STATISTICAL ANALYSIS PLAN

STUDY BCX9930-205

DATE OF PLAN:

Final Version 1.0: 23 September 2024

BASED ON:

Protocol Version (Date): Version 4.0: 23 July 2023

STUDY DRUG:

BCX9930

PROTOCOL NUMBER:

BCX9930-205

STUDY TITLE:

An Open-label Study to Evaluate the Long-term Safety of BCX9930 Monotherapy in Subjects with Paroxysmal Nocturnal Hemoglobinuria Who Previously Received BCX9930 in a BioCryst-sponsored Study

SPONSOR:

BioCryst Pharmaceuticals, Inc.
4505 Emperor Blvd., Suite 200
Durham, NC 27703
Phone: (919) 859-1302
Fax: (919) 851-1416

This study is being conducted in compliance with Good Clinical Practice, including the archiving of essential documents.

Technical Summary Report (TSR)

Name of Sponsor/Company **BioCryst Pharmaceuticals, Inc.**	**Individual Study Table Referring to Part of the Dossier:** **Volume:**	***(For National Authority Use Only)*:**
Name of Finished Product: BCX9930	Page:	
Name of Active Ingredient: 2-(2-((7-(2-(aminomethyl)-3-fluoropyridin-4-yl)benzofuran-5-yl)methoxy)phenyl)acetic acid		
Title of Study: An Open-label Study to Evaluate the Long-term Safety of BCX9930 Monotherapy in Subjects with Paroxysmal Nocturnal Hemoglobinuria Who Previously Received BCX9930 in a BioCryst-sponsored Study (BioCryst Protocol BCX9930-205)		
Investigators: Study Centers: This study will be conducted at study centers in multiple countries/regions		
Studied period (years): Approximately 2 years	**Phase of development:** Phase 2b	

Introduction

BioCryst stopped development of BCX9930 in December of 2022 based on changes in the competitive environment. This statistical analysis plan contains a detailed description of the statistical methods to support the abbreviated clinical study report (aCSR) for this study.

Objectives:

- To provide continued access to BCX9930 for subjects with PNH who have benefited from treatment with BCX9930 in another BioCryst-sponsored study and who, in the opinion of the investigator, would benefit from continued treatment with BCX9930, and who do not have access to other effective treatment options
- To monitor the safety of BCX9930 in subjects continuing to receive BCX9930 for the treatment of PNH

Endpoints:

- Subject incidence of graded treatment-emergent adverse events (TEAEs), laboratory abnormalities, changes to vital signs, and physical examination findings

Study Design:

This study is designed to provide continued access to BCX9930 for subjects currently receiving treatment with BCX9930 in another BioCryst-sponsored clinical study for PNH (i.e., Studies 201, 202, or 203, hereafter referred to as the “prior study”) who, in the opinion of the

investigator, have both benefited from treatment with BCX9930 and would benefit from continued treatment with BCX9930, who wish to continue treatment, and who do not have access to other effective treatment options.

Subjects will be eligible to receive study drug (BCX9930) under this version of the protocol for up to 96 weeks for as long as the investigator believes it is in the subject's best interest to continue treatment, or until the subject has access to another therapy for PNH, whichever comes first. Treatment with BCX9930 will be discontinued for subjects who are deriving no meaningful clinical benefit, or who experience an unacceptable drug-related AE or are otherwise intolerant of study drug.

An independent BCX9930 program-wide DMC will provide oversight of the safety of subjects receiving BCX9930 in this study.

Methodology:

Subjects who meet all of the inclusion and none of the exclusion criteria can be enrolled into Study 205. The last on-treatment visit completed for the prior study will also serve as the baseline visit for Study 205. If subjects have completed at least 24 weeks of BCX9930 treatment in the prior study, study visits will occur every 8 weeks to Week 48, then every 12 weeks until Week 96. Subjects who have not completed 24 weeks of treatment with BCX9930 prior to enrolling in Study 205 must return to the clinic every 4 weeks until they have completed 24 weeks of cumulative treatment with BCX9930. Subjects who discontinue treatment with BCX9930 for any reason (complete study visits or discontinue early), will be asked to complete an end-of-study or early termination visit, as applicable, approximately 3 weeks (± 3 days) after the last dose of BCX9930.

Number of Subjects (planned):

Up to 30 subjects are planned.

Investigational Product, Dosage and Mode of Administration:

Based on safety and efficacy data from previous studies, all subjects enrolled into this study will receive BCX9930 400 mg twice a day, with or without food.

Duration of Treatment:

Each subject will be eligible to receive study drug (BCX9930) under this protocol for up to 96 weeks as long as the investigator believes it is in the subject's best interest to continue treatment, or until the subject has access to other therapy for PNH, whichever comes first. Treatment with BCX9930 will be discontinued for subjects who are deriving no meaningful clinical benefit, or who experience an unacceptable drug-related AE or are otherwise intolerant of study drug.

Reference Therapy, Dosage and Mode of Administration:

Not applicable.

Statistical Methods:

A detailed statistical analysis plan (SAP) will be developed to describe the methods of analyses and summaries, including all endpoints, time points, populations, missing data, etc. Deviations from the analyses outlined in the SAP will be described in the clinical study report.

TABLE OF CONTENTS

List of Abbreviations

Table 1: List of Abbreviations and Definitions of Terms

Abbreviation	Term
AE	adverse event
ARC	absolute reticulocyte count
BID	twice daily
CTCAE	Common Terminology Criteria for Adverse Event
DMC	data monitoring committee
eCRF	electronic case report form
Hb	hemoglobin
ICH	International Council for Harmonisation
LDH	lactate dehydrogenase
MedDRA	Medical Dictionary for Regulatory Activities
PNH	paroxysmal nocturnal hemoglobinuria
RBC	red blood cell
SAE	serious adverse event
SAP	statistical analysis plan
TEAE	treatment-emergent adverse event
WBC	white blood cell

1. INTRODUCTION

BioCryst stopped development of BCX9930 in December of 2022 based on changes in the competitive environment. The purpose of this statistical analysis plan (SAP) is to describe the planned analyses and data displays to be included in the abbreviated clinical study report (aCSR) for Study BCX9930205 (Study 205).

Protocol Revision Chronology:		
Protocol v1.0	03 March 2022	Original
Protocol v2.0	05 August 2022	Amendment 1
Protocol v3.0	23 February 2023	Amendment 2
Protocol v4.0	27 July 2023	Amendment 3

This SAP was developed in accordance with the International Council for Harmonisation (ICH) E9 guideline. The purpose of this document is to provide details on the statistical methodology used to meet the objectives for Study 205. Study population definitions, derivations of variables, handling of missing data, and other information necessary for analysis of study data are provided. Planned tables and listings are specified.

The document may evolve over time, for example, to reflect the requirements of protocol amendments or regulatory requests. However, the final SAP must be finalized, approved by the sponsor, and placed on file before database is locked. Deviations from the final approved plan will be noted in the CSR.

2. STUDY OBJECTIVES AND ENDPOINTS

2.1. Objectives

The objectives of this study are:

- To provide continued access to BCX9930 for subjects with PNH who have benefited from treatment with BCX9930 in another BioCryst-sponsored study and who, in the opinion of the investigator, would benefit from continued treatment with BCX9930, and who do not have access to other effective treatment options.
- To monitor the safety of BCX9930 in subjects continuing to receive BCX9930 for the treatment of PNH.

2.2. Endpoints

The endpoints of this study are:

- Subject incidence of graded treatment-emergent adverse events (TEAEs) and laboratory abnormalities.

3. STUDY DESIGN

3.1. Summary of Study Design

This study is designed to provide continued access to BCX9930 for subjects currently receiving treatment with BCX9930 in another BioCryst-sponsored clinical study for PNH (i.e., Studies 201, 202, or 203, hereafter referred to as the "prior study") who, in the opinion of the investigator, have both benefited from treatment with BCX9930 and would benefit from continued treatment with BCX9930, who wish to continue treatment, and who do not have access to other effective treatment options.

Subjects will be eligible to receive study drug (BCX9930) under this version of the protocol for up to 96 weeks for as long as the investigator believes it is in the subject's best interest to continue treatment, or until the subject has access to another therapy for PNH, whichever comes first. Treatment with BCX9930 will be discontinued for subjects who are deriving no meaningful clinical benefit, or who experience an unacceptable drug-related AE or are otherwise intolerant of study drug.

An independent BCX9930 program-wide DMC will provide oversight of the safety of subjects receiving BCX9930 in this study.

3.2. Definition of Study Treatments

BCX9930 will be supplied as 100-mg tablets. Subjects will take four BCX9930 100-mg tablets orally BID, approximately 12 hours apart. Study drug may be administered with or without food.

3.3. Sample Size Considerations

No sample size calculations were conducted for this open-label, long-term safety study. Up to 30 subjects may be enrolled in this study, to allow continued access to BCX9930 following a subject's participation in another BCX9930 study.

3.4. Randomization

This is an open-label, non-randomized study.

4. PLANNED ANALYSES

4.1. Interim Analyses

No formal interim analyses are planned. DMC analysis will be conducted on an as-needed basis.

4.2. Final Analyses

Analysis of the data will be conducted after all subjects enrolled complete or discontinue the study, the resulting clinical database has been cleaned and quality checked, the analysis populations have been finalized, and the final database lock has occurred.

5. GENERAL CONSIDERATIONS FOR DATA ANALYSES AND HANDLING

This section addresses the definitions, algorithms, imputations, and conventions that will apply to the analysis and handling of the data in general. Complex derivations will be addressed in the detailed discussions of individual summary tables.

5.1. General Summary Table and Individual Subject Data Listing Considerations

Version 9.4 or higher of the SAS system will be used to analyze the data and to generate tables and listings. All SAS programs prepared to analyze the data will be properly annotated to permit uninvolved outside statistical experts to replicate all the analyses specified in this SAP.

A table of contents for the tables and listings can be found in Section 9.

5.2. Statistical Programming

The standard operating procedures (SOPs) of BioCryst will be used. Data will be mapped to Study Data Tabulation Model (SDTM)-compliant datasets prior to creation of Analysis Data Model (ADaM)-compliant derived datasets for use in the creation of summary tables.

5.3. Data Presentation Conventions

Summary tables and listings will include “footers” providing:

1. Date and time of output generation.
2. SAS® program name that generates the output.
3. The name(s) and location(s) of any input dataset(s) used in the creation of the output.
4. Any other output-specific details that require elaboration.

The date of output generation links the output to the locked and archived database to allow replication of the results.

5.4. Analysis Populations

5.4.1. Safety Population

The safety population is defined as all subjects who receive at least 1 dose of study drug. This population will be used for all analyses of exposure, demographics, and safety.

5.5. Baseline Definition

5.5.1. Study Baseline

The last on-treatment visit completed for the prior study will serve as the baseline visit for Study 205. If the baseline visit is missing in the database, the first available measurement from Study 205 will serve as the baseline.

For determination of Hb, ARC, total PNH RBC clone size, the ratio of total PNH RBC clone size to PNH WBC clone size, and haptoglobin, only central lab values that were not impacted by transfusions will be used. Transfusion impacted lab values are those collected within 14 days

after the subject received a pRBC or whole blood transfusion (for Hb, ARC, total PNH RBC clone size and the ratio of total PNH RBC clone size to PNH WBC clone size), or values that are collected within 3 days after the subject received a pRBC or whole blood transfusion (for haptoglobin).

5.6. Derived and Transformed Data

5.6.1. Baseline Age

The subject's baseline age in years will be the age provided in the eCRF as collected at the time of consent.

5.6.2. Study Day

If the date of interest occurs on or after the date of first dose of study treatment, then study day will be calculated as (date of interest – date of first dose) + 1. If the date of interest occurs prior to the date of first dose, then study day will be calculated as (date of interest – date of first dose). There is no study day zero.

5.6.3. Change from Baseline and Percent Change from Baseline

Change from baseline will be calculated as (post-baseline result – baseline result). Percent change from baseline will be calculated as (100 × change from baseline/baseline result). If either the baseline or the post-baseline result is missing, the change from baseline and percent change from baseline will be set to missing as well. If the baseline value is 0, the percent change from baseline cannot be calculated under this definition. In these cases, percent change will remain missing.

5.6.4. Treatment-emergent Adverse Events

An AE is considered treatment-emergent if its start date is on or after the date of first dose of study treatment in Study 205 or if the AE is on-going from the prior study. If the AE start date is missing and the AE stop date is after the start date of the first dose of study treatment (or the AE is ongoing) then the AE will be considered treatment emergent. If either or both times are missing, then dates alone will be compared. See Section 5.7.2 for incomplete dates or times.

AEs occurring 30 days after the last dose will be considered as TEAEs. All AEs that occurred more than 30 days after the last dose of study treatment will be excluded from the tables and listings. AEs that occurred during the dose tapering period will be included in the tables and listings. Adverse events that rolled over from the parent study are excluded from the tables but will be included in the listings.

5.6.5. Concomitant Medications

A medication will be classified as prior if it stopped before the first dose of study treatment; that is, its end date is on or before the date of the first dose of study treatment. A medication will be classified as concomitant; if the start date is on or after the date of the first dose of study treatment in Study 205, or its end date is after the start date of the first dose of study treatment in Study 205, or the medication is flagged as ongoing. See Section 5.7.1 for incomplete dates.

5.6.6. Visit Windows

Visit names are presented as collected in the database and no visit windowing will be performed. However, unscheduled visit values will be used for safety analyses of most severe event.

All information collected at an unscheduled visit will be identified as such and presented in the listings.

5.6.7. Multiple Assessments

For laboratory data, where multiple planned measurements are recorded for a given time point, the median of the measurements will be calculated and used in any derivation of summary statistics.

The endpoint data will be summarized for planned visits only. The baseline measurement and all post-baseline data will be listed.

5.6.8. Number of Units of Packed RBCs Transfused

The number of units of pRBCs will be the total count per subject of units of pRBCs or whole blood that are administered to the subject during the study as recorded in the eCRF. Transfusions of 1 unit of whole blood will count as 1 unit of pRBCs.

5.7. Handling of Missing Data

Every effort will be made to obtain all data. There will be no data imputation for missing data except for missing baseline labs. In this case, the first on-treatment value will be used as the baseline.

5.7.1. Missing Start and Stop Dates for Concomitant Medication

For analysis of medications, a complete date should be established to identify medication as occurring during treatment or not. For the purposes of handling partially reported start and stop dates for medication, the following algorithm will be applied:

- Missing start day, but month and year present:

  If study medication had been taken in the same month and year as the occurrence of the medication, then the start day of the medication will be assigned to the day of first dose of study medication.

  Otherwise, the start day will be set to the first day of the month.

- Missing start day and month, but year present:

  If study medication had been taken in the same year as the occurrence of the medication, then the start date of the medication will be assigned to the date of first application of study medication.

  Otherwise, the start day and month will be set to 01 January.

- Missing end day, but month and year present:

  The day will be set to the last day of the month.

- Missing end day and month, but year present:

  The end day and month will be set to the end of study date.

5.7.2. Missing Start Date, Stop Date, Severity, or Relationship for Adverse Events

The same conventions to address incomplete dates for prior and concomitant medications will also be used for AEs. Should an event have a missing severity or relationship, it will be classified as having the highest non-fatal severity (grade 4) and/or strongest relationship to study treatment (related).

5.7.3. Missing Time of First Dose

In case of missing time for first dose, it will be assumed that baseline measures that were to be taken prior to first dose according to the protocol were in fact taken prior to dosing.

5.7.4. Transfusion-impacted Period

The 14-day period following a transfusion of pRBCs or whole blood is defined as the transfusion-impacted period (i.e., the interval between the transfusion day and the current study day is ≤ 13 days and includes the day of transfusion). An exception to this rule is that the transfusion-impacted period for haptoglobin is the 3-day period following a transfusion (i.e., the interval between the transfusion day and the current study day is ≤ 2 days and includes the day of transfusion).

The following parameters are impacted by pRBC or whole blood transfusion:

- Hemoglobin
- Reticulocytes
- PNH RBC (Type II and III red blood cells)
- Ratio of PNH RBC to PNH WBC
- Haptoglobin (transfusion-impacted period is limited to 3 days instead of 14)

6. STUDY POPULATION

6.1. Subject Disposition

The subject disposition table for all subjects will summarize the number and percentage of subjects that received at least one dose of study drug, discontinued treatment, the reasons for discontinuation, and subjects that completed the study. Results will be summarized for the BCX9930 treatment group.

The percentages for subjects dosed, discontinued, and completed will be based on the number of subjects enrolled. Percentages for discontinuation reason will be based on the number of subjects that discontinued.

6.2. Demographic and Baseline Characteristics

The subject demographic and baseline characteristics table for the subjects in the safety population will descriptively summarize results for age at consent, race, ethnicity, and sex. Results will be summarized for the BCX9930 treatment group.

6.3. Concomitant Medications

Medications will be coded using the World Health Organization (WHO) drug dictionary version B3 March 2021, and summarized by Anatomical Therapeutic Class (ATC) 4 term, preferred term (PT), and treatment group.

6.3.1. Summary of Concomitant Medications

The concomitant medications table for the subjects in the safety population will summarize the number and percentage of subjects taking concomitant medication(s) by ATC 4 term and PT. The results will be presented for the BCX9930 treatment group.

6.4. Exposure to Study Treatment

The exposure to study treatment table for the subjects in the safety population will descriptively summarize the BCX9930 400 mg BID, dose taper and Total with the number and percentage of subjects dosed and descriptive statistics (i.e., mean, standard deviation, etc.) for the number of days of exposure.

The compliance data as reported on the eCRF will be listed.

7. EFFICACY

All study efficacy data in the aCSR will be presented in data listings.

Hypothesis testing will not be conducted due to sponsor discontinuation of the program. No subgroup analyses are planned.

7.1. Efficacy Analysis of Hemoglobin

Descriptive statistics for the observed values and changes from baseline in hemoglobin in the safety population will be presented for all scheduled visits during the treatment period. Values recorded within 14 days after the subject received a pRBC or whole blood transfusion will be excluded from the summary statistics. Unscheduled visits will be presented in the data listings but not summarized in the table.

7.2. Other Efficacy Endpoints

7.2.1. Percent CFB in Lactate Dehydrogenase (LDH)

Descriptive statistics for the observed values, changes from baseline, and percent changes from baseline in LDH in the safety population will be presented for all scheduled visits during the treatment period. Unscheduled visits will be presented in the data listings but not summarized in the table.

8. SAFETY AND TOLERABILITY

All study safety data to support the aCSR will be presented in data listings.

AEs will be assessed and recorded from the time of signing of the informed consent through the appropriate follow-up period. AEs will be mapped to MedDRA version 24.0 preferred term (PT) and system organ class (SOC). Relationship to study treatment will be assessed as not related, unlikely related, possibly related, probably related, or definitely related. AEs will be graded according to the CTCAE scales (Version 5.0, 27 November 2017). AEs not covered by CTCAE criteria will be assessed for severity as mild, moderate, severe, or life-threatening, corresponding to toxicity Grades 1 through 4.

8.1. Overall Summary of Treatment-emergent Adverse Events

The overall summary of TEAEs table for all subjects in the safety population will summarize the number and percentage of subjects that report at least 1 TEAE, have a treatment-related TEAE, have a TEAE leading to treatment withdrawal, have a serious TEAE requiring concomitant medication, have a severe (Grade 3) or life-threatening (Grade 4) TEAE, have a serious TEAE, have a TEAE leading to study discontinuation, and have a TEAE leading to death. In addition to summarizing the number and percentage of subjects that have at least 1 of these events, the table will also summarize the total number and percentage for each of these events. Results will be summarized for the BCX9930 400 mg BID, dose taper and Total. The percentages for number of subjects will use the safety population sample size as the denominator; the percentages for the number of events will use the total number of TEAEs as the denominator.

8.2. Adverse Event Preferred Term and Body/Organ System Summary Tables

8.2.1. Treatment-emergent Adverse Events by System Organ Class and Preferred Term

A summary of the number and percentage of subjects with treatment-emergent adverse events by system organ class and preferred term will be presented along with the number of events for all subjects in the safety population. Results will be summarized for the BCX9930 400 mg BID, dose taper and Total. The percentages for number of subjects will use the safety population sample size as the denominator.

8.2.2. Other Adverse Event Summary Tables

8.2.2.1. Serious Treatment-emergent Adverse Events by MedDRA System Organ Class and Preferred Term

A summary of the number and percentage of subjects with serious treatment-emergent adverse events by SOC and PT term will be presented along with the number of events for all subjects in the safety population. Results will be summarized for the BCX9930 400 mg BID, dose taper and

Total.. The percentages for number of subjects will use the safety population sample size as the denominator.

8.2.2.2. Non-Serious Treatment-emergent Adverse Events by MedDRA System Organ Class and Preferred Term

A summary of the number and percentage of subjects with non-serious treatment-emergent adverse events by SOC and PT term will be presented along with the number of events for all subjects in the safety population. Results will be summarized for the BCX9930 400 mg BID, dose taper and Total. The percentages for number of subjects will use the safety population sample size as the denominator.

8.2.2.3. Renal Treatment-emergent Adverse Events by System Organ Class and Preferred Term

A summary of the number and percentage of subjects with renal treatment-emergent adverse events by system organ class and preferred term will be presented along with the number of events for all subjects in the safety population. The table will include events in the Acute Renal Failure SMQ, Chronic Kidney Disease SMQ, and Tubulointerstitial Diseases. The percentages for number of subjects will use the safety population sample size as the denominator.

8.2.2.4. Hepatic Treatment-emergent Adverse Events by System Organ Class and Preferred Term

A summary of the number and percentage of subjects with hepatic treatment-emergent adverse events by system organ class and preferred term will be presented along with the number of events for all subjects in the safety population. The table will include events in the drug related hepatic disorders (comprehensive search SMQ). The percentages for number of subjects will use the safety population sample size as the denominator.

9. CHANGES FROM PROTOCOL-SPECIFIED ANALYSES

Due to the discontinuation of the BCX9930 drug development by the sponsor, only variables relevant to the aCSR will be summarized and listed.

9.1. Table of Contents for Data Display Specifications

This table of contents provides the expected titles and numbers of the tables and listings of the final report. Changes to titles or numbering in the final report, additional data listings supporting the tables, or displays being split into multiple smaller displays for clarity will not necessitate a revision to the SAP, nor will they be considered a deviation from planned analyses.

9.1.1. Tables

Title		Population
Study Population Section		
Tables		
14.1.1	Subject Disposition	All Subjects
14.1.3	Demographic and Baseline Characteristics	Safety Population
14.1.5.1	Concomitant Medications	Safety Population
14.1.6.1	Exposure to Study Treatment	Safety Population
Efficacy Section		
Tables		
14.2.1.1	Observed and Change from Baseline Hemoglobin (g/dL) by Treatment Group and Visit	Safety Population
14.2.2.3	Observed, Change from Baseline, and Percent Change from Baseline LDH by Visit	Safety Population
Safety Section		
Tables		
14.3.1.1	Overall Summary of Treatment-emergent Adverse Events	Safety Population
14.3.2.1	Treatment-emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety Population
14.3.2.3.1	Serious Treatment-emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety Population
14.3.2.3.2	Non-serious Treatment-emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety Population

Title		Population
14.3.2.4	Renal Treatment-emergent Adverse Events by System Organ Class and Preferred Term: Events in the Acute Renal Failure SMQ, Chronic Kidney Disease SMQ, and Tubulointerstitial Diseases SMQ	Safety Population
14.3.2.5	Hepatic Treatment-emergent Adverse Events by System Organ Class and Preferred Term: Events in the Drug related hepatic disorders - comprehensive search SMQ	Safety Population

9.1.2. Data Listings

Listing 16.2.1	Listing of Subject Disposition	All Subjects
Listing 16.2.2	Listing of Protocol Deviations	All Subjects
Listing 16.2.4.1	Listing of Demographics and Baseline Characteristics	Safety Population
Listing 16.2.4.3	Listing of Concomitant Medications	Safety Population
Listing 16.2.4.5	Listing of Transfusion Details	Safety Population
Listing 16.2.5.1	Listing of Exposure to Study Treatment	Safety Population
Listing 16.2.5.2	Listing of Study Drug Compliance	Safety Population
Listing 16.2.6.1	Listing of Hemoglobin and LDH Results, Change from Baseline, and Percent Change from Baseline	Safety Population
Listing 16.2.7.1	Listing of Treatment-emergent Adverse Events	Safety Population
Listing 16.2.7.2	Listing of Serious Adverse Events	Safety Population
Listing 16.2.7.3	Listing of Renal Treatment-emergent Adverse Events	Safety Population
Listing 16.2.7.4	Listing of Hepatic Treatment-emergent Adverse Events	Safety Population
Listing 16.2.8	Listing of Grade 3 or Grade 4 Laboratory Abnormalities by CTCAE Scale	Safety Population

Signature Page for VV-CLIN-006366 v1.0

Approval Task	[redacted] Clinical 07-Feb-2025 21:59:02 GMT+0000

Signature Page for VV-CLIN-006366 v1.0