/PM

	AM/PM		AM/PM	AM/PM		AM/PM
	AM/PM		AM/PM	AM/PM		AM/PM
	AM/PM		AM/PM	AM/PM		AM/PM

To be Completed by Clinic Staff			
Patient Initials:		Date Diary Provided to Patient	
Patient ID:		Date Diary Returned to Clinic:	

On this diary, please write down each time (written as HH:MM and circle AM or PM) you had a bowel movement and provide the type (1-7) of bowel movement you had by comparing it to the description and picture on the Bristol Stool Form Scale that your clinic staff provided you. If you had more than one bowel movement on any day, please enter a description for each on a separate line.

Date (DD/MMM/YYYY i.e. 25 Dec 2024)	Time of Bowel Movement	Stool Description	Time of Bowel Movement	Stool Description	Time of Bowel Movement	Stool Description	Time of Bowel Movement	Stool Description	Time of Bowel Movement	Stool Description	Time of Bowel Movement	Stool Description	Time of Bowel Movement	Stool Description
	AM/PM		AM/PM		AM/PM		AM/PM		AM/PM		AM/PM		AM/PM	
	AM/PM		AM/PM		AM/PM		AM/PM		AM/PM		AM/PM		AM/PM	
	AM/PM		AM/PM		AM/PM		AM/PM		AM/PM		AM/PM		AM/PM	
	AM/PM		AM/PM		AM/PM		AM/PM		AM/PM		AM/PM		AM/PM	
	AM/PM		AM/PM		AM/PM		AM/PM		AM/PM		AM/PM		AM/PM	
	AM/PM		AM/PM		AM/PM		AM/PM		AM/PM		AM/PM		AM/PM	
	AM/PM		AM/PM		AM/PM		AM/PM		AM/PM		AM/PM		AM/PM	

If you experience a severe change in your physical condition, please seek immediate medical attention at the nearest Emergency Room and notify the study site (Nucleus Network) as soon as possible @ 651-641-2900 (24 Hour).

9.5 Appendix V: Bristol Stool Form Scale

Bristol Stool Form Scale		
Type	Description	Image
Type 1	Separate hard lumps, like nuts	
Type 2	Sausage-shaped but lumpy	
Type 3	Like a sausage or snake but with cracks on its surface	
Type 4	Like a sausage or snake, smooth and soft	
Type 5	Soft blobs with clear-cut edges	
Type 6	Fluffy pieces with ragged edges, a mushy stool	
Type 7	Watery, no solid pieces	

9.6 Appendix VI: Management Plan for Diarrhea

Given the intestinal mechanism of action for RDX-002, gastrointestinal side effects including diarrhea, can sometimes be observed with treatment. Diarrhea from RDX-002 typically occurs during the first 2 weeks after initiation of treatment and is often-self-limiting after a few days of treatment. Patients with uncomplicated Grade 1 or Grade 2 diarrhea should discontinue any lactose-containing food products, alcohol, or high-osmolar supplements (beverages with high sugar content [juices, nectars, energy drinks, colas], beverages containing high amounts of caffeine etc.,). Patients should temporarily decrease consumption of high-fat foods and increase consumption of clear liquids (8 - 10 glasses per day). Loperamide can also be administered and a decrease in the RDX-002 dosing from 200 mg BID to 100 mg BID can also be considered. Patients with persistent or complicated diarrhea (see definition below) should consider temporary de-challenge or discontinuation of RDX-002 as well as more intensive treatment of the diarrhea.

The Common Terminology Criteria for Adverse Events (CTCAE) definitions for diarrhea intensity are as follows:

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline	Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline; limiting instrumental activities of daily living	Increase of ≥7 stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self-care activities of daily living	Life-threatening consequences; urgent intervention indicated	Death

Complicated diarrhea is defined as CTCAE Grade 3 or 4 diarrhea or Grade 1 or 2 diarrhea with 1 or more of the following signs or symptoms:

Cramping, Nausea/vomiting (≥ Grade 2), Decreased performance status, Fever, Sepsis, Neutropenia, Frank bleeding and Dehydration.

Certificate Of Completion

Envelope Id: DECAD0F6-ED4E-4395-A9E9-5AE21E5B64B8 Status: Completed

Subject: Complete with Docusign: Response Pharma_RDX-002-024-011_SAP_Final_V2.0_12JUN2025_CC.docx

Source Envelope:

Document Pages: 48 Signatures: 3 Envelope Originator:

Certificate Pages: 5 Initials: 0 Akhil John

AutoNav: Enabled akhil.john@veranex.com

EnvelopeId Stamping: Disabled IP Address: 2403:a080:1c:5c

Time Zone: (UTC+05:30) Chennai, Kolkata, Mumbai, New Delhi

Record Tracking

Status: Original Holder: Akhil John Location: DocuSign

12-Jun-2025 | 16:22 akhil.john@veranex.com

Signer Events	Signature	Timestamp
Bohdan Naida bohdan.naida@veranex.com Biostatistician 1 Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 383D72E6-BF97-4948-B53A-ADD1B5248172 Using IP Address: 178.74.236.95 With Signing Authentication via Docusign password With Signing Reasons (on each tab): I am the author of this document	Sent: 12-Jun-2025 | 16:25 Viewed: 12-Jun-2025 | 16:45 Signed: 13-Jun-2025 | 12:30
Electronic Record and Signature Disclosure: Accepted: 12-Apr-2023 | 19:17 ID: 6efea3e1-0708-453a-b251-918b05565009		
Saniya Goon saniya.goon@veranex.com Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 80459E16-4CA9-4698-A8B7-167EC812BC08 Using IP Address: 171.76.81.207 With Signing Authentication via Docusign password With Signing Reasons (on each tab): I have reviewed this document	Sent: 13-Jun-2025 | 12:31 Viewed: 13-Jun-2025 | 12:33 Signed: 13-Jun-2025 | 14:04
Electronic Record and Signature Disclosure: Accepted: 17-Jul-2024 | 10:23 ID: fcab1118-7d79-4acb-adf1-ac5c2422d035		

Signer Events	Signature	Timestamp
William J Sasiela bill@responsepharmaceuticals.com Security Level: Email, Account Authentication (Required)	William J Sasiela Signature Adoption: Pre-selected Style Signature ID: 142ACC6C-67F2-4697-8257-F4F29BA0B97B Using IP Address: 104.28.199.254 With Signing Authentication via Docusign password With Signing Reasons (on each tab): I approve this document	Sent: 13-Jun-2025 | 14:04 Resent: 17-Jun-2025 | 10:04 Resent: 18-Jun-2025 | 16:22 Viewed: 23-Jun-2025 | 13:15 Signed: 23-Jun-2025 | 13:16
Electronic Record and Signature Disclosure: Accepted: 26-Jul-2024 | 18:36 ID: 511277f6-3fdd-45a4-b266-9b467d07cc44		

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	12-Jun-2025 | 16:25
Certified Delivered	Security Checked	23-Jun-2025 | 13:15
Signing Complete	Security Checked	23-Jun-2025 | 13:16
Completed	Security Checked	23-Jun-2025 | 13:16

Payment Events	Status	Timestamps

Electronic Record and Signature Disclosure

ELECTRONIC RECORD AND SIGNATURE DISCLOSURE

From time to time, Veranex- Part 11 (we, us or Company) may be required by law to provide to you certain written notices or disclosures. Described below are the terms and conditions for providing to you such notices and disclosures electronically through the DocuSign system. Please read the information below carefully and thoroughly, and if you can access this information electronically to your satisfaction and agree to this Electronic Record and Signature Disclosure (ERSD), please confirm your agreement by selecting the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

Getting paper copies

At any time, you may request from us a paper copy of any record provided or made available electronically to you by us. You will have the ability to download and print documents we send to you through the DocuSign system during and immediately after the signing session and, if you elect to create a DocuSign account, you may access the documents for a limited period of time (usually 30 days) after such documents are first sent to you. After such time, if you wish for us to send you paper copies of any such documents from our office to you, you will be charged a $0.00 per-page fee. You may request delivery of such paper copies from us by following the procedure described below.

Withdrawing your consent

If you decide to receive notices and disclosures from us electronically, you may at any time change your mind and tell us that thereafter you want to receive required notices and disclosures only in paper format. How you must inform us of your decision to receive future notices and disclosure in paper format and withdraw your consent to receive notices and disclosures electronically is described below.

Consequences of changing your mind

If you elect to receive required notices and disclosures only in paper format, it will slow the speed at which we can complete certain steps in transactions with you and delivering services to you because we will need first to send the required notices or disclosures to you in paper format, and then wait until we receive back from you your acknowledgment of your receipt of such paper notices or disclosures. Further, you will no longer be able to use the DocuSign system to receive required notices and consents electronically from us or to sign electronically documents from us.

All notices and disclosures will be sent to you electronically

Unless you tell us otherwise in accordance with the procedures described herein, we will provide electronically to you through the DocuSign system all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To reduce the chance of you inadvertently not receiving any notice or disclosure, we prefer to provide all of the required notices and disclosures to you by the same method and to the same address that you have given us. Thus, you can receive all the disclosures and notices electronically or in paper format through the paper mail delivery system. If you do not agree with this process, please let us know as described below. Please also see the paragraph immediately above that describes the consequences of your electing not to receive delivery of the notices and disclosures electronically from us.

How to contact Veranex- Part 11:

You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:
To contact us by email send messages to: doug.dockhorn@veranex.com

To advise Veranex- Part 11 of your new email address

To let us know of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to us at doug.dockhorn@veranex.com and in the body of such request you must state: your previous email address, your new email address. We do not require any other information from you to change your email address.

If you created a DocuSign account, you may update it with your new email address through your account preferences.

To request paper copies from Veranex- Part 11

To request delivery from us of paper copies of the notices and disclosures previously provided by us to you electronically, you must send us an email to doug.dockhorn@veranex.com and in the body of such request you must state your email address, full name, mailing address, and telephone number. We will bill you for any fees at that time, if any.

To withdraw your consent with Veranex- Part 11

To inform us that you no longer wish to receive future notices and disclosures in electronic format you may:

i. decline to sign a document from within your signing session, and on the subsequent page, select the check-box indicating you wish to withdraw your consent, or you may;

ii. send us an email to doug.dockhorn@veranex.com and in the body of such request you must state your email, full name, mailing address, and telephone number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

Required hardware and software

The minimum system requirements for using the DocuSign system may change over time. The current system requirements are found here: https://support.docusign.com/guides/signer-guide-signing-system-requirements.

Acknowledging your access and consent to receive and sign documents electronically

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please confirm that you have read this ERSD, and (i) that you are able to print on paper or electronically save this ERSD for your future reference and access; or (ii) that you are able to email this ERSD to an email address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format as described herein, then select the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

By selecting the check-box next to 'I agree to use electronic records and signatures', you confirm that:

- You can access and read this Electronic Record and Signature Disclosure; and
- You can print on paper this Electronic Record and Signature Disclosure, or save or send this Electronic Record and Disclosure to a location where you can print it, for future reference and access; and
- Until or unless you notify Veranex- Part 11 as described above, you consent to receive exclusively through electronic means all notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you by Veranex- Part 11 during the course of your relationship with Veranex- Part 11.