STATISTICAL ANALYSIS PLAN
FOR PROTOCOL AL-2003

Sponsor:	Allarity Therapeutics, Inc Phone: [redacted] 210 Broadway Cambridge, MA 02139
Protocol Number:	AL-2003
Protocol Title:	A Phase Ib, Open Label, Multicenter Study to Determine the Maximum Tolerated Dose (MTD) of PARPi 2X-121 Monotherapy and the MTD of Dovitinib in Combination with 2X-121 in Patients with Advanced Solid Tumors
Protocol Version / Date:	Version 2.0/ 19 Jul 2022

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Plan Version:	SAP – Final Version 1.0
Plan Date:	6 Feb 2024

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Sponsor:	Allarity Therapeutics, Inc
Prepared by:	Amarex Clinical Research 20201 Century Boulevard Germantown, Maryland 20874
SAP Version:	SAP – Final Version 1.0
SAP Date:	6 Feb 2024

I have read and approve the Statistical Analysis Plan specified above and agree on its content:

Statistician, Amarex Clinical Research	Date
Allarity Therapeutics, Inc. Representative	Date

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ABBREVIATIONS, ACRONYMS, AND DEFINITIONS

Abbreviation/Acronym	**Definition**
ADL	Activities of Daily living
AE	Adverse Event
ALT	Alanine Aminotransferase
Amarex	Amarex Clinical Research, LLC.
ANC	Absolute Neutrophils Count
ASCO	American Society of Clinical Oncology
AST	Aspartate Aminotransferase
AUC	Area Under the Curve
BBB	Blood Brain Barrier
B.i.d	Twice daily
Bpm	Beats Per Minute
BRCA	Breast Cancer 1/2 Mutation
CBC	Complete Blood Count
CBR	Clinical Benefit Rate
CDK	Cyclin Dependent Kinase
CHF	Congestive Heart Failure
Cl	Clearance
Cmax	Concentration maximum
CNS	Central Nervous System
CR	Complete Response
CRA	Clinical Research Associate
CRF	Case Report Form
CSR	Clinical Study Report
CT scan	Computed Tomography scan
CTCAE	Common Toxicity Criteria for Adverse Events
DLT	Dose Limiting Toxicity
DM	Data Manager
DNA	DeoxyriboNucleic Acid
DRP	Drug Response Predictors
EC	Ethics Committee
ECOG	Eastern Cooperative Oncology Group

Abbreviation/Acronym	**Definition**
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
EMA	The European Medicines Agency
EOT	End Of Treatment
GCP	Good Clinical Practice
HDL	High Density Lipoprotein
HER2	Human Epidermal growth factor Receptor 2
HIV	Human Immunodeficiency Viru
HR	Homologous Recombination
IB	Investigator Brochure
ICF	Informed Consent Form
ICH	International Conference on Harmonization
ISF	Investigator Site File
ITT	Intention-To-Treat
Kg	Kilogram
LDL	Low Density Lipoprotein
Mg	Milligram
MPI	Medical Prognosis Institute
MRI	Magnetic Resonance Imaging
MTD	Maximum Tolerated Dose
NAD+	Nicotinamide-Adenine Dinucleotide
NCI	National Cancer institute
NYHA	New York Hart Association
ORR	Overall Response Rate
OS	Overall Survival
OTC	over the counter
PARP	Poly Adp Ribose Polymerase
PARPi	Poly Adp Ribose Polymerase inhibitor
PFS	Progression Free Survival
P-gp	Plasma P-Glycoprotein
PI	Principal Investigator
PIS	Patient Information Sheet

Abbreviation/Acronym	**Definition**
PR	Partial Response
RD	Recommended dose
RNA	RiboNucleic Acid
RP2D	Recommended phase 2 dose
s.c	Sub Cutaneous
SADR	Serious Adverse Drug Reaction
SAE	Serious Adverse Event
SD	Standard Deviation
SDV	Source Data Verification
SmPC	Summary of Products Characteristics
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reaction
t½	Half time
tmax	Time maximum
TEAE	Treatment Emergent Adverse Event
TIA	Transient Ischemic Attach
ULN	Upper Limit Normal
V2	Distribution

1. INTRODUCTION

This Statistical Analysis Plan describes the planned analyses and reporting for the clinical trial protocol AL-2003, conducted by Allarity Therapeutics, Inc.. The reader of this Statistical Analysis Plan (SAP) is encouraged to review the complete protocol and amendments as this plan contains only a limited overview of protocol information. The main objectives of this plan are to provide details pertaining to statistical methodology, data conventions, and processes used for the analysis of data from this trial.

The format and content of this SAP are structured to provide sufficient detail to meet the requirements specified by the International Council on Harmonization (ICH) E9: Guidance on Statistical Principles in Clinical Trials. All work planned and presented in this Statistical Analysis Plan will follow the ethical guidelines published by the American Statistical Association (ASA).

The following documents were reviewed in preparation of this Statistical Analysis Plan:

- Protocol version 2.0/ 19 Jul 2022
- ASA Ethical Guidelines for Statistical Practice (2016)
- The Royal Statistical Society: Code of Conduct (2014)
- ICH Guidance on the Structure and Content of Clinical Study Reports (ICH E3, 1996)
- ICH Guidance on the Structure and Content of Clinical Study Reports (ICH E3(R1), 2013)
- ICH Guidance on the Statistical Principles for Clinical Trials (ICH E9, 1998)
- ICH Guidance on the Statistical Principles for Clinical Trials (ICH E9(R1), 2017)

2. PROTOCOL DESIGN

2.1 Design Overview

2.1.1 Study Design

This is a Phase Ib, two-part, multi-center study. In Part 1, the study will evaluate the safety and tolerability, antitumor activity, pharmacokinetics, and determine the maximum tolerated dose (MTD) of 2X-121 monotherapy (at BID regimen) in patients with advanced solid tumors. In Part 2, the study will evaluate the safety and tolerability, antitumor activity, pharmacokinetics and determine the MTD of dovitinib when given in combination with the MTD of 2X-121 determined in Part 1.

Part 1

This part of the study will follow an accelerated titration method followed by a standard "3+3" design to determine the MTD of 2X-121. The MTD is defined as one dose level (cohort) below the dose in which dose limiting toxicities (DLTs) were observed in ≥ 33% of the participants.

The calculation of the sample size for this trial is based on the traditional 3 + 3 dose escalation scheme which is conducted as follows:

- Subjects are treated in cohorts of one (Cohort 1) or three (Cohorts 2-3), each receiving the same dose. For the assessment of a DLT subjects are observed for 14 days
- In Cohort 1, if the one subject does not exhibit a DLT, the next cohort of three subjects received the next higher dose. In Cohorts 2-3, if none of the three subjects of a cohort exhibits a DLT, the next cohort of three subjects receives the next higher dose.
- Otherwise, if at least one subject of a cohort exhibits a DLT, a further cohort of three subjects is treated at the same dose level (cohort) without escalating the dose.
- If exactly one out of the six subjects treated at this dose exhibits a DLT, the trial continues as planned at the next higher dose level (cohort).
- If two or more subjects out of the six subjects treated at this dose exhibit a DLT, the dose escalation stops at that level and the next lower dose is considered as the MTD. When the escalation has stopped, additional subjects will be treated at the MTD to a total of six subjects.

[redacted]

[redacted]

The dose levels to be evaluated in Part 1 are shown below:

Dose Cohort	2X-121 Monotherapy Dose (BID)
Cohort 1	600 mg (morning dose: 200 mg + evening dose: 400 mg)
Cohort 2	800 mg (morning dose: 400 mg + evening dose: 400 mg)
Cohort 3	1000 mg (morning dose: 400 mg + evening dose: 600 mg)

On Day 1 of first treatment cycle (C1D1), patients will be administered 2X-121 monotherapy as oral capsules taken twice daily. Each treatment cycle will consist of 28 days.

[redacted]

[redacted]

Once the MTD has been determined, subjects enrolled in lower dose cohorts will be allowed to escalate the dose to the MTD, if acceptable per the Investigator's discretion. Subjects will be eligible for continuing treatment in absence of progressive disease or unacceptable toxicity or withdrawal of consent.

Part 2

In Part 2 of the study, patients will receive dovitinib in combination with the MTD of 2X-121 determined in Part 1. Part 2 will also follow a "3+3" design to determine the MTD of dovitinib when given in combination with 2X-121. The MTD is defined as one dose level (cohort) below the dose in which dose limiting toxicities (DLTs) were observed in ⩾ 33% of the participants.

The dose levels to be evaluated in Part 2 are shown below:

Dose Cohort	Combination 2X-121 and Dovitinib
Cohort 1	2X-121 (MTD) + 300 mg dovitinib
Cohort 2	2X-121 (MTD) + 400 mg dovitinib
Cohort 3	2X-121 (MTD) + 500 mg dovitinib

Dovitinib will be administered once daily (morning) on a 5 days on/2 days off schedule. In a 28 day cycle, dovitinib will be administered C1D1 - C1D5, C1D8 - C1D12, C1D15 - C1D19, and C1D22 - C1D26.

[redacted]

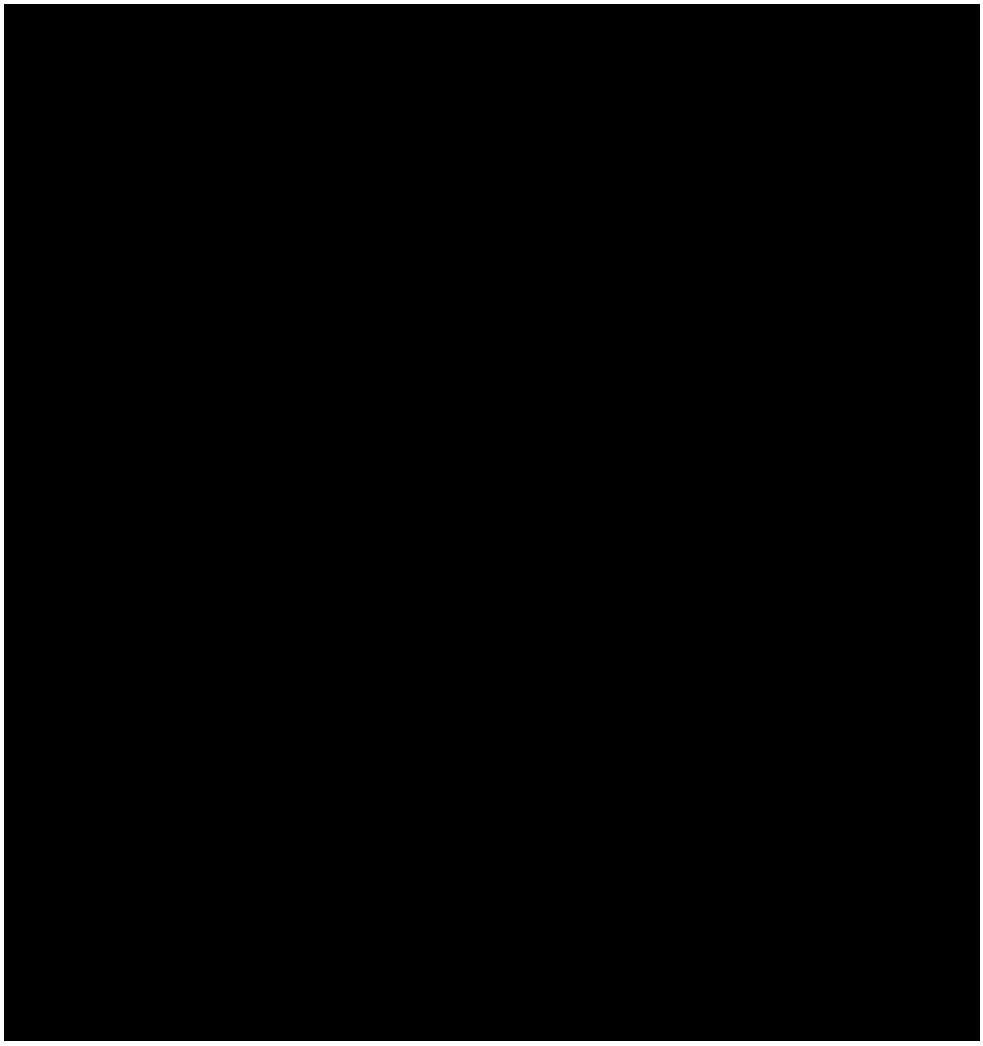
[redacted]

Once the MTD has been determined, subjects enrolled in lower dose cohorts will be allowed to escalate the dose to the MTD, if acceptable per the Investigator's discretion. Subjects will be eligible for continuing treatment in absence of progressive disease or unacceptable toxicity or withdrawal of consent.

An additional 3-6 patients will receive 2X-121 in combination with dovitinib once the MTD dose is determined.

A schematic of the "3 + 3" Dose Escalation Study Design is provided in Figure 2.1.

[redacted]



2.1.2 Study Visits

- **Screening Phase:** Up to 28 days
- **Treatment Phase:**
  - First Treatment Cycle: 4 weeks
  - Subsequent Treatment Cycles: Subjects will be eligible for continuing treatment in absence of progressive disease or unacceptable toxicity or withdrawal of consent
  - End of Treatment (EOT): EOT visit will be conducted 30 (±7) days after the last treatment visit (i.e., after last dose of 2X-121).

- **Follow-Up Phase:** Follow-up visits will be done for survival status, by clinic visits or phone or another method of contact at least every 3 months from the date of treatment discontinuation. All subsequent anti-cancer treatments are to be reported.

All patients are to be followed for 2 years or until death whichever comes first.

2.2 Cohort/Treatment Groups

Subjects in Part 1 of the study are described below in Table 2-1.

Table 2-1 Treatment Groups

Dose Cohort	2X-121 Monotherapy Dose (BID)
Cohort 1	600 mg (morning dose: 200 mg + evening dose: 400 mg)
Cohort 2	800 mg (morning dose: 400 mg + evening dose: 400 mg)
Cohort 3	1000 mg (morning dose: 400 mg + evening dose: 600 mg)

Subjects in Part 2 of the study are described below in Table 2-2.

Table 2-2 Treatment Groups

Dose Cohort	Combination 2X-121 and Dovitinib
Cohort 1	2X-121 (MTD) + 300 mg dovitinib
Cohort 2	2X-121 (MTD) + 400 mg dovitinib
Cohort 3	2X-121 (MTD) + 500 mg dovitinib

2.3 Randomization and Stratification

Not applicable.

2.4 Blinding

Not applicable.

2.5 Protocol Objective(s)

2.5.1 Primary Objectives

The primary objective of this study is:

Part 1

- To determine the maximum tolerated dose (MTD) of 2X-121 monotherapy given twice daily (BID) in patients with advanced solid tumors

Part 2

- To determine the MTD of dovitinib given in combination with 2X-121 (MTD) in patients with advanced solid tumors

2.5.2 Secondary Objectives

The secondary objectives of this study are:

- To evaluate the safety and tolerability of 2X-121 monotherapy (Part 1) and to evaluate the safety and tolerability of 2X-121 (MTD) in combination with dovitinib (Part 2) in patients with advanced solid tumors
- To evaluate the pharmacokinetics (PK) of 2X-121 monotherapy at each dose level (Part 1) and to evaluate the pharmacokinetics (PK) 2X-121 (MTD) in combination with dovitinib at each dose level (Part 1 and Part 2)
- To evaluate the anti-tumor activity of 2X-121 monotherapy (Part 1) and in combination with dovitinib (Part 2)

2.6 Study Outcome Measures

2.6.1 Primary Outcome Measure

The primary outcome measures in this study are:

Part 1

- Determination of the MTD of 2X-121 monotherapy

  Note: The MTD is defined as 1 dose level below the dose in which dose limiting toxicities (DLTs) were observed in ≥ 33% of the participants during the first 14 days of the main treatment period.

Part 2

- Determination of the MTD of dovitinib given in combination with 2X-121 (MTD)
  Note: The MTD is defined as 1 dose level below the dose in which dose limiting toxicities (DLTs) were observed in ≥ 33% of the participants during the first 14 days of the main treatment period.

2.6.2 Secondary Outcome Measures

The secondary anti-tumor activity outcome measures in this study are:

- To evaluate the objective response rate (ORR) of 2X-121 BID (Part 1) and in combination with dovitinib (Part 2)
  ORR is defined as the proportion of subjects who achieve a Complete Response (CR) or Partial Response (PR) as assessed by RECIST v1.1
- To evaluate the duration of overall response of 2X-121 BID (Part 1) and in combination with dovitinib (Part 2)
- To evaluate progression free survival (PFS) of 2X-121 monotherapy (Part 1) and in combination with dovitinib (Part 2)
  PFS is defined as the time from study treatment initiation to either first observation of progressive disease or occurrence of death.
- To evaluate overall survival (OS) of 2X-121 BID (Part 1) and in combination with dovitinib (Part 2)
  OS is defined as time from study treatment initiation to death from any cause or last day known to be alive.

2.6.3 Exploratory Outcome Measures

[redacted]

2.6.4 Pharmacokinetic (PK) Outcome Measures

The following pharmacokinetic parameters will be calculated for 2X-121 monotherapy at each dose level (Part 1) and for 2X-121 (MTD) in combination with dovitinib at each dose level (Part 2):

- Maximum concentration of 2X-121 (C_{max}) and dovitinib (C_{max})
- To Area under the plasma-time concentration curve (AUC)
- Elimination half-life of 2X-121 ($t_{½}$) and dovitinib ($t_{½}$)
- Time to maximum plasma concentration (t_{max})
- Total body clearance of 2X-121 (Cl/F) and dovitinib (Cl/F)
- Apparent volume of distribution (Vz/F)

2.6.5 Safety Assessments

The safety and overall tolerability of 2X-121 and dovitinib will be evaluated based on:

- Dose Limiting Toxicities
- Incidence and severity of treatment-emergent adverse events (TEAEs), including serious adverse events and adverse events resulting in permanent discontinuation of study treatment
- Laboratory data changes from baseline to subsequent scheduled visits
- Changes in physical examinations from baseline to subsequent scheduled visits
- Changes in vital signs from baseline to subsequent scheduled visits
- Changes in Eastern Cooperative Oncology Group (ECOG) performance status from baseline to subsequent scheduled visits
- Changes of electrocardiogram (ECG) results from baseline to subsequent scheduled visits

3. SAMPLE SIZE DETERMINATION, STATISTICAL POWER, AND SIGNIFICANCE LEVEL

A sample size of up to 16 subjects in Part 1 and up to 24 subjects in Part 2 will be used in this trial. This sample size is selected based on the conventional 3+3 study design and not

based on statistical power calculation; it is deemed adequate to provide clinically meaningful descriptive results consistent with study objectives.

4. INTERIM ANALYSIS

[redacted]

5. PRIMARY HYPOTHESIS TO BE TESTED

There is no formal hypothesis testing for this study as the study is a Phase I evaluation and is not intended to be hypothesis generating. The study is not powered to reliably yield statistically significant conclusions.

6. ANALYSIS POPULATIONS

[redacted]

[redacted]

7. DATA CONVENTION AND RELATED DEFINITIONS

7.1 Baseline Definition

For all parameters, baseline will be defined as the last available value before the first treatment.

7.2 Duplicate Data

[redacted]

7.3 Handling of Missing Data

7.3.1 Handling of Missing Data for Efficacy Evaluations

Every effort will be made to obtain required data at each scheduled evaluation from all subjects who have been enrolled to minimize missing data. [redacted]

7.3.2 Handling of Missing Data for Safety Evaluations

[redacted]

[redacted]

7.4 Multicenter Clinical Trials

This is a multi-center clinical trial.

7.5 Multiple Comparisons and Multiplicity

Not applicable.

7.6 Covariates and Prognostic Factors

[redacted]

7.7 Subgroups

There is no prespecified subgroup analysis for this study. Subgroup analysis may be conducted as needed.

7.8 Standard Calculations

7.8.1 Age

Age will be calculated according to the formula noted below.

Age (years) = integer of [(date of informed consent – date of birth)/ 365.25]

7.8.2 Body Mass Index (BMI)

BMI will be calculated using height (in cm) and weight (in kg) according to the formula noted below.

BMI (kg/m2) = Weight (kg)/[Height (cm)/100]^2

7.8.3 Change from baseline

Change from baseline will be calculated for each post baseline visit as follows:

Change From Baseline = Post baseline result at time - Baseline result

7.8.4 Time to event

Time to event will be calculated according to the formula noted below:

Time to event = (Date of Event – Date of study treatment initiation) + 1

[redacted]

[redacted]

8. STATISTICAL METHODS

All statistical analyses will be performed using SAS® for Windows, version 9.4 or later, and Phoenix® 8.1 WinNonlin® version or higher (Certara USA, Inc., Princeton, USA). All data collected during this study will be presented in subject data listings.

[redacted]

8.1 Summarizing Disposition and Baseline Data

8.1.1 Subject Disposition and Withdrawals

There will be a detailed accounting of all subjects who sign an informed consent to participate in this trial. [redacted]

[redacted]

8.1.2 Protocol Deviations

Protocol deviations for all enrolled subjects will be listed as by-subject listing and summarized descriptively.

8.1.3 Demographics and Baseline Characteristics

[redacted]

8.1.4 Medical History

Medical history will be coded using the most current available version of Medical Dictionary for Regulatory Activities (MedDRA) and will be summarized by system organ class (SOC) and preferred term (PT). Medical history results will be provided as by-subject listings and summarized.

8.1.5 Prior and Concomitant Medications

Prior medication is defined as any medications with an end date prior to the first treatment date.

All prior and concomitant medications recorded in the case report form will be listed and coded to matching Anatomic Therapeutic Classification codes using the most recent version of WHO Drug dictionary, and summarized by cohort and by the number and percentage of subjects taking each medication for the Safety population.

8.1.6 Prior Anti-Cancer Treatments

All prior anti-cancer treatments (i.e., Radiotherapy, Chemotherapy/Immunotherapy, and Surgery) recorded in the case report form will be presented as by-subject listings.

8.1.7 Extent of Exposure and Treatment Compliance

All treatment administration data will be listed and summarized for the Safety population by cohort.

[redacted]

[redacted]

[redacted]

8.2 Analysis of Efficacy Data

[redacted]

8.2.1 Primary Outcome Measure

The primary efficacy outcome measure for part 1 is determination of the MTD of 2X-121 monotherapy.

The primary efficacy outcome measure for part 2 is determination of the MTD of dovitinib given in combination with 2X-121 monotherapy.

8.2.1.1 Maximum Tolerated Dose (MTD)

The MTD is defined as the highest dose that does not produce unacceptable toxicity, or 1 dose level below the dose in which dose limiting toxicities (DLTs) were observed in ≥ 33% of the participants during the first 14 days of the main treatment period.

MTD will be determined by sponsor in consultation with the safety assessment committee.

8.2.1.2 Dose Limiting Toxicity (DLT)

All toxicities will be graded using NCI-CTCAE Version 5.0.

All DLTs will be presented as a by-subject listing and summarize descriptively for both parts of the study.

8.2.2 Secondary Outcome Measures

8.2.2.1 To evaluate the objective response rate (ORR) of 2X-121 BID (Part 1) and in combination with dovitinib (Part 2)

ORR is defined as the proportion of subjects who achieve a best overall response of Complete Response (CR) or Partial Response (PR) (confirmed or unconfirmed) as assessed by RECIST v1.1. [redacted]

8.2.2.2 To evaluate the duration of overall response of 2X-121 BID (Part 1) and in combination with dovitinib (Part 2)

The duration of overall response is measured from the time measurement criteria are met for CR or PR (confirmed or unconfirmed) (whichever is first recorded) until the first date that recurrent or progressive disease is objectively documented (taking as reference for progressive disease the smallest measurements recorded since the treatment started). The duration of overall CR is measured from the time measurement criteria are first met category when no lesions can be measured is not advised for CR until the first date that progressive disease is objectively documented. [redacted]

8.2.2.3 To evaluate progression free survival (PFS) of 2X-121 monotherapy (Part 1) and in combination with dovitinib (Part 2)

Time to PFS is defined as the time from study treatment initiation to either first observation of progressive disease or occurrence of death. Time to Progression Free Survival (PFS) will be calculated using the formula in Section 7.8.4.

[redacted]

The progression free survival (PFS) will be presented as by-subjects listings in both parts of the study.

[redacted]

[redacted]

8.2.2.4 To evaluate overall survival (OS) of 2X-121 BID (Part 1) and in combination with dovitinib (Part 2)

Time to OS is defined as time from study treatment initiation to death from any cause or last day known to be alive.

Time to OS will be defined in days and calculated using the formula in Section 7.8.4.

The overall survival (OS) will be presented and summarized descriptively by cohort.

[redacted]

8.2.3 Exploratory Outcome Measures

[redacted]

8.3 Analysis of Safety Data

All safety analyses will be conducted using the Safety population. All data collected will be summarized according to the variable type. No inferential statistics are planned.

[redacted]

8.3.1 Adverse Events

Adverse events will be classified by system organ class (SOC) and preferred term (PT) according to the most recent version of MedDRA dictionary.

TEAE are defined as adverse events with onset date on or after the first treatment. TEAEs will be summarized by treatment group, System Organ Class, and preferred term. [redacted]

All adverse events recorded in the eCRF will be presented as by-subject listings.

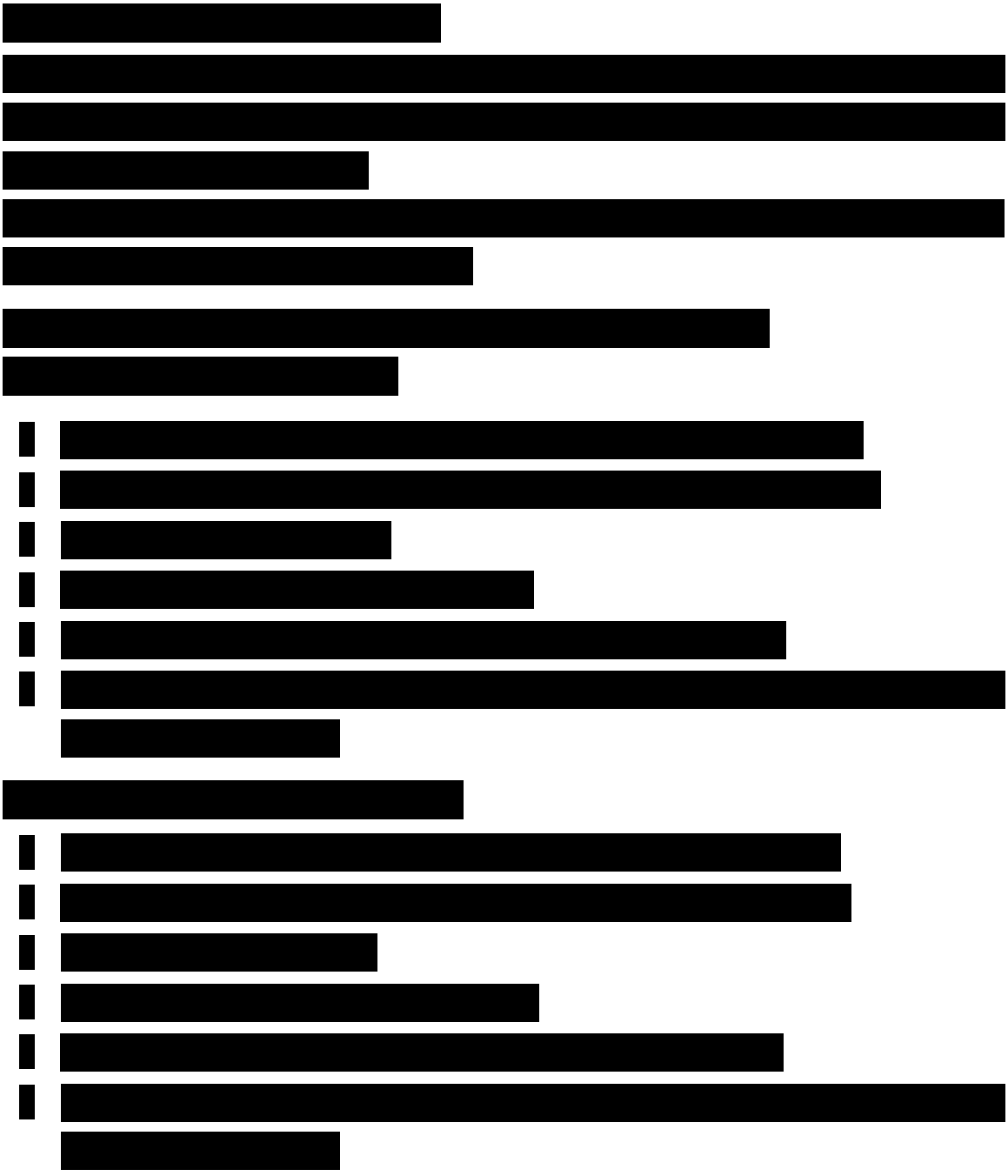
8.3.2 Clinical Laboratory Evaluations

All results of laboratory evaluations will be presented as by-subject listings.

[redacted]

8.3.3 Vital Signs

Vital sign assessments are performed in order to characterize basic body function. The parameters collected in this study are: systolic BP (mmHg), diastolic BP (mmHg), temperature (^{0}C), heart rate (bpm), respiratory rate (bpm). All vital sign results will be listed as by-subject listing.



[redacted]

8.3.4 Physical Examination

All results of physical examination evaluations will be listed as by-subject listing.

8.3.5 Electrocardiogram (ECGs)

[redacted] All ECG results will be listed as by-subject listing.

[redacted]

[redacted]

8.3.6 Serum Pregnancy Test

All the results for serum pregnancy test will be presented as a by-subject listing.

8.3.7 Urine Pregnancy Test

All data from Urine Pregnancy test will be presented as a by-subject listing.

8.3.8 Eastern Cooperative Oncology Group (ECOG) Test

All data from Eastern Cooperative Oncology Group (ECOG) test will be presented as a by-subject listing and/or summarized.

[redacted]

[redacted]

8.3.13 Pregnancy Notification

All data from Pregnancy Notification will be presented as a by-subject listing and/or summarized.

8.3.14 Pregnancy Outcome Report

All data from Pregnancy Outcome Report will be presented as a by-subject listing and/or summarized.

8.4 Analysis of Pharmacokinetic Outcome Measures

[redacted]

8.4.1 Estimate of Pharmacokinetic Parameters

The following PK parameters will be calculated using noncompartmental methods for each single dose administration in both parts of the study.

- Maximum observed plasma drug concentration (C_{max})
- Apparent terminal elimination half-life ($t_{1/2}$)
- Time to maximum observed plasma drug concentrat ion (T_{max})
- Area under the plasma drug concentration-time curve (AUC) from time 0 to the time of the last quantifiable concentration (T_{last}) (AUC_{0-t})
- AUC from time 0 to infinity ($AUC_{0-\infty}$)
- Percentage of $AUC_{0-\infty}$ extrapolated from Tlast to infinity (AUC_{ext})
- Apparent plasma clearance (CL/F)
- Apparent Volume of distribution (Vz/F)

9. APPENDIX 1

FIGURE 9-1: SCHEDULE OF ASSESSMENTS – PART 1

Study Phase	Screening Phase	Treatment Phase									Follow-up Phase	
		Treatment Cycle 1 (28 Days)				Treatment Cycle 2 (28 Days)			Subsequent Treatment Cycles (28 Days)			
Visit	SV	C1D1	C1D7	C1D15	C1D16	C2D1	C2D7	C2D15	CXD1	CXD15	EOT	FU
Window	Within 28 Days of C1D1		±1 Day	±1 Day	±1 Day	±1 Day	±1 Day	±1 Day	±1 Day	±1 Day	30 Days (±7) after last treatment dose	x (±3) Days after EOT
[redacted]												
[redacted]	X											
[redacted]	X											
[redacted]	X											
[redacted]	X											
[redacted]	X	X	X	X	X	X		X	X		X	
[redacted]	X	X [5]	X [5]	X [5]	X [5]	X [5]	X [5]	X [5]	X [5]	X [5]	X [5]	
[redacted]	X	X		X[6]		X[6]		X[6]	X[6]	X[6]	X	
[redacted]	X	X				X			X		X	
[redacted]	X	X				X			X		X	
[redacted]		X										X
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[redacted]	X [8]								X [7]			
[redacted]												
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[redacted]	X	X				X			X		X	
[redacted]	X	X									X	
[redacted]		X	X	X	X	X		X	X			


X

FIGURE 9-2: SCHEDULE OF ASSESSMENTS – PART 2

Study Phase	Screening Phase	Treatment Phase								Follow-Up Phase	
		Treatment Cycle 1 (28 Days)			Treatment Cycle 2 (28 Days)			Subsequent Treatment Cycles (28 Days)			
Visit	SV	C1D1	C1D7	C1D15	C2D1	C2D7	C2D15	CXD1	CXD15	EOT	FU
Window	Within 28 Days of C1D1		±1 Day	±1 Day	±1 Day	±1 Day	±1 Day	±1 Day	±1 Day	30 Days (±7) after last treatment dose	x (±3) Days after EOT
[redacted]											
[redacted]	X										
[redacted]	X										
[redacted]	X										
[redacted]	X										
[redacted]	X	X	X	X	X		X	X		X	
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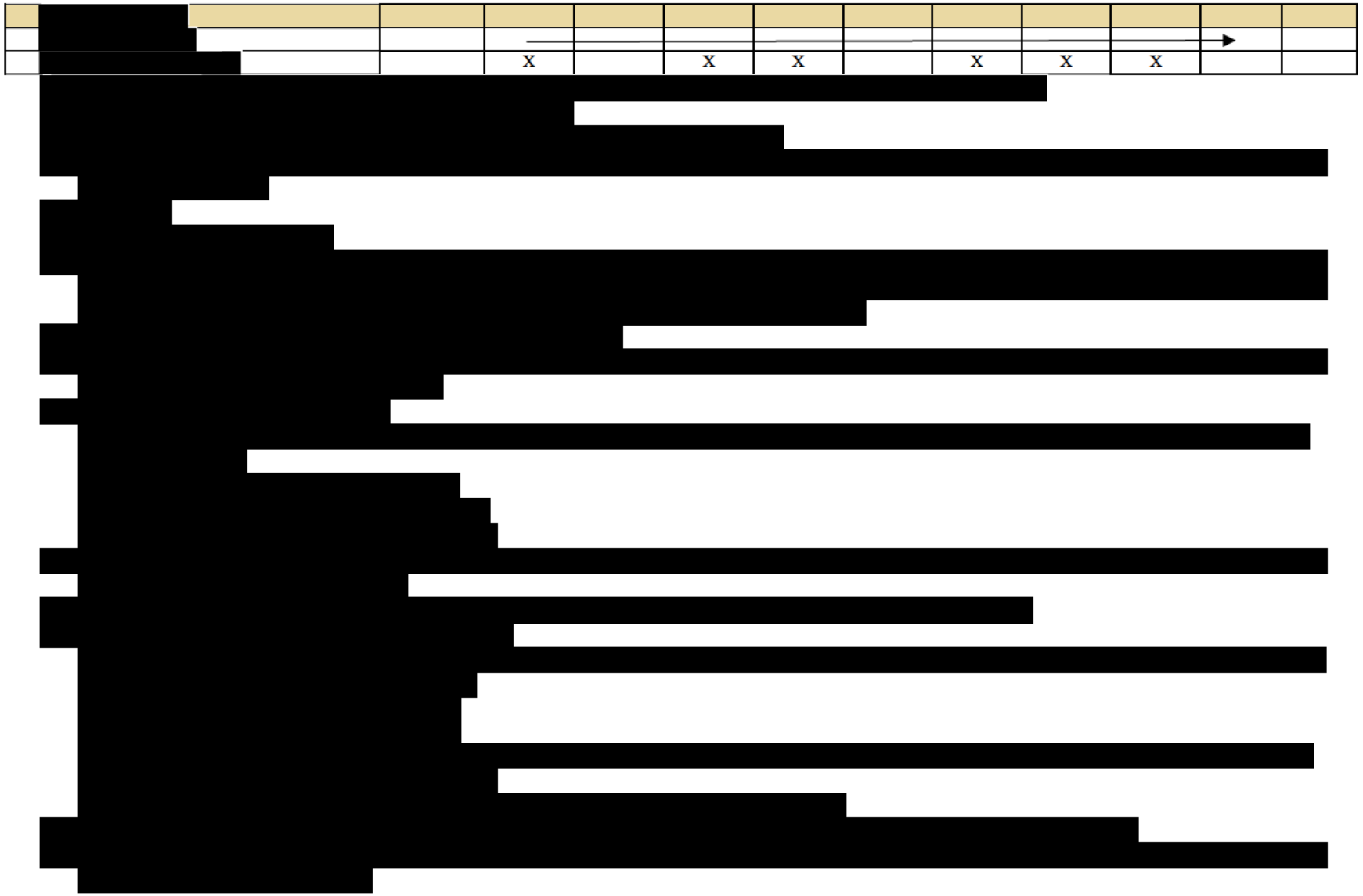
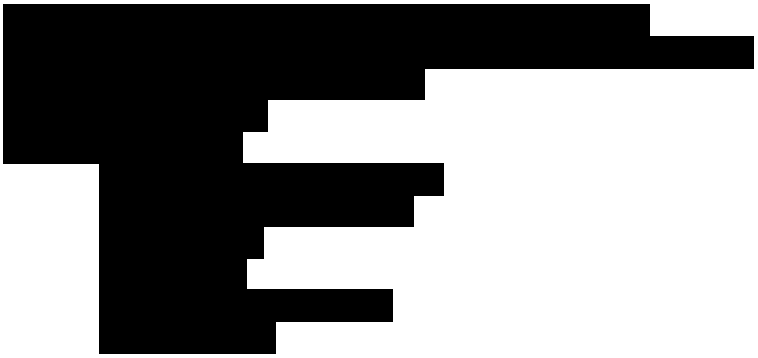
[redacted]											
[redacted]	X	X	X	X	X	X	X	X	X	X	
[redacted]	X	X		X	X		X	X	X	X	
[redacted]	X	X			X			X		X	
[redacted]	X	X								X	
[redacted]		X	X	X	X		X	X			
[redacted]	X										



10. APPENDIX 2

10.1 Planned by-subject listings

10.2 Planned Summary Tables



11. REFERENCES

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2. The Royal Statistical Society: Code of Conduct (2014)
3. ICH Guidance on the Structure and Content of Clinical Study Reports (ICH E3, 1996)
4. ICH Guidance on the Structure and Content of Clinical Study Reports (ICH E3(R1), 2013)
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12. VERSION HISTORY

This is the first version of this document.