SPONSOR:

BioMed Valley Discoveries

PROTOCOL NUMBER:

BVD-523-HCQ

STATISTICAL ANALYSIS PLAN

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Study Title:	A phase 2 basket trial of ulixertinib in combination with hydroxychloroquine in patients with advanced gastrointestinal malignancies harboring MAPK pathway mutations (BVD-523-HCQ)
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We, the undersigned, confirm that we have read, understood and agree to the content of this document and hereby authorise its approval.

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3 List of Abbreviations

AE	Adverse Event
ATC	Anatomical Therapeutic Chemical Classification
BOR	Best Overall Response
BRAF	V-raf murine sarcoma viral oncogene homolog B1
BVD	BioMed Valley Discoveries
CI	Confidence interval
CM	Concomitant medications
CR	Complete Response
CRA	Clinical Research Associates
CRC	Colorectal cancer
CRO	Clinical Research Organization
DBP	Diastolic blood pressure
DOR	Duration of response
EAS	Evaluable Analysis Set
EC	Ethics Committee
eCRF	Electronic Case Report Form
ERK	Extracellular signal-regulated kinase
FAS	Full Analysis Set
ICF	Informed consent form
ICH	International Conference on Harmonization
IRB	Institutional Review Boards
IxRS	Interactive Voice/Web Response System
MedDRA	Medical Dictionary for Regulatory Activities
MEK	Mitogen-activated protein kinase/extracellular signal-related kinase
mRNA	Messenger ribonucleic acid
NCI CTCAE	National Cancer Institute Common Terminology Criteria for Adverse Events
ORR	Overall Response Rate
OS	Overall survival
PD	Pharmacodynamic
PDCF	Protocol Deviation Criteria Form

PFS	Progression Free Survival
PK	Pharmacokinetic
PP	Per-protocol analysis set
PR	Partial Response
PT	Preferred Term
SAE	Serious adverse event
SAP	Statistical analysis plan
SBP	Systolic blood pressure
SMC	Safety Monitoring Committee
SOC	System Organ Class
TEAE	Treatment Emergent Adverse Event
TFLs	Tables, listings and figures
WHO	World Health Organization

4 Introduction

The purpose of this document is to describe the statistical methods, data derivations and data summaries to be employed in the analysis of the Phase II study titled "A phase 2 basket trial of ulixertinib in combination with hydroxychloroquine in patients with advanced gastrointestinal malignancies harboring MAPK pathway mutations (BVD-523-HCQ)". This is an open-label, prospective phase two basket trial assessing the efficacy of ulixertinib in combination with hydroxychloroquine in patients with advanced gastrointestinal malignancies. All patients enrolled must have a MAPK activating mutation to be deemed eligible for trial participation. Each disease-based basket will open to enrollment in two-stages. The opening of stage two will be dependent on the observed responses in the patients enrolled in the first stage.

This statistical analysis plan (SAP) covers the final analysis for the study. The list of tables, figures and listings (TFLs) to be developed for each analysis, as well as the shells for each TFL, are described in a separate document.

The preparation of this SAP is based on study Protocol version 2.0 from 02May2023, the most up to date electronic Case Report Form (eCRF) version and on the International Conference on Harmonization (ICH) E3 and E9 Guidelines.

5 Study Objectives

The primary, secondary, and exploratory objectives along with the associated endpoints as per the study protocol are presented as follows:

Primary Objective

- To assess the safety and tolerability of ulixertinib and hydroxychloroquine in patients with advanced, RAS, non-V600 BRAF, MEK1/2, or ERK1/2 mutated gastrointestinal (GI) malignancies.
- To assess the efficacy of ulixertinib and hydroxychloroquine in patients with advanced, RAS, non-V600 BRAF, ERK1/2, or MEK1/2 mutated gastrointestinal malignancies.

Primary Endpoint

- The incidence and frequency of adverse events (AEs) and serious adverse events (SAEs) characterized by type, severity (as defined by the national Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE, version 5.0), seriousness, duration, and relationship to study treatment.
- Overall response rate as defined by the proportion of patients achieving a confirmed PR and CR (defined by RECIST 1.1) as evaluated by the local treating investigator.

Secondary Objective

- To assess the duration of efficacy of ulixertinib and hydroxychloroquine in patients with advanced RAS, non-V600 BRAF, MEK1/2 or ERK1/2 mutated gastrointestinal malignancies.

Secondary Endpoint

- Progression-free survival (PFS) as defined as the time from study drug initiation to the time of documented disease progression (as assessed by RECIST 1.1) or death from any cause.

Exploratory Objective

- To evaluate the bioactivity of ulixertinib and hydroxychloroquine against ERK1/2, autophagy pathways, and pharmacodynamic biomarkers.

Exploratory Endpoint

- Pharmacokinetics (PK) of ulixertinib and hydroxychloroquine.
- Blood and/or tissue samples used to assess biomarkers (RPPA, Nanostring, circulation tumor (ctDNA) examples of assays planned but not limited to only these).

6 Study Design

6.1 STUDY DESIGN AND POPULATION

This is an open-label, multicenter, phase II basket study of ulixertinib in combination with hydroxychloroquine in patients with advanced gastrointestinal malignancies harboring RAS, non-V600 BRAF, MEK1/2, or ERK1/2 mutations. The trial will have five baskets based on primary disease as listed below:

- *Basket 1:* Cholangiocarcinoma including intrahepatic cholangiocarcinoma, perihilar cholangiocarcinoma, or extrahepatic cholangiocarcinoma.
- *Basket 2:* Pancreatic adenocarcinoma.
- *Basket 3:* Colorectal adenocarcinoma.
- *Basket 4:* Esophageal adenocarcinoma, esophageal squamous cell carcinoma, or GEJ adenocarcinoma.
- *Basket 5:* Gastric adenocarcinoma.

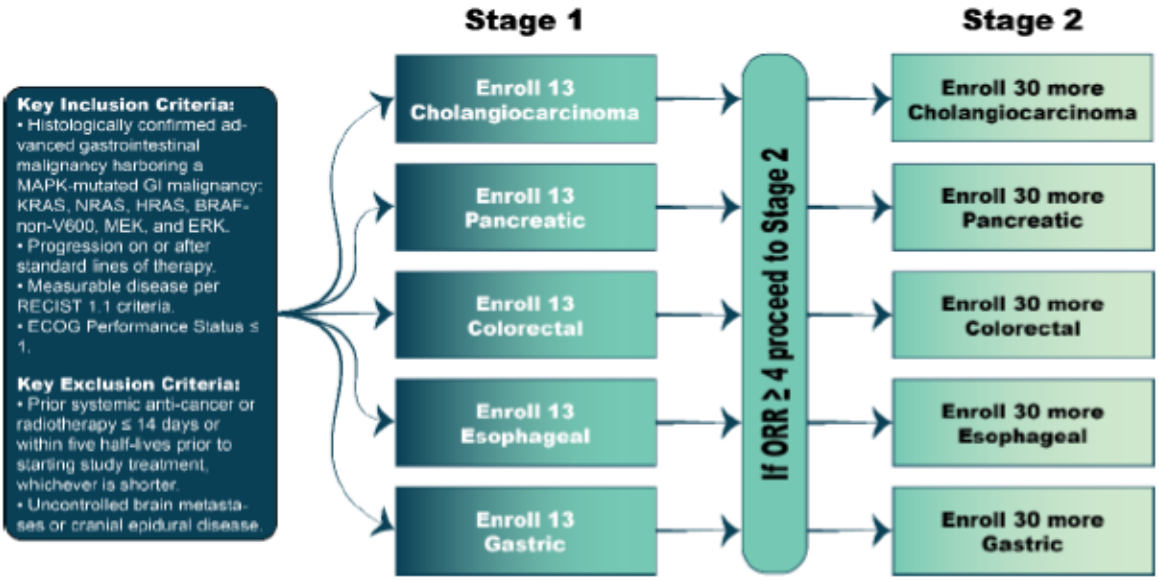
To assess eligibility, cancer mutational status must be confirmed through patient medical records by treating physician. Once deemed eligible, ulixertinib and hydroxychloroquine will be orally administered twice daily on 28-day cycles. Safety will be assessed regularly through the

monitoring of adverse events, laboratory values, physical exams, vital signs, echocardiogram, eye exams, and ECGs. Disease assessments will be performed regularly as well to assess treatment efficacy. Upon disease progression, patients will be followed for safety for 60 days ± 7 days.

While the overall trial is a basket design, each basket will operate as a Simon two-stage design and therefore, will open to enrollment in two-stages.

An overview of the study design is presented in Figure 1 below.

Figure 1. Study Design



The first stage in each basket will open to enrollment and remain open until 13 patients are declared evaluable for response, at which time enrollment will be placed on hold for the evaluation of efficacy. To be evaluable for this Stage 1 efficacy analysis, a patient must have completed at least one cycle of therapy and must have at least 75% of the prescribed doses of ulixertinib and hydroxychloroquine during Cycle 1. Non-evaluable patients may remain on study therapy if deemed to be clinically benefiting by the treating Investigator.

The Stage 1 efficacy analysis will occur when all evaluable patients have had at least one post-treatment disease evaluation or have discontinued study therapy due to clinical progressive disease or drug-related adverse events. Patients who have discontinued study therapy due to clinical progressive disease or drug-related adverse events prior to the first efficacy evaluation will be considered non-responders. If a patient in the first 13 evaluable patients has an unconfirmed partial or complete response but has not yet had a confirmatory scan at the time

of the Stage 1 efficacy analysis, that patient may be counted as a responder for the purposes of the Stage 1 evaluation. If ≥ 4 of the first 13 evaluable patients in Stage 1 have a complete or partial response, with permission of the SMC the sponsor may open enrollment to Stage 2 for that basket. Stage 2 will expand enrollment of each basket until a total of 43 patients, including those enrolled during Stage 1, have been enrolled. Any patient deemed non-evaluable for the primary efficacy endpoint may be replaced.

An internal SMC will be charged with assuring risk/benefit balance for patients involved in the study. They will make study conduct recommendations based on emerging safety and efficacy data. Stage 2 of enrollment on each basket will not open until data review and approval from the SMC.

6.2 STUDY TREATMENTS AND ASSESSMENTS

Ulixertinib and hydroxychloroquine will be administered twice-daily on a 28-day cycle starting with Cycle One Day One. Ulixertinib and hydroxychloroquine will be administered orally twice daily (every 12 hours ± 2 hours) together with food, at approximately the same time every day. Patients will be provided the study drug for a full cycle to self-administer at home.

Dose interruptions for study treatment-related AEs are allowed as per the dose modification recommendations (Table 1).

Table 1. Ulixertinib and Hydroxychloroquine Dose Levels

Dose Level	Ulixertinib
Dose Level 0	450 mg twice daily
Dose Level -1	300 mg twice daily
Dose Level -2	150 mg twice daily

Dose Level	Hydroxychloroquine
Dose Level 0	600 mg twice daily
Dose Level -1	800 mg daily

Doses of any investigational product that were not administered due to toxicity will not be replaced within the same cycle. In addition to dose interruption, the need for a dose reduction at the time of treatment resumption should also be considered based on the dose modifications recommendations. If toxicities require dose hold, both study drugs should be held and resumed concurrently. If a toxicity-related dose delay lasts for > 21 days, treatment will be discontinued permanently, and the patient should be removed from study treatment. If a patient requires a dose hold for > 21 days for a non-treatment related adverse event or situation (i.e. radiation therapy) the patient may continue on study only after approval and discussion with the Sponsor and Medical Monitor.

6.3 RANDOMIZATION AND BLINDING

Not applicable.

6.4 SAMPLE SIZE JUSTIFICATION

Under Simon's optimal two-stage design with a 5% significance level and 80% power, assuming a null hypothesis for ORR ≤ 20% versus the alternate hypothesis of ORR ≥ 40%, a total of 43 evaluable patients are required for the evaluation of the primary endpoint; 13 in Stage 1 and an additional 30 in Stage 2, for each basket.

In the first stage, if there are 3 or fewer patients achieving a response in the 13 patients, the study will be stopped for this basket. Otherwise, 30 additional patients will be accrued for a total of 43.

Then, if there are 12 or fewer responses in the 43 patients, the null hypothesis will not be rejected and any further investigation of the study medication in this basket will not be warranted. However, should at least 13 of the 43 evaluable patients achieve a response then the null hypothesis will be rejected, and it will be concluded that the study medication demonstrates activity for this basket to allow further investigation.

7 Statistical Considerations

7.1 STUDY TREATMENT

The study drugs are ulixertinib (BVD-523) and hydroxychloroquine. The study treatment refers to treatment with ulixertinib (BVD-523) and hydroxychloroquine.

7.2 PLANNING OF ANALYSES

This SAP covers the final analysis for the study. The planned timing of analysis for this study is after the last patient completes 8 cycles.

As per the Protocol a Safety Monitoring Committee (SMC) will occur for bi-annual or ad-hoc reviews as needed. The Tables, Figures and Listings (TFLs) planned in this SAP may also be used for SMC meetings as applicable. The TFLs shells table of contents will flag which outputs will be prepared for SMC purposes.

Given that the study was early terminated during Stage 1, an abbreviated CSR focusing on safety will be prepared. Therefore not all Tables, Listings and Figures planned in SAP version 1 will be required. The Shells table of contents will have an additional column to indicate which outputs will be delivered for the final analysis of Stage 1.

7.3 STUDY AND ANALYSIS PERIODS

Study periods are summarized in Table 1 below. Analysis periods will mirror these periods and are summarized in Table 2 below.

Table 1. Study periods

Period	Visit	Planned days
SCREENING	Screening (up to 4 weeks before Baseline)	Day -28 to Day -1
TREATMENT	Cycle 1	Baseline Day 8 ± 2 Day 15 ± 2
	Cycle 2	Day 1 ± 2 Day 15 ± 2
	Cycle 3 – Cycle n	Day 1 ± 2
POST TREATMENT	End of Treatment (EOT) Visit	+7 days after last dose
	Safety Follow-Up	60 ± 7 days after last dose
	Follow-Up	Every 8 months (± 7 days) until death, disease progression or initiation of subsequent anticancer therapy.

Table 2. Analysis periods

Period	Definition
PRE-TREATMENT	From informed consent form (ICF) signature to the day before first dose of study treatment.
ON-TREATMENT	From the day of first dose of study treatment to 28 days after last dose of study treatment, or the earliest date of subsequent anti-cancer drug therapy – 1 day, whichever occurs first.
FOLLOW-UP	Follow-up period will be from the end of the on-treatment period until end of study.

7.4 SOFTWARE

The SAS Viya version 3.5 or higher, will be used for all analysis, unless otherwise specified.

7.5 MISSING DATA HANDLING

No imputation for missing data will be carried out other than to complete partial dates using standard imputation techniques as described below in Section 7.6.

7.6 PARTIAL DATE IMPUTATION

Detailed rules for partial date imputation are described below.

A permanent new date variable should be created if there is a requirement to be used in

determining flags (such as on-treatment flags), sort orders and other derived variables needed for a table, listing, or figure. Imputed date variable names will be defined in the derived dataset specifications.

Original (raw) date variables must not be overwritten. Imputed dates will not be displayed in the listings.

General rules for Adverse events (AE) and prior and concomitant medications (CM)

In case of partial dates with missing day:

For AE and CM, any partial start date during the month of first dosing will be imputed to be the date of first dose, taking the worst-case scenario.

For any AE and CM starting after the month of first dosing, the start date will be imputed to be the first day of the month.

For any AE and CM starting before the month of first dosing, the start date will be imputed to be the last day of the month.

Partial AE and CM end dates will be imputed to be the last day of the month or at the date of study discontinuation/completion, whichever occurs first.

In case of partial dates with missing day and missing month:

For AE and CM, any partial start date during the year of first dosing will be imputed to be the date of first dose, taking the worst-case scenario.

For any AE and CM starting after the year of first dosing, the start date will be imputed to be the first day of the year (i.e. 01 January).

For any AE and CM started before the year of first dosing, the start date will be imputed to be the last day of the year (i.e. 31 December).

Partial AE and CM end dates will be imputed to be the last day of year (i.e. 31 December) or at the date of study discontinuation/completion, whichever occurs first.

Some examples are given below (DDMMMYYYY).

In most cases, start dates are imputed as first day of the month or first of January.

Table 3: Examples of missing dates imputation

Data Type	Start Date	Imputed Start Date	First Dose date	End Date	Imputed End Date
Adverse Event, Prior/Concomitant Meds	JAN2017	31JAN2017	11NOV2017	MAR2017	31MAR2017
Adverse Event, Prior/Concomitant Meds	MAR2017	01MAR2017	27JAN2017	MAR2017	31MAR2017
Adverse Event, Prior/Concomitant Meds	2017	27JAN2017	27JAN2017	2017	16MAR2017£
Adverse Event, Prior/Concomitant Meds	MAR2017	01MAR2017	27JAN2017	MAR2017	01MAR2017*
Adverse Event, Prior/Concomitant Meds	JAN2017	31JAN2017	27FEB2017	2017	31DEC2017

£ Patient discontinued on 16MAR2017; * Patient discontinued on 01MAR2017.

Rules for other partial dates

Partial dates are not expected for death. However, should a partial date be present for death, the date will be imputed to be the day after the last visit/assessment date when the patient was known to be alive, if there is at least one visit/assessment during the month of the corresponding partial death date. If there is no visit/assessment performed during the month of the corresponding partial death date, then the partial death date would be imputed as the first day of the month. A similar approach will be followed for partial date for death in which only year is known.

If partial date is present for dates related to disease history, the same rules as for AE and CM will be applied.

7.7 VISIT WINDOWING

Planned assessments will not be re-assigned to any planned visits using statistical programming based on assessment date. All the data will be analysed according to the planned visit as collected in the eCRF. Data obtained at unscheduled and repeat assessments will be considered for the derivation of baseline, worst on-treatment result for safety analyses (clinical safety laboratory evaluation, other safety data), and time to event analyses.

7.8 REPORTING GUIDELINES

Visit labels

The visit labels displayed in Table 4 will be used to display results in the TFLs. Following Cycle 2, any subsequent Cycle will consider Day 1 as start of Cycle and not the days since first study dose as for Cycle 2.

Table 4. Visit Labels

Period	Visit	TFLs Label
Screening: Day -28 to Day -1	Screening Day -28 to Day -1	Screening
Cycle 1	Cycle 1 Day 1	Baseline
	Cycle 1 Day 8	C1D8
	Cycle 1 Day 15	C1D15
Cycle 2	Cycle 2 Day 29	C2D29
	Cycle 2 Day 36	C2D36
	Cycle 2 Day 43	C2D43
Cycle 3	Cycle 3 Day 1	C3D1
...	...	...
Cycle n	Cycle n Day 1	CnD1
End of Treatment: +7 days after last dose of study treatment.	End of Treatment Visit	EOT
Safety Follow-Up: 60 ± 7 days after last dose of study treatment.	Safety Follow-Up	SFU
Follow-Up: every eight months (± 7 days) until death, disease progression or initiation of subsequent anticancer therapy whichever comes first.	Follow-Up	FUn

Summaries of baseline and change from baseline

Baseline and change from baseline will be calculated for all assessments, including additional assessments (if applicable), as follows:

- Baseline is defined as the last available assessment prior to first dose of both study treatment, including additional assessments (where applicable). Assessments that occurred on the same day as first dose, when time of assessment is not available, will be assumed to be prior to first dose (unless the assessment is planned after first dose in the protocol).
- Change from baseline will be calculated as the difference between the post-baseline assessment value and the baseline value.

Whenever applicable, percent change from baseline will be calculated as the difference between the post-baseline assessment value and baseline value divided by the baseline value multiplied by 100. Percent change will only be calculated when possible (e.g. if baseline value is 0 or the data has negative values as a possible occurrence percent change will not be calculated).

Unscheduled visit / Repeat assessments

Data obtained at unscheduled and repeat assessments will be considered for the derivation of baseline, worst on-treatment result for safety analyses (clinical safety laboratory evaluation and vital signs), and time to event analyses.

All other data from unscheduled or repeat assessments will not be included in summaries and will only be presented in data listings, if not otherwise specified.

N

N will be the number of patients in the specified population and group.

Summary presentation

All outputs will be presented by basket as defined in SAP section 6.1 and overall if not otherwise specified.

Continuous data

Continuous data will be summarized using number of patients (n), mean, standard deviation, median, first and third quartiles (Q1 and Q3), minimum value, and maximum value.

Categorical data

Categorical data will be summarized using n and percentage.

- All categories will be presented, even if no patients are counted in a particular category, unless otherwise stated.
- A missing category will be displayed in all tables for categories where at least one missing value exists, unless otherwise specified.
- Counts of zero in any category will be presented without percentage.
- All summary percentages will be calculated using N, unless otherwise stated in a footnote.
- For AEs, medical history, prior and concomitant medications, the counts are based on single counts of patients with multiple events/treatments under the same category, while the percentages are calculated using N. Counts will be displayed by descending order of frequency for the overall group by dictionary hierarchy.

Precision of summary statistics

- Integer – Sample size (n, N) and number of missing data (if displayed).
- One additional decimal place than reported/collected – Mean, median, other percentile, confidence interval.
- Two additional decimal places than reported/collected – Standard deviation.
- Same number of decimal places as reported/collected – Minimum, maximum.
- Percentages – One decimal place.

Study day

Study day will be calculated as (assessment date – date of first study treatment dose) for pre-baseline assessments and [(assessment date – date of first study treatment dose) + 1] for post-baseline assessments, i.e. there will be no study day 0 and study day 1 will correspond to the first study treatment dose.

Ordering

Data will be presented in listings in order of group, patient ID, visit, assessment date/time, and assessment type/parameters chronological order unless otherwise specified. In case of clinical laboratory results, the listings will be presented in order of group, patient ID, parameter, assessment date/time, visit.

Date format

Dates will be presented in format DDMMMYYYY.

Dictionaries

Latest version of Medical Dictionary for Regulatory Activities (MedDRA) will be used for the relevant outputs.

Latest version of World Health Organization (WHO) Drug Global B3 will be used for the relevant outputs.

NCI-CTCAE v5.0 will be used for the relevant outputs.

The version will be documented in the footnote of the corresponding TFLs.

File naming

Each TFL output file will be named with a t, l, or f added before the TFL number to denote the output type and then according to its table numbering in the following way: Table 14.2-1.1 would be t14_2_1_1, Table 14.2-11 would be t14_2_11, Listing 16.2.7-1.1 would be l16_2_7_1_1, and Figure 14.2-2.1 would be f14_2_2_1.

Reporting guidelines

- Page Orientation: Landscape.
- Tables and listings: will be created in .rtf.
- Figures: will be generated directly in .rtf.
- Font: Courier New font with minimum of 8-point font size.
- Margins: Left: 3.8 cm, Right: 2 cm, Top: 3 cm, Bottom: 2 cm, on A4 paper.
- Columns header will be left aligned for listings.

8 Analysis Sets

All Patients Analysis Set

All Patients Set will include all patients who were enrolled (signed informed consent) regardless

of whether they received the study drug or not.

Full Analysis Set

The full analysis set (FAS) will consist of all patients who received at least one dose of both study medications. This analysis set will be used for all safety and efficacy analyses.

Stage 1 Analysis Set

The Stage 1 analysis set (S1AS) will consist of the first 13 patients who have completed at least one cycle of therapy and who have received a minimum of 75% of prescribed study therapy during Cycle 1. This analysis set will be used only for the purpose of the Stage 1 efficacy analysis.

Evaluable Analysis Set

The evaluable analysis set (EAS) will consist of all patients who received at least one dose of study drug and have at least one post-treatment study evaluation or who have discontinued therapy prior to the first post-treatment study evaluation due to clinical progressive disease or drug-related adverse events. This analysis set will be used for the evaluation of the primary efficacy endpoint, i.e., ORR, and all the secondary efficacy endpoints.

PK Analysis Set

The PK analysis set will consist of all patients who have received at least one dose of study medication and have at least one post dose PK measurement. This analysis set will be used for PK analyses.

Given that the study was early terminated and an abbreviated CSR focusing mostly on safety data will be prepared, S1AS, EAS and PK will not be used in any analysis.

9 Methods of Analyses and Presentations

9.1 PATIENT DISPOSITION

The patient disposition data will be presented by basket and overall, on the All Patients Analysis Set. The number and percentage of patients belonging to the following disposition modalities will be presented along with the reason for discontinuation: patients enrolled, patients eligible for inclusion in the study, patients completed/discontinued screening, patients rescreened, patients treated, patients completed/discontinued treatment, patients completed/discontinued study.

The number and percentage of patients in each analysis set will also be presented.

A consort diagram with disposition information will also be provided.

In addition, information on analysis sets, study completion and discontinuation, informed consent

and failed inclusion and exclusion criteria will be included in the listings.

9.2 PROTOCOL DEVIATIONS AND/OR VIOLATIONS

ICH E3 Q&A R1 defines a protocol deviation as "any change, divergence, or departure from the study design or procedures defined in the protocol", and important protocol deviations as "a subset of protocol deviations that may significantly impact the completeness, accuracy, and/or reliability of the study data or that may significantly affect a patient's rights, safety, or well-being". The non-compliance may be either on the part of the patient, the investigator, or the study site staff. The list of potential protocol deviations, including classification (Important/Non-important) for each protocol deviation, will be pre-defined in the Protocol Deviation Criteria Form (PDCF).

Protocol deviations identified during the trial by the Clinical Research Associates (CRAs), Medical Monitors, or Data Managers will be tracked throughout the study using a protocol deviation tracker and classified as Important/Non-important. All protocol deviations will be read into SAS® prior to reporting.

Prior to data lock for the primary and final analyses, a review classification meeting will be held to review protocol deviations and classifications, and to agree on the final analysis sets.

Important protocol deviations will be summarized (frequencies and percentages) by deviation category and summary term on the FAS.

A listing of all protocol deviations will be provided for all patients.

9.3 DEMOGRAPHIC AND BASELINE CHARACTERISTICS

The following demographic and baseline characteristics will be summarized using descriptive statistics and presented by basket and overall on the FAS:

- Age at baseline (years), as derived in the eCRF - continuous and categorical using EudraCT categorization (18-64, 65-84, ≥ 85)
- Sex at Birth
- Childbearing/Reproductive potential
- Ethnicity
- Race
- Height at baseline (cm)
- Weight at baseline (kg)
- ECOG performance status at baseline
- Smoking history
- Gene/Codon/Amino acid change as reported in the eCRF

The following disease history characteristics will be summarized using descriptive statistics and presented by basket and overall on the FAS:

- Cancer Diagnosis (only reported diagnosis will be displayed, not all categories displayed in the CRF)
- Time since initial diagnosis (in months)
- Disease stage at initial diagnosis (from 1 to 4)
- Disease stage at enrollment (from 1 to 4)
- Prior Radiation Therapies (Yes/No)

Time since initial diagnosis will be calculated as [(date of first dose of study treatment - date of diagnosis) / 30.4375].

In addition, listings of the above data will be produced for all patients.

A by-patient, detailed listing of smoking history will be also presented.

9.4 MEDICAL HISTORY AND CONCOMITANT DISEASES

Medical history and concomitant diseases will be coded using MedDRA.

Medical histories are defined as events reported on the Medical History and Disease History eCRF pages, which started before the first study treatment date and were not ongoing at the first study treatment date.

Concomitant diseases are defined as diseases which started before the first study treatment date but were ongoing at the first study treatment date.

The number and percentage of patients with a medical history will be tabulated by basket and overall, by system organ class (SOC) and preferred term (PT) on the FAS. A by-patient listing will be produced.

The number and percentage of patients with a concomitant disease will be tabulated by basket and overall, for each SOC and PT using the FAS. A by-patient listing will be produced.

9.5 PRIOR THERAPIES

The following summaries will be created by basket and overall, on the FAS:

Prior radiotherapy:

- Received at least one prior radiotherapy
- Number of prior radiotherapy courses
- Site of prior radiotherapies (only reported sites will be displayed, not all categories displayed in the eCRF)
- Most recent therapy received before study treatment start: duration of therapy (months) and site

For prior radiotherapy, duration in months will be calculated as [(end date of therapy – start date of therapy) + 1] / 30.4375.

Prior Systemic Anti-Cancer Therapies:

- Received at least one prior anti-cancer therapy
- Lines of prior anti-cancer therapies
- Most recent therapy received before study treatment start: regimen name, BOR, duration of therapy (months), time since BOR, time since relapse/progression, and reason for discontinuation.

For prior anti-cancer therapies, duration in months will be calculated as [(end date of therapy - start date of therapy) + 1] / 30.4375.

Time since BOR (months) will be calculated as [(date of first study treatment - date of BOR) + 1] / 30.4375.

Time since relapse/progression (months) will be calculated as [(date of first study treatment - date of Relapse/Progression) + 1] / 30.4375.

Prior and Concomitant Medication:

Medications other than the study treatment will be coded using the WHO Drug Global dictionary. The version of the dictionary will be provided in the corresponding TFLs footnotes.

Medications will be defined as follows:

- Prior Medication: any medications whose end date is before the first study treatment date.
- Concomitant Medication: any medications whose start or end date is either the same or after the first dose of study treatment and up to the end of the on-treatment period.
    - Any medication with a missing medication end date will be assumed to be concomitant medication.

9.5 PRIOR THERAPIES

The following summaries will be created by basket and overall, on the FAS:

Prior radiotherapy:

- Received at least one prior radiotherapy
- Number of prior radiotherapy courses
- Site of prior radiotherapies (only reported sites will be displayed, not all categories displayed in the eCRF)
- Most recent therapy received before study treatment start: duration of therapy (months) and site

For prior radiotherapy, duration in months will be calculated as [(end date of therapy – start date of therapy) + 1] / 30.4375.

Prior Systemic Anti-Cancer Therapies:

- Received at least one prior anti-cancer therapy
- Lines of prior anti-cancer therapies
- Most recent therapy received before study treatment start: regimen name, BOR, duration of therapy (months), time since BOR, time since relapse/progression, and reason for discontinuation.

For prior anti-cancer therapies, duration in months will be calculated as [(end date of therapy - start date of therapy) + 1] / 30.4375.

Time since BOR (months) will be calculated as [(date of first study treatment - date of BOR) + 1] / 30.4375.

Time since relapse/progression (months) will be calculated as [(date of first study treatment - date of Relapse/Progression) + 1] / 30.4375.

Prior and Concomitant Medication:

Medications other than the study treatment will be coded using the WHO Drug Global dictionary. The version of the dictionary will be provided in the corresponding TFLs footnotes.

Medications will be defined as follows:

- Prior Medication: any medications whose end date is before the first study treatment date.
- Concomitant Medication: any medications whose start or end date is either the same or after the first dose of study treatment and up to the end of the on-treatment period.
    - Any medication with a missing medication end date will be assumed to be concomitant medication.

- Ongoing medications are considered as concomitant medications.

The number and percentage of patients with prior and concomitant medications will be tabulated by basket and overall, by Anatomical Therapeutic Chemical Classification (ATC) and preferred term (PT) on the FAS. A by-patient listing will be produced for prior and concomitant medications as well as for all prior therapies.

On treatment Radiation, Surgery and Medical Procedures, and Blood Transfusions:

On treatment Radiation, Surgery and Medical Procedures, and Blood Transfusions will be listed on the FAS.

9.6 STUDY DRUG EXPOSURE AND/OR COMPLIANCE

Duration on treatment and cumulative dose received will be calculated for both ulixertinib and hydroychloroquine as defined below with the same tables and listings.

- *Number of cycles received* =
  Number of cycles where the patient received at least one dose.

- *Duration of exposure (months)* =
  [(Date of last known treatment dosing with study treatment – date of initial dosing with ulixertinib) + 1] / 30.4375

- *Planned cumulative dose (mg)* =
  Number of cycles received x number of doses per day x mg prescribed per dose.

- *Actual cumulative dose received (mg)* =
  For each time period reported in the eCRF:
  (Stop date – Start date + 1)*Dose
  Sum all available periods where dose was given.

- *Relative dose intensity* =
  100 x Actual dose intensity / Planned dose intensity, with:
  - Actual dose intensity (mg/day) = Actual cumulative dose received (mg) / Duration of exposure (days).
  - Planned dose intensity (mg/day) = Planned cumulative dose (mg) / Duration of exposure (days).

Summary statistics will be presented for the number of cycles received, duration of exposure, actual cumulative dose, and relative dose intensity, by basket and overall on the FAS.

The number and percentage of patients having at least one dosing interruption or adjustment will be tabulated with the corresponding reason by basket and overall on the FAS. A by-patient listing will be produced.

9.7 PHARMACOKINETIC/ PHARMACODYNAMIC ENDPOINTS AND ANALYSES

9.7.1 Pharmacokinetic Data

For patients enrolled in stage 1 of each basket, PK concentrations of ulixertinib and hydroxychloroquine will be determined pre-dose and post-dose in plasma at cycle 1 day 15. Summary parameters such as AUC, Cmax, Cmin, t1/2, tmax will be calculated.

PK parameters in plasma will be tabulated and summarized, by basket, using descriptive statistics (e.g., sample size, arithmetic and geometric mean, % coefficient of variation, standard deviation, median, minimum, and maximum).

For patients enrolled in stage 2 of each basket, PK concentration of ulixertinib will be measured on cycle 1 day 15. This will be a single timepoint collection prior to taking study drug on this day.

PK values will be presented in by-patient listings.

PK analysis will be conducted on the PK analysis set.

9.7.2 Pharmacodynamic Data

Not applicable.

9.8 EFFICACY DATA ENDPOINTS AND ANALYSES

9.8.1 Primary Efficacy

9.8.1.1 Overall Response Rate (ORR)

Tumor response will be assessed by the Investigator using RECIST 1.1 criteria[1].

Disease assessments must include all known or suspected sites of disease; therefore, the decision for body areas to be scanned will depend on the extent of disease. The minimum recommended body areas to be scanned is chest, abdomen, and pelvis.

Disease assessments will be evaluated radiologically and conducted at baseline (within 28 days prior to the first dose of study treatment) and then every 8 weeks thereafter ≤ 7 days prior to the start of the following cycle (e.g., prior to cycle 3 day one, cycle 5 day 1, cycle 7 day 1, etc.). If a response is observed (CR or PR), confirmation of response is required ≥ 4 weeks from the first documentation of response. Disease assessments will continue until disease progression, the

initiation of subsequent anti-cancer therapy, or death. In addition, radiological tumor assessments will be conducted whenever disease progression is suspected (e.g., symptomatic deterioration) or when clinically indicated. The schedule of tumor assessments should be fixed according to the calendar, starting with cycle one day one, regardless of treatment delays or interruptions due to toxicity.

Brain CT or MRI scans are required at baseline for all patients with stable brain lesions and for those for whom Central Nervous System (CNS) involvement is suspected. If stable brain metastases are present at baseline, brain imaging should be repeated at each tumor assessment. Otherwise, brain imaging will be conducted post-baseline only when clinically indicated.

The table below provides a summary of the overall response status determination at each time point.

Table 5. Evaluation of Overall Response

Target lesions	Non-target lesions	New lesions	Overall response
CR	CR (or no non-target lesions)	No	CR
No target lesion [a]	CR	No	CR
CR	NE [b]	No	PR
CR	Non-CR/non-PD	No	PR
PR	Non-PD and NE (or no non-target lesions) [b]	No	PR
SD	Non-PD and NE (or no non-target lesions) [b]	No	SD
Not all evaluated	Non-PD	No	NE
No target lesion [a]	Not all evaluated	No	NE
No target lesion [a]	Non-CR/non-PD	No	Non-CR/non-PD
PD	Any	Yes or No	PD
Any	PD	Yes or No	PD
Any	Any	Yes	PD
No target lesion [a]	Unequivocal PD	Yes or No	PD
No target lesion [a]	Any	Yes	PD

CR = complete response, PR = partial response, SD = stable disease, PD = progressive disease, and NE = not evaluable.
[a] Defined as no target lesion at baseline.
[b] Not evaluable is defined as when either no or only a subset of lesion measurements is made at an assessment.

The ORR is defined as the number of patients having a confirmed response of either CR or PR divided by the total number of patients in the FAS/EAS. ORR will be calculated with the 95% confidence intervals (CIs), by basket and overall on the FAS and EAS. The 95% CIs will be estimated using the Clopper-Pearson method.

Complete and partial response must be confirmed by a repeat assessment performed ≥ 4 weeks after the criteria for response are first met. Date of confirmed CR/PR will be the date of the first CR/PR that qualifies for confirmation. Additionally, patients with no post-baseline efficacy measurement due to reasons accountable for disease progression, will be assessed as non-evaluable and will count in the denominator of the ORR.

BOR will be assessed based on the tumor response at different evaluation time points from baseline until the first documented disease progression for RECIST or the last response assessment if there is no documented disease progression at the time of the analysis. The order used to determine BOR is CR>PR>SD>PD, ignoring visits with missing tumor assessments. For SD to qualify for BOR, the SD assessment should be at least 6 weeks after first ulixertinib dose. BOR date in this case will be the date of the first SD/PR/CR documented after 6 weeks.

The following table, based on Table 3 from the RECIST 1.1 guidelines[1], summarizes the algorithm describing how confirmed response and BOR are determined from the overall tumor assessments.

Table 6. Evaluation of Confirmed BOR

Case	Overall response first timepoint	Overall response subsequent timepoint	Confirmed response/BOR
1	CR	CR	CR (if assessments at least 28 days apart). (note: sequence of CR – NE – CR would be considered as confirmed CR)
2	CR	PR	SD, PD, or PR • If CR truly met at first timepoint, any subsequent assessment of PR should make the disease PD at that point. That is, neither a PR nor SD may follow CR. • Therefore, SD, if CR assessment >=6 weeks (42 days after date of first treatment), otherwise PD. • However, BOR may be PR if subsequent scans suggest small lesions were still present at first assessment (in which case first assessment of CR should be changed to PR)
3	CR	SD	SD or PD • SD, if CR or SD assessment >=6 weeks (42 days) after date of first treatment, otherwise PD
4	CR	PD	SD or PD • SD, if CR assessment >=6 weeks (42 days after date of first treatment), otherwise PD
5	CR	NE	SD or NE • SD, if CR assessment >=6 weeks (42 days after date of first treatment otherwise NE
6	PR	CR	PR (if assessments at least 28 days apart).
7	PR	PR	PR (if assessments at least 28 days apart). (note: sequence of PR – NE – PR would be considered as confirmed PR) Where there are cases of more than one SD assessment between two PR assessments, then this should be discussed.
8	PR	SD	SD
9	PR	PD	SD or PD • SD, if PR assessment >=6 weeks (42 days after date of first treatment), otherwise PD

Case	Overall response first timepoint	Overall response subsequent timepoint	Confirmed response/BOR
10	PR	NE	SD or NE • SD, if PR assessment >=6 weeks (42 days after date of first treatment), otherwise NE
11	SD	SD, PR, CR	SD
12	SD	PD	SD or PD • SD, if SD assessment >=6 weeks (42 days after date of first treatment), otherwise PD
13	SD	NE	SD or NE • SD, if SD assessment >=6 weeks (42 days after date of first treatment), otherwise NE
14	NE, -	SD	SD
15	CR, PR, SD	-	SD or NE • SD, if assessment >=6 weeks (42 days after date of first treatment) and does not qualify for CR or PR, otherwise NE.
16	PD		PD. Ignore all assessments after initial overall response of PD.
17	NE	NE	NE Where all assessments are Not evaluable

For changes in target tumor size, spider and waterfall plots will be presented. For all response assessments, swimmer plots will be presented. Target and Non-Target Lesions response assessments and incidence of new lesions will be summarized by visit and listed. All response assessments will be listed.

9.8.2 Secondary Efficacy

9.8.2.1 Progression-free Survival (PFS)

The PFS (in months) is defined as the time from the first ulixertinib dose until the first radiographically documented progression of disease or death from any cause, whichever occurs first.

PFS = [(Date of first PD/death – Date of first study treatment) + 1] / 30.4375

Patients with no documented progression or death will be censored at the last available tumor assessment (last assessment that is CR, PR or SD):

PFS = [(Date of last assessment where patient is PD free – Date of first study treatment) + 1] / 30.4375

For patients with no post baseline tumor assessment a censored PFS at day 1 will be considered.

PFS = (Date of first study treatment – Date of first study treatment) + 1

The analysis of PFS will be performed with a Kaplan-Meier method (product-limit estimates) and a summary of associated statistics will be presented including corresponding two-sided 95% CI. The CI for the median will be calculated according to Brookmeyer and Crowley and CI for the survival function estimates at Month 3, 6, 9, 12, and 18 will be derived using the log-log transformation (SAS PROC LIFETEST CONFTYPE=LOGLOG). However, the final choice of timepoints may be updated dependent upon the data.

9.8.3 Exploratory Efficacy

9.8.3.1 Duration of Response (DOR)

The DOR (in months) is defined as the period from the date of initial confirmed PR or CR until the date of first radiographically documented progressive disease or death from any cause. Only patients with BOR of CR or PR (i.e. responders) will be included in the analysis of DOR.

DOR = [(Date of first PD/death – Date of first recorded confirmed CR/PR) + 1] / 30.4375

Patients with no documented progression or death after CR or PR will be censored at the last available tumor assessment (last assessment that is CR, PR, or SD):

DOR = [(Date of last assessment where patient is PD free – Date of first recorded CR/PR) + 1] / 30.4375

The analysis of DOR will be performed with a Kaplan-Meier method (product-limit estimates) and a summary of associated statistics will be presented including corresponding two-sided 95% CI. The CI for the median will be calculated according to Brookmeyer and Crowley and CI for the survival function estimates at Month 3, 6, 9, 12, and 18 will be derived using the log-log transformation (SAS PROC LIFETEST CONFTYPE=LOGLOG), only if there are sufficient data for responders. However, the final choice of timepoints may be updated dependent upon the data.

9.8.3.2 Overall Survival (OS)

The OS (in months) is defined as the time from first treatment to death. Patients who did not die during the study will be censored at the last known alive date.

OS = [(Date of death – Date of first study treatment) + 1] / 30.4375

For censored patients:

OS = [(Last known alive date – Date of first study treatment) + 1] / 30.4375

The last known alive date will be determined among study treatment administrations, any visits where at least one assessment has been completed, or any follow-up assessment where the patient has been confirmed to be alive.

OS will be analyzed using the same Kaplan-Meier method used to analyze the DOR.

9.9 SAFETY DATA ENDPOINTS AND ANALYSES

All safety analyses will be performed by basket and overall on the FAS, using descriptive statistics.

9.9.1 Adverse Events (AEs)

The following definitions will be used:

- ***Treatment-emergent AEs (TEAEs):*** Treatment-emergent adverse event (TEAE) is defined as any AE that emerges during on-treatment period.
- ***Related AEs:*** AEs suspected by the Investigator and/or Sponsor to have a relationship to study treatment (as recorded on the AE eCRF page, Causality = Related, Possibly Related, or missing), including ulixertinib or hydroxychloroquine or both.
- ***Serious Adverse Events (SAE):*** serious AEs (as recorded on the AE eCRF page, Does AE Meet the Definition of an SAE = Yes).
- ***AEs leading to treatment discontinuation:*** AEs leading to permanent discontinuation of study treatment (as recorded on the AE eCRF page, Action taken with study treatment = Drug withdrawn).
- ***AEs leading to dose reduction:*** AEs leading to dose reduction of study treatment (as recorded on the AE eCRF page, Action taken with study treatment = Dose Reduced).
- ***AEs leading to treatment interruption:*** AEs leading to treatment interruption of study treatment (as recorded on the AE eCRF page, Action taken with study treatment = Drug Interrupted).
- ***AEs leading to Death:*** adverse event leading to death (as recorded on the AE eCRF page, Results in death, or Outcome = Fatal, or Grade = 5).

An overview summary table will present the number and percentage of patients with a TEAE, all treatment-related adverse events will be indicated as Ulixertinib-related or Hydroxychloroquine-related or both, including:

- TEAEs / TEAEs related to study treatment
- SAEs / SAEs related to study treatment
- TEAEs leading to treatment discontinuation / TEAEs related to study treatment leading to treatment discontinuation

- TEAEs leading to treatment discontinuation within 1 cycle / TEAEs related to study treatment leading to treatment discontinuation within 1 cycle
- TEAEs leading to treatment discontinuation following 1 cycle / TEAEs related to study treatment leading to treatment discontinuation following 1 cycle
- TEAEs leading to treatment interruption / TEAEs related to study treatment leading to treatment interruption
- TEAEs leading to treatment interruption within 1 cycle / TEAEs related to study treatment leading to treatment interruption within 1 cycle
- TEAEs leading to treatment interruption following 1 cycle / TEAEs related to study treatment leading to treatment interruption following 1 cycle
- TEAEs leading to dose reduction / TEAEs related to study treatment leading to dose reduction
- TEAEs leading to dose reduction within 1 cycle / TEAEs related to study treatment leading to dose reduction within cycle 1
- TEAEs leading to dose reduction following 1 cycle / TEAEs related to study treatment leading to dose reduction following cycle 1
- TEAEs leading to death / TEAEs related to study treatment leading to death
- TEAEs with grade ≥ 3 / TEAEs related to study treatment with grade ≥ 3

In addition, the following tables will be produced by SOC and PT:

- TEAEs / TEAEs related to study treatment
- Serious TEAEs / Serious TEAEs related to study treatment
- TEAEs and maximum CTCAE grade / TEAEs related to study treatment and maximum CTCAE grade
- TEAEs leading to treatment discontinuation within/following cycle 1 / TEAEs related to study treatment leading to treatment discontinuation within/following cycle 1
- TEAEs leading to treatment interruption within/following cycle 1 / TEAEs related to study treatment leading to treatment interruption within/following cycle 1
- TEAEs leading to dose reduction within/following cycle 1 / TEAEs related to study treatment leading to dose reduction within/following cycle 1
- TEAEs leading to death / TEAEs related to study treatment leading to death

The following tables will be produced by PT:

- TEAEs / TEAEs related to study treatment
- Serious TEAEs / Serious TEAEs related to study treatment

A patient with multiple occurrences of an AE will be counted only once in the AE category. SOCs will be sorted by descending order of frequency for the overall group, PTs will be sorted by descending order of frequency for the overall group within each SOC.

All deaths will be summarized and listed with the corresponding reasons, split by overall deaths, and deaths occurring after the first dose of ulixertinib.

The following listings will be provided:

- All AEs (All Patient Set)
- TEAEs (FAS)
- SAEs (FAS)
- Deaths (FAS)

9.9.2 Clinical Safety Laboratory Evaluation

All haematology, biochemistry, coagulation and urinalysis laboratory tests collected will be reported.

The numerical measurements and change from baseline of all haematology, biochemistry, and urinalysis laboratory tests will be summarized using descriptive summary statistics for each visit.

For laboratory tests covered by the NCI-CTCAE (version 5), laboratory data will be graded accordingly. 'Normal' will be assigned for all non-missing values not graded as 1 or higher. For laboratory tests where grades are not defined by NCI-CTCAE, results will be graded by the low/normal/high classifications based on laboratory normal ranges as collected in the CRF. Separate tables will be created for Gradable and Non-gradable laboratory values.

Haematology and biochemistry laboratory tests will be summarized by:

- Tables (Gradable and Non-gradable) to describe the worst on-treatment value by cycle.
- Shift tables (Gradable and Non-gradable) to compare baseline to the worst on-treatment value.

Listings of all laboratory data with values flagged to show the corresponding NCI-CTCAE grades and the classifications relative to the laboratory normal ranges will also be provided. Also results of serum pregnancy tests and tumor markers will be listed.

9.9.3 Other Safety data

9.9.3.1 Vital signs

Vital signs include the following parameters: systolic blood pressure (SBP) (mmHg), diastolic blood pressure (DBP) (mmHg), pulse (beats/min), respiratory rate (breaths/min), pulse oximetry (%) and temperature (°C).

The numerical measurements and change from baseline of all vital signs parameters will be summarized using descriptive summary statistics for each visit.

Shift tables of baseline to worst on-treatment result (low, normal, high, very high) will be presented.

Table 7. Thresholds for classification of vital signs test results

Vital Sign	Criteria	Flag
Temperature	< 36.4°C	Low
	36.4°C – 37.7°C	Normal
	> 37.7°C	High
Pulse	< 55 bpm	Low
	55-100 bpm	Normal
	101-150 bpm	High
	> 150 bpm	Very High
Respiratory rate	<12 breaths/min	Low
	12-16 breaths/min	Normal
	>16 breaths/min	High
Pulse oximetry	<90 %	Very Low
	90-95 %	Low
	≥95 %	Normal
Systolic Blood Pressure	< 90 mmHg	Low
	90-130 mmHg	Normal
	131-160 mmHg	High
	≥ 161 mmHg	Very High
Diastolic Blood Pressure	< 60 mmHg	Low
	60-85 mmHg	Normal
	86-100 mmHg	High
	≥ 101 mmHg	Very High

All Vital Signs will be Listed.

9.9.3.2 Electrocardiogram (ECG)

ECG includes the following parameters: Heart Rate (beats/min), PR Interval (msec), QRS Duration (msec), RR Interval (msec), QT Interval (msec), and QT interval corrected for heart rate by the Fridericia's formula (QTcF) Interval (msec).

The numerical measurements and change from baseline of all ECG parameters will be summarized using descriptive summary statistics for each visit.

A listing of ECG evaluations will be created.

9.9.3.3 ECHO

ECHO assessments at baseline will be summarized using descriptive summary statistics.

A listing of ECHO evaluations will be created.

9.9.3.4 Physical Examination

Physical Examination includes the following parameters: HEENT, Thorax, Abdomen, Skin and Mucosae, Neurological, Extremities, Urogenital, General Appearance, Heart, Back, and Lymph Nodes.

All physical examination assessments at baseline will be summarized using descriptive summary statistics.

A listing of physical examination evaluations will be created.

9.9.3.5 Ophthalmology exam

A listing of ophthalmological examination assessments will be created.

9.9.3.6 ECOG Performance status

The number and percentages of patients will be tabulated for ECOG performance score categories at each visit.

A listing of all ECOG Performance status at all visits will be presented.

10 Interim Analyses

No interim analysis is planned.

11 Changes to Planned Analyses

No major changes to analyses planned in the protocol are expected.

12 Document History

Date	Version	Modified by	Brief details of changes made to template
17Jul2023	1.0	David Manteigas	First SAP Version.
20-Aug-2024	1.1	Julien Lucas	Updated version to include required changes after the study was terminated early.
02-Sep-2024	2.0	Julien Lucas	Second SAP version.

13 References

1. Eisenhauer EA, Therasse P, Bogaerts J, et al. (2009), New response evaluation criteria in solid tumours: Revised RECIST guideline (version 1.1). Eur J Cancer; 45:228-47.

14 Appendices

14.1 Schedule of events

Protocol Activities	Screening[i]	On-Treatment Period: One Cycle = 28 days						Post-Treatment Period		
		Cycle 1			Cycle 2		Cycle 3+	EOT[ii]	Safety Follow-Up[iii]	Follow-Up
Day of Cycle (Visit Window)	(≤ -28 days)	1[iv]	8 (± 2 days)	15 (± 2 days)	1 (± 2 days)	15 (± 2 days)	1 (± 2 days)	(+7 days)	(± 7 days)	
Informed Consent	X									
Demographics	X									
Cancer History[v]	X									
Medical History	X									
Eligibility Criteria	X									
Clinical Assessments										
Vital Signs[vi]	X	X	X	X	X	X	X	X	X	
Physical Exam[vii]	X	X	X	X	X	X	X	X	X	
ECOG Score	X	X	X	X	X	X	X	X	X	
ECG	X		X	X	X			X		
Echocardiogram	X	ACI								

Protocol Activities	Screening[i]	On-Treatment Period: One Cycle = 28 days						Post-Treatment Period		
		Cycle 1			Cycle 2		Cycle 3+	EOT[ii]	Safety Follow-Up[iii]	Follow-Up
Day of Cycle (Visit Window)	(≤ -28 days)	1[iv]	8 (± 2 days)	15 (± 2 days)	1 (± 2 days)	15 (± 2 days)	1 (± 2 days)	(+7 days)	(± 7 days)	
Ophthalmologic Exam[viii]	X				X		X			
Adverse event collection	X	X								
Concomitant medications	X	X								
Laboratory Studies[ix]										
Hematology	X	X	X	X	X	X	X	X	X	
Chemistry	X	X	X	X	X	X	X	X	X	
Creatine kinase[x]	X	ACI								
LDH and Phosphorus	X	X	X	X	X	ACI				
Coagulation	X	ACI								
Urinalysis	X	ACI								
Tumor Marker[xi]		X			X		X	X		
Pregnancy Test[xii]	X	ACI								
Disease Assessments										
CT Scans or MRI[xiii]	X						X	X		X[xiv]

Protocol Activities	Screening[I]	On-Treatment Period: One Cycle = 28 days						Post-Treatment Period		
		Cycle 1			Cycle 2		Cycle 3+	EOT[II]	Safety Follow-Up[III]	Follow-Up
Day of Cycle (Visit Window)	(≤ -28 days)	1[IV]	8 (± 2 days)	15 (± 2 days)	1 (± 2 days)	15 (± 2 days)	1 (± 2 days)	(+7 days)	(± 7 days)	
RECIST 1.1 Assessment	X						X	X		X
Treatment Compliance and Distribution										
Hydroxychloroquine		X			X		X			
Ulixertinib		X			X		X			
Treatment administration on site				X[15]			X			
Meal provided by site				X			X[16]			

Abbreviations: ACI = as clinically indicated; LDH = lactate dehydrogenase; CT = computed tomography; MRI = magnetic resonance imaging; ECG = electrocardiogram; EOT = end of treatment

[1] Screening procedures must be completed ≤ 28 days prior to C1D1 unless noted otherwise.
[2] The end of treatment visit should occur when the decision to discontinue treatment is made. If this visit overlaps with a regularly scheduled visit, only the procedures listed in the calendar for the EOT visit will be performed. All end of treatment procedures should be completed within 7 days after the decision to discontinue treatment has been made.
[3] Patients will have a safety follow-up visit 60 days (± 7 days) after last dose of study drug.
[4] C1D1 procedures do not need to be repeated if screening procedures were performed ≤ 7 days of the start of treatment.
[5] Oncologic history of the malignancy under study including prior regimens (duration of therapy, best response on therapy, date of discontinuation, and reason for discontinuation), surgery, and radiation therapy.
[6] Vital signs include systolic/diastolic blood pressure, heart rate, respiration rate, pulse oximetry, weight, and body temperature. Height will be captured at screening only.
[7] If necessary to facilitate scheduling, the physical exam may occur one day prior to study treatment.
[8] A standard ophthalmologic exam must be completed at screening, C2D1, and every 3 cycles thereafter (i.e. C5D1, C8D1, etc.) and as clinically indicated to assess for retinopathies. All assessments must be conducted up to 7 days prior to the clinic visit to enable timely results review.
[9] Labs may be performed ≤ 3 days prior to a scheduled day one visit except for C1D1 labs which may be completed ≤ 7 days prior to C1D1.
[10] After screening, creatine kinase should only be drawn if creatinine is elevated.
[11] Tumor marker should be drawn on day one of each cycle. Tumor markers will be disease specific: pancreatic adenocarcinoma only CA 19-9; colorectal carcinoma only CEA; cholangiocarcinoma only CEA and CA 19-9. Tumor markers are not required for patients with esophageal or stomach cancers.
[12] Pregnancy test (serum or urine) must be obtained at screening ≤ 7 days prior to C1D1 for all women of childbearing potential and as clinically indicated while on treatment.
[13] Disease assessment will be repeated every 8 weeks (± 7 days) regardless of dose holds or delays. Patients who discontinue treatment for reasons other than progression will have computed tomography (CT) scans at the EOT visit (unless their previous restaging was performed within 6 weeks).
[14] Patients that discontinue study treatment for any reason other than disease progression, must continue to have disease assessments every 8 weeks (± 7 days) until disease progression or initiation of subsequent anticancer therapy.
[15] Patient should be instructed to not take their study treatment before arriving at clinic. Study treatment and meal should be provided after the pre-dose PK draw.
[16] Meal is only required to be given at C3D1, i.e., at the time of drug administration for ctDNA and tumor biopsy for stage 1.

14.2 Schedule of Correlative Sample Collection

Correlative Test	**Screening**	**C1D1**	**C1D15**								**C3D1**	**EOT**
			Pre-Dose	Post-Dose								
Time Point (hour)				0.5	1	2	4	6	8	12	± 7 days	
Window (min)			≤ 60	±2	±3	±6	±12	±18	±24	±36		
STAGE 1												
PK Blood[1]			X	X	X	X	X	X	X	X		
ctDNA		X									X[2]	X[3]
Biopsy	X										X	X
STAGE 2												
PK Blood[4]			X									

Abbreviations: C = cycle; ctDNA = circulating tumor DNA; D = day; EOT = end of treatment; PK = pharmacokinetics.

[1]To accommodate PK blood draws, patients should be instructed not to take their morning doses of both medications until told to do so in the clinic. A meal should be provided by the site when taking the medications in the clinic. Pre-dose PK sample should be collected prior to the administration of study drugs. Post-dose PK samples should be collected at the appropriate time points following administration of study drugs. PK samples should be drawn while patients are at steady state, which is 5 days, or 10 consecutive doses.
[2]To be drawn at the time of the tumor biopsy.
[3]Required blood draw at EOT. If optional biopsy is collected at EOT, ctDNA should be drawn at the time of the tumor biopsy.
[4]Biopsies at screening and C3D1 (± 7 days) are required. When blood is being drawn at D3D1, site will provide a meal when study drugs are taken. An optional biopsy will be offered at the time when the decision to discontinue treatment is made (+ 7 days).

14.3 CTCAE v5.0 Grading for Laboratory Values

Table 8. Hematology Tests

Parameter	CTCAE Gradable†	SOC	CTCAE v5.0 Term
Hematocrit	No		
Hemoglobin	Yes	Blood and lymphatic system disorders	Anemia
		Investigations	Hemoglobin increased
Platelets	Yes	Investigations	Platelet count decreased
White blood cells	Yes	Investigations	White blood cell decreased
		Blood and lymphatic system disorders	Leukocytosis
Neutrophils absolute	Yes	Investigations	Neutrophil count decreased
Lymphocytes absolute	Yes	Investigations	Lymphocyte count decreased
			Lymphocyte count increased

† For laboratory tests where grades are not defined by NCI-CTCAE, results will be graded by the low/normal/high classification based on laboratory normal ranges.

Table 9. Coagulation Tests

Parameter	CTCAE Gradable†	SOC	CTCAE v5.0 Term
PT	No		
INR	Yes	Investigations	INR increased
PTT	No		

† For laboratory tests where grades are not defined by NCI-CTCAE, results will be graded by the low/normal/high classification based on laboratory normal ranges.

Table 10. Serum Chemistry Tests

Parameter	CTCAE Gradable†	SOC	CTCAE v5.0 Term
Albumin	Yes	Metabolism and nutrition disorders	Hypoalbuminemia
Alkaline phosphatase	Yes	Investigations	Alkaline phosphatase increased
ALT	Yes	Investigations	Alanine aminotransferase increased
AST	Yes	Investigations	Aspartate aminotransferase increased
Blood urea nitrogen	No		
Uric acid	No		
Chloride	No		
Calcium	Yes	Metabolism and nutrition disorders	Hypocalcemia
			Hypocalcemia

Parameter	CTCAE Gradable†	SOC	CTCAE v5.0 Term
Creatinine	Yes	Investigations	Creatinine increased
Lactate Dehydrogenase	Yes	Investigations	Lactate Dehydrogenase increased
Glucose	Yes	Metabolism and nutrition disorders	Hyperglycemia
			Hypoglycemia
Potassium	Yes	Metabolism and nutrition disorders	Hyperkalemia
			Hypokalemia
Sodium	Yes	Metabolism and nutrition disorders	Hypernatremia
			Hyponatremia
Inorganic Phosphorus	No		
Total bilirubin	Yes	Investigations	Blood bilirubin increased
Direct bilirubin	No		
Total protein	No		
Urea Nitrogen	No		
Carbon Dioxide	No		

† For laboratory tests where grades are not defined by NCI-CTCAE, results will be graded by the low/normal/high classification based on laboratory normal ranges.

Table 11. Urinalysis Tests

Parameter	CTCAE Gradable†	SOC	CTCAE v5.0 Term
Dipstick Evaluation Of Bilirubin	No		
Dipstick Evaluation Of Blood	No		
Dipstick Evaluation Of Glucose	No		
Dipstick Evaluation Of Ketones	No		
Dipstick Evaluation Of Leukocytes	No		
Dipstick Evaluation Of Protein	No		
Microscopic Examination Of Casts	No		
Microscopic Examination Of Rbc	No		
Microscopic Examination Of Wbc	No		
pH	No		
Specific Gravity	No		

† For laboratory tests where grades are not defined by NCI-CTCAE, results will be graded by the low/normal/high classification based on laboratory normal ranges.

SPONSOR:

BioMed Valley Discoveries

PROTOCOL NUMBER:

BVD-523-HCQ

STATISTICAL ANALYSIS PLAN
TFL SHELLS

Author:	**Julien Lucas**
Version:	2.0
Date:	02-Sep-2024

1 Cover and signature pages

Sponsor:	BioMed Valley Discoveries
Protocol Number:	BVD-523-HCQ
Study Title:	A phase 2 basket trial of ulixertinib in combination with hydroxychloroquine in patients with advanced gastrointestinal malignancies harboring MAPK pathway mutations (BVD-523-HCQ)
Document Version No	1.0

We, the undersigned, confirm that we have read, understood and agree to the content of this document and hereby authorize its approval.

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	Senior Scientist		Signed by: Anna Groover Signer Name: Anna Groover Signing Reason: I approve this document Signing Time: 03-Sep-2024 | 08:40 CDT 71380BDD08BC4D289E63FA3831CD4243
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2 Document History

Date	Version	Modified by	Brief details of changes made to template
27Jul2023	1.0	David Manteigas	First SAP version
20Aug2024	1.1	Julien Lucas	Updated version to include required changes after the study was early terminated.
02Sep2024	2.0	Julien Lucas	Second SAP version.

3 List of Tables, Figures and Listings

TFL Type	TFL Number	Title	Population	SMC*	Included in Final Analysis
14.1		**Demographic Data**			
Table	14.1-1.1	Patient Disposition	All Patients Set	Y	Y
Table	14.1-1.2	Number of Patients in the Analysis Sets	All Patients Set		Y
Table	14.1-1.3	Summary of Important Protocol Deviations	Full Analysis Set		Y
Table	14.1-2.1	Demographics and Baseline Characteristics	Full Analysis Set	Y	Y
Table	14.1-2.2	Disease History	Full Analysis Set	Y	Y
Table	14.1-2.3	Summary of Medical History	Full Analysis Set		Y
Table	14.1-2.4	Summary of Concomitant Diseases	Full Analysis Set		Y
Table	14.1-3.1	Prior Systemic Anti-Cancer Therapies	Full Analysis Set	Y	Y
Table	14.1-3.2	Prior Radiotherapy Courses	Full Analysis Set	Y	Y
Table	14.1-3.3	Prior Medications	Full Analysis Set		Y
Table	14.1-3.4	Concomitant Medications	Full Analysis Set		Y
Table	14.1-4.1.1	Treatment Exposure (Ulixertinib)	Full Analysis Set	Y	Y
Table	14.1-4.1.2	Treatment Exposure (Hydroxychloroquine)	Full Analysis Set	Y	Y
Table	14.1-4.2.1	Dosing Interruptions and Adjustments (Ulixertinib)	Full Analysis Set	Y	Y
Table	14.1-4.2.2	Dosing Interruptions and Adjustments (Hydroxychloroquine)	Full Analysis Set	Y	Y
14.2		**Efficacy Data**			
Table	14.2-1.1.1	Best Overall Response and Overall Response Rate	Full Analysis Set		Y
Table	14.2-1.1.2	Best Overall Response and Overall Response Rate	Evaluable Analysis Set		
Table	14.2-1.2.1	Overall, Target and Non-Target Lesion Response	Full Analysis Set		Y
Table	14.2-1.2.2	Overall, Target and Non-Target Lesion Response	Evaluable Analysis Set		
Table	14.2-1.3.1	Incidence of New Lesions	Full Analysis Set		Y
Table	14.2-1.3.2	Incidence of New Lesions	Evaluable Analysis Set		
Table	14.2-1.4.1	Progression-free Survival (PFS)	Full Analysis Set		Y
Table	14.2-1.4.2	Progression-free Survival (PFS)	Evaluable Analysis Set		
Table	14.2-1.5.1	Overall Survival (OS)	Full Analysis Set		Y
Table	14.2-1.5.2	Overall Survival (OS)	Evaluable Analysis Set		
Table	14.2-1.6.1	Duration of Response (DOR)	Full Analysis Set		
14.3		**Safety Data**			

Table	14.3-1.1	Overview Summary of Treatment-Emergent Adverse Events	Full Analysis Set	Y	Y
Table	14.3-1.2	Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term	Full Analysis Set	Y	Y
Table	14.3-1.3	Summary of Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term	Full Analysis Set	Y	Y
Table	14.3-1.4	Summary of Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term	Full Analysis Set	Y	Y
Table	14.3-1.5	Summary of Related Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term	Full Analysis Set	Y	Y
Table	14.3-1.6	Summary of Treatment-Emergent Adverse Events by Preferred Term	Full Analysis Set		
Table	14.3-1.7	Summary of Related Treatment-emergent Adverse Events by Preferred Term	Full Analysis Set		
Table	14.3-1.8	Summary of Serious Treatment-emergent Adverse Events by Preferred Term	Full Analysis Set		
Table	14.3-1.9	Summary of Related Serious Treatment-emergent Adverse Events by Preferred Term	Full Analysis Set		
Table	14.3-1.10	Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term for Maximum CTCAE grade	Full Analysis Set		Y
Table	14.3-1.11	Summary of Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term for Maximum CTCAE grade	Full Analysis Set	Y	Y
Table	14.3-1.12	Summary of Treatment-emergent Adverse Leading to Treatment Discontinuation Events by System Organ Class and Preferred Term	Full Analysis Set	Y	Y
Table	14.3-1.13	Summary of Related Treatment-emergent Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term	Full Analysis Set	Y	Y
Table	14.3-1.14	Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation within Cycle 1 by System Organ Class and Preferred Term	Full Analysis Set	Y	Y
Table	14.3-1.15	Summary of Related Treatment-emergent Adverse Events Leading to Treatment Discontinuation within Cycle 1 by System Organ Class and Preferred Term	Full Analysis Set	Y	Y
Table	14.3-1.16	Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation following Cycle 1 by System Organ Class and Preferred Term	Full Analysis Set	Y	Y
Table	14.3-1.17	Summary of Related Treatment-emergent Adverse Events Leading to Treatment Discontinuation following Cycle 1 by System Organ Class and Preferred Term	Full Analysis Set	Y	Y
Table	14.3-1.18	Summary of Treatment-emergent Adverse Events Leading to Treatment Interruption by System Organ Class and Preferred Term	Full Analysis Set		Y
Table	14.3-1.19	Summary of Related Treatment-emergent Adverse Events Leading to Treatment Interruption by System Organ Class and Preferred Term	Full Analysis Set		Y
Table	14.3-1.20	Summary of Treatment-emergent Adverse Events Leading to Treatment Interruption within Cycle 1 by System Organ Class and Preferred Term	Full Analysis Set	Y	Y

Table	14.3-1.21	Summary of Related Treatment-emergent Adverse Events Leading to Treatment Interruption within Cycle 1 by System Organ Class and Preferred Term	Full Analysis Set	Y	Y
Table	14.3-1.22	Summary of Treatment-emergent Adverse Events Leading to Treatment Interruption following Cycle 1 by System Organ Class and Preferred Term	Full Analysis Set		Y
Table	14.3-1.23	Summary of Related Treatment-emergent Adverse Events Leading to Treatment Interruption following Cycle 1 by System Organ Class and Preferred Term	Full Analysis Set		Y
Table	14.3-1.24	Summary of Treatment-emergent Adverse Events Leading to Dose Reduction by System Organ Class and Preferred Term	Full Analysis Set		Y
Table	14.3-1.25	Summary of Related Treatment-emergent Adverse Events Leading to Dose Reduction by System Organ Class and Preferred Term	Full Analysis Set		Y
Table	14.3-1.26	Summary of Treatment-Emergent Adverse Events Leading to Dose Reduction within Cycle 1 by System Organ Class and Preferred Term	Full Analysis Set	Y	Y
Table	14.3-1.27	Summary of Related Treatment-Emergent Adverse Events Leading to Dose Reduction within Cycle 1 by System Organ Class and Preferred Term	Full Analysis Set	Y	Y
Table	14.3-1.28	Summary of Treatment-Emergent Adverse Events Leading to Dose Reduction following Cycle 1 by System Organ Class and Preferred Term	Full Analysis Set		Y
Table	14.3-1.29	Summary of Related Treatment-Emergent Adverse Events Leading to Dose Reduction following Cycle 1 by System Organ Class and Preferred Term	Full Analysis Set		Y
Table	14.3-1.30	Summary of Treatment-emergent Adverse Events by System Organ Class and Preferred Term Leading to Death	Full Analysis Set		Y
Table	14.3-1.31	Summary of Related Treatment-emergent Adverse Events by System Organ Class and Preferred Term Leading to Death	Full Analysis Set		Y
Table	14.3-1.32	Summary of Deaths	All Patients Set	Y	Y
Table	14.3-2.1	Summary and Change from Baseline in Hematology Laboratory Results by Visit	Full Analysis Set		Y
Table	14.3-2.2.1	Gradable Hematology Laboratory Results – Worst On-treatment Value by Cycle	Full Analysis Set		
Table	14.3-2.2.2	Non-gradable Hematology Laboratory Results – Worst On-treatment Value by Cycle	Full Analysis Set		
Table	14.3-2.3.1	Shift Table of Gradable Hematology Laboratory Results – Baseline vs Worst On-treatment Value	Full Analysis Set	Y	Y
Table	14.3-2.3.2	Shift Table of Non-gradable Hematology Laboratory Results – Baseline vs Worst On-treatment Value	Full Analysis Set		Y
Table	14.3-2.4	Summary and Change from Baseline in Biochemistry Laboratory Results by Visit	Full Analysis Set		Y
Table	14.3-2.5.1	Gradable Biochemistry Laboratory Results – Worst On-treatment Value by Cycle	Full Analysis Set		
Table	14.3-2.5.2	Non-gradable Biochemistry Laboratory Results – Worst On-treatment Value by Cycle	Full Analysis Set		
Table	14.3-2.6.1	Shift Table of Gradable Biochemistry Laboratory Results – Baseline vs Worst On-treatment Value	Full Analysis Set	Y	Y

Table	14.3-2.6.2	Shift Table of Non-gradable Biochemistry Laboratory Results – Baseline vs Worst On-treatment Value	Full Analysis Set		Y
Table	14.3-2.7	Summary at Baseline in Coagulation Laboratory Results by Visit	Full Analysis Set		Y
Table	14.3-2.8	Summary at Baseline in Urinalysis Laboratory Results by Visit	Full Analysis Set		
Table	14.3-3.1	Summary and Change from Baseline in Vital Signs by Visit	Full Analysis Set		Y
Table	14.3-3.2	Shift table of Vital Signs – Baseline vs worst on-treatment value	Full Analysis Set		Y
Table	14.3-3.3	Summary and Change from Baseline in ECG parameters by Visit	Full Analysis Set	Y	Y
Table	14.3-3.4	Summary of ECHO at Baseline	Full Analysis Set		
Table	14.3-3.5	Summary of Physical Examination at Baseline	Full Analysis Set		
Table	14.3-3.6	Summary of ECOG Performance Status by Visit	Full Analysis Set	Y	
14.4		**Other Efficacy Data**			
14.5		**Pharmacokinetic Data**			
Table	14.5-1.1	Pharmacokinetic Concentration Data	PK Analysis Set		Y
Table	14.5-1.2	Pharmacokinetic Parameters Data	PK Analysis Set		Y
14.2		**Figures**			
Figure	14.2-1.1	Consort Diagram	Full Analysis Set	Y	Y
Figure	14.2-1.2.1	Spider plot of Percentage Change from Baseline in Sum of Longest Diameter	Full Analysis Set		Y
Figure	14.2-1.2.2	Spider plot of Percentage Change from Baseline in Sum of Longest Diameter	Evaluable Analysis Set		
Figure	14.2-1.3.1	Waterfall plot of Maximum Percentage Change from Baseline in Sum of Longest Diameter	Full Analysis Set		Y
Figure	14.2-1.3.2	Waterfall plot of Maximum Percentage Change from Baseline in Sum of Longest Diameter	Evaluable Analysis Set		
Figure	14.2-1.4.1	Swimmer Plot of Response Assessments	Full Analysis Set		Y
Figure	14.2-1.4.2	Swimmer Plot of Response Assessments	Evaluable Analysis Set		
Figure	14.2-1.5.1	Kaplan-Meier Estimate for Progression-free Survival (PFS)	Full Analysis Set		Y
Figure	14.2-1.5.2	Kaplan-Meier Estimate for Progression-free Survival (PFS)	Evaluable Analysis Set		
Figure	14.2-1.6.1	Kaplan-Meier Estimate for Overall Survival (OS)	Full Analysis Set		Y
Figure	14.2-1.6.2	Kaplan-Meier Estimate for Overall Survival (OS)	Evaluable Analysis Set		
Figure	14.2-1.7.1	Kaplan-Meier Estimate for Duration of Response (DOR)	Full Analysis Set		
16.2		**Patient Data Listings**			
16.2.1		**Patient Disposition**			
Listing	16.2.1-1	Patient Informed Consent	All Patients Set		Y
Listing	16.2.1-2	Failed Inclusion and Exclusion Criteria	All Patients Set		Y
Listing	16.2.1-3	Patient Disposition	All Patients Set		Y
16.2.2		**Analysis Sets**			
Listing	16.2.2-1	Analysis Sets	All Patients Set		
16.2.3		**Protocol Deviations**			
Listing	16.2.3-1	Protocol Deviations	Full Analysis Set		Y
16.2.4		**Demographic Data**			
Listing	16.2.4-1	Demographics and Baseline Characteristics	Full Analysis Set		Y
Listing	16.2.4-2	Smoking History	Full Analysis Set		

Listing	16.2.4-3	Disease History	Full Analysis Set		Y
Listing	16.2.4-4	Medical History and Concomitant Diseases	Full Analysis Set		Y
Listing	16.2.4-5	Prior Systemic Anti-Cancer Therapies	Full Analysis Set		Y
Listing	16.2.4-6	Prior Radiotherapy Courses	Full Analysis Set		Y
Listing	16.2.4-7	Prior and Concomitant Medications	Full Analysis Set		Y
Listing	16.2.4-8	On Treatment Radiation	Full Analysis Set		
Listing	16.2.4-9	On Treatment Surgery and Medical Procedures	Full Analysis Set		
Listing	16.2.4-10	On Treatment Blood Transfusions	Full Analysis Set		
Listing	16.2.4-11	NGS Data	Full Analysis Set		Y
16.2.5		**Compliance and/or Drug Concentration Data**			
Listing	16.2.5-1	Ulixertinib In-clinic Administration	Full Analysis Set		
Listing	16.2.5-2	Hydroxychloroquine In-clinic Administration	Full Analysis Set		
Listing	16.2.5-3	Ulixertinib Interruptions and Adjustments	Full Analysis Set		Y
Listing	16.2.5-4	Hydroxychloroquine Interruptions and Adjustments	Full Analysis Set		Y
Listing	16.2.5-5	Ulixertinib Exposure	Full Analysis Set		Y
Listing	16.2.5-6	Hydroxychloroquine Exposure	Full Analysis Set		Y
Listing	16.2.5-7	Ulixertinib Dispensed	Full Analysis Set		
Listing	16.2.5-8	Hydroxychloroquine Dispensed	Full Analysis Set		
Listing	16.2.5-9	Ulixertinib Returned	Full Analysis Set		
Listing	16.2.5-10	Hydroxychloroquine Returned	Full Analysis Set		
16.2.6		**Individual Efficacy Response data**			
Listing	16.2.6-1	Target Lesions	Full Analysis Set		Y
Listing	16.2.6-2	Non-Target Lesions	Full Analysis Set		Y
Listing	16.2.6-3	New Lesions	Full Analysis Set		Y
Listing	16.2.6-4	Overall Response	Full Analysis Set		Y
Listing	16.2.6-5	Progression-Free Survival (PFS	Full Analysis Set		Y
Listing	16.2.6-6	Survival Status	Full Analysis Set		Y
Listing	16.2.6-7	Duration of Response (DOR)	Full Analysis Set		
16.2.7		**Adverse Events**	Full Analysis Set		
Listing	16.2.7-1	Adverse Events	All Patients Set		Y
Listing	16.2.7-2	Treatment Emergent Adverse Events	Full Analysis Set		Y
Listing	16.2.7-3	Serious Adverse Events	Full Analysis Set		Y
Listing	16.2.7-4	Deaths	All Patients Set		Y
16.2.8		**Laboratory Data**			
Listing	16.2.8-1	Hematology	Full Analysis Set		Y
Listing	16.2.8-2	Biochemistry	Full Analysis Set		Y
Listing	16.2.8-3	Coagulation	Full Analysis Set		Y
Listing	16.2.8-4	Urinalysis	Full Analysis Set		Y
Listing	16.2.8-5	Tumor Markers	Full Analysis Set		
Listing	16.2.8-6	Pregnancy	Full Analysis Set		
16.2.9		**Other Safety Data**			
Listing	16.2.9-1	Vital Signs	Full Analysis Set		Y
Listing	16.2.9-2	Electrocardiogram	Full Analysis Set		Y
Listing	16.2.9-3	ECHO/MUGA	Full Analysis Set		Y
Listing	16.2.9-4	Physical Examination	Full Analysis Set		Y
Listing	16.2.9-5	Ophthalmology exam	Full Analysis Set		Y
Listing	16.2.9-6	ECOG Performance Status	Full Analysis Set		Y
16.2.11		**Pharmacokinetic Data**			
Listing	16.2.11-1	Pharmacokinetic Concentration Data	PK Analysis Set		Y
Listing	16.2.11-2	Pharmacokinetic Parameters Data	PK Analysis Set		Y

*Table, Figure or Listing that will be used for SMC purposes. Y=Yes

4 General programming notes

All tables will be reported by treatment Basket.

An 'Overall' column will be included in all tables.

Column headers					
Basket 1	Basket 2	Basket 3	Basket 4	Basket 5	Overall

For tables reporting data on All Patients Set, a screening failures column will be added.

The full-page header to be included for each delivery is indicated in the table below:

Delivery	Type	Page Header
Dry run	Dry run	Dry-run
SMC *N**	Final	Final
Final analysis	Draft	Draft
	Final	Final

*N references to the SMC chronological number

For the listings, all cases where 'Other' is present, please present the respective 'Other' specification.

All Listings will be sorted by Basket and patient ID. A programming note will be added to each Listing when another variable is needed to make the sorting meaningful (e.g., assessment date).

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.1-1.1 – Patient Disposition
All Patients Set

	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Screen Failures N=XX n (%)	Overall N=XX n (%)
Patients enrolled [a]	XX	XX	XX	XX	XX	XX	XX
Patients completed screening [b]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Discontinued from screening [b]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Primary reason for discontinuation [c]							
Adverse Event	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Death	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Pregnancy	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Screen Failure	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Study Terminated by Sponsor	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Lost to Follow-up	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Technical Problems	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Physician Decision	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Withdrawal by Patient	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Patients rescreened [b]							
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Patients eligible for inclusion in the study [b]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Patients treated with study drug [b]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)

[a] Patients who signed the informed consent.
[b] Percentages are calculated from the number of patients enrolled.
[c] Percentages are calculated from the number of patients who discontinued from screening.
[d] Percentages are calculated from the number of patients who were treated with study drug.
[e] Percentages are calculated from the number of patients who discontinued from treatment.
[f] Percentages are calculated from the number of patients who discontinued from study.
Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Table 14.1-1.1 – Patient Disposition
All Patients Set

	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Screen Failures N=XX n (%)	Overall N=XX n (%)
Patients completed treatment [d]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Discontinued from treatment [d]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Primary reason for discontinuation [e]							
Death	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Progressive Disease	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Adverse Event	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Pregnancy	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Withdrawal by Patient	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Protocol Violation	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Lost to Follow-up	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Physician Decision	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Study Terminated by Sponsor	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)

[a] Patients who signed the informed consent.
[b] Percentages are calculated from the number of patients enrolled.
[c] Percentages are calculated from the number of patients who discontinued from screening.
[d] Percentages are calculated from the number of patients who were treated with study drug.
[e] Percentages are calculated from the number of patients who discontinued from treatment.
[f] Percentages are calculated from the number of patients who discontinued from study.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Table 14.1-1.1 – Patient Disposition
All Patients Set

	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Screen Failures N=XX n (%)	Overall N=XX n (%)
Patients completed study [b]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Primary reason for completion [f]							
Adverse Event	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Progressive Disease	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Death	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Withdrawal by Patient	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Physician Decision	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Lost to Follow-up	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Pregnancy	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Protocol Violation	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Sponsor Request	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Protocol-Specified Withdrawal Criterion Met	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)

[a] Patients who signed the informed consent.
[b] Percentages are calculated from the number of patients enrolled.
[c] Percentages are calculated from the number of patients who discontinued from screening.
[d] Percentages are calculated from the number of patients who were treated with study drug.
[e] Percentages are calculated from the number of patients who discontinued from treatment.
[f] Percentages are calculated from the number of patients who completed the study.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Display all possible reasons, either reported for at least one patient or not.

Table 14.1-1.2 – Number of Patients in the Analysis Sets
All Patients Set

	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Screen Failures N=XX n (%)	Overall N=XX n (%)
All Patients Set [a]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Full Analysis Set [b]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Stage 1 Analysis Set [c]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Evaluable Analysis Set [d]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
PK Analysis Set [e]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)

[a] Patients who were enrolled regardless of whether they received the study drug or not.
[b] Patients who received at least 1 dose of the study drug.
[c] First 13 patients who have completed at least one cycle of therapy and who have received a minimum of 75% of prescribed study therapy during Cycle 1
[d] Patients who received at least one dose of study drug and have at least one post-treatment study evaluation or who have discontinued therapy prior to the first post-treatment study evaluation due to clinical progressive disease or drug-related adverse events.
[e] Patients who received at least one dose of study medication and have at least one post dose PK measurement.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.1-1.3 – Summary of Important Protocol Deviations
Full Analysis Set

	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
Number of patients with at least one important protocol deviation	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Deviation category 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Summary term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Summary term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Deviation category 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Summary term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Summary term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: A patient with multiple occurences of a protocol deviation is counted only once in this deviation category/summary term.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Categories / Summary terms to match the PDCF.
- Present only important protocol deviations with at least one occurrence (where classification=Important).

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.1-2.1 – Demographics and Baseline Characteristics
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Age (Years)						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XXX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)
Median	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Min; Max	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X
Age category (Years) n (%)						
18 - 64	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
65 - 84	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
>=85	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Gender - n (%)						
Female	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Childbearing potential n (%)						
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Male	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Reproductive potential n (%)						
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

[a] Last non-missing value prior to first dose of study treatment.
[b] Body Mass Index (BMI)=Weight (kg)/ Height(m)^2.
[c] 0=Fully active, able to carry on all pre-disease performance without restriction; 1=Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature; 2=Ambulatory and capable of all self-care but unable to carry out any work activities.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.doc)

Table 14.1-2.1 - Demographics and Baseline Characteristics
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Race - n (%)						
American Indian or Alaska Native	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Asian	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Black or African American	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Native Hawaiian or Other Pacific Islander	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
White	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Ethnicity - n (%)						
Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Unknown	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Weight (kg) [a]						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX

[a] Last non-missing value prior to first dose of study treatment.
[b] Body Mass Index (BMI)=Weight (kg)/ Height(m)^2.
[c] 0=Fully active, able to carry on all pre-disease performance without restriction; 1=Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature; 2=Ambulatory and capable of all self-care but unable to carry out any work activities.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.doc)

Table 14.1-2.1 - Demographics and Baseline Characteristics
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Height (cm) [a]						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX
ECOG performance at Baseline - n (%) [b]						
0	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Smoking History - n (%)						
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Current	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Former	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

[a] Last non-missing value prior to first dose of study treatment.
[b] 0=Fully active, able to carry on all pre-disease performance without restriction; 1=Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature; 2=Ambulatory and capable of all self-care but unable to carry out any work activities.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)
Filename: (Specify file name.doc)

Table 14.1-2.1 - Demographics and Baseline Characteristics
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Gene/Codon/Amino acid change						
HRAS/G469/Alanine A	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
KRAS/G469/Arginine R	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
NRAS/G469/Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
…						

[a] Last non-missing value prior to first dose of study treatment.
[b] Body Mass Index (BMI)=Weight (kg)/ Height(m)^2.
[c] 0=Fully active, able to carry on all pre-disease performance without restriction; 1=Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature; 2=Ambulatory and capable of all self-care but unable to carry out any work activities.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.doc)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.1-2.2 – Disease History
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Cancer Diagnosis – n (%)						
Intrahepatic cholangiocarcinoma	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Perihilar cholangiocarcinoma	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Extrahepatic cholangiocarcinoma	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Pancreatic adenocarcinoma	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....						
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Time since initial diagnosis (months) [a]						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX
Disease stage at enrollment – n (%)						
1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
4	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

[a] Calculated as (date of first dose of study treatment – date of diagnosis) / 30.4375.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.1-2.2 – Disease History
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Disease stage at initial diagnosis – n (%)						
1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
4	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Method of diagnosis – n (%)						
Cytological	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Histological	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Prior Radiation Therapies – n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No						

[a] Calculated as (date of first dose of study treatment – date of diagnosis) / 30.4375.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.1-2.3 – Summary of Medical History
Full Analysis Set

System Organ Class Preferred Term	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
Any relevant medical history	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: MedDRA <vx.x>.
If there is more than one medical history within a system organ class (SOC), the patient is counted only once under that SOC. If there is more than one medical history within a SOC and preferred term (PT), the patient is counted only once in that SOC and PT.
Primary SOCs are presented by descending order of frequency for the overall Basket, PTs are sorted by descending order of frequency for the overall Basket within primary SOC.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.1-2.4 – Summary of Concomitant Diseases
Full Analysis Set

System Organ Class Preferred Term	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
Any relevant concomitant disease	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: MedDRA <vx.x>.
If there is more than one concomitant disease within a system organ class (SOC), the patient is counted only once under that SOC. If there is more than one concomitant disease within a SOC and preferred term (PT), the patient is counted only once in that SOC and PT. Primary SOCs are presented by descending order of frequency for the overall Basket, PTs are sorted by descending order of frequency for the overall Basket within primary SOC.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.1-3.1 – Prior Systemic Anti-Cancer Therapies
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Received at least one systemic prior anti-cancer Therapy – n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Lines of systemic prior anti-cancer therapies – n (%)						
1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
4	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
…						
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX
Most recent therapy before study treatment start						
Regimen name – n (%)						
xxxxxxxx	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
xxxxxxxx	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
xxxxxxxx	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

[a] Calculated as [(end date of therapy – start date of therapy)+1] / 30.4375.
[b] Calculated as [(date of first study treatment – date of BOR)+1] / 30.4375.
[c] Calculated as [(date of first study treatment – date of Relapse/Progression)+1] / 30.4375.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Table 14.1-3.1 – Prior Systemic Anti-Cancer Therapies
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Best Response – n (%)						
Complete Response	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Partial Response	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Stable Disease	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Progressive Disease	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Evaluable	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Done	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Duration of therapy (months) [a]						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX
Time since Best Overall Response (months) [b]						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX

[a] Calculated as [(end date of therapy – start date of therapy)+1] / 30.4375.
[b] Calculated as [(date of first study treatment – date of BOR)+1] / 30.4375.
[c] Calculated as [(date of first study treatment – date of Relapse/Progression)+1] / 30.4375.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Table 14.1-3.1 – Prior Systemic Anti-Cancer Therapies
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Time since Relapse/Progression (months) [c]						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX
Reason for discontinuation – n (%)						
Intolerance	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Lack of Efficacy (incl. PD)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Completed Therapy	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

[a] Calculated as [(end date of therapy – start date of therapy)+1] / 30.4375.
[b] Calculated as [(date of first study treatment – date of BOR)+1] / 30.4375.
[c] Calculated as [(date of first study treatment – date of Relapse/Progression)+1] / 30.4375.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)
Filename: (Specify file name.rtf)

Table 14.1-3.2 – Prior Radiotherapy Courses
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Received at least one prior radiotherapy – n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Total number of prior radiotherapy courses – n (%)						
1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Site of prior radiotherapy – n (%) [a]						
Abdominal Cavity	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Adrenal Gland	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
…….						
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Most recent prior radiotherapy before study treatment start						
Site of prior radiotherapy – n (%)						
Abdominal Cavity	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
…….						
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Duration of therapy (months) [b]						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX

[a] Patients can have more than 1 site of prior radiotherapy if they had multiple prior radiotherapies.
[b] Calculated as [(end date of therapy – start date of therapy)+1] / 30.4375.
Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.1-3.3 – Prior Medications
Full Analysis Set

ATC Class Preferred Term	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
Any Prior Medications	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
ATC class 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
……	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
ATC class 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
……	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: WHOHD-B3 <vx.x>. ATC=Anatomical Therapeutic Chemical.
If there is more than one medication within an ATC class, the patient is counted only once under that ATC class. If there is more than one medication within an ATC class and preferred term (PT), the patient is counted only once in that ATC class and PT.
ATC classes are presented by descending order of frequency for the overall Basket, PTs are sorted by descending order of frequency for the overall Basket within ATC class.
Prior medication is defined as any medications whose end date is before the first study treatment date.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Table 14.1-3.4 – Concomitant Medications
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.1-3.3
- Present concomitant medications.
- Replace footnote 'Prior medication is defined as…' with the following footnote:
  'Concomitant medication is defined as any medication ongoing at first day of study drug or started after first day of study drug up to the end of the on-treatment period.'

Table 14.1-4.1.1 – Treatment exposure (Ulixertinib)
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Number of cycles received [a] – n (%)						
1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
…						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)
Median	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Min; Max	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X
Duration of exposure to ulixertinib (months) [b] – n (%)						
< 1 month	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1-2 months	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2-3 months	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
…						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)
Median	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Min; Max	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X

[a] Number of cycles received = Number of cycles where the patient received at least one dose.
[b] Duration of exposure (months) = [(Date of last known treatment dosing with drug – date of initial dosing with drug) + 1] / 30.4375.
[c] Actual cumulative dose received (mg) = Sum of [(Stop date – Start date for each time period reported in the dairy) x Dose].
[d] Relative dose intensity = 100 x Actual dose intensity / Planned dose intensity. Actual dose intensity (mg/day) is defined as Actual cumulative dose received (mg) / Duration of exposure (days). Planned dose intensity (mg/day) is defined as Planned cumulative dose (mg) / Duration of exposure (days).
Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Table 14.1-4.1.1 – Treatment exposure (Ulixertinib)
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Actual cumulative dose on ulixertinib (mg) [c]						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)
Median	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Min; Max	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X
Relative dose intensity [d]						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)
Median	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Min; Max	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X

[a] Number of cycles received = Number of cycles where the patient received at least one dose.
[b] Duration of exposure (months) = [(Date of last known treatment dosing with drug – date of initial dosing with drug) + 1] / 30.4375.
[c] Actual cumulative dose received (mg) = Sum of [(Stop date – Start date for each time period reported in the dairy) x Dose].
[d] Relative dose intensity = 100 x Actual dose intensity / Planned dose intensity. Actual dose intensity (mg/day) is defined as Actual cumulative dose received (mg) / Duration of exposure (days). Planned dose intensity (mg/day) is defined as Planned cumulative dose (mg) / Duration of exposure (days).
Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Table 14.1-4.1.2 – Treatment exposure (Hydroxychloroquine)
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.1-4.1.1

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.1-4.2.1 – Dosing Interruptions and Adjustments (Ulixertinib)
Full Analysis Set

	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
At least one dose adjustment – n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Reason dose changed – n (%) [a]						
Adverse event	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Parental/Guardian decision	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Consent withdrawal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
…	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other						
Dose changed to – n (%) [b]						
150mg	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
300mg	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
450mg	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
At least one dose interruption – n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Reason dose interrupted [a]						
Adverse Event	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Dispensing Error	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Investigator Decision	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Consent Withdrawal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Patient Decision	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

[a] A patient can be counted under several reasons if they had multiple different dose changes/interruptions.
[b] A patient can be counted under more than one dose level if they had multiple different dose changes.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Table 14.1-4.2.2 – Dosing Interruptions and Adjustments (Hydroxychloroquine)
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.1-4.2.1

Table 14.2-1.1.1 – Best Overall Response and Overall Response Rate
Full Analysis Set

	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
Best overall response – n (%) [a]						
Complete response (CR)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Partial response (PR)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Stable disease (SD)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Progressive disease (PD)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not evaluable (NE)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Overall response rate (CR+PR) – n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
95 % CI for Overall response rate	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
Disease control rate (CR+PR+SD) – n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
95 % CI for Disease Control rate	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
Non-responders (SD+PD+NE) – n (%) [b]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

CR=Complete Response, PR=Partial Response, SD=Stable Disease, PD=Progressive Disease, NE=Not Evaluable , CI=Confidence Interval.
95% CI is estimated using the Clopper-Pearson method.
[a] Confirmed Best overall response as per RECIST 1.1
[b] Non responders: Patients without a confirmed response or a missing baseline/screening tumor assessment will be considered non-responders

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Table 14.2-1.1.2 – Best Overall Response and Overall Response Rate
Evaluable Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.2-1.1.1
- Present data on Evaluable Analysis Set.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.2-1.2.1 – Overall, Target and Non-Target Lesion Response
Full Analysis Set

	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
C3D1						
Target Lesion Response – n (%)						
Complete response (CR)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Partial response (PR)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Stable disease (SD)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Progressive disease (PD)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not evaluable (NE)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Non-Target Lesion Response – n (%)						
Complete response (CR)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Non-Complete Response/Non Progressive Disease	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Progressive disease (PD)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Evaluable (NE)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Applicable	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Overall Response – n (%)						
Complete response (CR)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Partial Response (PR)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Stable Disease (SD)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Progressive disease (PD)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Evaluable (NE)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Programming Note: Repeat for all available assessments

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Table 14.2-1.2.2 – Overall, Target and Non-Target Lesion Response
Evaluable Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.2-1.2.1
- Present data on Evaluable AnalysisSet.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.2-1.3.1 – Incidence of New Lesions
Full Analysis Set

	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
C3D1						
New Lesions – n (%)						
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Number of New Lesions – n (%)						
1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
…						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)
Median	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Min; Max	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X

Programming Note: Repeat for all available assessments

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Table 14.2-1.3.2 – Incidence of New Lesions
Evaluable Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.2-1.3.1
- Present data on Evaluable Analysis Set.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.2-1.4.1 – Progression-Free Survival (PFS)
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Patients with events – n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Patients censored – n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
PFS (months) [a]						
Median (95% CI)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
Min, Max	XX, XX*	XX, XX	XX, XX	XX, XX*	XX, XX	XX, XX
KM probability estimates for PFS (95% CI) [b]						
3 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
6 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
9 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
12 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
18 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)

Note: CI=Confidence Interval.
Progression-Free Survival (PFS) is the time from the first ulixertinib dose dose until the first radiographically documented progression of disease or death from any cause, whichever occurs first.
[a] Product-limit (Kaplan-Meier) estimates. 95% CI for median calculated using the Brookmeyer and Crowley method.
[b] Based upon Kaplan-Meier (KM) estimates and 95% CI use the log-log transformation.
* Censored observation at maximum value.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Table 14.2-1.4.2 – Progression-Free Survival (PFS)
Evaluable Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.2-1.4.1
- Present data on Evaluable Analysis Set.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.2-1.5.1 – Overall Survival (OS)
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Patients with events – n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Patients censored – n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
OS (months) [a]						
Median (95% CI)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
Min, Max	XX, XX*	XX, XX	XX, XX	XX, XX*	XX, XX	XX, XX
KM probability estimates for PFS (95% CI) [b]						
3 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
6 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
9 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
12 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
18 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)

Note: CI=Confidence Interval.
Overall Survival is defined as the time from first treatment to death.
[a] Product-limit (Kaplan-Meier) estimates. 95% CI for median calculated using the Brookmeyer and Crowley method.
[b] Based upon Kaplan-Meier (KM) estimates and 95% CI use the log-log transformation.
* Censored observation at maximum value.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Table 14.2-1.5.2 – Overall Survival (OS)
Evaluable Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.2-1.4.1
- Present data on Evaluable Analysis Set.

Table 14.2-1.6.1 – Duration of Response
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Patients with response (CR+PR)	XX	XX	XX	XX	XX	XX
Patients with events – n (%) [a]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Patients censored – n (%) [a]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
DOR (months) [b]						
Median (95% CI)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
Min, Max	XX, XX*	XX, XX	XX, XX	XX, XX*	XX, XX	XX, XX
KM probability estimates for PFS (95% CI) [c]						
3 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
6 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
9 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
12 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
18 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)

Note: CI=Confidence Interval, CR=Complete Response, PR=Partial Response.
Duration of response is the period from the date of initial confirmed PR or CR until the date of first radiographically documented progressive disease or death from any cause. +1
[a] Percentage calculated on patients with response. Events are death or disease progression.
[b] Product-limit (Kaplan-Meier) estimates. 95% CI for median calculated using the Brookmeyer and Crowley method.
[c] Based upon Kaplan-Meier (KM) estimates and 95% CI use the log-log transformation.
* Censored observation at maximum value.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-1.1 – Overview Summary of Treatment-Emergent Adverse Events
Full Analysis Set

	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
Number of patients with:						
Any TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any Related TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Related TEAE to Both	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Related TEAE to Uli.	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Related TEAE to HCQ.	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any SAE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any Related SAE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any TEAE leading to treatment discontinuation	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any Related TEAE leading to treatment discontinuation	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any TEAE leading to treatment discontinuation within 1 cycle	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any Related TEAE leading to treatment discontinuation within 1 cycle	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any TEAE leading to treatment discontinuation following 1 cycle	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any Related TEAE leading to treatment discontinuation following 1 cycle	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any TEAE leading to treatment interruption	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any Related TEAE leading to treatment interruption	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any TEAE leading to treatment interruption within 1 cycle	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any Related TEAE leading to treatment interruption within 1 cycle	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any TEAE leading to treatment interruption following 1 cycle	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any Related TEAE leading to treatment interruption following 1 cycle	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: SAE=Serious Adverse Events, TEAE=Treatment-Emergent Adverse Events
Note 2: Any related TEAE includes TEAEs that are considered related to either hydroxychloroquine or ulixertinib.
Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Table 14.3-1.1 – Overview Summary of Treatment-Emergent Adverse Events

Full Analysis Set

	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
Number of patients with:						
Any TEAE leading to dose reduction	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any related TEAE leading to dose reduction	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any TEAE leading to dose reduction within Cycle 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any Related TEAE leading to dose reduction within Cycle 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any TEAE leading to dose reduction following Cycle 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any Related TEAE leading to dose reduction following Cycle 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any TEAE leading to death	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any Related TEAE leading to death	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any TEAE with Grade >= 3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any Related TEAE with Grade >= 3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: SAE=Serious Adverse Events, TEAE=Treatment-Emergent Adverse Events
Note 2: Any related TEAE includes TEAEs that are considered related to either hydroxychloroquine or ulixertinib.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- "Related TEAE to Both", "Related TEAE to Uli." and "Related TEAE to HCQ." will be presented for all treatment-related adverse events [...]" in the above table.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-1.2 – Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Full Analysis Set

System Organ Class Preferred Term	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
Any TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
……	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
……	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: MedDRA <vx.x>. TEAE=Treatment-Emergent Adverse Events.
If there is more than one TEAE within a system organ class (SOC), the patient is counted only once under that SOC. If there is more than one TEAE within a SOC and preferred term (PT), the patient is counted only once in that SOC and PT.
Primary SOCs are presented by descending order of frequency for the overall Basket, PTs are sorted by descending order of frequency for the overall Basket within each SOC.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-1.3 – Summary of Related Treatment-emergent Adverse Events by System Organ Class and Preferred Term
Full Analysis Set

System Organ Class / Preferred Term	Basket 1 N=XX n (%)			Basket 2 N=XX n (%)			Basket 3 N=XX n (%)			Basket 4 N=XX n (%)			Basket 5 N=XX n (%)			Overall N=XX n (%)		
	Both	Uli	HCQ	**Both**	Uli	HCQ	**Both**	Uli	HCQ	**Both**	Uli	HCQ	**Both**	Uli	HCQ	**Both**	Uli	HCQ
Any related TEAE	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)
System organ class 1	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)
Preferred term 1	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)
Preferred term 2	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)
.....																		

Note: MedDRA <vx.x>. TEAE=Treatment-Emergent Adverse Events.
Note 2: Both = TEAE related to both treatments, Uli = TEAE related to ulixertinib, HCQ = TEAE related to Hydroxychloriquine.
Related TEAE: TEAEs with causality=Related, Possibly Related or missing.
If there is more than one TEAE within a system organ class (SOC), the patient is counted only once under that SOC. If there is more than one TEAE within a SOC and preferred term (PT), the patient is counted only once in that SOC and PT.
Primary SOCs are presented by descending order of frequency for the overall Basket, PTs are sorted by descending order of frequency for the overall Basket within each SOC.

Table 14.3-1.4 – Summary of Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.2
- Present Serious TEAE: TEAEs with SAE =" Yes".
- Add footnote:
  "Serious TEAE: TEAEs with SAE =" Yes"."

Table 14.3-1.5 – Summary of Related Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.3
- Present Related Serious TEAE: SAEs with causality=Related, Possibly Related or missing.
- Add footnote:
  "SAEs with causality=Related, Possibly Related or missing."

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-1.6 – Summary of Treatment-Emergent Adverse Events by Preferred Term
Full Analysis Set

System Organ Class Preferred Term	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
Any TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....						

Note: MedDRA <vx.x>. TEAE=Treatment-Emergent Adverse Events.
If there is more than one TEAE within a preferred term (PT), the patient is counted only once in that PT.
PTs are sorted in descending order of frequency for the overall Basket.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-1.7 – Summary of Related Treatment-emergent Adverse Events by Preferred Term
Full Analysis Set

Preferred Term	Basket 1 N=XX n (%)			Basket 2 N=XX n (%)			Basket 3 N=XX n (%)			Basket 4 N=XX n (%)			Basket 5 N=XX n (%)			Overall N=XX n (%)		
	Both	Uli	HCQ	**Both**	Uli	HCQ	**Both**	Uli	HCQ	**Both**	Uli	HCQ	**Both**	Uli	HCQ	**Both**	Uli	HCQ
Any related TEAE	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)
Preferred term 1	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)
Preferred term 2	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)
.....																		

Note: MedDRA <vx.x>. TEAE=Treatment-Emergent Adverse Events.
Note 2: Both = TEAE related to both treatments, Uli = TEAE related to ulixertinib, HCQ = TEAE related to Hydroxychloriquine.
Related TEAE: TEAEs with causality=Related, Possibly Related or missing.
If there is more than one TEAE within a preferred term (PT), the patient is counted only once in that PT.
PTs are sorted in descending order of frequency for the overall Basket.

Table 14.3-1.8 – Summary of Serious Treatment-emergent Adverse Events by Preferred Term
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.3-1.6
- Present Serious TEAE: TEAEs with SAE =" Yes".
- Add footnote:
  "Serious TEAE: TEAEs with SAE =" Yes"."

Table 14.3-1.9 – Summary of Related Serious Treatment-emergent Adverse Events by Preferred Term
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.3-1.7
- Present Related Serious TEAE: SAEs with causality=Related, Possibly Related or missing.
- Add footnote:
  "SAEs with causality=Related, Possibly Related or missing."

Table 14.3-1.10 – Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term for Maximum CTCAE Grade
Full Analysis Set

Basket: Basket X

System Organ Class Preferred Term	Any CTC Grade n (%) [Events]	CTC Grade 1 n (%)	CTC Grade 2 n (%)	CTC Grade 3 n (%)	CTC Grade 4 n (%)	CTC Grade 5 n (%)
Any TEAE	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 1	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 2	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: MedDRA <vx.x>; CTCAE v5.0. TEAE=Treatment-Emergent Adverse Events.
If there is more than one TEAE within a system organ class (SOC), the patient is counted only once under that SOC and maximum severity.
If there is more than one TEAE within a SOC and preferred term (PT), the patient is counted only once in that SOC, PT and maximum severity.
Primary SOCs are presented by descending order of frequency for the overall Basket, PTs are sorted within primary SOC descending order of frequency for the overall Basket within each SOC.
[Events] presents the number of TEAEs reported overall, by primary SOC and PT regardless of severity.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Present for each Basket and overall.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-1.11 – Summary of Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term for Maximum CTCAE Grade
Full Analysis Set

Basket: Basket X, Related to both study treatments

System Organ Class Preferred Term	Any CTC Grade n (%) [Events]	CTC Grade 1 n (%)	CTC Grade 2 n (%)	CTC Grade 3 n (%)	CTC Grade 4 n (%)	CTC Grade 5 n (%)
Any related TEAE	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 1	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 2	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: MedDRA <vx.x>; CTCAE v5.0. TEAE=Treatment-Emergent Adverse Events.
If there is more than one TEAE within a system organ class (SOC), the patient is counted only once under that SOC and maximum severity.
If there is more than one TEAE within a SOC and preferred term (PT), the patient is counted only once in that SOC, PT and maximum severity.
Primary SOCs are presented by descending order of frequency for the overall Basket, PTs are sorted within primary SOC descending order of frequency for the overall Basket within each SOC.
[Events] presents the number of TEAEs reported overall, by primary SOC and PT regardless of severity.
Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Present for each Basket and overall. For each Basket and Overall present TEAEs that are Related to both study treatments, related to ulixertinib and related to hydroxychloriquine
- Present Related TEAE: TEAEs with causality=Related, Possibly Related or missing.
- Add footnote:
  "Related TEAE: TEAEs with causality=Related, Possibly Related or missing."

Table 14.3-1.12 – Summary of Treatment-Emergent Adverse Events Leading to Treatment Discontinuation
by System Organ Class and Preferred Term
Full Analysis Set

System Organ Class Preferred Term	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
Any TEAE leading to treatment discontinuation	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: MedDRA <vx.x>. TEAE=Treatment-Emergent Adverse Events.
If there is more than one TEAE leading to treatment discontinuation within a system organ class (SOC), the patient is counted only once under that SOC. If there is more than one TEAE leading to treatment discontinuation within a SOC and preferred term (PT), the patient is counted only once in that SOC and PT.
Primary SOCs are presented by descending order of frequency for the overall Basket, PTs are sorted within primary SOC descending order of frequency for the overall Basket within each SOC.
TEAEs leading to treatment discontinuation: any TEAEs with Action taken with study treatment=Drug withdrawn.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Table 14.3-1.13 – Summary of Related Treatment-Emergent Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.3
- Replace 'Any TEAE' by 'Any TEAE leading to treatment discontinuation'
- Present Related TEAE: TEAEs with causality=Related, Possibly Related or missing.
- Add footnote:
  "Related TEAE: TEAEs with causality=Related, Possibly Related or missing."

Table 14.3-1.14 – Summary of Treatment-Emergent Adverse Events Leading to Treatment Discontinuation Within Cycle 1 by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.12
- Add footnote:
  "TEAEs leading to treatment discontinuation: any TEAEs with Action taken with study treatment=Drug withdrawn within the first 28 days of study."

Table 14.3-1.15 – Summary of Related Treatment-Emergent Adverse Events Leading to Treatment Discontinuation Within Cycle 1 by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.3
- Replace 'Any TEAE' by 'Any TEAE leading to treatment discontinuation within cycle 1'
- Present Related TEAE: TEAEs with causality=Related, Possibly Related or missing.
- Add footnote:
  "TEAEs leading to treatment discontinuation: any TEAEs with Action taken with study treatment=Drug withdrawn within the first 28 days of study."

Table 14.3-1.16 – Summary of Treatment-Emergent Adverse Events Leading to Treatment Discontinuation Following Cycle 1 by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.12
- Add footnote:
  "TEAEs leading to treatment discontinuation: any TEAEs with Action taken with study treatment=Drug withdrawn after the first 28 days of study."
  "Related TEAE: TEAEs with causality=Related, Possibly Related or missing."

Table 14.3-1.17 – Summary of Related Treatment-Emergent Adverse Events Leading to Treatment Discontinuation Following Cycle 1 by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.3
- Replace 'Any TEAE' by 'Any TEAE leading to treatment discontinuation following cycle 1'
- Present Related TEAE: TEAEs with causality=Related, Possibly Related or missing.'
- Add footnote:
  "TEAEs leading to treatment discontinuation: any TEAEs with Action taken with study treatment=Drug withdrawn after the first 28 days of study."
  "Related TEAE: TEAEs with causality=Related, Possibly Related or missing."

Table 14.3-1.18 – Summary of Treatment-Emergent Adverse Events Leading to Treatment Interruption by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.12
- Replace 'Any TEAE' by 'Any TEAE leading to treatment interruption.'
- Add footnote:
- "Includes TEAE with 'Action Taken with treatment' = 'Drug Interrupted'.

Table 14.3-1.19 – Summary of Related Treatment-Emergent Adverse Events Leading to Treatment Interruption by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.3
- Replace 'Any TEAE' by 'Any related TEAE leading to treatment interruption.'
- Add footnotes:
  "Includes TEAE with 'Action Taken with treatment' = 'Drug Interrupted'.
  "Related TEAE: TEAEs with causality=Related, Possibly Related or missing."

Table 14.3-1.20 – Summary of Treatment-Emergent Adverse Events Leading to Treatment Interruption Within Cycle 1 by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.12
- Replace 'Any TEAE' by 'Any TEAE leading to treatment interruption within Cycle 1.'
- Add footnote:
  "Includes TEAE with 'Action Taken with treatment' = 'Drug Interrupted' within the first 28 days of study.

Table 14.3-1.21 – Summary of Related Treatment-Emergent Adverse Events Leading to Treatment Interruption Within Cycle 1 by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.3
- Replace 'Any TEAE' by 'Any related TEAE leading to treatment interruption within Cycle 1.'
- Add footnotes:
  "Includes TEAE with 'Action Taken with treatment' = 'Drug Interrupted' within the first 28 days of study.
  "Related TEAE: TEAEs with causality=Related, Possibly Related or missing."

Table 14.3-1.22 – Summary of Treatment-Emergent Adverse Events Leading to Treatment Interruption Following Cycle 1 by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.12
- Replace 'Any TEAE' by 'Any TEAE leading to treatment interruption following Cycle 1.'
- Add footnote:
  "Includes TEAE with 'Action Taken with treatment' = 'Drug Interrupted' after the first 28 days of study.

Table 14.3-1.23 – Summary of Related Treatment-Emergent Adverse Events Leading to Treatment Interruption Following Cycle 1 by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.3
- Replace 'Any TEAE' by 'Any related TEAE leading to treatment interruption following Cycle 1'.
- Add footnotes:
  "Includes TEAE with 'Action Taken with treatment' = 'Drug Interrupted' after the first 28 days of study.
  "Related TEAE: TEAEs with causality=Related, Possibly Related or missing."

Table 14.3-1.24 – Summary of Treatment-Emergent Adverse Events Leading to Dose Reduction by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.3-1.12
- Replace 'Any TEAE' by 'Any TEAE leading to dose reduction.'
- Add footnote:
  "Includes TEAE with 'Action Taken with treatment' = 'Dose Reduced'".

Table 14.3-1.25 – Summary of Related Treatment-Emergent Adverse Events Leading to Dose Reduction by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.3-1.3
- Replace 'Any TEAE' by 'Any related TEAE leading to dose reduction.'
- Add footnotes:
  "Includes TEAE with 'Action Taken with treatment' = 'Dose Reduced'".
  "Related TEAE: TEAEs with causality=Related, Possibly Related or missing."

Table 14.3-1.26 – Summary of Treatment-Emergent Adverse Events Leading to Dose Reduction within Cycle 1 by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.12
- Replace 'Any TEAE' by 'Any TEAE leading to dose reduction within Cycle 1.'
- Add footnote:
  "Includes TEAE with 'Action Taken with treatment' = 'Dose Reduced' within the first 28 days of study".

Table 14.3-1.27 – Summary of Related Treatment-Emergent Adverse Events Leading to Dose Reduction within Cycle 1 by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.3
- Replace 'Any TEAE' by 'Any related TEAE leading to dose reduction within Cycle 1.'
- Add footnotes:
  "Includes TEAE with 'Action Taken with treatment' = 'Dose Reduced' within the first 28 days of study".
  "Related TEAE: TEAEs with causality=Related, Possibly Related or missing."

Table 14.3-1.28 – Summary of all Treatment-Emergent Adverse Events Leading to Dose Reduction following Cycle 1 by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.3-1.12
- Replace 'Any TEAE' by 'Any TEAE leading to dose reduction following Cycle 1.
- Add footnote:
  "Includes TEAE with 'Action Taken with treatment' = 'Dose Reduced' after the first 28 days of study".

Table 14.3-1.29 – Summary of Related Treatment-Emergent Adverse Events Leading to Dose Reduction following Cycle 1 by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.3-1.3
- Replace 'Any TEAE' by 'Any related TEAE leading to dose reduction following Cycle 1.
- Add footnote:
  "Includes TEAE with 'Action Taken with treatment' = 'Dose Reduced' after the first 28 days of study".
  "Related TEAE: TEAEs with causality=Related, Possibly Related or missing."

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-1.30 – Summary of Treatment-Emergent Adverse Events Leading to Death by System Organ Class and Preferred Term
Full Analysis Set

System Organ Class Preferred Term	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
Any TEAE leading to death	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: MedDRA <vx.x>. TEAE=Treatment-Emergent Adverse Events.
If there is more than one TEAE leading to death within a system organ class (SOC), the patient is counted only once under that SOC. If there is more than one TEAE leading to death within a SOC and preferred term (PT), the patient is counted only once in that SOC and PT.
Primary SOCs are presented by descending order of frequency for the overall Basket, PTs are sorted within primary SOC descending order of frequency for the overall Basket within each SOC.
TEAEs leading to Death: any TEAE resulting in death, Outcome=Fatal, CTC Grade=5.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Table 14.3-1.31 – Summary of Related Treatment-Emergent Adverse Events Leading to Death by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.3-1.3
- Replace 'Any TEAE' by 'Any related TEAE leading to death'
- Present Related TEAE: TEAEs with causality=Related, Possibly Related or missing.
- Add footnote:
  "Related TEAE: TEAEs with causality=Related, Possibly Related or missing."
  "TEAEs leading to Death: any TEAE resulting in death, Outcome=Fatal, CTC Grade=5."

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-1.32 – Summary of Deaths
All Patients Set

	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Screen Failures N=XX n (%)	Overall N=XX n (%)
Patients who died during the study	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Primary cause of death							
Progressive Disease	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Adverse Event	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Unknown	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Patients who died after taking the first dose of ulixertinib	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Primary cause of death							
Progressive Disease	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Adverse Event	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Unknown	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-2.1 – Summary and Change from Baseline in Hematology Laboratory Results by Visit
Full Analysis Set

Parameter: XXXXX (XX)

Visit Statistics	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Baseline						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX
C1D8						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX
Change from Baseline to C1D8						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX

Note: Baseline is the last available assessment prior to first dose of study treatment.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Present for all hematology parameters: hematocrit, hemoglobin, platelets, white blood cells (WBC), neutrophil absolute, lymphocyte absolute with respective unit measure.
- Present for all available visits.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-2.2.1 – Gradable Hematology Laboratory Results – Worst On-treatment Value by Cycle
Full Analysis Set

Parameter (unit) Cycle CTCAE Grade	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
XXXXX (XXX)						
Cycle 1						
Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
4	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Missing	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Cycle 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
4	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Missing						
…						

Note: CTCAE v5.0.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Present for all hematology parameters where CTCAE grades are defined as per the SAP appendix 14.2.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-2.2.2 – Non-gradable Hematology Laboratory Results – Worst On-treatment Value by Cycle
Full Analysis Set

Parameter (unit) Cycle CTCAE Grade	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
XXXXX (XXX)						
Cycle 1						
Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Low	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
High	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Missing	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Cycle 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Low	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
High	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Missing						
…						

Note: CTCAE v5.0.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Present for all hematology parameters where CTCAE grades are **not** defined as per the SAP appendix 14.2.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-2.3.1 – Shift Table of Gradable Hematology Laboratory Results – Baseline vs Worst On-treatment Value
Full Analysis Set

Basket: Basket 1 (N=XX)

Parameter (unit)	Baseline Grade	Worst CTCAE grade during treatment period: Normal n (%)	1 n (%)	2 n (%)	3 n (%)	4 n (%)	Missing n (%)	Total n (%)
XXXXX (XXX)	Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	4	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Missing	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Total	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: CTCAE v5.0.
Baseline is the last available assessment prior to first dose of study treatment.
Percentages are based on the number of patients in the Basket.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Present for each Basket and overall, and for all hematology parameters where CTCAE grades are defined as per the SAP appendix 14.2.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-2.3.2 – Shift Table of Non-gradable Hematology Laboratory Results – Baseline vs Worst On-treatment Value
Full Analysis Set

Basket: Basket 1 (N=XX)

Parameter (unit)	Baseline Grade	Worst grade during treatment period: Low n (%)	Normal n (%)	High n (%)	Missing n (%)	Total n (%)
XXXXX (XXX)	Low	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	High	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Missing	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Total	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: Baseline is the last available assessment prior to first dose of study treatment.
Percentages are based on the number of patients in the Basket.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Present for all Baskets and overall, and for all hematology parameters where CTCAE grades are not defined as per the SAP appendix 14.2.

Table 14.3-2.4 – Summary and Change from Baseline in Biochemistry Laboratory Results by Visit
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-2.1
- Present for all biochemistry parameters: alanine aminotransferase, albumin, alkaline phosphatase, aspartate aminotransferase, carbon dioxide, calcium, chloride, cholesterol, creatinine, glucose, inorganic phosphorus, lactate dehydrogenase, potassium, total protein, sodium, total bilirubin, triglycerides, uric acid, urea nitrogen.
- Present for all available visits.

Table 14.3-2.5.1 – Gradable Biochemistry Laboratory Results – Worst On-treatment Value by Cycle
Full Analysis Set

PROGRAMMING NOTES:
- Repeat of Table 14.3-2.2.1
- Present for all biochemistry parameters where CTCAE grades are defined as per the SAP appendix 14.2.

Table 14.3-2.5.2 – Non-gradable Biochemistry Laboratory Results – Worst On-treatment Value by Cycle
Full Analysis Set

PROGRAMMING NOTES:
- Repeat of Table 14.3-2.2.2
- Present for all biochemistry parameters where CTCAE grades are defined as per the SAP appendix 14.2.

Table 14.3-2.6.1 – Shift Table of Gradable Biochemistry Laboratory Results – Baseline vs Worst On-treatment Value
Full Analysis Set

PROGRAMMING NOTES:
- Repeat of Table 14.3-2.3.1
- Present for all Baskets and overall, and for all biochemistry parameters where CTCAE grades are defined as per the SAP appendix 14.2.

Table 14.3-2.6.2 – Shift Table of Non-gradable Biochemistry Laboratory Results – Baseline vs Worst On-treatment Value
Full Analysis Set

PROGRAMMING NOTES:

- Repeat of Table 14.3-2.3.2
- Present for all Baskets and overall, and for all biochemistry parameters where CTCAE grades are not defined as per the SAP appendix 14.2.

Table 14.3-2.7 – Summary at Baseline in Coagulation Laboratory Results
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.3-2.1
- Present for all coagulation parameters: PT, INR, PTT

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-2.8 – Summary at Baseline in Urinalysis Laboratory Results
Full Analysis Set

Parameter: Specific gravity (XX)

Visit Statistics	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Baseline						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX

Note: Baseline is the last available assessment prior to first dose of study treatment.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Table 14.3-2.8 – Summary and Change from Baseline in Urinalysis Laboratory Results by Visit
Full Analysis Set

Parameter: Blood (XX)

Visit Statistics	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
Baseline						
Negative	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1+	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2+	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3+	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
4+	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

<cont.>

Note: Baseline is the last available assessment prior to first dose of study treatment.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Present for all urinalysis parameters: specific gravity, protein, glucose, occult blood, microscopic examination of RBC, microscopic examination of WBC, microscopic examination of casts.
- Present for all available visits.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-3.1 – Summary and Change from Baseline in Vital Signs by Visit
Full Analysis Set

Parameter: XXXXX (XX)

Visit Statistics	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Baseline						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX
C1D8						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX
Change from Baseline to C1D8						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX

Note: Baseline is the last available assessment prior to first dose of study treatment.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Present for all vital signs: systolic blood pressure, diastolic blood pressure, pulse, respiratory rate, pulse oximetry and temperature with respective unit measure.
- Present for all available visits.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-3.2 – Shift Table of Vital Signs Results – Baseline vs Worst On-treatment Value
Full Analysis Set

Basket: Basket 1 (N=XX)

Parameter (unit)	Baseline Value	Worst value during on-treatment period: Low n (%)	Normal n (%)	High n (%)	Very High n (%)	Missing n (%)	Total n (%)
XXXXX (XXX)	Low	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	High	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Very High	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Missing	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Total	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: Baseline is the last available assessment prior to first dose of study treatment.
Percentages are based on the number of patients in the Basket.
For Temperature, Low: < 36.4°C, Normal: 36.4°C – 37.7°C, High: > 37.7°C.
For Pulse, Low: < 55 bpm, Normal: 55–100 bpm, High: 101–150 bpm, Very high: > 150 bpm.
For Systolic blood pressure, Low: < 90 mmHg, Normal: 90–130 mmHg, High: 131–160 mmHg, Very high: ≥ 161 mmHg.
For Diastolic blood pressure, Low: < 60 mmHg, Normal: 60–85 mmHg, High: 86–100 mmHg, Very high: ≥ 101 mmHg.
For Pulse oximetry, Very Low: < 90 %, Low: 90–95 %, Normal: ≥ 95 %.
For Respiratory Rate, Low: < 12 breaths/min, Normal: 12–16 breaths/min, High: > 16 breaths/min.
Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Present for each Basket and overall, and for all vital signs parameters.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-3.3 – Summary and Change from Baseline in ECG parameters by Visit
Full Analysis Set

Parameter: XXXXX (XX)

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Baseline						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX
C1D8						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX
Change from Baseline to C1D8						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX

Note: Baseline is the last available assessment prior to first dose of study treatment.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Present for all ECG parameters: heart rate, PR interval, QRS duration, RR interval, QT interval, QTcF with respective unit measure.
- Present for all available visits.

Table 14.3-3.4 – Summary of ECHO at Baseline
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Significant findings – n (%)						
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
LVEF						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX

Note: Baseline is the last available assessment prior to first dose of study treatment.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-3.5 – Summary of Physical Examination at Baseline
Full Analysis Set

	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
HEENT						
Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Abnormal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Done	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Thorax						
Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Abnormal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Done	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Abdomen						
Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Abnormal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Done	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

<cont.>

Note: Baseline is the last available assessment prior to first dose of study treatment.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Present for all Region/Body System parameters: HEENT, thorax, abdomen, skin and mucosae, neurological, extremities, urogenital, general appearance, heart, back, lymph nodes.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-3.6 – Summary of ECOG Performance Status by Visit
Full Analysis Set

Visit Grade	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
Baseline [a]						
0	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
C1D8 [a]						
0	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
4	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
5	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
C1D15 [a]						
.....	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<cont.>	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: Baseline is the last available assessment prior to first dose of study treatment.
[a] (0) Fully active, able to carry on all pre-disease performance without restriction
(1) Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work
(2) Ambulatory and capable of all self-care but unable to carry out any work activities
(3) Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
(4) Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
(5) Death

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Present for all available visits.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.5-1.1 – Pharmacokinetic Concentration Data
PK Analysis Set

Visit Analyte	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
C1D15						
BVD-523 (ng/mL)						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XXX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)
Geometric Mean (CV%)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XXX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)
Median	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Min; Max	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X

GSD=Geometric Standard Deviation, SD=Standard Deviation

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.doc)

PROGRAMMING NOTES:
- Present for all available analytes (BVD-523, BVD-502/503,BVD-506, BVD-513) and visits

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.5-1.2 – Pharmacokinetic Parameters Data
PK Analysis Set

Analyte: BVD-523

Visit	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
C1D15						
C_{Max} (ng/mL)						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XXX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)
Geometric Mean (CV%)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XXX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)
Median	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Min; Max	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X

GSD=Geometric Standard Deviation, SD=Standard Deviation

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

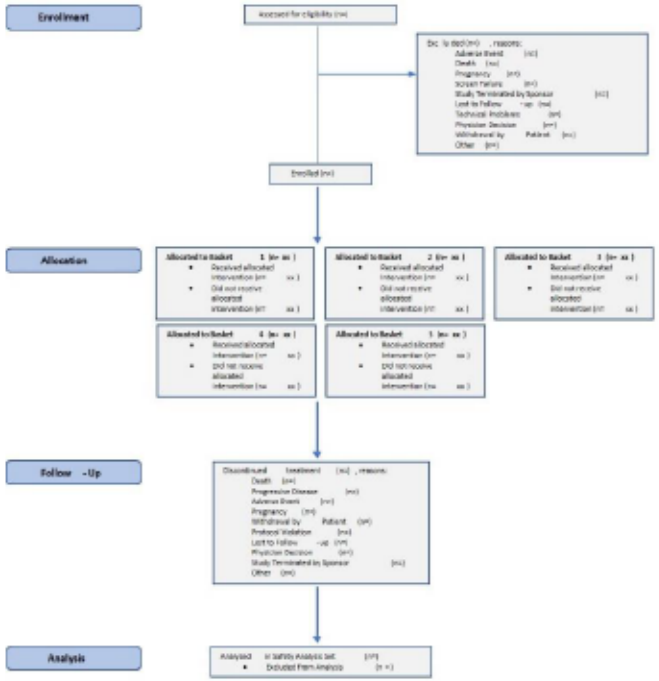
Filename: (Specify file name.doc)

PROGRAMMING NOTES:

- Present for all available analytes (BVD-523, BVD-502/503,BVD-506, BVD-513), PK parameters (AUC, C_{max}, Cmin, $t_{1/2}$, t_{max}), and visits

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Figure 14.2-1.1 – Consort Diagram
Full Analysis Set



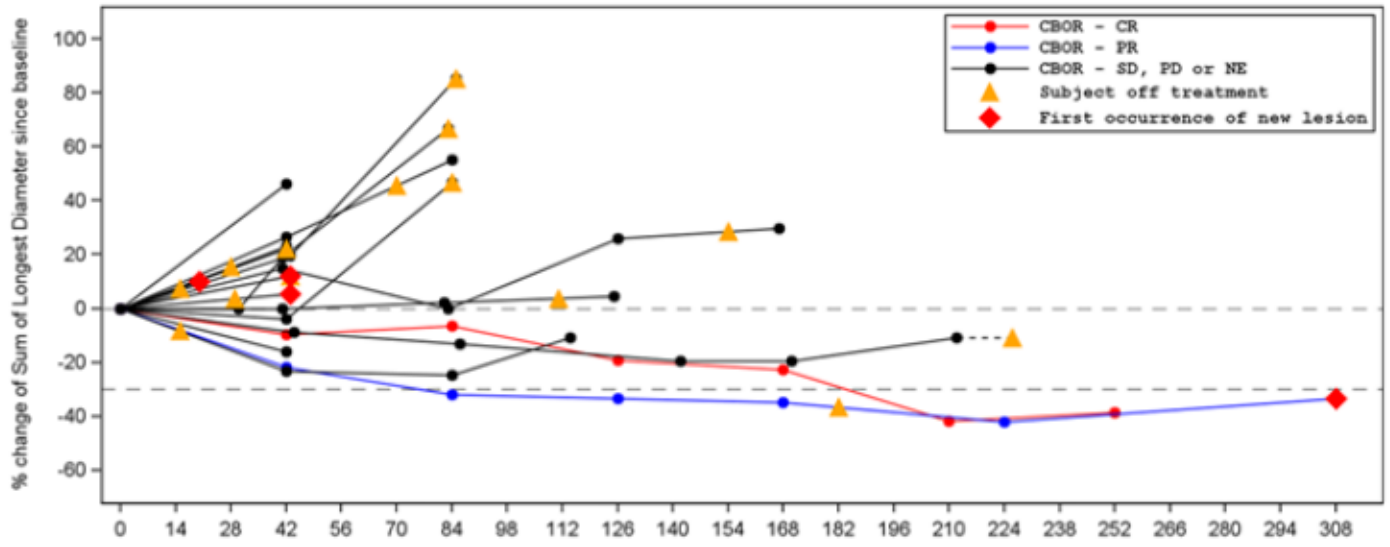
Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Figure 14.2-1.2.1 – Spider plot of Percentage Change from Baseline in Sum of Longest Diameter
Full Analysis Set

Basket = Basket X (N=XX)



Best overall response: CR=Complete Response, PR=Partial Response, SD=Stable Disease, PD=Progression Disease, NE=Not Evaluable.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

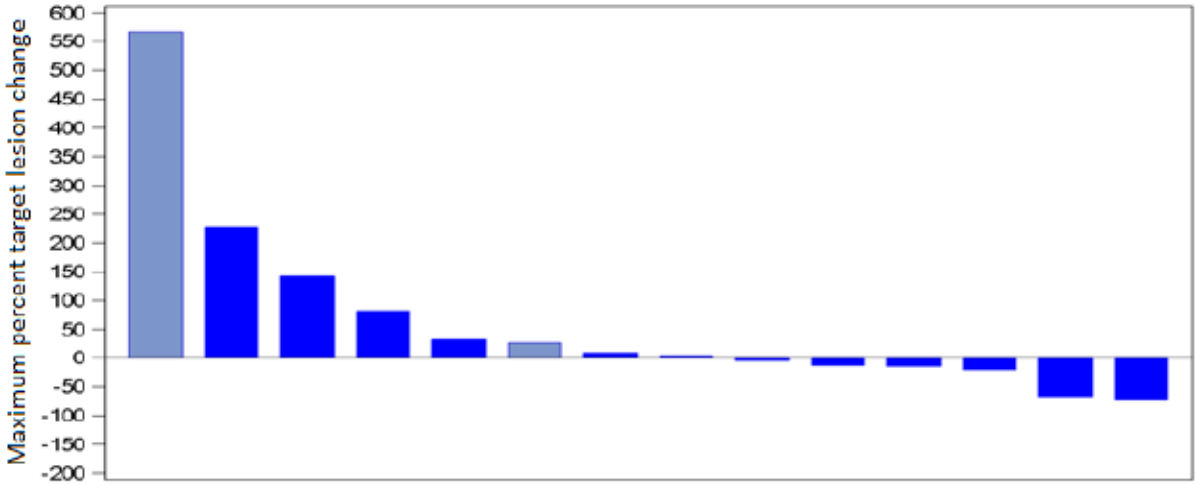
PROGRAMMING NOTES:
- Present all Baskets in separate figures and one figure with all patients.
- Use a different line style for each BOR (dotted line, dashed line, etc).
- Add reference lines for +20% and -30%.

Figure 14.2-1.2.2 – Spider plot of Percentage Change from Baseline in Sum of Longest Diameter
Evaluable Analysis Set

PROGRAMMING NOTES:
- Repeat Figure 14.2-1.2.1
- Present data on Evaluable Analysis Set.

Figure 14.2-1.3.1 – Waterfall plot of Maximum Percentage Change from Baseline in Sum of Longest Diameter
Full Analysis Set

Basket = Basket X (N=XX)



Maximum percentage decrease from baseline in total tumor size is the maximum percentage decrease in the sum of longest diameters/short axis for all target lesions observed from baseline for each patient.

Best overall response: CR=Complete Response, PR=Partial Response, SD=Stable Disease, PD=Progression Disease, NE=Not Evaluable.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Present each Basket on one figure and one figure with all patients. For overall figure, use a different color for each basket
- Each bar is an individual patient.
- Add reference lines for +20% and -30%.
- Add the best overall response (CR, PR, SD, PD, NE) of each patient on the top of each bar.

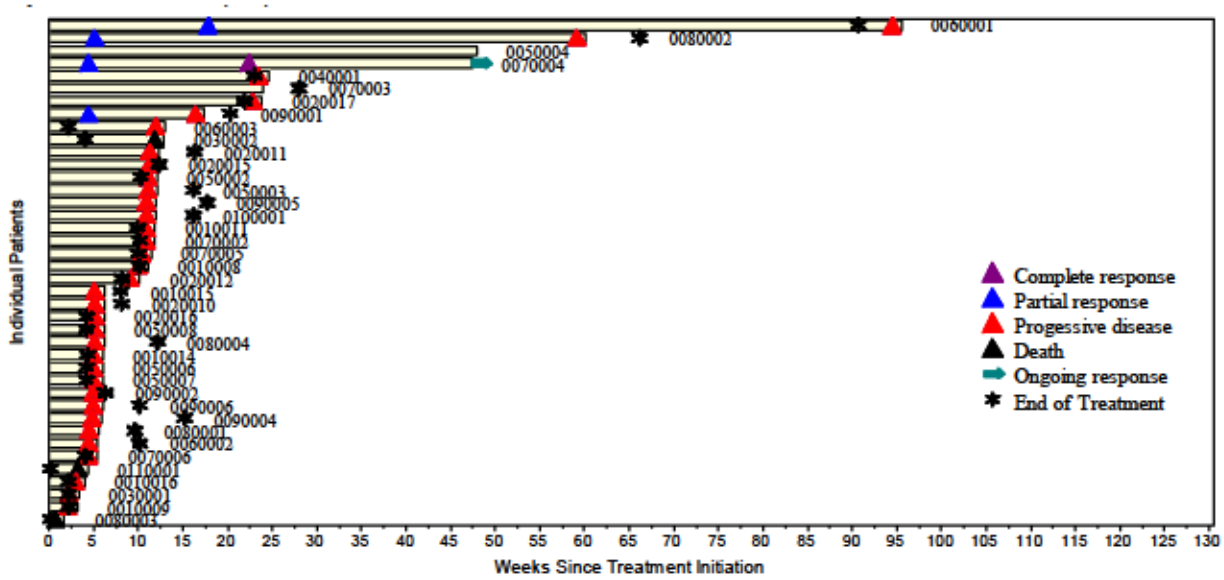
Figure 14.2-1.3.2 – Waterfall plot of Maximum Percentage Change from Baseline in Sum of Longest Diameter
Evaluable Analysis Set

PROGRAMMING NOTES:

- Repeat Figure 14.2-1.3.1
- Present data on Evaluable Analysis Set.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Figure 14.2-1.4.1 – Swimmer Plot of Response Assessments
Full Analysis Set



Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Present each Basket on one figure and a figure including all patients.
- Display patient ID on the left outside the figure except for the figure where all patients are displayed.
- The bar displays time to PD/Death (PFS), with "PD" or "death" displayed at the end of the bar; if no PD/death occurred before cutoff date, the bar stops at cutoff date.
- For responders, display the date of first CR or PR, and display "Ongoing response" arrow if no PD or death occurred before cutoff date.
- "End of Treatment" is the date of treatment discontinuation, this must be displayed only for patients who discontinued the treatment before the cut-off date.

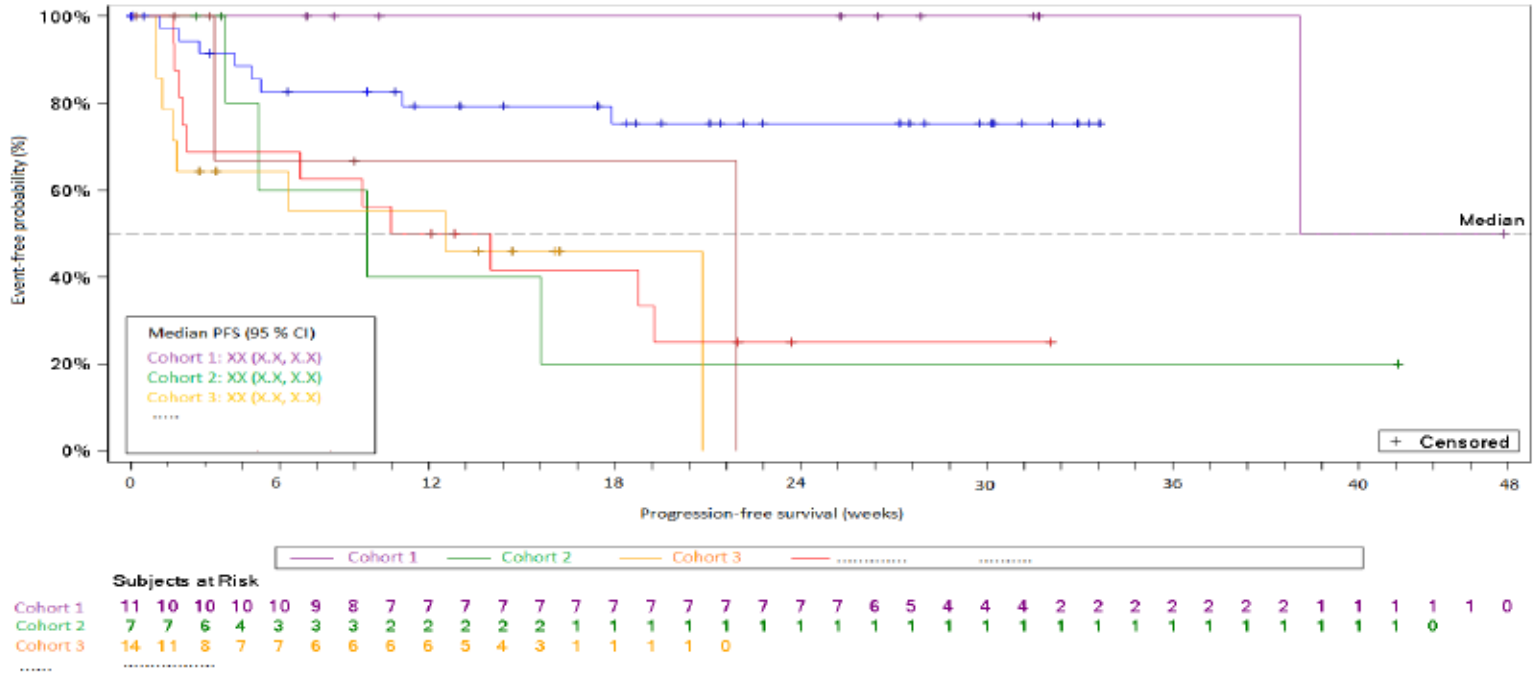
Figure 14.2-1.4.2 – Swimmer Plot of Response Assessments
Evaluable Analysis Set

PROGRAMMING NOTES:

- Repeat Figure 14.2-1.4.1
- Present data on Evaluable Analysis Set.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Figure 14.2-1.5.1 – Kaplan-Meier Estimate for Progression-Free survival (PFS)
Full Analysis Set



Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- X-axis – Label "Progression Free Survival (months)"
- Y-axis – Label "Event-free probability (%)."
- Legend: overall number of events, "Median Duration of Response" and 95% CI.
- Flag censored observations with '+' and add legend.
- If the median time to event has not been reached, present as "Median (95% CI) NR (xx.x, xx.x)" [replacing xx.x with '-' if there is no upper or lower confidence limit] and add footnote:
  NR=Median time not reached.
- Present all Baskets on the same figure but with different colors and separate figures for each Basket. In the sample shell where it is 'Cohort' replace with 'Basket'

Figure 14.2-1.5.2 – Kaplan-Meier Estimate for Progression-Free survival (PFS)
Evaluable Analysis Set

PROGRAMMING NOTES:

- Repeat Figure 14.2-1.5.1
- Present data on Evaluable Analysis Set.

Figure 14.2-1.6.1 – Kaplan-Meier Estimate for Overall Survival (OS)
Full Analysis Set

PROGRAMMING NOTES:

- Replicate figure 14.2-1.5.1, replacing "Progression Free Survival" by "Overall Survival" in X-axis label and legend.

Figure 14.2-1.6.2 – Kaplan-Meier Estimate for Overall Survival (OS)
Evaluable Analysis Set

PROGRAMMING NOTES:

- Replicate figure 14.2-1.5.1, replacing "Progression Free Survival" by "Overall Survival" in X-axis label and legend.
- Present data on Evaluable Analysis Set.

Figure 14.2-1.7.1 – Kaplan-Meier Estimate for Duration of Response
Full Analysis Set

PROGRAMMING NOTES:

- Replicate figure 14.2-1.5.1, replacing "Progression Free Survival" by "Duration of Response" in X-axis label and legend.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.1-1 – Patients informed consent
All Patients Set

Basket: Basket 1

			Main Informed Consent		Sample banking for future Biospecimen research consent		Optional End of Treatment Biopsy	
Patient ID	Age / Gender	Protocol Version	Consent Obtained / Withdrawn?	Date Consent Obtained / Withdrawn	Consent Obtained / Withdrawn?	Date Consent Obtained / Withdrawn	Consent Obtained / Withdrawn?	Date Consent Obtained / Withdrawn
XXXXXX	XX/M	1.0	Yes / Yes	DDMMMYYYY / DDMMMYYYY	Yes	DDMMMYYYY / DDMMMYYYY	Yes	DDMMMYYYY / DDMMMYYYY
XXXXXX	XX/F	1.0	Yes / No	DDMMMYYYY	Yes	DDMMMYYYY	Yes	DDMMMYYYY
XXXXXX	XX/F	1.0	Yes / No	DDMMMYYYY	Yes	DDMMMYYYY	Yes	DDMMMYYYY
XXXXXX	XX/F	1.0	No / Yes	DDMMMYYYY DDMMMYYYY	No	DDMMMYYYY	No	DDMMMYYYY

<cont.>

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.doc)

PROGRAMMING NOTE:
- For all Listings, repeat for each Basket. For All Patients Set present group Screen Failures

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.1-2 – Failed Inclusion and Exclusion Criteria
All Patients Set

Basket: Basket 1

Patient ID	Age / Gender	Protocol Version	Failed Inclusion / Exclusion No.	Description
xxx-xx	xx/M	1.0	INCL01	xxxxxxxxxxxx
xxx-xx	xx/M	1.0	EXCL01	xxxxxxxxxxxx
xxx-xx	xx/M	1.0	EXCL02	xxxxxxxxxxxx
xxx-xx	xx/F	1.0	INCL02	xxxxxxxxxxxx

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- List all failed Inclusion / Exclusion criteria as per eCRF.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.1-3 – Patient Disposition
All Patients Set

Basket: Basket 1

Patient ID	Age / Gender	Enrolled	Date of Assignment	Gene/ Codon/ Amino acid change	Completed Screening / Reason	Date of Screening Completion / Discontinuation	Eligible for inclusion?	Rescreened? / Previous patient number
xxx-xx	xx/M	Yes	DDMMMYYYY	BRAF /D594 / Alanine A	Yes	DDMMMYYYY	Yes	No
xxx-xx	xx/F	Yes	DDMMMYYYY	MEK1/MAP2K1 / K601 /Arginine R	No / Physician Decision	DDMMMYYYY	Yes	Yes /xxxxxxx

Note: M=Male, F=Female.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Listing 16.2.1-3 - Patient Disposition
All Patients Set

Basket: Basket 1

Patient ID	Age / Gender	Completed Treatment / Reason	Date of Treatment Discontinuation	Date of Last Study Dose	Completed Study / If no, reason	Date of Completion
xxx-xx	xx/M	Yes	DDMMMYYYY	DDMMMYYYY	Yes	DDMMMYYYY
xxx-xx	xx/F	No/ Progressive Disease	DDMMMYYYY	DDMMMYYYY	No/ xxxxxx	DDMMMYYYY

Note: M=Male, F=Female.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Listing 16.2.2-1 – Analysis Sets
All Patients Set

Basket: Basket 1

Patient ID	Age / Gender	All Patients Set [a]	Full Analysis Set [b]	Stage 1 Analysis Set [c]	Evaluable Analysis Set [d]	PK Analysis Set [e]
xxx-xx	xx/M	Yes	Yes	Yes	Yes	Yes
xxx-xx	xx/F	Yes	Yes	Yes	Yes	Yes

Note: M=Male, F=Female.
[a] Patients who were enrolled regardless of whether they received the study drug or not.
[b] Patients who received at least 1 dose of the study drug.
[c] First 13 patients who have completed at least one cycle of therapy and who have received a minimum of 75% of prescribed study therapy during Cycle 1
[d] Patients who received at least one dose of study drug and have at least one post-treatment study evaluation or who have discontinued therapy prior to the first post-treatment study evaluation due to clinical progressive disease or drug-related adverse events.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.3-1 – Protocol Deviations
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Deviation Category	Summary Term	Deviation Description	Classification	Exclusion from Analysis Sets
xxx-xx	xx/M	Inclusion Criteria …	xxxxxxxxxxxxx	xxxxxxxxxxxxx	Important	Evaluable Analysis Set
xxx-xx	xx/F	Study Assessments …	xxxxxxxxxxxxx	xxxxxxxxxxxxx	Non-Important	Full Analysis Set

Note: M=Male, F=Female.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Categories / Summary Term / Description to match the PDCF.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.4-1 – Demographics and Baseline Characteristics
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Childbearing/ Reproductive Potential	Surgery Name	Date of Surgery/Post-Menopausal	Date of Last Menstrual Period	Race	Ethnicity	Height at Screening (cm)	Weight at Screening (kg)
xxx-xx	xx/M	Surgically Sterile	Vasectomy	DDMMMYYY		White	Hispanic or Latino	xx	xx
xxx-xx	xx/F	Able to Bear Children			DDMMMYYY	Other, xxxx	Not Hispanic or Latino	xx	xx
xxx-xx	xx/F	Sterile – Other Reason, xxxxxx			DDMMMYYY				

Note: M=Male, F=Female.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.4-2 - Smoking History
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Smoking History?	Substance	Usage
xxx-xx	xx/M	Yes	Cigarettes	Former
xxx-xx	xx/F	No		

Note: M=Male, F=Female.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Listing 16.2.4-3 - Disease History
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Cancer Diagnosis	Date of Initial Diagnosis	Time since Initial Diagnosis [a]	Stage at Diagnosis	Method of Diagnosis	Current Stage at Enrollment	Prior Radiation Therapies?
xxx-xx	xx/M	Stomach	DDMMMYYYY	xx	1	Cytological	1	Yes
xxx-xx	xx/F	Other, xxxxx	DDMMMYYYY	xx	2	Histological	4	No

Listing 16.2.4-4 – Medical History and Concomitant Diseases
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Reported Term	System Organ Class	Preferred Term	Start Date (Day) /End Date (Day)	Ongoing	MH or Conc.
xxx-xx	xx/M	xxxxxxxx	xxxxxxxxx	xxxxxxxx	DDMMMYYYY (xx) / DDMMMYYYY (xx)	No	MH
xxx-xx	xx/F	xxxxxxxx	xxxxxxxxx	xxxxxxxx	DDMMMYYYY (xx)	Yes	Conc.

Note: M=Male, F=Female.
MedDRA <vx.x>.
Study day is calculated as (Event Date – Study treatment start date) for dates before Study treatment start date and (Event date – First treatment date + 1) for dates after Study treatment start date.
Medical history (MH): any conditions that started before the first study treatment date and were not ongoing at the first study treatment date.
Concomitant disease (Conc.): any conditions that started before first study treatment administration and were ongoing at first study treatment administration.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.4-5 – Prior Systemic Anti-Cancer Therapies
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Line of Therapy	Name of Therapy	Start Date (Day)	End Date (Day)	Best Overall Response	Date of Best Overall Response	Date of Relapse/ Progression	Reason for Discontinuation
xxx-xx	xx/M	1	xxxxxx	DDMMMYYYY (xx)	DDMMMYYYY (xx)	Stable Disease	DDMMMYYYY	DDMMMYYYY	Intolerance
xxx-xx	xx/M	1	xxxxxx	DDMMMYYYY (xx)	DDMMMYYYY (xx)	Stable Disease	DDMMMYYYY	DDMMMYYYY	Lack of Efficacy
xxx-xx	xx/F	4	xxxxxx	DDMMMYYYY (xx)	DDMMMYYYY (xx)	Partial Response	DDMMMYYYY	DDMMMYYYY	Other, xxxxx

Note: M=Male, F=Female.
Study day is calculated as (Medication Date – Study treatment start date) for dates before Study treatment start date and (Medication date – First treatment date + 1) for dates after Study treatment start date.
Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Data taken from 'Prior Cancer Medications' page.

Listing 16.2.4-6 – Prior Radiotherapy Courses
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Site of Radiotherapy	Dose (Unit)	Start Date (Day)	End Date (Day)	Duration (months) [a]
xxx-xx	xx/M	Abdominal Cavity	xxx (xxx)	DDMMMYYYY (xx)	DDMMMYYYY (xx)	xx
xxx-xx	xx/M	Adrenal Gland	xxx (xxx)	DDMMMYYYY (xx)	DDMMMYYYY (xx)	xx
xxx-xx	xx/F	Bile Duct	xxx (xxx)	DDMMMYYYY (xx)	DDMMMYYYY (xx)	xx

Note: M=Male, F=Female.
Study day is calculated as (Medication Date – Study treatment start date) for dates before Study treatment start date and (Medication date – First treatment date + 1) for dates after Study treatment start date.
[a] Duration of radiotherapy calculated as [(end date – start date) + 1] / 30.4375.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Data taken from 'Prior Radiotherapy' page.

Listing 16.2.4-7 – Prior and Concomitant Medications
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Reported Term / Preferred Term / ATC Class	Indication	Start Date (Day)	End Date (Day)	Dose (Units) / Frequency	Route	Medication to treat adverse event? / Adverse Event (ID)	Ongoing	Prior / Conc.
xxx-xx	xx/M	Xxxxxxxxxxx / xxxxxxxxxxxx / xxxxxx	xxxxxx	DDMMMYYYY (xx)	DDMMMYYYY (xx)	xxx (xx) / Daily	Oral	Yes / xxxx (x)	Yes	Conc.
xxx-xx	xx/F	xxxxxxxxxxx/ xxxxxxxxxxxx / xxxxxx	xxxxxx	DDMMMYYYY (xx)	Ongoing	xxx (xx) / Twice per day	Oral, xxxx	No	No	Prior

Note: M=Male, F=Female, ATC=Anatomical Therapeutic Chemical.
WHOHD-B3 <vx.x>.
Study day is calculated as (Medication Date - Study treatment start date) for dates before Study treatment start date and (Medication date - First treatment date + 1) for dates after Study treatment start date.
Prior medication (Prior): any medications whose end date is before the first study treatment date.
Concomitant medication (Conc.): any medication whose start or end date is either the same or after the first dose of study treatment and up to the end of the on-treatment period.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Data taken from 'Prior and Concomitant Medications' page.
- Adverse Event ID taken from collected ID.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.4-8 – On Treatment Radiation
Full Analysis Set

Cohort: Basket 1

Patient ID	Age / Gender	Received Radiation?	Site of Radiotherapy	Dose (Unit)	Start Date (Day)	End Date (Day)
xxx-xx	xx/M	Yes	Abdominal Cavity	xxx (xxx)	DDMMMYYYY (xx)	DDMMMYYYY (xx)
xxx-xx	xx/M	Yes	Adrenal Gland	xxx (xxx)	DDMMMYYYY (xx)	DDMMMYYYY (xx)
xxx-xx	xx/F	No				

Note: M=Male, F=Female.
Study day is calculated as Procedure date – First treatment date + 1.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Data taken from 'On Treatment Radiation' page.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.4-9 – On Treatment Surgery and Medical Procedures
Full Analysis Set

Cohort: Basket 1

Patient ID	Age / Gender	Any Surgeries/ Procedures	Name of Surgery/ Procedure	Indication?	Start Date (Day)	End Date (Day)	Ongoing?
xxx-xx	xx/M	Yes	xxxxxxxxxx	xxxxxxxxxx	DDMMMYYYY (xx)	DDMMMYYYY (xx)	No
xxx-xx	xx/M	Yes	xxxxxxxxxx	xxxxxxxxxx	DDMMMYYYY (xx)	DDMMMYYYY (xx)	Yes
xxx-xx	xx/F	No					

Note: M=Male, F=Female.
Study day is calculated as Procedure date – First treatment date + 1.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Data taken from 'On Treatment Surgery and Medical Procedures' page.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.4-10 – On Treatment Blood Transfusions
Full Analysis Set

Cohort: Basket 1

Patient ID	Age/ Gender	Any blood transfusions	Transfusion ID	Date of Transfusion	Category of Transfusion	Units
xxx-xx	xx/M	Yes	xxxxxxxxxx	DDMMMYYYY (xx)	Platelet transfusion	xx
	xx/M	Yes	xxxxxxxxxx	DDMMMYYYY (xx)	Plasma	xx
xxx-xx	xx/F	No				

Note: M=Male, F=Female.
Study day is calculated as Procedure date – First treatment date + 1.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Data taken from 'On Treatment Blood Transfusions' page.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.4-11 – NGS Data
Full Analysis Set

Cohort: Basket 1

Patient ID	Age/ Gender	Gene / Codon / Amino acid change	Vendor	Date of Report	Report Redacted	Report Uploaded
xxx-xx	xx/M	BRAF /D594 / Alanine A	STRATA	DDMMMYYYY (xx)	Yes	Yes
xxx-xx	xx/F	MEK1/MAP2K1 / K601 /Arginine R	GUARDANT		No	No

Note: M=Male, F=Female.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.5-1 – Ulixertinib In-clinic Administration
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Treatment Administered?	Dose (mg)	Dose Date and Time (day)
xxx-xx	xx/M	Yes	xxx	DDMMMYYYY hh:mm (xx)
xxx-xx	xx/F	Yes	xxx	DDMMMYYYY hh:mm (xx)
xxx-xx	xx/F	Yes	Xxx	DDMMMYYYY hh:mm (xx)

Note: M=Male, F=Female.
Study day is calculated as Administration date – First treatment date + 1.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Listing 16.2.5-2 – Hydroxychloroquine In-clinic Administration
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Listing 16.2.5-1

Listing 16.2.5-3 – Ulixertinib Interruptions and Adjustments
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Type of Change	Start Date / End Date / Duration (days)	If Adjustment, new dose amount (mg)	Reason for Interruption/Adjustment
xxx-xx	xx/M	Interruption	DDMMMYYYY / DDMMMYYYY / (xx)	xxx	Adverse Event
xxx-xx	xx/F	Adjustment	DDMMMYYYY / DDMMMYYYY / (xx)	xxx	Other, xxxxx
xxx-xx	xx/F				

Note: M=Male, F=Female.
Study day is calculated as Interruption/Change date – First treatment date + 1.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Listing 16.2.5-4 – Hydroxychloroquine Interruptions and Adjustments
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Listing 16.2.5-3

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.5-5 – Ulixertinib Exposure
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Number of cycles received [a]	Duration of exposure (months) [b]	Planned cumulative dose (mg)	Actual cumulative dose received (mg) [c]	Relative dose intensity [d]
xxx-xx	xx/M	xx	xxx	xxx (mg)	xxx (mg)	xxx
xxx-xx	xx/F	xx	xxx	xxx (mg)	xxx (mg)	xxx

Note: M=Male, F=Female.
[a] Number of cycles received = Number of cycles where the patient received at least one dose.
[b] Duration of exposure (months) = (Date of last known treatment dosing with ulixertinib– date of initial dosing with ulixertinib) + 1 / 30.4375.
[c] Actual cumulative dose received (mg) = Sum of [(number of capsules dispensed – number of capsules returned) x 150].
[d] Relative dose intensity = 100 x Actual dose intensity / Planned dose intensity. Actual dose intensity (mg/day) is defined as Actual cumulative dose received (mg) / Duration of exposure (days). Planned dose intensity (mg/day) is defined as Planned cumulative dose (mg) / Duration of exposure (days). Planned cumulative dose is the number of cycles received x number of doses per day x mg prescribed per dose.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Listing 16.2.5-6 – Hydroxychloroquine Exposure
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Listing 16.2.5-5

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.5-7 – Ulixertinib Dispensed
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Mg prescribed per dose	Date Bottles Dispensed (day)	Number of Bottles Dispensed	Lot Number of the bottles dispensed	Different Lot number dispensed to the patient?	Lot number dispensed to patient /No of bottles	Total Number of Capsules Dispensed
xxx-xx	xx/M	xxx	DDMMMYYYY (xx)	xx	xxxx	Yes	Xxxx/XX	xx
xxx-xx	xx/F	xxx	DDMMMYYYY (xx)	xx	xxxx	No		xx

Note: M=Male, F=Female.
Study day is calculated as Dispensed date – First treatment date + 1.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Listing 16.2.5-8 – Hydroxychloroquine Dispensed
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Listing 16.2.5-7

Listing 16.2.5-9 – Ulixertinib Returned
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Cycle	Reason capsules not returned	Date Returned (day)	Patient compliant since last visit? If no, reason	Missed dose related to an adverse event?	Number of Bottles Returned	Lot Number of the bottles returned	Total Number of Capsules Returned
xxx-xx	xx/M	2	Lost	DDMMMYYYY (xx)	Yes	Yes	xx	xxxx	xxx
xxx-xx	xx/F	3	Other, xxxxx	DDMMMYYYY (xx)	No, xxxxx	Yes	xx	xxxx	xxx

Note: M=Male, F=Female.
Study day is calculated as Returned date – First treatment date + 1.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Listing 16.2.5-10 – Hydroxychloroquine Returned
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Listing 16.2.5-9

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.6-1 – Target Lesions
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Visit	Target Lesions at Screening?	Lesion Number	Tumor Type	Organ Site	Method	Date of Scan (Day)	Longest Diameter/ Short-axis (mm)	Sum of Longest Diameter (mm) / Change from baseline / % Change from baseline
xxx-xx	xx/M	Screening	Yes	T01	Primary	Bladder	CT Scan	DDMMMYYYY (xx)	xxx	xxx
		C2D1								
		…								
xxx-xx	xx/F	Screening	Yes	T02	Metastasis	Other, xxxxx	MRI	DDMMMYYYY (xx)	xxx	xxx / xxx / xxx
		…								

Note: M=Male, F=Female.
Study day is calculated as (Scan Date - Study treatment start date) for dates before Study treatment start date and (Scan date - First treatment date + 1) for dates after Study treatment start date.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Sort by Basket, patient ID, visit.

Listing 16.2.6-2 – Non-Target Lesions
Full Analysis Set

Basket: Basket 1

Patient ID	Age/ Gender	Visit	Assessment Performed / Reason	Non-Target Lesions at screening	Lesion Number	Organ Site	Method	Date of Scan (Day)	Result
xxx-xx	xx/M	Screening	Yes	Yes	NT01	Bladder	CT Scan	DDMMMYYYY (xx)	Present
		C2D1	No, xxx						
		…							
xxx-xx	xx/F	Screening	Yes	Yes	NT02	Other, xxxx	MRI	DDMMMYYYY (xx)	Absent (Disappeared)
		…							

Note: M=Male, F=Female.
Study day is calculated as (Scan Date – Study treatment start date) for dates before Study treatment start date and (Scan date – First treatment date + 1) for dates after Study treatment start date.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Sort by Basket, patient ID, visit.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.6-3 – New Lesions
Full Analysis Set

Basket: Basket 1

Patient ID	Age/ Gender	Visit	Any New Lesions	Lesion Number	Method	Date of Scan (Day)	Organ Site
xxx-xx	xx/M	C2D29	Yes	NL01	CT Scan	DDMMMYYYY (xx)	Abdomen
xxx-xx	xx/F	C2D29	Yes	NL02	Other, xxxx	DDMMMYYYY (xx)	Bone

Note: M=Male, F=Female.
Study day is calculated as Scan date – First treatment date + 1.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.6-4 – Overall Response
Full Analysis Set

Basket: Basket 1

Patient ID	Age/ Gender	Best Overall Response [a]	Assessment Performed/ Reason	Date of Assessment (Day)	Target Lesion Response	Non-Target Lesion Response	New Lesions	Overall Response
xxx-xx	xx/M	CR	Yes	DDMMMYYYY (xx)	CR	CR	Yes	PD
xxx-xx	xx/F	PD	Yes	DDMMMYYYY (xx)	NE	PD	No	NE, xxxx

Note: M=Male, F=Female, CR=Complete Response, Non CR/Non PD=Non Complete Response/Non Progressive Disease, PR=Partial Response, SD=Stable Disease, PD=Progressive Disease, NE=Not Evaluable.
Study day is calculated as Assessment date – First treatment date + 1.
[a] Confirmed best overall response.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.6-5 – Progression-Free Survival (PFS)
Full Analysis Set

Basket: Basket 1

Patient ID	Age/ Gender	Treatment Start Date	Date of Last Tumor Assessment	Date of Event/ Censoring	Event / Censoring Reason	PFS (months)
xxx-xx	xx/M	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	Death	xx.x
xxx-xx	xx/F	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	Censored: xxxxx	xx.x

Note: M=Male, F=Female, PFS=Progression-Free Survival.
Event: progressive disease (PD) or death from any cause.
The PFS (in months) is defined as the time from the first ulixertinib dose until the first radiographically documented progression of disease or death from any cause, whichever occurs first.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Listing 16.2.6-6 – Survival Status
Full Analysis Set

Basket: Basket 1

Patient ID	Age/ Gender	Completed End of Study?	Any Anti-Cancer Treatment Since End of treatment or Last FUP/ Start Date	Any Tumor Assessment Since End of Study or Last FUP/ Assessment Date/ Overall Response	Survival Status at Follow-Up	Date of Death	Last Known Date Patient Alive [a]
xxx-xx	xx/M	Yes	Yes/ DDMMMYYYY	Yes/ DDMMMYYYY/ Complete Response	Alive		
xxx-xx	xx/F	Yes	No	No	Dead	DDMMMYYYY	

Note: M=Male, F=Female, FUP=Follow-up, CR=Complete Response, Non CR/Non PD=Non Complete Response/Non Progressive Disease, PR=Partial Response, SD=Stable Disease, PD=Progressive Disease, NE=Not Evaluable.
[a] If Survival status at the time of follow-up is unknown.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.6-7 – Duration of Response (DOR)
Full Analysis Set

Basket: Basket 1

Patient ID	Age/ Gender	Best Overall Response [a]	Treatment Start Date	Date of First Response	Date of Last Tumor Assessment	Date of Event / Censoring	Event / Censoring Reason	Duration of Response (months)
xxx-xx	xx/M	CR	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	Death	xx.x
xxx-xx	xx/F	PR	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	Censored: xxxxx	xx.x

Note: M=Male, F=Female, CR=Complete Response, PR=Partial Response, SD=Stable Disease, PD=Progressive Disease, NE=Not Evaluable.
Event: progressive disease (PD) or death from any cause.
This listing includes only patients with response (CR or PR).
Duration of response is the period from the date of initial confirmed PR or CR until the date of first radiographically documented progressive disease or death from any cause.
[a] Confirmed best overall response.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.7-1 – Adverse Events
All Patients Set

Basket: Basket 1

Patient ID	Age / Gender	ID	Reported Term	System Organ Class	Preferred Term	Start Date (day)	End Date (day)	TEAE?	SAE?
xxx-xx	xx/M	xx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxx	DDMMMYYYY (xx)	DDMMMYYYY (xx)	Yes	Yes
xxx-xx	xx/F	xx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxx	DDMMMYYYY (xx)	DDMMMYYYY (xx)	No	No

Note: M=Male, F=Female, TEAE=Treatment Emergent Adverse Event, SAE=Serious Adverse Event.
ID as collected in the databased.
MedDRA <vx.x>. NCI CTCAE v5.0.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.7-2 – Treatment-Emergent Adverse Events
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	ID	Reported Term / System Organ Class /Preferred Term	Start Date (Day) / End Date (Day) / Duration (days)	SAE / Seriousness	NCI-CTCAE Grade	Relation Ship to Disease	Relation Ship to Ulixertinib / Hydroxychloroquine	Action Taken with Ulixertinib / Hydroxychloroquine	Medication or Therapies? / Medication Name	Outcome [a]
xxx-xx	xx/M	xx	xxxxxxxx/ xxxxxxxxx/ xxxxxxxxx …	DDMMMYYYY (xx) / DDMMMYYYY (xx) / xx	Yes / Hospitalization	1	Related	Related /Related	Drug Interrupted /Drug Interrupted	Yes /xxxxxxxx, xxxxxxx	Res'd
xxx-xx	xx/F	xx	xxxxxxxx/ xxxxxxxxx/ xxxxxxxxx …	DDMMMYYYY (xx) / DDMMMYYYY (xx) / xx	No	3	Possibly Related	Possibly Related /Related	Drug Interrupted /Drug Interrupted	Yes /xxxxxxxx	Res'd seq, xxxxxx

Note: M=Male, F=Female, TEAE=Treatment Emergent Adverse Event, SAE=Serious Adverse Event.
MedDRA <vx.x>. NCI CTCAE v5.0.
ID as collected in the databased.
Study day is calculated as TEAE date – First treatment date + 1.
[a] Res'd=Resolved, Res'd seq=Recovered/Resolved with sequelae, Ong=Ongoing, Unk=Unknown, Fatal=Fatal.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Sort by Basket, patient ID, ascending Adverse Event Start Date and Reported Term.
- Outcome = "Res'd seq" please specify sequelae.

Listing 16.2.7-3 – Serious Adverse Events
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Listing 16.2.7-2 and include only AEs classified as Serious.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.7-4 – Deaths
All Patients Set

Basket: Basket 1

Patient ID	Age / Gender	Date of Death (Day)	Autopsy Performed? / Date of Autopsy	Primary Cause of Death	Treatment-Emergent Death [a]
xxx-xx	xx/M	DDMMMYYYY (xx)	No	Progressive Disease	Yes
xxx-xx	xx/F	DDMMMYYYY (xx)	Yes /DDMMMYYYY	Adverse Event, xxxxxxx	No

Note: M=Male, F=Female.
[a] A death is considered Treatment-Emergent if occurred after Ulixertinib administration.
Study day is calculated as Death date – First treatment date + 1.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Specify primary cause of death if not PD.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.8-1 – Hematology
Full Analysis Set

Basket: Basket 1

Patient ID	Age/ Gender	Study Visit	Sample Date and Time (Day)	Parameter (Unit)	Result / Reference Range Indicator / CS? [a]	LLN – ULN	CTC Grade	Change from Baseline
xxx-xx	xx/M	Screening	DDMMMYYYY / hh:mm (xx)	RBC (xxx)	xx / L / CS	xx – xx	xx	
				…				
		C1D1	DDMMMYYYY / hh:mm (xx)	RBC (xxx)	xx / L / CS	xx – xx	xx	xx
		…		…				
xxx-xx	xx/F	Screening	DDMMMYYYY / hh:mm (xx)	RBC (xxx)	Not Done			
				…				
		C1D1						
		…						

Note: M=Male, F=Female, L=Low, H=High, ULN=Upper Limit of Normal, LLN=Lower Limit of Normal, CS=Clinically Significant, NCS=Non Clinically Significant.
CTCAE v5.0.
Baseline is the last available assessment prior to first dose of study treatment.
Study day is calculated as (Sample Date – Study treatment start date) for dates before Study treatment start date and (Sample date – First treatment date + 1) for dates after Study treatment start date.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Sort by Basket, patient ID, ascending Sample Date and Time and Parameter.
- Include all hematology parameters.

Listing 16.2.8-2 – Biochemistry
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Listing 16.2-8.1 for all biochemistry parameters.

Listing 16.2.8-3 – Coagulation
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Listing 16.2-8.1 for all coagulation parameters.

Listing 16.2.8-4 – Urinalysis
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Listing 16.2-8.1 for all urinalysis parameters.

Listing 16.2.8-5 – Tumor Markers
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Listing 16.2-8.1 for all tumor marker parameters.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.8-6 – Pregnancy
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Study Visit	Sample Type	Assessment Performed? /Reason	Sample Date (Day)	Result
xxx-xx	xx/F	Screening Baseline	Serum	Yes	DDMMMYYYY (xx)	Positive
xxx-xx	xx/F	Screening	Serum	No /xxxxx		

Note: F=Female.
Baseline is the last available assessment prior to first dose of study treatment.
Study day is calculated as (Sample Date – Study treatment start date) for dates before Study treatment start date and (Sample date – First treatment date + 1) for dates after Study treatment start date.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Sort by Basket, patient ID, visit.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.9-1 – Vital Signs
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Study Visit	Assessment Performed? / Reason	Assessment Date and Time (Day)	Parameter (Unit)	Result/ Reference Range Indicator / CS? [a]	Position	Change from baseline
xxx-xx	xx/M	Screening	Yes	DDMMMYYYY hh:mm (xx)	Systolic Blood Pressure (xxx)	xx / H / CS	Sitting	
					…			
		Baseline	Yes	DDMMMYYYY hh:mm (xx)	Systolic Blood Pressure (xxx)	xx / H / CS	Supine	
		…			…			
xxx-xx	xx/F	Screening	No / xxxxxx			Not Done		
		…						

Note: M=Male, F=Female, L=Low, H=High, VH=Very High, ND=Not Done, CS=Clinically Significant, NCS=Non Clinically Significant.
[a] If status = "Not Done" populate with "Not Done".
* Baseline is the last available assessment prior to first dose of study treatment.
For temperature, Low if < 36.4°C; high if > 37.7°C.
For pulse, Low if < 55bpm; high if 101-150bpm; very high if > 150bpm.
For systolic blood pressure, Low if < 90mmHg; high if 131-160mmHg; very high if >= 161mmHg.
For diastolic blood pressure, Low if < 60mmHg; high if 86-100mmHg; very high if >= 101mmHg.
For Pulse oximetry, Very Low: < 90 %, Low: 90-95 %, Normal: ≥ 95 %.
For Respiratory Rate, Low: < 12 breaths/min, Normal: 12-16 breaths/min, High: > 16 breaths/min.
Study day is calculated as (Assessment Date - Study treatment start date) for dates before Study treatment start date and (Assessment date - First treatment date + 1) for dates after Study treatment start date.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Sort by Basket, patient ID, ascending Assessment Date and Time and Parameter.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.9-2 – Electrocardiogram
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Study Visit	Assessment Performed? / Reason	Assessment Date and Time (Day)	Method/ Position	Parameter (Unit)	Result /CS?	Change from baseline
xxx-xx	xx/M	Screening	Yes	DDMMMYYYY hh:mm (xx)	12 Lead Standard/ Supine	Heart Rate (xxx)	xx /No	
xxx-xx	xx/F	Screening	Yes	DDMMMYYYY hh:mm (xx)	12 Lead Standard/ Supine	Heart Rate (xxx)	xx /Yes	

Note: M=Male, F=Female, L=Low, H=High.
Study day is calculated as (Assessment Date – Study treatment start date) for dates before Study treatment start date and (Assessment date – First treatment date + 1) for dates after Study treatment start date.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Sort by Basket, patient ID, ascending Assessment Date and Time and Parameter.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.9-3 – ECHO
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Assessment Performed? / Reason	Method	Assessment Date (Day)	Parameter (Unit)	Result /CS?
xxx-xx	xx/M	Yes	Echocardiography	DDMMMYYYY (xx)	LVEF (xx)	xx /No

Note: M=Male, F=Female, LVEF=Left Ventricular Ejection Fraction.
Study day is calculated as (Assessment Date – Study treatment start date) for dates before Study treatment start date and (Assessment date – First treatment date + 1) for dates after Study treatment start date.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Sort by Basket, patient ID, ascending Assessment Date and Time.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.9-4 – Physical Examination
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Study Visit	Assessment Performed? / Reason	Assessment Date	Region /Body System	Result /CS? [a]	Abnormal Findings
xxx-xx	xx/M	Screening	Yes	DDMMMYYYY	HEENT	Abnormal/ CS	xxxxxxx
xxx-xx	xx/F	Screening	Yes	DDMMMYYYY	Thorax	Not Done	

Note: M=Male, F=Female, CS=Clinically Significant, NCS=Non Clinically Significant.
[a] If status = "Not Done" populate with "Not Done".

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Sort by Basket, patient ID, visit, Region/body system.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.9-5 – Ophthalmology Exam
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Study Visit	Assessment Performed? / Reason	Assessment Date	Examination Test Name	Any Abnormal Clinically Significant Result?	Eyes Affected	Abnormal Finding
xxx-xx	xx/M	Screening	Yes	DDMMMYYYY	Best-corrected visual acuity …	Yes	Left	xxxxxxxxxxx
xxx-xx	xx/F	Screening	Yes	DDMMMYYYY		Yes	Both	

Note: M=Male, F=Female, CS=Clinically Significant, NCS=Non Clinically Significant.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Sort by Basket, patient ID, visit, examination test name

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.9-6 – ECOG Performance Status
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Study Visit	Assessment Performed? / Reason	Date of Assessment (Day)	ECOG Performance Status [a]
xxx-xx	xx/M	Screening	Yes	DDMMMYYYY (xx)	(0) Fully Active
		Baseline	Yes	DDMMMYYYY (xx)	(0) Fully Active
		…			
xxx-xx	xx/F	Screening	Yes	DDMMMYYYY (xx)	(1) Restricted
		Baseline	No, xxxx		
		…			

Note: M=Male, F=Female.
Baseline is the last available assessment prior to first dose of study treatment.
[a] (0) Fully active, able to carry on all pre-disease performance without restriction
(1) Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work
(2) Ambulatory and capable of all self-care but unable to carry out any work activities
(3) Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
(4) Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
(5) Death
Study day is calculated as (Assessment Date – Study treatment start date) for dates before Study treatment start date and (Assessment date – First treatment date + 1) for dates after Study treatment start date.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Sort by Basket, patient ID, visit, assessment date.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.11-1 – Pharmacokinetic Concentration Data
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Study Visit	Collection Date/Time (Day) / Timepoint	Analyte	Concentration (Unit)
					xxxx (ng/mL)
xxx-xx	xx/M	C1D15	ddmmmyyyy hh:mm (xx) / Pre-dose	BVD-523	
		…			

Note: M=Male, F=Female.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Sort by Basket, patient ID, visit, assessment date and time.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.11-2 – Pharmacokinetic Parameters Data
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Study Visit	Visit	Analyte	PK Parameter	Result
xxx-xx	xx/M	C1D15	C1D15	BVD-523	AUC	xxxx
		…				

Note: M=Male, F=Female.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Sort by Basket, patient ID, visit and analyte.

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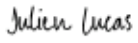
Julien Lucas julien.lucas@aixial.com Junior Statistician Aixial Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 1805EF25-9FF0-4719-80A6-4D0037F8D5D3 Using IP Address: 77.214.124.54 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document I approve this document	Sent: 02-Sep-2024 | 16:33 Viewed: 02-Sep-2024 | 16:34 Signed: 09-Sep-2024 | 11:20
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- Ongoing medications are considered as concomitant medications.

The number and percentage of patients with prior and concomitant medications will be tabulated by basket and overall, by Anatomical Therapeutic Chemical Classification (ATC) and preferred term (PT) on the FAS. A by-patient listing will be produced for prior and concomitant medications as well as for all prior therapies.

On treatment Radiation, Surgery and Medical Procedures, and Blood Transfusions:

On treatment Radiation, Surgery and Medical Procedures, and Blood Transfusions will be listed on the FAS.

9.6 STUDY DRUG EXPOSURE AND/OR COMPLIANCE

Duration on treatment and cumulative dose received will be calculated for both ulixertinib and hydroychloroquine as defined below with the same tables and listings.

- *Number of cycles received* =
  Number of cycles where the patient received at least one dose.

- *Duration of exposure (months)* =
  [(Date of last known treatment dosing with study treatment – date of initial dosing with ulixertinib) + 1] / 30.4375

- *Planned cumulative dose (mg)* =
  Number of cycles received x number of doses per day x mg prescribed per dose.

- *Actual cumulative dose received (mg)* =
  For each time period reported in the eCRF:
  (Stop date – Start date + 1)*Dose
  Sum all available periods where dose was given.

- *Relative dose intensity* =
  100 x Actual dose intensity / Planned dose intensity, with:
  - Actual dose intensity (mg/day) = Actual cumulative dose received (mg) / Duration of exposure (days).
  - Planned dose intensity (mg/day) = Planned cumulative dose (mg) / Duration of exposure (days).

Summary statistics will be presented for the number of cycles received, duration of exposure, actual cumulative dose, and relative dose intensity, by basket and overall on the FAS.

The number and percentage of patients having at least one dosing interruption or adjustment will be tabulated with the corresponding reason by basket and overall on the FAS. A by-patient listing will be produced.

9.7 PHARMACOKINETIC/ PHARMACODYNAMIC ENDPOINTS AND ANALYSES

9.7.1 Pharmacokinetic Data

For patients enrolled in stage 1 of each basket, PK concentrations of ulixertinib and hydroxychloroquine will be determined pre-dose and post-dose in plasma at cycle 1 day 15. Summary parameters such as AUC, Cmax, Cmin, t1/2, tmax will be calculated.

PK parameters in plasma will be tabulated and summarized, by basket, using descriptive statistics (e.g., sample size, arithmetic and geometric mean, % coefficient of variation, standard deviation, median, minimum, and maximum).

For patients enrolled in stage 2 of each basket, PK concentration of ulixertinib will be measured on cycle 1 day 15. This will be a single timepoint collection prior to taking study drug on this day.

PK values will be presented in by-patient listings.

PK analysis will be conducted on the PK analysis set.

9.7.2 Pharmacodynamic Data

Not applicable.

9.8 EFFICACY DATA ENDPOINTS AND ANALYSES

9.8.1 Primary Efficacy

9.8.1.1 Overall Response Rate (ORR)

Tumor response will be assessed by the Investigator using RECIST 1.1 criteria[1].

Disease assessments must include all known or suspected sites of disease; therefore, the decision for body areas to be scanned will depend on the extent of disease. The minimum recommended body areas to be scanned is chest, abdomen, and pelvis.

Disease assessments will be evaluated radiologically and conducted at baseline (within 28 days prior to the first dose of study treatment) and then every 8 weeks thereafter ≤ 7 days prior to the start of the following cycle (e.g., prior to cycle 3 day one, cycle 5 day 1, cycle 7 day 1, etc.). If a response is observed (CR or PR), confirmation of response is required ≥ 4 weeks from the first documentation of response. Disease assessments will continue until disease progression, the

initiation of subsequent anti-cancer therapy, or death. In addition, radiological tumor assessments will be conducted whenever disease progression is suspected (e.g., symptomatic deterioration) or when clinically indicated. The schedule of tumor assessments should be fixed according to the calendar, starting with cycle one day one, regardless of treatment delays or interruptions due to toxicity.

Brain CT or MRI scans are required at baseline for all patients with stable brain lesions and for those for whom Central Nervous System (CNS) involvement is suspected. If stable brain metastases are present at baseline, brain imaging should be repeated at each tumor assessment. Otherwise, brain imaging will be conducted post-baseline only when clinically indicated.

The table below provides a summary of the overall response status determination at each time point.

Table 5. Evaluation of Overall Response

Target lesions	Non-target lesions	New lesions	Overall response
CR	CR (or no non-target lesions)	No	CR
No target lesion [a]	CR	No	CR
CR	NE [b]	No	PR
CR	Non-CR/non-PD	No	PR
PR	Non-PD and NE (or no non-target lesions) [b]	No	PR
SD	Non-PD and NE (or no non-target lesions) [b]	No	SD
Not all evaluated	Non-PD	No	NE
No target lesion [a]	Not all evaluated	No	NE
No target lesion [a]	Non-CR/non-PD	No	Non-CR/non-PD
PD	Any	Yes or No	PD
Any	PD	Yes or No	PD
Any	Any	Yes	PD
No target lesion [a]	Unequivocal PD	Yes or No	PD
No target lesion [a]	Any	Yes	PD

CR = complete response, PR = partial response, SD = stable disease, PD = progressive disease, and NE = not evaluable.
[a] Defined as no target lesion at baseline.
[b] Not evaluable is defined as when either no or only a subset of lesion measurements is made at an assessment.

The ORR is defined as the number of patients having a confirmed response of either CR or PR divided by the total number of patients in the FAS/EAS. ORR will be calculated with the 95% confidence intervals (CIs), by basket and overall on the FAS and EAS. The 95% CIs will be estimated using the Clopper-Pearson method.

Complete and partial response must be confirmed by a repeat assessment performed ≥ 4 weeks after the criteria for response are first met. Date of confirmed CR/PR will be the date of the first CR/PR that qualifies for confirmation. Additionally, patients with no post-baseline efficacy measurement due to reasons accountable for disease progression, will be assessed as non-evaluable and will count in the denominator of the ORR.

BOR will be assessed based on the tumor response at different evaluation time points from baseline until the first documented disease progression for RECIST or the last response assessment if there is no documented disease progression at the time of the analysis. The order used to determine BOR is CR>PR>SD>PD, ignoring visits with missing tumor assessments. For SD to qualify for BOR, the SD assessment should be at least 6 weeks after first ulixertinib dose. BOR date in this case will be the date of the first SD/PR/CR documented after 6 weeks.

The following table, based on Table 3 from the RECIST 1.1 guidelines[1], summarizes the algorithm describing how confirmed response and BOR are determined from the overall tumor assessments.

Table 6. Evaluation of Confirmed BOR

Case	Overall response first timepoint	Overall response subsequent timepoint	Confirmed response/BOR
1	CR	CR	CR (if assessments at least 28 days apart). (note: sequence of CR – NE – CR would be considered as confirmed CR)
2	CR	PR	SD, PD, or PR • If CR truly met at first timepoint, any subsequent assessment of PR should make the disease PD at that point. That is, neither a PR nor SD may follow CR. • Therefore, SD, if CR assessment >=6 weeks (42 days after date of first treatment), otherwise PD. • However, BOR may be PR if subsequent scans suggest small lesions were still present at first assessment (in which case first assessment of CR should be changed to PR)
3	CR	SD	SD or PD • SD, if CR or SD assessment >=6 weeks (42 days) after date of first treatment, otherwise PD
4	CR	PD	SD or PD • SD, if CR assessment >=6 weeks (42 days after date of first treatment), otherwise PD
5	CR	NE	SD or NE • SD, if CR assessment >=6 weeks (42 days after date of first treatment otherwise NE
6	PR	CR	PR (if assessments at least 28 days apart).
7	PR	PR	PR (if assessments at least 28 days apart). (note: sequence of PR – NE – PR would be considered as confirmed PR) Where there are cases of more than one SD assessment between two PR assessments, then this should be discussed.
8	PR	SD	SD
9	PR	PD	SD or PD • SD, if PR assessment >=6 weeks (42 days after date of first treatment), otherwise PD

Case	Overall response first timepoint	Overall response subsequent timepoint	Confirmed response/BOR
10	PR	NE	SD or NE • SD, if PR assessment >=6 weeks (42 days after date of first treatment), otherwise NE
11	SD	SD, PR, CR	SD
12	SD	PD	SD or PD • SD, if SD assessment >=6 weeks (42 days after date of first treatment), otherwise PD
13	SD	NE	SD or NE • SD, if SD assessment >=6 weeks (42 days after date of first treatment), otherwise NE
14	NE, -	SD	SD
15	CR, PR, SD	-	SD or NE • SD, if assessment >=6 weeks (42 days after date of first treatment) and does not qualify for CR or PR, otherwise NE.
16	PD		PD. Ignore all assessments after initial overall response of PD.
17	NE	NE	NE Where all assessments are Not evaluable

For changes in target tumor size, spider and waterfall plots will be presented. For all response assessments, swimmer plots will be presented. Target and Non-Target Lesions response assessments and incidence of new lesions will be summarized by visit and listed. All response assessments will be listed.

9.8.2 Secondary Efficacy

9.8.2.1 Progression-free Survival (PFS)

The PFS (in months) is defined as the time from the first ulixertinib dose until the first radiographically documented progression of disease or death from any cause, whichever occurs first.

PFS = [(Date of first PD/death – Date of first study treatment) + 1] / 30.4375

Patients with no documented progression or death will be censored at the last available tumor assessment (last assessment that is CR, PR or SD):

PFS = [(Date of last assessment where patient is PD free – Date of first study treatment) + 1] / 30.4375

For patients with no post baseline tumor assessment a censored PFS at day 1 will be considered.

PFS = (Date of first study treatment – Date of first study treatment) + 1

The analysis of PFS will be performed with a Kaplan-Meier method (product-limit estimates) and a summary of associated statistics will be presented including corresponding two-sided 95% CI. The CI for the median will be calculated according to Brookmeyer and Crowley and CI for the survival function estimates at Month 3, 6, 9, 12, and 18 will be derived using the log-log transformation (SAS PROC LIFETEST CONFTYPE=LOGLOG). However, the final choice of timepoints may be updated dependent upon the data.

9.8.3 Exploratory Efficacy

9.8.3.1 Duration of Response (DOR)

The DOR (in months) is defined as the period from the date of initial confirmed PR or CR until the date of first radiographically documented progressive disease or death from any cause. Only patients with BOR of CR or PR (i.e. responders) will be included in the analysis of DOR.

DOR = [(Date of first PD/death – Date of first recorded confirmed CR/PR) + 1] / 30.4375

Patients with no documented progression or death after CR or PR will be censored at the last available tumor assessment (last assessment that is CR, PR, or SD):

DOR = [(Date of last assessment where patient is PD free – Date of first recorded CR/PR) + 1] / 30.4375

The analysis of DOR will be performed with a Kaplan-Meier method (product-limit estimates) and a summary of associated statistics will be presented including corresponding two-sided 95% CI. The CI for the median will be calculated according to Brookmeyer and Crowley and CI for the survival function estimates at Month 3, 6, 9, 12, and 18 will be derived using the log-log transformation (SAS PROC LIFETEST CONFTYPE=LOGLOG), only if there are sufficient data for responders. However, the final choice of timepoints may be updated dependent upon the data.

9.8.3.2 Overall Survival (OS)

The OS (in months) is defined as the time from first treatment to death. Patients who did not die during the study will be censored at the last known alive date.

OS = [(Date of death – Date of first study treatment) + 1] / 30.4375

For censored patients:

OS = [(Last known alive date – Date of first study treatment) + 1] / 30.4375

The last known alive date will be determined among study treatment administrations, any visits where at least one assessment has been completed, or any follow-up assessment where the patient has been confirmed to be alive.

OS will be analyzed using the same Kaplan-Meier method used to analyze the DOR.

9.9 SAFETY DATA ENDPOINTS AND ANALYSES

All safety analyses will be performed by basket and overall on the FAS, using descriptive statistics.

9.9.1 Adverse Events (AEs)

The following definitions will be used:

- ***Treatment-emergent AEs (TEAEs):*** Treatment-emergent adverse event (TEAE) is defined as any AE that emerges during on-treatment period.
- ***Related AEs:*** AEs suspected by the Investigator and/or Sponsor to have a relationship to study treatment (as recorded on the AE eCRF page, Causality = Related, Possibly Related, or missing), including ulixertinib or hydroxychloroquine or both.
- ***Serious Adverse Events (SAE):*** serious AEs (as recorded on the AE eCRF page, Does AE Meet the Definition of an SAE = Yes).
- ***AEs leading to treatment discontinuation:*** AEs leading to permanent discontinuation of study treatment (as recorded on the AE eCRF page, Action taken with study treatment = Drug withdrawn).
- ***AEs leading to dose reduction:*** AEs leading to dose reduction of study treatment (as recorded on the AE eCRF page, Action taken with study treatment = Dose Reduced).
- ***AEs leading to treatment interruption:*** AEs leading to treatment interruption of study treatment (as recorded on the AE eCRF page, Action taken with study treatment = Drug Interrupted).
- ***AEs leading to Death:*** adverse event leading to death (as recorded on the AE eCRF page, Results in death, or Outcome = Fatal, or Grade = 5).

An overview summary table will present the number and percentage of patients with a TEAE, all treatment-related adverse events will be indicated as Ulixertinib-related or Hydroxychloroquine-related or both, including:

- TEAEs / TEAEs related to study treatment
- SAEs / SAEs related to study treatment
- TEAEs leading to treatment discontinuation / TEAEs related to study treatment leading to treatment discontinuation

- TEAEs leading to treatment discontinuation within 1 cycle / TEAEs related to study treatment leading to treatment discontinuation within 1 cycle
- TEAEs leading to treatment discontinuation following 1 cycle / TEAEs related to study treatment leading to treatment discontinuation following 1 cycle
- TEAEs leading to treatment interruption / TEAEs related to study treatment leading to treatment interruption
- TEAEs leading to treatment interruption within 1 cycle / TEAEs related to study treatment leading to treatment interruption within 1 cycle
- TEAEs leading to treatment interruption following 1 cycle / TEAEs related to study treatment leading to treatment interruption following 1 cycle
- TEAEs leading to dose reduction / TEAEs related to study treatment leading to dose reduction
- TEAEs leading to dose reduction within 1 cycle / TEAEs related to study treatment leading to dose reduction within cycle 1
- TEAEs leading to dose reduction following 1 cycle / TEAEs related to study treatment leading to dose reduction following cycle 1
- TEAEs leading to death / TEAEs related to study treatment leading to death
- TEAEs with grade ≥ 3 / TEAEs related to study treatment with grade ≥ 3

In addition, the following tables will be produced by SOC and PT:

- TEAEs / TEAEs related to study treatment
- Serious TEAEs / Serious TEAEs related to study treatment
- TEAEs and maximum CTCAE grade / TEAEs related to study treatment and maximum CTCAE grade
- TEAEs leading to treatment discontinuation within/following cycle 1 / TEAEs related to study treatment leading to treatment discontinuation within/following cycle 1
- TEAEs leading to treatment interruption within/following cycle 1 / TEAEs related to study treatment leading to treatment interruption within/following cycle 1
- TEAEs leading to dose reduction within/following cycle 1 / TEAEs related to study treatment leading to dose reduction within/following cycle 1
- TEAEs leading to death / TEAEs related to study treatment leading to death

The following tables will be produced by PT:

- TEAEs / TEAEs related to study treatment
- Serious TEAEs / Serious TEAEs related to study treatment

A patient with multiple occurrences of an AE will be counted only once in the AE category. SOCs will be sorted by descending order of frequency for the overall group, PTs will be sorted by descending order of frequency for the overall group within each SOC.

All deaths will be summarized and listed with the corresponding reasons, split by overall deaths, and deaths occurring after the first dose of ulixertinib.

The following listings will be provided:

- All AEs (All Patient Set)
- TEAEs (FAS)
- SAEs (FAS)
- Deaths (FAS)

9.9.2 Clinical Safety Laboratory Evaluation

All haematology, biochemistry, coagulation and urinalysis laboratory tests collected will be reported.

The numerical measurements and change from baseline of all haematology, biochemistry, and urinalysis laboratory tests will be summarized using descriptive summary statistics for each visit.

For laboratory tests covered by the NCI-CTCAE (version 5), laboratory data will be graded accordingly. 'Normal' will be assigned for all non-missing values not graded as 1 or higher. For laboratory tests where grades are not defined by NCI-CTCAE, results will be graded by the low/normal/high classifications based on laboratory normal ranges as collected in the CRF. Separate tables will be created for Gradable and Non-gradable laboratory values.

Haematology and biochemistry laboratory tests will be summarized by:

- Tables (Gradable and Non-gradable) to describe the worst on-treatment value by cycle.
- Shift tables (Gradable and Non-gradable) to compare baseline to the worst on-treatment value.

Listings of all laboratory data with values flagged to show the corresponding NCI-CTCAE grades and the classifications relative to the laboratory normal ranges will also be provided. Also results of serum pregnancy tests and tumor markers will be listed.

9.9.3 Other Safety data

9.9.3.1 Vital signs

Vital signs include the following parameters: systolic blood pressure (SBP) (mmHg), diastolic blood pressure (DBP) (mmHg), pulse (beats/min), respiratory rate (breaths/min), pulse oximetry (%) and temperature (°C).

The numerical measurements and change from baseline of all vital signs parameters will be summarized using descriptive summary statistics for each visit.

Shift tables of baseline to worst on-treatment result (low, normal, high, very high) will be presented.

Table 7. Thresholds for classification of vital signs test results

Vital Sign	Criteria	Flag
Temperature	< 36.4°C	Low
	36.4°C – 37.7°C	Normal
	> 37.7°C	High
Pulse	< 55 bpm	Low
	55-100 bpm	Normal
	101-150 bpm	High
	> 150 bpm	Very High
Respiratory rate	<12 breaths/min	Low
	12-16 breaths/min	Normal
	>16 breaths/min	High
Pulse oximetry	<90 %	Very Low
	90-95 %	Low
	≥95 %	Normal
Systolic Blood Pressure	< 90 mmHg	Low
	90-130 mmHg	Normal
	131-160 mmHg	High
	≥ 161 mmHg	Very High
Diastolic Blood Pressure	< 60 mmHg	Low
	60-85 mmHg	Normal
	86-100 mmHg	High
	≥ 101 mmHg	Very High

All Vital Signs will be Listed.

9.9.3.2 Electrocardiogram (ECG)

ECG includes the following parameters: Heart Rate (beats/min), PR Interval (msec), QRS Duration (msec), RR Interval (msec), QT Interval (msec), and QT interval corrected for heart rate by the Fridericia's formula (QTcF) Interval (msec).

The numerical measurements and change from baseline of all ECG parameters will be summarized using descriptive summary statistics for each visit.

A listing of ECG evaluations will be created.

9.9.3.3 ECHO

ECHO assessments at baseline will be summarized using descriptive summary statistics.

A listing of ECHO evaluations will be created.

9.9.3.4 Physical Examination

Physical Examination includes the following parameters: HEENT, Thorax, Abdomen, Skin and Mucosae, Neurological, Extremities, Urogenital, General Appearance, Heart, Back, and Lymph Nodes.

All physical examination assessments at baseline will be summarized using descriptive summary statistics.

A listing of physical examination evaluations will be created.

9.9.3.5 Ophthalmology exam

A listing of ophthalmological examination assessments will be created.

9.9.3.6 ECOG Performance status

The number and percentages of patients will be tabulated for ECOG performance score categories at each visit.

A listing of all ECOG Performance status at all visits will be presented.

10 Interim Analyses

No interim analysis is planned.

11 Changes to Planned Analyses

No major changes to analyses planned in the protocol are expected.

12 Document History

Date	Version	Modified by	Brief details of changes made to template
17Jul2023	1.0	David Manteigas	First SAP Version.
20-Aug-2024	1.1	Julien Lucas	Updated version to include required changes after the study was terminated early.
02-Sep-2024	2.0	Julien Lucas	Second SAP version.

13 References

1. Eisenhauer EA, Therasse P, Bogaerts J, et al. (2009), New response evaluation criteria in solid tumours: Revised RECIST guideline (version 1.1). Eur J Cancer; 45:228-47.

14 Appendices

14.1 Schedule of events

Protocol Activities	Screening[i]	On-Treatment Period: One Cycle = 28 days						Post-Treatment Period		
		Cycle 1			Cycle 2		Cycle 3+	EOT[ii]	Safety Follow-Up[iii]	Follow-Up
Day of Cycle (Visit Window)	(≤ -28 days)	1[iv]	8 (± 2 days)	15 (± 2 days)	1 (± 2 days)	15 (± 2 days)	1 (± 2 days)	(+7 days)	(± 7 days)	
Informed Consent	X									
Demographics	X									
Cancer History[v]	X									
Medical History	X									
Eligibility Criteria	X									
Clinical Assessments										
Vital Signs[vi]	X	X	X	X	X	X	X	X	X	
Physical Exam[vii]	X	X	X	X	X	X	X	X	X	
ECOG Score	X	X	X	X	X	X	X	X	X	
ECG	X		X	X	X			X		
Echocardiogram	X	ACI								

Protocol Activities	Screening[i]	On-Treatment Period: One Cycle = 28 days						Post-Treatment Period		
		Cycle 1			Cycle 2		Cycle 3+	EOT[ii]	Safety Follow-Up[iii]	Follow-Up
Day of Cycle (Visit Window)	(≤ -28 days)	1[iv]	8 (± 2 days)	15 (± 2 days)	1 (± 2 days)	15 (± 2 days)	1 (± 2 days)	(+7 days)	(± 7 days)	
Ophthalmologic Exam[viii]	X				X		X			
Adverse event collection	X	X								
Concomitant medications	X	X								
Laboratory Studies[ix]										
Hematology	X	X	X	X	X	X	X	X	X	
Chemistry	X	X	X	X	X	X	X	X	X	
Creatine kinase[x]	X	ACI								
LDH and Phosphorus	X	X	X	X	X	ACI				
Coagulation	X	ACI								
Urinalysis	X	ACI								
Tumor Marker[xi]		X			X		X	X		
Pregnancy Test[xii]	X	ACI								
Disease Assessments										
CT Scans or MRI[xiii]	X						X	X		X[xiv]

Protocol Activities	Screening[I]	On-Treatment Period: One Cycle = 28 days						Post-Treatment Period		
		Cycle 1			Cycle 2		Cycle 3+	EOT[II]	Safety Follow-Up[III]	Follow-Up
Day of Cycle (Visit Window)	(≤ -28 days)	1[IV]	8 (± 2 days)	15 (± 2 days)	1 (± 2 days)	15 (± 2 days)	1 (± 2 days)	(+7 days)	(± 7 days)	
RECIST 1.1 Assessment	X						X	X		X
Treatment Compliance and Distribution										
Hydroxychloroquine		X			X		X			
Ulixertinib		X			X		X			
Treatment administration on site				X[15]			X			
Meal provided by site				X			X[16]			

Abbreviations: ACI = as clinically indicated; LDH = lactate dehydrogenase; CT = computed tomography; MRI = magnetic resonance imaging; ECG = electrocardiogram; EOT = end of treatment

[1] Screening procedures must be completed ≤ 28 days prior to C1D1 unless noted otherwise.
[2] The end of treatment visit should occur when the decision to discontinue treatment is made. If this visit overlaps with a regularly scheduled visit, only the procedures listed in the calendar for the EOT visit will be performed. All end of treatment procedures should be completed within 7 days after the decision to discontinue treatment has been made.
[3] Patients will have a safety follow-up visit 60 days (± 7 days) after last dose of study drug.
[4] C1D1 procedures do not need to be repeated if screening procedures were performed ≤ 7 days of the start of treatment.
[5] Oncologic history of the malignancy under study including prior regimens (duration of therapy, best response on therapy, date of discontinuation, and reason for discontinuation), surgery, and radiation therapy.
[6] Vital signs include systolic/diastolic blood pressure, heart rate, respiration rate, pulse oximetry, weight, and body temperature. Height will be captured at screening only.
[7] If necessary to facilitate scheduling, the physical exam may occur one day prior to study treatment.
[8] A standard ophthalmologic exam must be completed at screening, C2D1, and every 3 cycles thereafter (i.e. C5D1, C8D1, etc.) and as clinically indicated to assess for retinopathies. All assessments must be conducted up to 7 days prior to the clinic visit to enable timely results review.
[9] Labs may be performed ≤ 3 days prior to a scheduled day one visit except for C1D1 labs which may be completed ≤ 7 days prior to C1D1.
[10] After screening, creatine kinase should only be drawn if creatinine is elevated.
[11] Tumor marker should be drawn on day one of each cycle. Tumor markers will be disease specific: pancreatic adenocarcinoma only CA 19-9; colorectal carcinoma only CEA; cholangiocarcinoma only CEA and CA 19-9. Tumor markers are not required for patients with esophageal or stomach cancers.
[12] Pregnancy test (serum or urine) must be obtained at screening ≤ 7 days prior to C1D1 for all women of childbearing potential and as clinically indicated while on treatment.
[13] Disease assessment will be repeated every 8 weeks (± 7 days) regardless of dose holds or delays. Patients who discontinue treatment for reasons other than progression will have computed tomography (CT) scans at the EOT visit (unless their previous restaging was performed within 6 weeks).
[14] Patients that discontinue study treatment for any reason other than disease progression, must continue to have disease assessments every 8 weeks (± 7 days) until disease progression or initiation of subsequent anticancer therapy.
[15] Patient should be instructed to not take their study treatment before arriving at clinic. Study treatment and meal should be provided after the pre-dose PK draw.
[16] Meal is only required to be given at C3D1, i.e., at the time of drug administration for ctDNA and tumor biopsy for stage 1.

14.2 Schedule of Correlative Sample Collection

Correlative Test	**Screening**	**C1D1**	**C1D15**								**C3D1**	**EOT**
			Pre-Dose	Post-Dose								
Time Point (hour)				0.5	1	2	4	6	8	12	± 7 days	
Window (min)			≤ 60	±2	±3	±6	±12	±18	±24	±36		
STAGE 1												
PK Blood[1]			X	X	X	X	X	X	X	X		
ctDNA		X									X[2]	X[3]
Biopsy	X										X	X
STAGE 2												
PK Blood[4]			X									

Abbreviations: C = cycle; ctDNA = circulating tumor DNA; D = day; EOT = end of treatment; PK = pharmacokinetics.

[1]To accommodate PK blood draws, patients should be instructed not to take their morning doses of both medications until told to do so in the clinic. A meal should be provided by the site when taking the medications in the clinic. Pre-dose PK sample should be collected prior to the administration of study drugs. Post-dose PK samples should be collected at the appropriate time points following administration of study drugs. PK samples should be drawn while patients are at steady state, which is 5 days, or 10 consecutive doses.
[2]To be drawn at the time of the tumor biopsy.
[3]Required blood draw at EOT. If optional biopsy is collected at EOT, ctDNA should be drawn at the time of the tumor biopsy.
[4]Biopsies at screening and C3D1 (± 7 days) are required. When blood is being drawn at D3D1, site will provide a meal when study drugs are taken. An optional biopsy will be offered at the time when the decision to discontinue treatment is made (+ 7 days).

14.3 CTCAE v5.0 Grading for Laboratory Values

Table 8. Hematology Tests

Parameter	CTCAE Gradable†	SOC	CTCAE v5.0 Term
Hematocrit	No		
Hemoglobin	Yes	Blood and lymphatic system disorders	Anemia
		Investigations	Hemoglobin increased
Platelets	Yes	Investigations	Platelet count decreased
White blood cells	Yes	Investigations	White blood cell decreased
		Blood and lymphatic system disorders	Leukocytosis
Neutrophils absolute	Yes	Investigations	Neutrophil count decreased
Lymphocytes absolute	Yes	Investigations	Lymphocyte count decreased
			Lymphocyte count increased

† For laboratory tests where grades are not defined by NCI-CTCAE, results will be graded by the low/normal/high classification based on laboratory normal ranges.

Table 9. Coagulation Tests

Parameter	CTCAE Gradable†	SOC	CTCAE v5.0 Term
PT	No		
INR	Yes	Investigations	INR increased
PTT	No		

† For laboratory tests where grades are not defined by NCI-CTCAE, results will be graded by the low/normal/high classification based on laboratory normal ranges.

Table 10. Serum Chemistry Tests

Parameter	CTCAE Gradable†	SOC	CTCAE v5.0 Term
Albumin	Yes	Metabolism and nutrition disorders	Hypoalbuminemia
Alkaline phosphatase	Yes	Investigations	Alkaline phosphatase increased
ALT	Yes	Investigations	Alanine aminotransferase increased
AST	Yes	Investigations	Aspartate aminotransferase increased
Blood urea nitrogen	No		
Uric acid	No		
Chloride	No		
Calcium	Yes	Metabolism and nutrition disorders	Hypocalcemia
			Hypocalcemia

Parameter	CTCAE Gradable†	SOC	CTCAE v5.0 Term
Creatinine	Yes	Investigations	Creatinine increased
Lactate Dehydrogenase	Yes	Investigations	Lactate Dehydrogenase increased
Glucose	Yes	Metabolism and nutrition disorders	Hyperglycemia
			Hypoglycemia
Potassium	Yes	Metabolism and nutrition disorders	Hyperkalemia
			Hypokalemia
Sodium	Yes	Metabolism and nutrition disorders	Hypernatremia
			Hyponatremia
Inorganic Phosphorus	No		
Total bilirubin	Yes	Investigations	Blood bilirubin increased
Direct bilirubin	No		
Total protein	No		
Urea Nitrogen	No		
Carbon Dioxide	No		

† For laboratory tests where grades are not defined by NCI-CTCAE, results will be graded by the low/normal/high classification based on laboratory normal ranges.

Table 11. Urinalysis Tests

Parameter	CTCAE Gradable†	SOC	CTCAE v5.0 Term
Dipstick Evaluation Of Bilirubin	No		
Dipstick Evaluation Of Blood	No		
Dipstick Evaluation Of Glucose	No		
Dipstick Evaluation Of Ketones	No		
Dipstick Evaluation Of Leukocytes	No		
Dipstick Evaluation Of Protein	No		
Microscopic Examination Of Casts	No		
Microscopic Examination Of Rbc	No		
Microscopic Examination Of Wbc	No		
pH	No		
Specific Gravity	No		

† For laboratory tests where grades are not defined by NCI-CTCAE, results will be graded by the low/normal/high classification based on laboratory normal ranges.

SPONSOR:

BioMed Valley Discoveries

PROTOCOL NUMBER:

BVD-523-HCQ

STATISTICAL ANALYSIS PLAN
TFL SHELLS

Author:	**Julien Lucas**
Version:	2.0
Date:	02-Sep-2024

1 Cover and signature pages

Sponsor:	BioMed Valley Discoveries
Protocol Number:	BVD-523-HCQ
Study Title:	A phase 2 basket trial of ulixertinib in combination with hydroxychloroquine in patients with advanced gastrointestinal malignancies harboring MAPK pathway mutations (BVD-523-HCQ)
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We, the undersigned, confirm that we have read, understood and agree to the content of this document and hereby authorize its approval.

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2 Document History

Date	Version	Modified by	Brief details of changes made to template
27Jul2023	1.0	David Manteigas	First SAP version
20Aug2024	1.1	Julien Lucas	Updated version to include required changes after the study was early terminated.
02Sep2024	2.0	Julien Lucas	Second SAP version.

3 List of Tables, Figures and Listings

TFL Type	TFL Number	Title	Population	SMC*	Included in Final Analysis
14.1		**Demographic Data**			
Table	14.1-1.1	Patient Disposition	All Patients Set	Y	Y
Table	14.1-1.2	Number of Patients in the Analysis Sets	All Patients Set		Y
Table	14.1-1.3	Summary of Important Protocol Deviations	Full Analysis Set		Y
Table	14.1-2.1	Demographics and Baseline Characteristics	Full Analysis Set	Y	Y
Table	14.1-2.2	Disease History	Full Analysis Set	Y	Y
Table	14.1-2.3	Summary of Medical History	Full Analysis Set		Y
Table	14.1-2.4	Summary of Concomitant Diseases	Full Analysis Set		Y
Table	14.1-3.1	Prior Systemic Anti-Cancer Therapies	Full Analysis Set	Y	Y
Table	14.1-3.2	Prior Radiotherapy Courses	Full Analysis Set	Y	Y
Table	14.1-3.3	Prior Medications	Full Analysis Set		Y
Table	14.1-3.4	Concomitant Medications	Full Analysis Set		Y
Table	14.1-4.1.1	Treatment Exposure (Ulixertinib)	Full Analysis Set	Y	Y
Table	14.1-4.1.2	Treatment Exposure (Hydroxychloroquine)	Full Analysis Set	Y	Y
Table	14.1-4.2.1	Dosing Interruptions and Adjustments (Ulixertinib)	Full Analysis Set	Y	Y
Table	14.1-4.2.2	Dosing Interruptions and Adjustments (Hydroxychloroquine)	Full Analysis Set	Y	Y
14.2		**Efficacy Data**			
Table	14.2-1.1.1	Best Overall Response and Overall Response Rate	Full Analysis Set		Y
Table	14.2-1.1.2	Best Overall Response and Overall Response Rate	Evaluable Analysis Set		
Table	14.2-1.2.1	Overall, Target and Non-Target Lesion Response	Full Analysis Set		Y
Table	14.2-1.2.2	Overall, Target and Non-Target Lesion Response	Evaluable Analysis Set		
Table	14.2-1.3.1	Incidence of New Lesions	Full Analysis Set		Y
Table	14.2-1.3.2	Incidence of New Lesions	Evaluable Analysis Set		
Table	14.2-1.4.1	Progression-free Survival (PFS)	Full Analysis Set		Y
Table	14.2-1.4.2	Progression-free Survival (PFS)	Evaluable Analysis Set		
Table	14.2-1.5.1	Overall Survival (OS)	Full Analysis Set		Y
Table	14.2-1.5.2	Overall Survival (OS)	Evaluable Analysis Set		
Table	14.2-1.6.1	Duration of Response (DOR)	Full Analysis Set		
14.3		**Safety Data**			

Table	14.3-1.1	Overview Summary of Treatment-Emergent Adverse Events	Full Analysis Set	Y	Y
Table	14.3-1.2	Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term	Full Analysis Set	Y	Y
Table	14.3-1.3	Summary of Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term	Full Analysis Set	Y	Y
Table	14.3-1.4	Summary of Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term	Full Analysis Set	Y	Y
Table	14.3-1.5	Summary of Related Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term	Full Analysis Set	Y	Y
Table	14.3-1.6	Summary of Treatment-Emergent Adverse Events by Preferred Term	Full Analysis Set		
Table	14.3-1.7	Summary of Related Treatment-emergent Adverse Events by Preferred Term	Full Analysis Set		
Table	14.3-1.8	Summary of Serious Treatment-emergent Adverse Events by Preferred Term	Full Analysis Set		
Table	14.3-1.9	Summary of Related Serious Treatment-emergent Adverse Events by Preferred Term	Full Analysis Set		
Table	14.3-1.10	Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term for Maximum CTCAE grade	Full Analysis Set		Y
Table	14.3-1.11	Summary of Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term for Maximum CTCAE grade	Full Analysis Set	Y	Y
Table	14.3-1.12	Summary of Treatment-emergent Adverse Leading to Treatment Discontinuation Events by System Organ Class and Preferred Term	Full Analysis Set	Y	Y
Table	14.3-1.13	Summary of Related Treatment-emergent Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term	Full Analysis Set	Y	Y
Table	14.3-1.14	Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation within Cycle 1 by System Organ Class and Preferred Term	Full Analysis Set	Y	Y
Table	14.3-1.15	Summary of Related Treatment-emergent Adverse Events Leading to Treatment Discontinuation within Cycle 1 by System Organ Class and Preferred Term	Full Analysis Set	Y	Y
Table	14.3-1.16	Summary of Treatment-emergent Adverse Events Leading to Treatment Discontinuation following Cycle 1 by System Organ Class and Preferred Term	Full Analysis Set	Y	Y
Table	14.3-1.17	Summary of Related Treatment-emergent Adverse Events Leading to Treatment Discontinuation following Cycle 1 by System Organ Class and Preferred Term	Full Analysis Set	Y	Y
Table	14.3-1.18	Summary of Treatment-emergent Adverse Events Leading to Treatment Interruption by System Organ Class and Preferred Term	Full Analysis Set		Y
Table	14.3-1.19	Summary of Related Treatment-emergent Adverse Events Leading to Treatment Interruption by System Organ Class and Preferred Term	Full Analysis Set		Y
Table	14.3-1.20	Summary of Treatment-emergent Adverse Events Leading to Treatment Interruption within Cycle 1 by System Organ Class and Preferred Term	Full Analysis Set	Y	Y

Table	14.3-1.21	Summary of Related Treatment-emergent Adverse Events Leading to Treatment Interruption within Cycle 1 by System Organ Class and Preferred Term	Full Analysis Set	Y	Y
Table	14.3-1.22	Summary of Treatment-emergent Adverse Events Leading to Treatment Interruption following Cycle 1 by System Organ Class and Preferred Term	Full Analysis Set		Y
Table	14.3-1.23	Summary of Related Treatment-emergent Adverse Events Leading to Treatment Interruption following Cycle 1 by System Organ Class and Preferred Term	Full Analysis Set		Y
Table	14.3-1.24	Summary of Treatment-emergent Adverse Events Leading to Dose Reduction by System Organ Class and Preferred Term	Full Analysis Set		Y
Table	14.3-1.25	Summary of Related Treatment-emergent Adverse Events Leading to Dose Reduction by System Organ Class and Preferred Term	Full Analysis Set		Y
Table	14.3-1.26	Summary of Treatment-Emergent Adverse Events Leading to Dose Reduction within Cycle 1 by System Organ Class and Preferred Term	Full Analysis Set	Y	Y
Table	14.3-1.27	Summary of Related Treatment-Emergent Adverse Events Leading to Dose Reduction within Cycle 1 by System Organ Class and Preferred Term	Full Analysis Set	Y	Y
Table	14.3-1.28	Summary of Treatment-Emergent Adverse Events Leading to Dose Reduction following Cycle 1 by System Organ Class and Preferred Term	Full Analysis Set		Y
Table	14.3-1.29	Summary of Related Treatment-Emergent Adverse Events Leading to Dose Reduction following Cycle 1 by System Organ Class and Preferred Term	Full Analysis Set		Y
Table	14.3-1.30	Summary of Treatment-emergent Adverse Events by System Organ Class and Preferred Term Leading to Death	Full Analysis Set		Y
Table	14.3-1.31	Summary of Related Treatment-emergent Adverse Events by System Organ Class and Preferred Term Leading to Death	Full Analysis Set		Y
Table	14.3-1.32	Summary of Deaths	All Patients Set	Y	Y
Table	14.3-2.1	Summary and Change from Baseline in Hematology Laboratory Results by Visit	Full Analysis Set		Y
Table	14.3-2.2.1	Gradable Hematology Laboratory Results – Worst On-treatment Value by Cycle	Full Analysis Set		
Table	14.3-2.2.2	Non-gradable Hematology Laboratory Results – Worst On-treatment Value by Cycle	Full Analysis Set		
Table	14.3-2.3.1	Shift Table of Gradable Hematology Laboratory Results – Baseline vs Worst On-treatment Value	Full Analysis Set	Y	Y
Table	14.3-2.3.2	Shift Table of Non-gradable Hematology Laboratory Results – Baseline vs Worst On-treatment Value	Full Analysis Set		Y
Table	14.3-2.4	Summary and Change from Baseline in Biochemistry Laboratory Results by Visit	Full Analysis Set		Y
Table	14.3-2.5.1	Gradable Biochemistry Laboratory Results – Worst On-treatment Value by Cycle	Full Analysis Set		
Table	14.3-2.5.2	Non-gradable Biochemistry Laboratory Results – Worst On-treatment Value by Cycle	Full Analysis Set		
Table	14.3-2.6.1	Shift Table of Gradable Biochemistry Laboratory Results – Baseline vs Worst On-treatment Value	Full Analysis Set	Y	Y

Table	14.3-2.6.2	Shift Table of Non-gradable Biochemistry Laboratory Results – Baseline vs Worst On-treatment Value	Full Analysis Set		Y
Table	14.3-2.7	Summary at Baseline in Coagulation Laboratory Results by Visit	Full Analysis Set		Y
Table	14.3-2.8	Summary at Baseline in Urinalysis Laboratory Results by Visit	Full Analysis Set		
Table	14.3-3.1	Summary and Change from Baseline in Vital Signs by Visit	Full Analysis Set		Y
Table	14.3-3.2	Shift table of Vital Signs – Baseline vs worst on-treatment value	Full Analysis Set		Y
Table	14.3-3.3	Summary and Change from Baseline in ECG parameters by Visit	Full Analysis Set	Y	Y
Table	14.3-3.4	Summary of ECHO at Baseline	Full Analysis Set		
Table	14.3-3.5	Summary of Physical Examination at Baseline	Full Analysis Set		
Table	14.3-3.6	Summary of ECOG Performance Status by Visit	Full Analysis Set	Y	
14.4		**Other Efficacy Data**			
14.5		**Pharmacokinetic Data**			
Table	14.5-1.1	Pharmacokinetic Concentration Data	PK Analysis Set		Y
Table	14.5-1.2	Pharmacokinetic Parameters Data	PK Analysis Set		Y
14.2		**Figures**			
Figure	14.2-1.1	Consort Diagram	Full Analysis Set	Y	Y
Figure	14.2-1.2.1	Spider plot of Percentage Change from Baseline in Sum of Longest Diameter	Full Analysis Set		Y
Figure	14.2-1.2.2	Spider plot of Percentage Change from Baseline in Sum of Longest Diameter	Evaluable Analysis Set		
Figure	14.2-1.3.1	Waterfall plot of Maximum Percentage Change from Baseline in Sum of Longest Diameter	Full Analysis Set		Y
Figure	14.2-1.3.2	Waterfall plot of Maximum Percentage Change from Baseline in Sum of Longest Diameter	Evaluable Analysis Set		
Figure	14.2-1.4.1	Swimmer Plot of Response Assessments	Full Analysis Set		Y
Figure	14.2-1.4.2	Swimmer Plot of Response Assessments	Evaluable Analysis Set		
Figure	14.2-1.5.1	Kaplan-Meier Estimate for Progression-free Survival (PFS)	Full Analysis Set		Y
Figure	14.2-1.5.2	Kaplan-Meier Estimate for Progression-free Survival (PFS)	Evaluable Analysis Set		
Figure	14.2-1.6.1	Kaplan-Meier Estimate for Overall Survival (OS)	Full Analysis Set		Y
Figure	14.2-1.6.2	Kaplan-Meier Estimate for Overall Survival (OS)	Evaluable Analysis Set		
Figure	14.2-1.7.1	Kaplan-Meier Estimate for Duration of Response (DOR)	Full Analysis Set		
16.2		**Patient Data Listings**			
16.2.1		**Patient Disposition**			
Listing	16.2.1-1	Patient Informed Consent	All Patients Set		Y
Listing	16.2.1-2	Failed Inclusion and Exclusion Criteria	All Patients Set		Y
Listing	16.2.1-3	Patient Disposition	All Patients Set		Y
16.2.2		**Analysis Sets**			
Listing	16.2.2-1	Analysis Sets	All Patients Set		
16.2.3		**Protocol Deviations**			
Listing	16.2.3-1	Protocol Deviations	Full Analysis Set		Y
16.2.4		**Demographic Data**			
Listing	16.2.4-1	Demographics and Baseline Characteristics	Full Analysis Set		Y
Listing	16.2.4-2	Smoking History	Full Analysis Set		

Listing	16.2.4-3	Disease History	Full Analysis Set		Y
Listing	16.2.4-4	Medical History and Concomitant Diseases	Full Analysis Set		Y
Listing	16.2.4-5	Prior Systemic Anti-Cancer Therapies	Full Analysis Set		Y
Listing	16.2.4-6	Prior Radiotherapy Courses	Full Analysis Set		Y
Listing	16.2.4-7	Prior and Concomitant Medications	Full Analysis Set		Y
Listing	16.2.4-8	On Treatment Radiation	Full Analysis Set		
Listing	16.2.4-9	On Treatment Surgery and Medical Procedures	Full Analysis Set		
Listing	16.2.4-10	On Treatment Blood Transfusions	Full Analysis Set		
Listing	16.2.4-11	NGS Data	Full Analysis Set		Y
16.2.5		**Compliance and/or Drug Concentration Data**			
Listing	16.2.5-1	Ulixertinib In-clinic Administration	Full Analysis Set		
Listing	16.2.5-2	Hydroxychloroquine In-clinic Administration	Full Analysis Set		
Listing	16.2.5-3	Ulixertinib Interruptions and Adjustments	Full Analysis Set		Y
Listing	16.2.5-4	Hydroxychloroquine Interruptions and Adjustments	Full Analysis Set		Y
Listing	16.2.5-5	Ulixertinib Exposure	Full Analysis Set		Y
Listing	16.2.5-6	Hydroxychloroquine Exposure	Full Analysis Set		Y
Listing	16.2.5-7	Ulixertinib Dispensed	Full Analysis Set		
Listing	16.2.5-8	Hydroxychloroquine Dispensed	Full Analysis Set		
Listing	16.2.5-9	Ulixertinib Returned	Full Analysis Set		
Listing	16.2.5-10	Hydroxychloroquine Returned	Full Analysis Set		
16.2.6		**Individual Efficacy Response data**			
Listing	16.2.6-1	Target Lesions	Full Analysis Set		Y
Listing	16.2.6-2	Non-Target Lesions	Full Analysis Set		Y
Listing	16.2.6-3	New Lesions	Full Analysis Set		Y
Listing	16.2.6-4	Overall Response	Full Analysis Set		Y
Listing	16.2.6-5	Progression-Free Survival (PFS	Full Analysis Set		Y
Listing	16.2.6-6	Survival Status	Full Analysis Set		Y
Listing	16.2.6-7	Duration of Response (DOR)	Full Analysis Set		
16.2.7		**Adverse Events**	Full Analysis Set		
Listing	16.2.7-1	Adverse Events	All Patients Set		Y
Listing	16.2.7-2	Treatment Emergent Adverse Events	Full Analysis Set		Y
Listing	16.2.7-3	Serious Adverse Events	Full Analysis Set		Y
Listing	16.2.7-4	Deaths	All Patients Set		Y
16.2.8		**Laboratory Data**			
Listing	16.2.8-1	Hematology	Full Analysis Set		Y
Listing	16.2.8-2	Biochemistry	Full Analysis Set		Y
Listing	16.2.8-3	Coagulation	Full Analysis Set		Y
Listing	16.2.8-4	Urinalysis	Full Analysis Set		Y
Listing	16.2.8-5	Tumor Markers	Full Analysis Set		
Listing	16.2.8-6	Pregnancy	Full Analysis Set		
16.2.9		**Other Safety Data**			
Listing	16.2.9-1	Vital Signs	Full Analysis Set		Y
Listing	16.2.9-2	Electrocardiogram	Full Analysis Set		Y
Listing	16.2.9-3	ECHO/MUGA	Full Analysis Set		Y
Listing	16.2.9-4	Physical Examination	Full Analysis Set		Y
Listing	16.2.9-5	Ophthalmology exam	Full Analysis Set		Y
Listing	16.2.9-6	ECOG Performance Status	Full Analysis Set		Y
16.2.11		**Pharmacokinetic Data**			
Listing	16.2.11-1	Pharmacokinetic Concentration Data	PK Analysis Set		Y
Listing	16.2.11-2	Pharmacokinetic Parameters Data	PK Analysis Set		Y

*Table, Figure or Listing that will be used for SMC purposes. Y=Yes

4 General programming notes

All tables will be reported by treatment Basket.

An 'Overall' column will be included in all tables.

Column headers					
Basket 1	Basket 2	Basket 3	Basket 4	Basket 5	Overall

For tables reporting data on All Patients Set, a screening failures column will be added.

The full-page header to be included for each delivery is indicated in the table below:

Delivery	Type	Page Header
Dry run	Dry run	Dry-run
SMC *N**	Final	Final
Final analysis	Draft	Draft
	Final	Final

*N references to the SMC chronological number

For the listings, all cases where 'Other' is present, please present the respective 'Other' specification.

All Listings will be sorted by Basket and patient ID. A programming note will be added to each Listing when another variable is needed to make the sorting meaningful (e.g., assessment date).

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.1-1.1 – Patient Disposition
All Patients Set

	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Screen Failures N=XX n (%)	Overall N=XX n (%)
Patients enrolled [a]	XX	XX	XX	XX	XX	XX	XX
Patients completed screening [b]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Discontinued from screening [b]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Primary reason for discontinuation [c]							
Adverse Event	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Death	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Pregnancy	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Screen Failure	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Study Terminated by Sponsor	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Lost to Follow-up	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Technical Problems	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Physician Decision	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Withdrawal by Patient	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Patients rescreened [b]							
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Patients eligible for inclusion in the study [b]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Patients treated with study drug [b]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)

[a] Patients who signed the informed consent.
[b] Percentages are calculated from the number of patients enrolled.
[c] Percentages are calculated from the number of patients who discontinued from screening.
[d] Percentages are calculated from the number of patients who were treated with study drug.
[e] Percentages are calculated from the number of patients who discontinued from treatment.
[f] Percentages are calculated from the number of patients who discontinued from study.
Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Table 14.1-1.1 – Patient Disposition
All Patients Set

	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Screen Failures N=XX n (%)	Overall N=XX n (%)
Patients completed treatment [d]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Discontinued from treatment [d]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Primary reason for discontinuation [e]							
Death	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Progressive Disease	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Adverse Event	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Pregnancy	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Withdrawal by Patient	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Protocol Violation	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Lost to Follow-up	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Physician Decision	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Study Terminated by Sponsor	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)

[a] Patients who signed the informed consent.
[b] Percentages are calculated from the number of patients enrolled.
[c] Percentages are calculated from the number of patients who discontinued from screening.
[d] Percentages are calculated from the number of patients who were treated with study drug.
[e] Percentages are calculated from the number of patients who discontinued from treatment.
[f] Percentages are calculated from the number of patients who discontinued from study.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Table 14.1-1.1 – Patient Disposition
All Patients Set

	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Screen Failures N=XX n (%)	Overall N=XX n (%)
Patients completed study [b]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Primary reason for completion [f]							
Adverse Event	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Progressive Disease	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Death	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Withdrawal by Patient	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Physician Decision	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Lost to Follow-up	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Pregnancy	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Protocol Violation	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Sponsor Request	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Protocol-Specified Withdrawal Criterion Met	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)

[a] Patients who signed the informed consent.
[b] Percentages are calculated from the number of patients enrolled.
[c] Percentages are calculated from the number of patients who discontinued from screening.
[d] Percentages are calculated from the number of patients who were treated with study drug.
[e] Percentages are calculated from the number of patients who discontinued from treatment.
[f] Percentages are calculated from the number of patients who completed the study.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Display all possible reasons, either reported for at least one patient or not.

Table 14.1-1.2 – Number of Patients in the Analysis Sets
All Patients Set

	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Screen Failures N=XX n (%)	Overall N=XX n (%)
All Patients Set [a]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Full Analysis Set [b]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Stage 1 Analysis Set [c]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
Evaluable Analysis Set [d]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)
PK Analysis Set [e]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)		XX (XX.X)

[a] Patients who were enrolled regardless of whether they received the study drug or not.
[b] Patients who received at least 1 dose of the study drug.
[c] First 13 patients who have completed at least one cycle of therapy and who have received a minimum of 75% of prescribed study therapy during Cycle 1
[d] Patients who received at least one dose of study drug and have at least one post-treatment study evaluation or who have discontinued therapy prior to the first post-treatment study evaluation due to clinical progressive disease or drug-related adverse events.
[e] Patients who received at least one dose of study medication and have at least one post dose PK measurement.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.1-1.3 – Summary of Important Protocol Deviations
Full Analysis Set

	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
Number of patients with at least one important protocol deviation	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Deviation category 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Summary term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Summary term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Deviation category 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Summary term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Summary term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: A patient with multiple occurences of a protocol deviation is counted only once in this deviation category/summary term.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Categories / Summary terms to match the PDCF.
- Present only important protocol deviations with at least one occurrence (where classification=Important).

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.1-2.1 – Demographics and Baseline Characteristics
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Age (Years)						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XXX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)
Median	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Min; Max	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X
Age category (Years) n (%)						
18 - 64	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
65 - 84	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
>=85	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Gender - n (%)						
Female	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Childbearing potential n (%)						
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Male	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Reproductive potential n (%)						
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

[a] Last non-missing value prior to first dose of study treatment.
[b] Body Mass Index (BMI)=Weight (kg)/ Height(m)^2.
[c] 0=Fully active, able to carry on all pre-disease performance without restriction; 1=Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature; 2=Ambulatory and capable of all self-care but unable to carry out any work activities.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.doc)

Table 14.1-2.1 - Demographics and Baseline Characteristics
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Race - n (%)						
American Indian or Alaska Native	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Asian	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Black or African American	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Native Hawaiian or Other Pacific Islander	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
White	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Ethnicity - n (%)						
Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Unknown	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Weight (kg) [a]						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX

[a] Last non-missing value prior to first dose of study treatment.
[b] Body Mass Index (BMI)=Weight (kg)/ Height(m)^2.
[c] 0=Fully active, able to carry on all pre-disease performance without restriction; 1=Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature; 2=Ambulatory and capable of all self-care but unable to carry out any work activities.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.doc)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.1-2.1 – Demographics and Baseline Characteristics
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Height (cm) [a]						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX
ECOG performance at Baseline – n (%) [b]						
0	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Smoking History – n (%)						
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Current	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Former	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

[a] Last non-missing value prior to first dose of study treatment.
[b] 0=Fully active, able to carry on all pre-disease performance without restriction; 1=Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature; 2=Ambulatory and capable of all self-care but unable to carry out any work activities.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.doc)

Table 14.1-2.1 - Demographics and Baseline Characteristics
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Gene/Codon/Amino acid change						
HRAS/G469/Alanine A	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
KRAS/G469/Arginine R	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
NRAS/G469/Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
…						

[a] Last non-missing value prior to first dose of study treatment.
[b] Body Mass Index (BMI)=Weight (kg)/ Height(m)^2.
[c] 0=Fully active, able to carry on all pre-disease performance without restriction; 1=Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature; 2=Ambulatory and capable of all self-care but unable to carry out any work activities.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.doc)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.1-2.2 – Disease History
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Cancer Diagnosis – n (%)						
Intrahepatic cholangiocarcinoma	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Perihilar cholangiocarcinoma	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Extrahepatic cholangiocarcinoma	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Pancreatic adenocarcinoma	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....						
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Time since initial diagnosis (months) [a]						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX
Disease stage at enrollment – n (%)						
1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
4	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

[a] Calculated as (date of first dose of study treatment – date of diagnosis) / 30.4375.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Table 14.1-2.2 – Disease History
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Disease stage at initial diagnosis – n (%)						
1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
4	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Method of diagnosis – n (%)						
Cytological	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Histological	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Prior Radiation Therapies – n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No						

[a] Calculated as (date of first dose of study treatment – date of diagnosis) / 30.4375.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.1-2.3 – Summary of Medical History
Full Analysis Set

System Organ Class Preferred Term	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
Any relevant medical history	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: MedDRA <vx.x>.
If there is more than one medical history within a system organ class (SOC), the patient is counted only once under that SOC. If there is more than one medical history within a SOC and preferred term (PT), the patient is counted only once in that SOC and PT.
Primary SOCs are presented by descending order of frequency for the overall Basket, PTs are sorted by descending order of frequency for the overall Basket within primary SOC.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.1-2.4 – Summary of Concomitant Diseases
Full Analysis Set

System Organ Class Preferred Term	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
Any relevant concomitant disease	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: MedDRA <vx.x>.
If there is more than one concomitant disease within a system organ class (SOC), the patient is counted only once under that SOC. If there is more than one concomitant disease within a SOC and preferred term (PT), the patient is counted only once in that SOC and PT. Primary SOCs are presented by descending order of frequency for the overall Basket, PTs are sorted by descending order of frequency for the overall Basket within primary SOC.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Table 14.1-3.1 – Prior Systemic Anti-Cancer Therapies
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Received at least one systemic prior anti-cancer Therapy – n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Lines of systemic prior anti-cancer therapies – n (%)						
1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
4	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
…						
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX
Most recent therapy before study treatment start						
Regimen name – n (%)						
xxxxxxxx	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
xxxxxxxx	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
xxxxxxxx	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

[a] Calculated as [(end date of therapy – start date of therapy)+1] / 30.4375.
[b] Calculated as [(date of first study treatment – date of BOR)+1] / 30.4375.
[c] Calculated as [(date of first study treatment – date of Relapse/Progression)+1] / 30.4375.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Table 14.1-3.1 – Prior Systemic Anti-Cancer Therapies
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Best Response – n (%)						
Complete Response	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Partial Response	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Stable Disease	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Progressive Disease	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Evaluable	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Done	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Duration of therapy (months) [a]						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX
Time since Best Overall Response (months) [b]						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX

[a] Calculated as [(end date of therapy – start date of therapy)+1] / 30.4375.
[b] Calculated as [(date of first study treatment – date of BOR)+1] / 30.4375.
[c] Calculated as [(date of first study treatment – date of Relapse/Progression)+1] / 30.4375.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Table 14.1-3.1 – Prior Systemic Anti-Cancer Therapies
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Time since Relapse/Progression (months) [c]						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX
Reason for discontinuation – n (%)						
Intolerance	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Lack of Efficacy (incl. PD)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Completed Therapy	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

[a] Calculated as [(end date of therapy – start date of therapy)+1] / 30.4375.
[b] Calculated as [(date of first study treatment – date of BOR)+1] / 30.4375.
[c] Calculated as [(date of first study treatment – date of Relapse/Progression)+1] / 30.4375.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)
Filename: (Specify file name.rtf)

Table 14.1-3.2 – Prior Radiotherapy Courses
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Received at least one prior radiotherapy – n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Total number of prior radiotherapy courses – n (%)						
1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Site of prior radiotherapy – n (%) [a]						
Abdominal Cavity	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Adrenal Gland	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
…….						
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Most recent prior radiotherapy before study treatment start						
Site of prior radiotherapy – n (%)						
Abdominal Cavity	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
…….						
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Duration of therapy (months) [b]						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX

[a] Patients can have more than 1 site of prior radiotherapy if they had multiple prior radiotherapies.
[b] Calculated as [(end date of therapy – start date of therapy)+1] / 30.4375.
Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.1-3.3 – Prior Medications
Full Analysis Set

ATC Class Preferred Term	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
Any Prior Medications	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
ATC class 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
……	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
ATC class 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
……	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: WHOHD-B3 <vx.x>. ATC=Anatomical Therapeutic Chemical.
If there is more than one medication within an ATC class, the patient is counted only once under that ATC class. If there is more than one medication within an ATC class and preferred term (PT), the patient is counted only once in that ATC class and PT.
ATC classes are presented by descending order of frequency for the overall Basket, PTs are sorted by descending order of frequency for the overall Basket within ATC class.
Prior medication is defined as any medications whose end date is before the first study treatment date.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Table 14.1-3.4 – Concomitant Medications
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.1-3.3
- Present concomitant medications.
- Replace footnote 'Prior medication is defined as…' with the following footnote:
  'Concomitant medication is defined as any medication ongoing at first day of study drug or started after first day of study drug up to the end of the on-treatment period.'

Table 14.1-4.1.1 – Treatment exposure (Ulixertinib)
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Number of cycles received [a] – n (%)						
1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
…						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)
Median	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Min; Max	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X
Duration of exposure to ulixertinib (months) [b] – n (%)						
< 1 month	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1-2 months	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2-3 months	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
…						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)
Median	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Min; Max	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X

[a] Number of cycles received = Number of cycles where the patient received at least one dose.
[b] Duration of exposure (months) = [(Date of last known treatment dosing with drug – date of initial dosing with drug) + 1] / 30.4375.
[c] Actual cumulative dose received (mg) = Sum of [(Stop date – Start date for each time period reported in the dairy) x Dose].
[d] Relative dose intensity = 100 x Actual dose intensity / Planned dose intensity. Actual dose intensity (mg/day) is defined as Actual cumulative dose received (mg) / Duration of exposure (days). Planned dose intensity (mg/day) is defined as Planned cumulative dose (mg) / Duration of exposure (days).
Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Table 14.1-4.1.1 – Treatment exposure (Ulixertinib)
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Actual cumulative dose on ulixertinib (mg) [c]						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)
Median	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Min; Max	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X
Relative dose intensity [d]						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)
Median	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Min; Max	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X

[a] Number of cycles received = Number of cycles where the patient received at least one dose.
[b] Duration of exposure (months) = [(Date of last known treatment dosing with drug – date of initial dosing with drug) + 1] / 30.4375.
[c] Actual cumulative dose received (mg) = Sum of [(Stop date – Start date for each time period reported in the dairy) x Dose].
[d] Relative dose intensity = 100 x Actual dose intensity / Planned dose intensity. Actual dose intensity (mg/day) is defined as Actual cumulative dose received (mg) / Duration of exposure (days). Planned dose intensity (mg/day) is defined as Planned cumulative dose (mg) / Duration of exposure (days).
Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Table 14.1-4.1.2 – Treatment exposure (Hydroxychloroquine)
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.1-4.1.1

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.1-4.2.1 – Dosing Interruptions and Adjustments (Ulixertinib)
Full Analysis Set

	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
At least one dose adjustment – n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Reason dose changed – n (%) [a]						
Adverse event	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Parental/Guardian decision	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Consent withdrawal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
…	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other						
Dose changed to – n (%) [b]						
150mg	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
300mg	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
450mg	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
At least one dose interruption – n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Reason dose interrupted [a]						
Adverse Event	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Dispensing Error	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Investigator Decision	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Consent Withdrawal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Patient Decision	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

[a] A patient can be counted under several reasons if they had multiple different dose changes/interruptions.
[b] A patient can be counted under more than one dose level if they had multiple different dose changes.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Table 14.1-4.2.2 – Dosing Interruptions and Adjustments (Hydroxychloroquine)
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.1-4.2.1

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.2-1.1.1 – Best Overall Response and Overall Response Rate
Full Analysis Set

	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
Best overall response – n (%) [a]						
Complete response (CR)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Partial response (PR)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Stable disease (SD)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Progressive disease (PD)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not evaluable (NE)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Overall response rate (CR+PR) – n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
95 % CI for Overall response rate	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
Disease control rate (CR+PR+SD) – n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
95 % CI for Disease Control rate	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
Non-responders (SD+PD+NE) – n (%) [b]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

CR=Complete Response, PR=Partial Response, SD=Stable Disease, PD=Progressive Disease, NE=Not Evaluable , CI=Confidence Interval.
95% CI is estimated using the Clopper-Pearson method.
[a] Confirmed Best overall response as per RECIST 1.1
[b] Non responders: Patients without a confirmed response or a missing baseline/screening tumor assessment will be considered non-responders

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Table 14.2-1.1.2 – Best Overall Response and Overall Response Rate
Evaluable Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.2-1.1.1
- Present data on Evaluable Analysis Set.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.2-1.2.1 – Overall, Target and Non-Target Lesion Response
Full Analysis Set

	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
C3D1						
Target Lesion Response – n (%)						
Complete response (CR)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Partial response (PR)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Stable disease (SD)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Progressive disease (PD)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not evaluable (NE)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Non-Target Lesion Response – n (%)						
Complete response (CR)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Non-Complete Response/Non Progressive Disease	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Progressive disease (PD)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Evaluable (NE)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Applicable	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Overall Response – n (%)						
Complete response (CR)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Partial Response (PR)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Stable Disease (SD)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Progressive disease (PD)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Evaluable (NE)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Programming Note: Repeat for all available assessments

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Table 14.2-1.2.2 – Overall, Target and Non-Target Lesion Response
Evaluable Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.2-1.2.1
- Present data on Evaluable AnalysisSet.

Table 14.2-1.3.1 – Incidence of New Lesions
Full Analysis Set

	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
C3D1						
New Lesions – n (%)						
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Number of New Lesions – n (%)						
1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
…						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)
Median	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Min; Max	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X

Programming Note: Repeat for all available assessments

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Table 14.2-1.3.2 – Incidence of New Lesions
Evaluable Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.2-1.3.1
- Present data on Evaluable Analysis Set.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.2-1.4.1 – Progression-Free Survival (PFS)
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Patients with events – n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Patients censored – n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
PFS (months) [a]						
Median (95% CI)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
Min, Max	XX, XX*	XX, XX	XX, XX	XX, XX*	XX, XX	XX, XX
KM probability estimates for PFS (95% CI) [b]						
3 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
6 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
9 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
12 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
18 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)

Note: CI=Confidence Interval.
Progression-Free Survival (PFS) is the time from the first ulixertinib dose dose until the first radiographically documented progression of disease or death from any cause, whichever occurs first.
[a] Product-limit (Kaplan-Meier) estimates. 95% CI for median calculated using the Brookmeyer and Crowley method.
[b] Based upon Kaplan-Meier (KM) estimates and 95% CI use the log-log transformation.
* Censored observation at maximum value.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Table 14.2-1.4.2 – Progression-Free Survival (PFS)
Evaluable Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.2-1.4.1
- Present data on Evaluable Analysis Set.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.2-1.5.1 – Overall Survival (OS)
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Patients with events – n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Patients censored – n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
OS (months) [a]						
Median (95% CI)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
Min, Max	XX, XX*	XX, XX	XX, XX	XX, XX*	XX, XX	XX, XX
KM probability estimates for PFS (95% CI) [b]						
3 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
6 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
9 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
12 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
18 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)

Note: CI=Confidence Interval.
Overall Survival is defined as the time from first treatment to death.
[a] Product-limit (Kaplan-Meier) estimates. 95% CI for median calculated using the Brookmeyer and Crowley method.
[b] Based upon Kaplan-Meier (KM) estimates and 95% CI use the log-log transformation.
* Censored observation at maximum value.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Table 14.2-1.5.2 – Overall Survival (OS)
Evaluable Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.2-1.4.1
- Present data on Evaluable Analysis Set.

Table 14.2-1.6.1 – Duration of Response
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Patients with response (CR+PR)	XX	XX	XX	XX	XX	XX
Patients with events – n (%) [a]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Patients censored – n (%) [a]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
DOR (months) [b]						
Median (95% CI)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
Min, Max	XX, XX*	XX, XX	XX, XX	XX, XX*	XX, XX	XX, XX
KM probability estimates for PFS (95% CI) [c]						
3 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
6 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
9 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
12 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)
18 Months	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)	XX (X.X, X.X)

Note: CI=Confidence Interval, CR=Complete Response, PR=Partial Response.
Duration of response is the period from the date of initial confirmed PR or CR until the date of first radiographically documented progressive disease or death from any cause. +1
[a] Percentage calculated on patients with response. Events are death or disease progression.
[b] Product-limit (Kaplan-Meier) estimates. 95% CI for median calculated using the Brookmeyer and Crowley method.
[c] Based upon Kaplan-Meier (KM) estimates and 95% CI use the log-log transformation.
* Censored observation at maximum value.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-1.1 – Overview Summary of Treatment-Emergent Adverse Events
Full Analysis Set

	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
Number of patients with:						
Any TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any Related TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Related TEAE to Both	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Related TEAE to Uli.	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Related TEAE to HCQ.	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any SAE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any Related SAE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any TEAE leading to treatment discontinuation	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any Related TEAE leading to treatment discontinuation	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any TEAE leading to treatment discontinuation within 1 cycle	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any Related TEAE leading to treatment discontinuation within 1 cycle	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any TEAE leading to treatment discontinuation following 1 cycle	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any Related TEAE leading to treatment discontinuation following 1 cycle	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any TEAE leading to treatment interruption	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any Related TEAE leading to treatment interruption	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any TEAE leading to treatment interruption within 1 cycle	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any Related TEAE leading to treatment interruption within 1 cycle	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any TEAE leading to treatment interruption following 1 cycle	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any Related TEAE leading to treatment interruption following 1 cycle	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: SAE=Serious Adverse Events, TEAE=Treatment-Emergent Adverse Events
Note 2: Any related TEAE includes TEAEs that are considered related to either hydroxychloroquine or ulixertinib.
Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Table 14.3-1.1 – Overview Summary of Treatment-Emergent Adverse Events

Full Analysis Set

	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
Number of patients with:						
Any TEAE leading to dose reduction	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any related TEAE leading to dose reduction	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any TEAE leading to dose reduction within Cycle 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any Related TEAE leading to dose reduction within Cycle 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any TEAE leading to dose reduction following Cycle 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any Related TEAE leading to dose reduction following Cycle 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any TEAE leading to death	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any Related TEAE leading to death	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any TEAE with Grade >= 3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Any Related TEAE with Grade >= 3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: SAE=Serious Adverse Events, TEAE=Treatment-Emergent Adverse Events
Note 2: Any related TEAE includes TEAEs that are considered related to either hydroxychloroquine or ulixertinib.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- "Related TEAE to Both", "Related TEAE to Uli." and "Related TEAE to HCQ." will be presented for all treatment-related adverse events [...]" in the above table.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-1.2 – Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Full Analysis Set

System Organ Class Preferred Term	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
Any TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
……	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
……	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: MedDRA <vx.x>. TEAE=Treatment-Emergent Adverse Events.
If there is more than one TEAE within a system organ class (SOC), the patient is counted only once under that SOC. If there is more than one TEAE within a SOC and preferred term (PT), the patient is counted only once in that SOC and PT.
Primary SOCs are presented by descending order of frequency for the overall Basket, PTs are sorted by descending order of frequency for the overall Basket within each SOC.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-1.3 – Summary of Related Treatment-emergent Adverse Events by System Organ Class and Preferred Term
Full Analysis Set

System Organ Class / Preferred Term	Basket 1 N=XX n (%)			Basket 2 N=XX n (%)			Basket 3 N=XX n (%)			Basket 4 N=XX n (%)			Basket 5 N=XX n (%)			Overall N=XX n (%)		
	Both	Uli	HCQ	**Both**	Uli	HCQ	**Both**	Uli	HCQ	**Both**	Uli	HCQ	**Both**	Uli	HCQ	**Both**	Uli	HCQ
Any related TEAE	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)
System organ class 1	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)
Preferred term 1	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)
Preferred term 2	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)
.....																		

Note: MedDRA <vx.x>. TEAE=Treatment-Emergent Adverse Events.
Note 2: Both = TEAE related to both treatments, Uli = TEAE related to ulixertinib, HCQ = TEAE related to Hydroxychloriquine.
Related TEAE: TEAEs with causality=Related, Possibly Related or missing.
If there is more than one TEAE within a system organ class (SOC), the patient is counted only once under that SOC. If there is more than one TEAE within a SOC and preferred term (PT), the patient is counted only once in that SOC and PT.
Primary SOCs are presented by descending order of frequency for the overall Basket, PTs are sorted by descending order of frequency for the overall Basket within each SOC.

Table 14.3-1.4 – Summary of Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.3-1.2
- Present Serious TEAE: TEAEs with SAE =" Yes".
- Add footnote:
  "Serious TEAE: TEAEs with SAE =" Yes"."

Table 14.3-1.5 – Summary of Related Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.3-1.3
- Present Related Serious TEAE: SAEs with causality=Related, Possibly Related or missing.
- Add footnote:
  "SAEs with causality=Related, Possibly Related or missing."

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-1.6 – Summary of Treatment-Emergent Adverse Events by Preferred Term
Full Analysis Set

System Organ Class Preferred Term	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
Any TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....						

Note: MedDRA <vx.x>. TEAE=Treatment-Emergent Adverse Events.
If there is more than one TEAE within a preferred term (PT), the patient is counted only once in that PT.
PTs are sorted in descending order of frequency for the overall Basket.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-1.7 – Summary of Related Treatment-emergent Adverse Events by Preferred Term
Full Analysis Set

Preferred Term	Basket 1 N=XX n (%)			Basket 2 N=XX n (%)			Basket 3 N=XX n (%)			Basket 4 N=XX n (%)			Basket 5 N=XX n (%)			Overall N=XX n (%)		
	Both	Uli	HCQ	**Both**	Uli	HCQ	**Both**	Uli	HCQ	**Both**	Uli	HCQ	**Both**	Uli	HCQ	**Both**	Uli	HCQ
Any related TEAE	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)
Preferred term 1	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)
Preferred term 2	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)	**XX (XX.X)**	XX (XX.X)	XX (XX.X)
.....																		

Note: MedDRA <vx.x>. TEAE=Treatment-Emergent Adverse Events.
Note 2: Both = TEAE related to both treatments, Uli = TEAE related to ulixertinib, HCQ = TEAE related to Hydroxychloriquine.
Related TEAE: TEAEs with causality=Related, Possibly Related or missing.
If there is more than one TEAE within a preferred term (PT), the patient is counted only once in that PT.
PTs are sorted in descending order of frequency for the overall Basket.

Table 14.3-1.8 – Summary of Serious Treatment-emergent Adverse Events by Preferred Term
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.3-1.6
- Present Serious TEAE: TEAEs with SAE =" Yes".
- Add footnote:
  "Serious TEAE: TEAEs with SAE =" Yes"."

Table 14.3-1.9 – Summary of Related Serious Treatment-emergent Adverse Events by Preferred Term
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.3-1.7
- Present Related Serious TEAE: SAEs with causality=Related, Possibly Related or missing.
- Add footnote:
  "SAEs with causality=Related, Possibly Related or missing."

Table 14.3-1.10 – Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term for Maximum CTCAE Grade
Full Analysis Set

Basket: Basket X

System Organ Class Preferred Term	Any CTC Grade n (%) [Events]	CTC Grade 1 n (%)	CTC Grade 2 n (%)	CTC Grade 3 n (%)	CTC Grade 4 n (%)	CTC Grade 5 n (%)
Any TEAE	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 1	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 2	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: MedDRA <vx.x>; CTCAE v5.0. TEAE=Treatment-Emergent Adverse Events.
If there is more than one TEAE within a system organ class (SOC), the patient is counted only once under that SOC and maximum severity.
If there is more than one TEAE within a SOC and preferred term (PT), the patient is counted only once in that SOC, PT and maximum severity.
Primary SOCs are presented by descending order of frequency for the overall Basket, PTs are sorted within primary SOC descending order of frequency for the overall Basket within each SOC.
[Events] presents the number of TEAEs reported overall, by primary SOC and PT regardless of severity.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Present for each Basket and overall.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-1.11 – Summary of Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term for Maximum CTCAE Grade
Full Analysis Set

Basket: Basket X, Related to both study treatments

System Organ Class Preferred Term	Any CTC Grade n (%) [Events]	CTC Grade 1 n (%)	CTC Grade 2 n (%)	CTC Grade 3 n (%)	CTC Grade 4 n (%)	CTC Grade 5 n (%)
Any related TEAE	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 1	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 2	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X) [XX]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: MedDRA <vx.x>; CTCAE v5.0. TEAE=Treatment-Emergent Adverse Events.
If there is more than one TEAE within a system organ class (SOC), the patient is counted only once under that SOC and maximum severity.
If there is more than one TEAE within a SOC and preferred term (PT), the patient is counted only once in that SOC, PT and maximum severity.
Primary SOCs are presented by descending order of frequency for the overall Basket, PTs are sorted within primary SOC descending order of frequency for the overall Basket within each SOC.
[Events] presents the number of TEAEs reported overall, by primary SOC and PT regardless of severity.
Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Present for each Basket and overall. For each Basket and Overall present TEAEs that are Related to both study treatments, related to ulixertinib and related to hydroxychloriquine
- Present Related TEAE: TEAEs with causality=Related, Possibly Related or missing.
- Add footnote:
  "Related TEAE: TEAEs with causality=Related, Possibly Related or missing."

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-1.12 – Summary of Treatment-Emergent Adverse Events Leading to Treatment Discontinuation
by System Organ Class and Preferred Term
Full Analysis Set

System Organ Class Preferred Term	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
Any TEAE leading to treatment discontinuation	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: MedDRA <vx.x>. TEAE=Treatment-Emergent Adverse Events.
If there is more than one TEAE leading to treatment discontinuation within a system organ class (SOC), the patient is counted only once under that SOC. If there is more than one TEAE leading to treatment discontinuation within a SOC and preferred term (PT), the patient is counted only once in that SOC and PT.
Primary SOCs are presented by descending order of frequency for the overall Basket, PTs are sorted within primary SOC descending order of frequency for the overall Basket within each SOC.
TEAEs leading to treatment discontinuation: any TEAEs with Action taken with study treatment=Drug withdrawn.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Table 14.3-1.13 – Summary of Related Treatment-Emergent Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.3
- Replace 'Any TEAE' by 'Any TEAE leading to treatment discontinuation'
- Present Related TEAE: TEAEs with causality=Related, Possibly Related or missing.
- Add footnote:
  "Related TEAE: TEAEs with causality=Related, Possibly Related or missing."

Table 14.3-1.14 – Summary of Treatment-Emergent Adverse Events Leading to Treatment Discontinuation Within Cycle 1 by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.12
- Add footnote:
  "TEAEs leading to treatment discontinuation: any TEAEs with Action taken with study treatment=Drug withdrawn within the first 28 days of study."

Table 14.3-1.15 – Summary of Related Treatment-Emergent Adverse Events Leading to Treatment Discontinuation Within Cycle 1 by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.3
- Replace 'Any TEAE' by 'Any TEAE leading to treatment discontinuation within cycle 1'
- Present Related TEAE: TEAEs with causality=Related, Possibly Related or missing.
- Add footnote:
  "TEAEs leading to treatment discontinuation: any TEAEs with Action taken with study treatment=Drug withdrawn within the first 28 days of study."

Table 14.3-1.16 – Summary of Treatment-Emergent Adverse Events Leading to Treatment Discontinuation Following Cycle 1 by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.12
- Add footnote:
  "TEAEs leading to treatment discontinuation: any TEAEs with Action taken with study treatment=Drug withdrawn after the first 28 days of study."
  "Related TEAE: TEAEs with causality=Related, Possibly Related or missing."

Table 14.3-1.17 – Summary of Related Treatment-Emergent Adverse Events Leading to Treatment Discontinuation Following Cycle 1 by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.3
- Replace 'Any TEAE' by 'Any TEAE leading to treatment discontinuation following cycle 1'
- Present Related TEAE: TEAEs with causality=Related, Possibly Related or missing.'
- Add footnote:
  "TEAEs leading to treatment discontinuation: any TEAEs with Action taken with study treatment=Drug withdrawn after the first 28 days of study."
  "Related TEAE: TEAEs with causality=Related, Possibly Related or missing."

Table 14.3-1.18 – Summary of Treatment-Emergent Adverse Events Leading to Treatment Interruption by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.12
- Replace 'Any TEAE' by 'Any TEAE leading to treatment interruption.'
- Add footnote:
- "Includes TEAE with 'Action Taken with treatment' = 'Drug Interrupted'.

Table 14.3-1.19 – Summary of Related Treatment-Emergent Adverse Events Leading to Treatment Interruption by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.3
- Replace 'Any TEAE' by 'Any related TEAE leading to treatment interruption.'
- Add footnotes:
  "Includes TEAE with 'Action Taken with treatment' = 'Drug Interrupted'.
  "Related TEAE: TEAEs with causality=Related, Possibly Related or missing."

Table 14.3-1.20 – Summary of Treatment-Emergent Adverse Events Leading to Treatment Interruption Within Cycle 1 by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.12
- Replace 'Any TEAE' by 'Any TEAE leading to treatment interruption within Cycle 1.'
- Add footnote:
  "Includes TEAE with 'Action Taken with treatment' = 'Drug Interrupted' within the first 28 days of study.

Table 14.3-1.21 – Summary of Related Treatment-Emergent Adverse Events Leading to Treatment Interruption Within Cycle 1 by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.3
- Replace 'Any TEAE' by 'Any related TEAE leading to treatment interruption within Cycle 1.'
- Add footnotes:
  "Includes TEAE with 'Action Taken with treatment' = 'Drug Interrupted' within the first 28 days of study.
  "Related TEAE: TEAEs with causality=Related, Possibly Related or missing."

Table 14.3-1.22 – Summary of Treatment-Emergent Adverse Events Leading to Treatment Interruption Following Cycle 1 by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.12
- Replace 'Any TEAE' by 'Any TEAE leading to treatment interruption following Cycle 1.'
- Add footnote:
  "Includes TEAE with 'Action Taken with treatment' = 'Drug Interrupted' after the first 28 days of study.

Table 14.3-1.23 – Summary of Related Treatment-Emergent Adverse Events Leading to Treatment Interruption Following Cycle 1 by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.3
- Replace 'Any TEAE' by 'Any related TEAE leading to treatment interruption following Cycle 1'.
- Add footnotes:
  "Includes TEAE with 'Action Taken with treatment' = 'Drug Interrupted' after the first 28 days of study.
  "Related TEAE: TEAEs with causality=Related, Possibly Related or missing."

Table 14.3-1.24 – Summary of Treatment-Emergent Adverse Events Leading to Dose Reduction by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.3-1.12
- Replace 'Any TEAE' by 'Any TEAE leading to dose reduction.'
- Add footnote:
  "Includes TEAE with 'Action Taken with treatment' = 'Dose Reduced'".

Table 14.3-1.25 – Summary of Related Treatment-Emergent Adverse Events Leading to Dose Reduction by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.3-1.3
- Replace 'Any TEAE' by 'Any related TEAE leading to dose reduction.'
- Add footnotes:
  "Includes TEAE with 'Action Taken with treatment' = 'Dose Reduced'".
  "Related TEAE: TEAEs with causality=Related, Possibly Related or missing."

Table 14.3-1.26 – Summary of Treatment-Emergent Adverse Events Leading to Dose Reduction within Cycle 1 by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.12
- Replace 'Any TEAE' by 'Any TEAE leading to dose reduction within Cycle 1.'
- Add footnote:
  "Includes TEAE with 'Action Taken with treatment' = 'Dose Reduced' within the first 28 days of study".

Table 14.3-1.27 – Summary of Related Treatment-Emergent Adverse Events Leading to Dose Reduction within Cycle 1 by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-1.3
- Replace 'Any TEAE' by 'Any related TEAE leading to dose reduction within Cycle 1.'
- Add footnotes:
  "Includes TEAE with 'Action Taken with treatment' = 'Dose Reduced' within the first 28 days of study".
  "Related TEAE: TEAEs with causality=Related, Possibly Related or missing."

Table 14.3-1.28 – Summary of all Treatment-Emergent Adverse Events Leading to Dose Reduction following Cycle 1 by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.3-1.12
- Replace 'Any TEAE' by 'Any TEAE leading to dose reduction following Cycle 1.
- Add footnote:
  "Includes TEAE with 'Action Taken with treatment' = 'Dose Reduced' after the first 28 days of study".

Table 14.3-1.29 – Summary of Related Treatment-Emergent Adverse Events Leading to Dose Reduction following Cycle 1 by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.3-1.3
- Replace 'Any TEAE' by 'Any related TEAE leading to dose reduction following Cycle 1.
- Add footnote:
  "Includes TEAE with 'Action Taken with treatment' = 'Dose Reduced' after the first 28 days of study".
  "Related TEAE: TEAEs with causality=Related, Possibly Related or missing."

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-1.30 – Summary of Treatment-Emergent Adverse Events Leading to Death by System Organ Class and Preferred Term
Full Analysis Set

System Organ Class Preferred Term	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
Any TEAE leading to death	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System organ class 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred term 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
.....	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: MedDRA <vx.x>. TEAE=Treatment-Emergent Adverse Events.
If there is more than one TEAE leading to death within a system organ class (SOC), the patient is counted only once under that SOC. If there is more than one TEAE leading to death within a SOC and preferred term (PT), the patient is counted only once in that SOC and PT.
Primary SOCs are presented by descending order of frequency for the overall Basket, PTs are sorted within primary SOC descending order of frequency for the overall Basket within each SOC.
TEAEs leading to Death: any TEAE resulting in death, Outcome=Fatal, CTC Grade=5.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Table 14.3-1.31 – Summary of Related Treatment-Emergent Adverse Events Leading to Death by System Organ Class and Preferred Term
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.3-1.3
- Replace 'Any TEAE' by 'Any related TEAE leading to death'
- Present Related TEAE: TEAEs with causality=Related, Possibly Related or missing.
- Add footnote:
  "Related TEAE: TEAEs with causality=Related, Possibly Related or missing."
  "TEAEs leading to Death: any TEAE resulting in death, Outcome=Fatal, CTC Grade=5."

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-1.32 - Summary of Deaths
All Patients Set

	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Screen Failures N=XX n (%)	Overall N=XX n (%)
Patients who died during the study	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Primary cause of death							
Progressive Disease	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Adverse Event	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Unknown	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Patients who died after taking the first dose of ulixertinib	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Primary cause of death							
Progressive Disease	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Adverse Event	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Unknown	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-2.1 – Summary and Change from Baseline in Hematology Laboratory Results by Visit
Full Analysis Set

Parameter: XXXXX (XX)

Visit Statistics	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Baseline						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX
C1D8						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX
Change from Baseline to C1D8						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX

Note: Baseline is the last available assessment prior to first dose of study treatment.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Present for all hematology parameters: hematocrit, hemoglobin, platelets, white blood cells (WBC), neutrophil absolute, lymphocyte absolute with respective unit measure.
- Present for all available visits.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-2.2.1 – Gradable Hematology Laboratory Results – Worst On-treatment Value by Cycle
Full Analysis Set

Parameter (unit) Cycle CTCAE Grade	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
XXXXX (XXX)						
Cycle 1						
Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
4	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Missing	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Cycle 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
4	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Missing						
…						

Note: CTCAE v5.0.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Present for all hematology parameters where CTCAE grades are defined as per the SAP appendix 14.2.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-2.2.2 – Non-gradable Hematology Laboratory Results – Worst On-treatment Value by Cycle
Full Analysis Set

Parameter (unit) Cycle CTCAE Grade	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
XXXXX (XXX)						
Cycle 1						
Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Low	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
High	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Missing	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Cycle 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Low	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
High	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Missing						
…						

Note: CTCAE v5.0.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Present for all hematology parameters where CTCAE grades are **not** defined as per the SAP appendix 14.2.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-2.3.1 – Shift Table of Gradable Hematology Laboratory Results – Baseline vs Worst On-treatment Value
Full Analysis Set

Basket: Basket 1 (N=XX)

Parameter (unit)	Baseline Grade	Worst CTCAE grade during treatment period: Normal n (%)	1 n (%)	2 n (%)	3 n (%)	4 n (%)	Missing n (%)	Total n (%)
XXXXX (XXX)	Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	4	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Missing	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Total	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: CTCAE v5.0.
Baseline is the last available assessment prior to first dose of study treatment.
Percentages are based on the number of patients in the Basket.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Present for each Basket and overall, and for all hematology parameters where CTCAE grades are defined as per the SAP appendix 14.2.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-2.3.2 – Shift Table of Non-gradable Hematology Laboratory Results – Baseline vs Worst On-treatment Value
Full Analysis Set

Basket: Basket 1 (N=XX)

Parameter (unit)	Baseline Grade	Worst grade during treatment period: Low n (%)	Normal n (%)	High n (%)	Missing n (%)	Total n (%)
XXXXX (XXX)	Low	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	High	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Missing	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Total	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: Baseline is the last available assessment prior to first dose of study treatment.
Percentages are based on the number of patients in the Basket.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Present for all Baskets and overall, and for all hematology parameters where CTCAE grades are not defined as per the SAP appendix 14.2.

Table 14.3-2.4 – Summary and Change from Baseline in Biochemistry Laboratory Results by Visit
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Table 14.3-2.1
- Present for all biochemistry parameters: alanine aminotransferase, albumin, alkaline phosphatase, aspartate aminotransferase, carbon dioxide, calcium, chloride, cholesterol, creatinine, glucose, inorganic phosphorus, lactate dehydrogenase, potassium, total protein, sodium, total bilirubin, triglycerides, uric acid, urea nitrogen.
- Present for all available visits.

Table 14.3-2.5.1 – Gradable Biochemistry Laboratory Results – Worst On-treatment Value by Cycle
Full Analysis Set

PROGRAMMING NOTES:
- Repeat of Table 14.3-2.2.1
- Present for all biochemistry parameters where CTCAE grades are defined as per the SAP appendix 14.2.

Table 14.3-2.5.2 – Non-gradable Biochemistry Laboratory Results – Worst On-treatment Value by Cycle
Full Analysis Set

PROGRAMMING NOTES:
- Repeat of Table 14.3-2.2.2
- Present for all biochemistry parameters where CTCAE grades are defined as per the SAP appendix 14.2.

Table 14.3-2.6.1 – Shift Table of Gradable Biochemistry Laboratory Results – Baseline vs Worst On-treatment Value
Full Analysis Set

PROGRAMMING NOTES:
- Repeat of Table 14.3-2.3.1
- Present for all Baskets and overall, and for all biochemistry parameters where CTCAE grades are defined as per the SAP appendix 14.2.

Table 14.3-2.6.2 – Shift Table of Non-gradable Biochemistry Laboratory Results – Baseline vs Worst On-treatment Value
Full Analysis Set

PROGRAMMING NOTES:

- Repeat of Table 14.3-2.3.2
- Present for all Baskets and overall, and for all biochemistry parameters where CTCAE grades are not defined as per the SAP appendix 14.2.

Table 14.3-2.7 – Summary at Baseline in Coagulation Laboratory Results
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Table 14.3-2.1
- Present for all coagulation parameters: PT, INR, PTT

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-2.8 – Summary at Baseline in Urinalysis Laboratory Results
Full Analysis Set

Parameter: Specific gravity (XX)

Visit Statistics	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Baseline						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX

Note: Baseline is the last available assessment prior to first dose of study treatment.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Table 14.3-2.8 – Summary and Change from Baseline in Urinalysis Laboratory Results by Visit
Full Analysis Set

Parameter: Blood (XX)

Visit Statistics	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
Baseline						
Negative	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1+	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2+	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3+	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
4+	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

<cont.>

Note: Baseline is the last available assessment prior to first dose of study treatment.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Present for all urinalysis parameters: specific gravity, protein, glucose, occult blood, microscopic examination of RBC, microscopic examination of WBC, microscopic examination of casts.
- Present for all available visits.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-3.1 – Summary and Change from Baseline in Vital Signs by Visit
Full Analysis Set

Parameter: XXXXX (XX)

Visit Statistics	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Baseline						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX
C1D8						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX
Change from Baseline to C1D8						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX

Note: Baseline is the last available assessment prior to first dose of study treatment.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Present for all vital signs: systolic blood pressure, diastolic blood pressure, pulse, respiratory rate, pulse oximetry and temperature with respective unit measure.
- Present for all available visits.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-3.2 – Shift Table of Vital Signs Results – Baseline vs Worst On-treatment Value
Full Analysis Set

Basket: Basket 1 (N=XX)

Parameter (unit)	Baseline Value	Worst value during on-treatment period: Low n (%)	Normal n (%)	High n (%)	Very High n (%)	Missing n (%)	Total n (%)
XXXXX (XXX)	Low	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	High	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Very High	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Missing	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Total	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: Baseline is the last available assessment prior to first dose of study treatment.
Percentages are based on the number of patients in the Basket.
For Temperature, Low: < 36.4°C, Normal: 36.4°C – 37.7°C, High: > 37.7°C.
For Pulse, Low: < 55 bpm, Normal: 55–100 bpm, High: 101–150 bpm, Very high: > 150 bpm.
For Systolic blood pressure, Low: < 90 mmHg, Normal: 90–130 mmHg, High: 131–160 mmHg, Very high: ≥ 161 mmHg.
For Diastolic blood pressure, Low: < 60 mmHg, Normal: 60–85 mmHg, High: 86–100 mmHg, Very high: ≥ 101 mmHg.
For Pulse oximetry, Very Low: < 90 %, Low: 90–95 %, Normal: ≥ 95 %.
For Respiratory Rate, Low: < 12 breaths/min, Normal: 12–16 breaths/min, High: > 16 breaths/min.
Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Present for each Basket and overall, and for all vital signs parameters.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-3.3 – Summary and Change from Baseline in ECG parameters by Visit
Full Analysis Set

Parameter: XXXXX (XX)

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Baseline						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX
C1D8						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX
Change from Baseline to C1D8						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX

Note: Baseline is the last available assessment prior to first dose of study treatment.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Present for all ECG parameters: heart rate, PR interval, QRS duration, RR interval, QT interval, QTcF with respective unit measure.
- Present for all available visits.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-3.4 – Summary of ECHO at Baseline
Full Analysis Set

	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
Significant findings – n (%)						
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
LVEF						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Min; Max	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX	XX; XX

Note: Baseline is the last available assessment prior to first dose of study treatment.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-3.5 – Summary of Physical Examination at Baseline
Full Analysis Set

	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
HEENT						
Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Abnormal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Done	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Thorax						
Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Abnormal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Done	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Abdomen						
Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Abnormal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Done	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

<cont.>

Note: Baseline is the last available assessment prior to first dose of study treatment.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Present for all Region/Body System parameters: HEENT, thorax, abdomen, skin and mucosae, neurological, extremities, urogenital, general appearance, heart, back, lymph nodes.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.3-3.6 – Summary of ECOG Performance Status by Visit
Full Analysis Set

Visit Grade	Basket 1 N=XX n (%)	Basket 2 N=XX n (%)	Basket 3 N=XX n (%)	Basket 4 N=XX n (%)	Basket 5 N=XX n (%)	Overall N=XX n (%)
Baseline [a]						
0	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
C1D8 [a]						
0	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
4	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
5	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
C1D15 [a]						
.....	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<cont.>	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: Baseline is the last available assessment prior to first dose of study treatment.
[a] (0) Fully active, able to carry on all pre-disease performance without restriction
(1) Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work
(2) Ambulatory and capable of all self-care but unable to carry out any work activities
(3) Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
(4) Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
(5) Death

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Present for all available visits.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.5-1.1 – Pharmacokinetic Concentration Data
PK Analysis Set

Visit Analyte	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
C1D15						
BVD-523 (ng/mL)						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XXX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)
Geometric Mean (CV%)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XXX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)
Median	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Min; Max	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X

GSD=Geometric Standard Deviation, SD=Standard Deviation

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.doc)

PROGRAMMING NOTES:
- Present for all available analytes (BVD-523, BVD-502/503,BVD-506, BVD-513) and visits

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Table 14.5-1.2 – Pharmacokinetic Parameters Data
PK Analysis Set

Analyte: BVD-523

Visit	Basket 1 N=XX	Basket 2 N=XX	Basket 3 N=XX	Basket 4 N=XX	Basket 5 N=XX	Overall N=XX
C1D15						
C_{Max} (ng/mL)						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XXX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)
Geometric Mean (CV%)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XXX)	XX.XX (XX.XX)	XX.XX (XX.XX)	XX.XX (XX.XX)
Median	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Min; Max	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X	XX.X; XX.X

GSD=Geometric Standard Deviation, SD=Standard Deviation

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

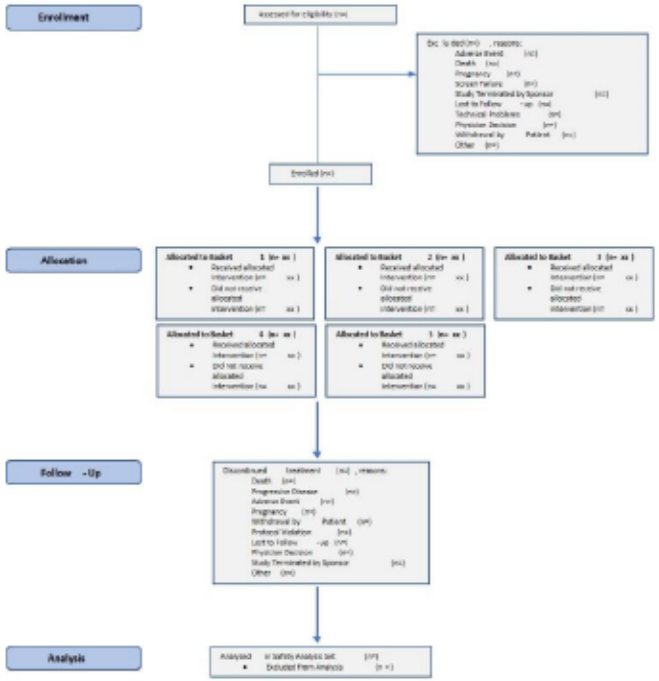
Filename: (Specify file name.doc)

PROGRAMMING NOTES:

- Present for all available analytes (BVD-523, BVD-502/503,BVD-506, BVD-513), PK parameters (AUC, C_{max}, Cmin, $t_{1/2}$, t_{max}), and visits

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Figure 14.2-1.1 – Consort Diagram
Full Analysis Set



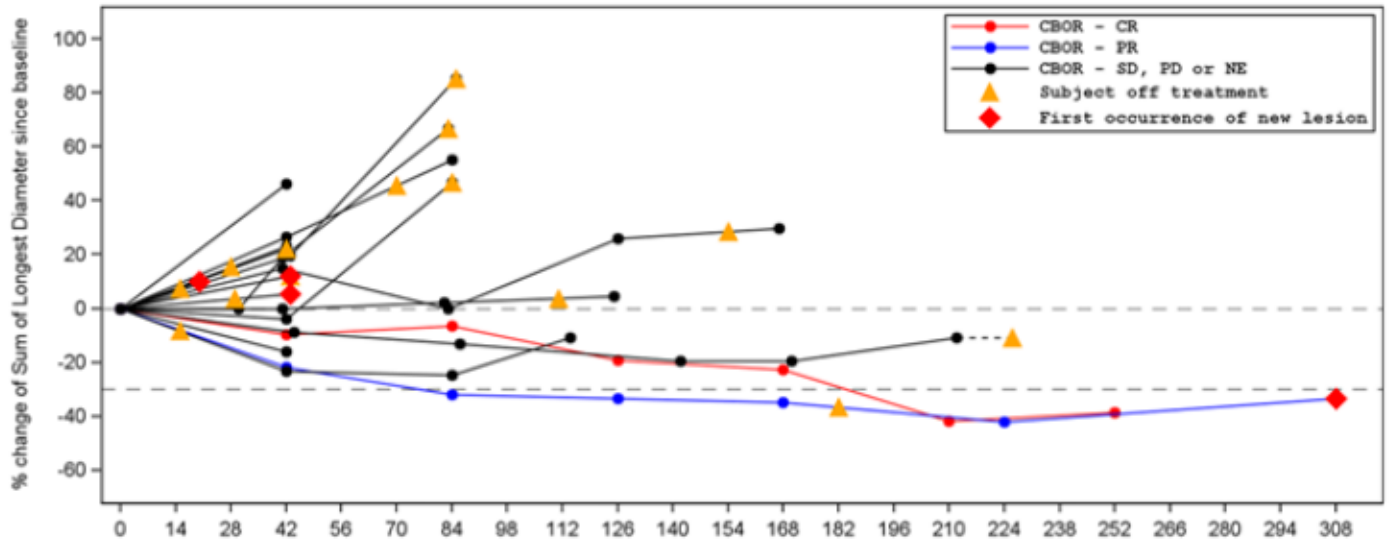
Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Figure 14.2-1.2.1 – Spider plot of Percentage Change from Baseline in Sum of Longest Diameter
Full Analysis Set

Basket = Basket X (N=XX)



Best overall response: CR=Complete Response, PR=Partial Response, SD=Stable Disease, PD=Progression Disease, NE=Not Evaluable.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Present all Baskets in separate figures and one figure with all patients.
- Use a different line style for each BOR (dotted line, dashed line, etc).
- Add reference lines for +20% and -30%.

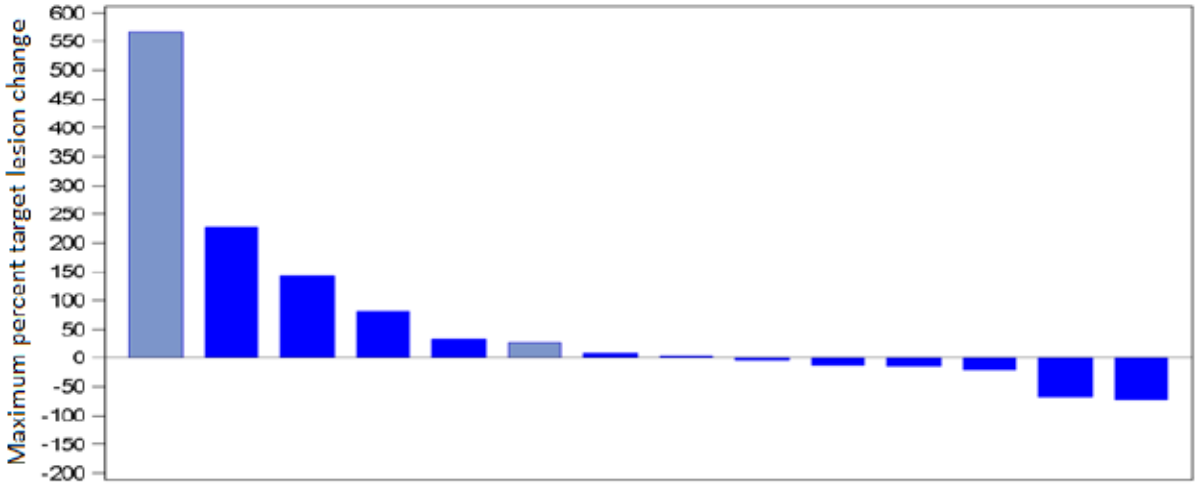
Figure 14.2-1.2.2 – Spider plot of Percentage Change from Baseline in Sum of Longest Diameter
Evaluable Analysis Set

PROGRAMMING NOTES:
- Repeat Figure 14.2-1.2.1
- Present data on Evaluable Analysis Set.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Figure 14.2-1.3.1 – Waterfall plot of Maximum Percentage Change from Baseline in Sum of Longest Diameter
Full Analysis Set

Basket = Basket X (N=XX)



Maximum percentage decrease from baseline in total tumor size is the maximum percentage decrease in the sum of longest diameters/short axis for all target lesions observed from baseline for each patient.

Best overall response: CR=Complete Response, PR=Partial Response, SD=Stable Disease, PD=Progression Disease, NE=Not Evaluable.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Present each Basket on one figure and one figure with all patients. For overall figure, use a different color for each basket
- Each bar is an individual patient.
- Add reference lines for +20% and -30%.
- Add the best overall response (CR, PR, SD, PD, NE) of each patient on the top of each bar.

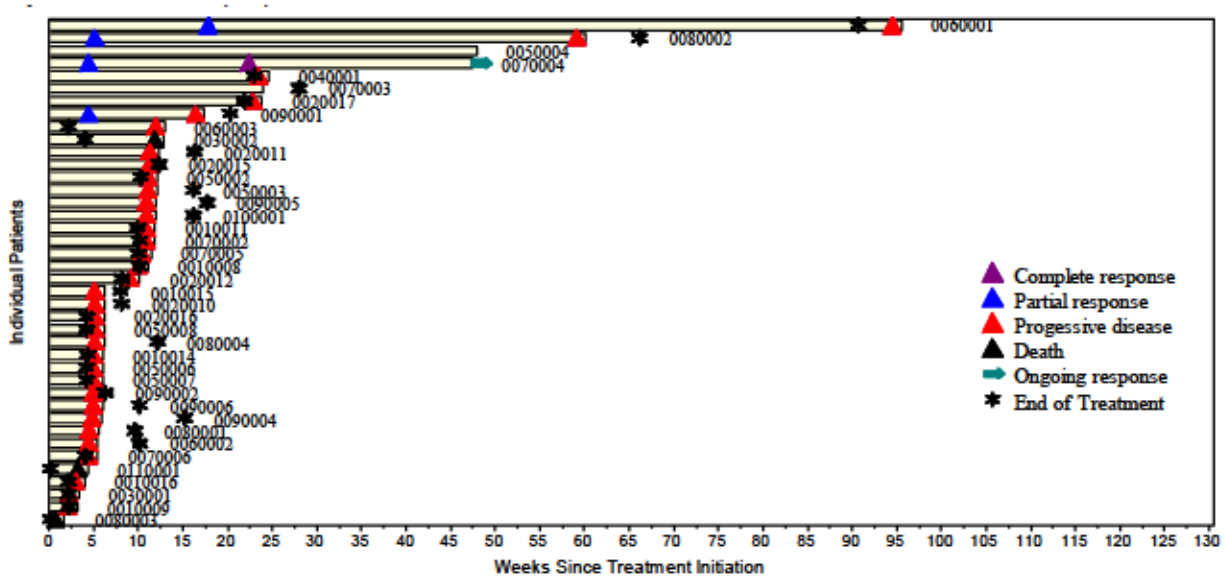
Figure 14.2-1.3.2 – Waterfall plot of Maximum Percentage Change from Baseline in Sum of Longest Diameter
Evaluable Analysis Set

PROGRAMMING NOTES:

- Repeat Figure 14.2-1.3.1
- Present data on Evaluable Analysis Set.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Figure 14.2-1.4.1 – Swimmer Plot of Response Assessments
Full Analysis Set



Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Present each Basket on one figure and a figure including all patients.
- Display patient ID on the left outside the figure except for the figure where all patients are displayed.
- The bar displays time to PD/Death (PFS), with "PD" or "death" displayed at the end of the bar; if no PD/death occurred before cutoff date, the bar stops at cutoff date.
- For responders, display the date of first CR or PR, and display "Ongoing response" arrow if no PD or death occurred before cutoff date.
- "End of Treatment" is the date of treatment discontinuation, this must be displayed only for patients who discontinued the treatment before the cut-off date.

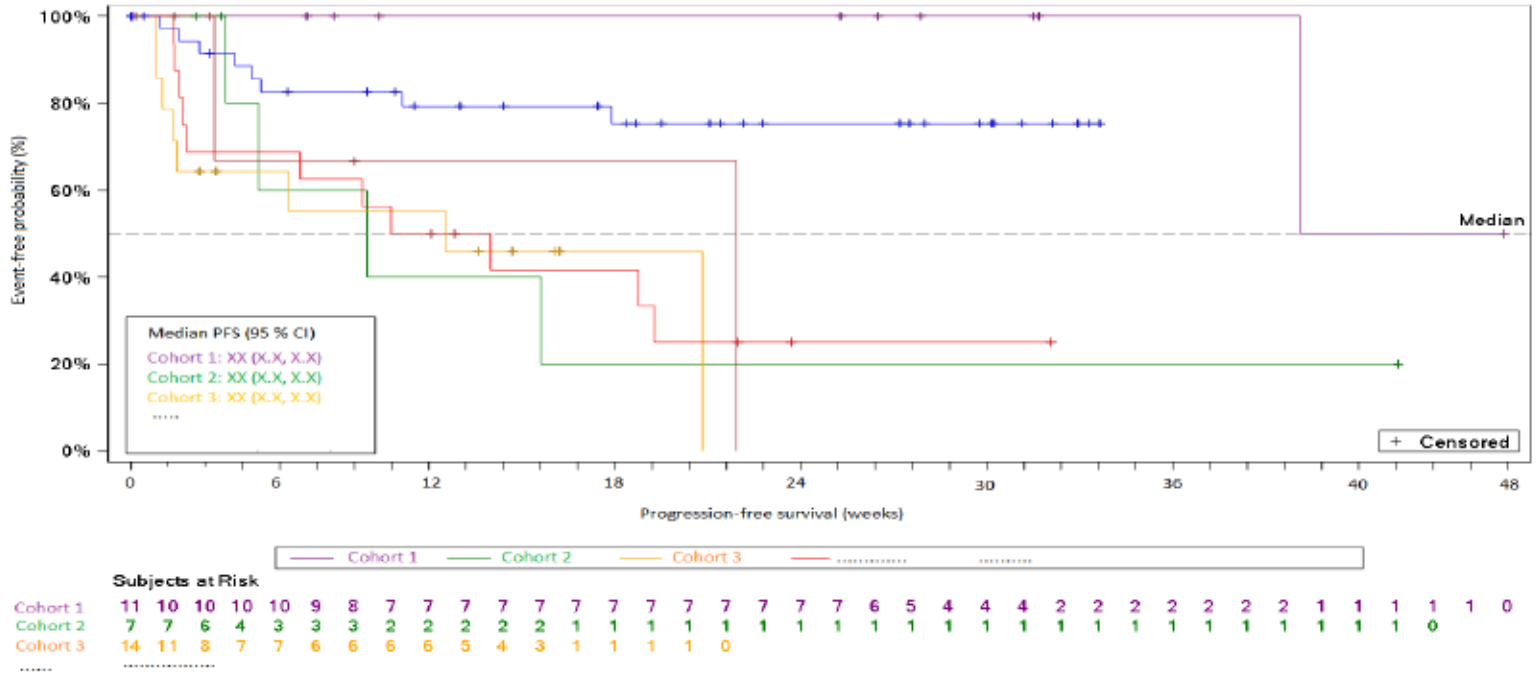
Figure 14.2-1.4.2 – Swimmer Plot of Response Assessments
Evaluable Analysis Set

PROGRAMMING NOTES:

- Repeat Figure 14.2-1.4.1
- Present data on Evaluable Analysis Set.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Figure 14.2-1.5.1 – Kaplan-Meier Estimate for Progression-Free survival (PFS)
Full Analysis Set



Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- X-axis – Label "Progression Free Survival (months)"
- Y-axis – Label "Event-free probability (%)."
- Legend: overall number of events, "Median Duration of Response" and 95% CI.
- Flag censored observations with '+' and add legend.
- If the median time to event has not been reached, present as "Median (95% CI) NR (xx.x, xx.x)" [replacing xx.x with '-' if there is no upper or lower confidence limit] and add footnote:
  NR=Median time not reached.
- Present all Baskets on the same figure but with different colors and separate figures for each Basket. In the sample shell where it is 'Cohort' replace with 'Basket'

Figure 14.2-1.5.2 – Kaplan-Meier Estimate for Progression-Free survival (PFS)
Evaluable Analysis Set

PROGRAMMING NOTES:

- Repeat Figure 14.2-1.5.1
- Present data on Evaluable Analysis Set.

Figure 14.2-1.6.1 – Kaplan-Meier Estimate for Overall Survival (OS)
Full Analysis Set

PROGRAMMING NOTES:

- Replicate figure 14.2-1.5.1, replacing "Progression Free Survival" by "Overall Survival" in X-axis label and legend.

Figure 14.2-1.6.2 – Kaplan-Meier Estimate for Overall Survival (OS)
Evaluable Analysis Set

PROGRAMMING NOTES:

- Replicate figure 14.2-1.5.1, replacing "Progression Free Survival" by "Overall Survival" in X-axis label and legend.
- Present data on Evaluable Analysis Set.

Figure 14.2-1.7.1 – Kaplan-Meier Estimate for Duration of Response
Full Analysis Set

PROGRAMMING NOTES:

- Replicate figure 14.2-1.5.1, replacing "Progression Free Survival" by "Duration of Response" in X-axis label and legend.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.1-1 – Patients informed consent
All Patients Set

Basket: Basket 1

			Main Informed Consent		Sample banking for future Biospecimen research consent		Optional End of Treatment Biopsy	
Patient ID	Age / Gender	Protocol Version	Consent Obtained / Withdrawn?	Date Consent Obtained / Withdrawn	Consent Obtained / Withdrawn?	Date Consent Obtained / Withdrawn	Consent Obtained / Withdrawn?	Date Consent Obtained / Withdrawn
XXXXXX	XX/M	1.0	Yes / Yes	DDMMMYYYY / DDMMMYYYY	Yes	DDMMMYYYY / DDMMMYYYY	Yes	DDMMMYYYY / DDMMMYYYY
XXXXXX	XX/F	1.0	Yes / No	DDMMMYYYY	Yes	DDMMMYYYY	Yes	DDMMMYYYY
XXXXXX	XX/F	1.0	Yes / No	DDMMMYYYY	Yes	DDMMMYYYY	Yes	DDMMMYYYY
XXXXXX	XX/F	1.0	No / Yes	DDMMMYYYY DDMMMYYYY	No	DDMMMYYYY	No	DDMMMYYYY

<cont.>

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.doc)

PROGRAMMING NOTE:
- For all Listings, repeat for each Basket. For All Patients Set present group Screen Failures

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.1-2 – Failed Inclusion and Exclusion Criteria
All Patients Set

Basket: Basket 1

Patient ID	Age / Gender	Protocol Version	Failed Inclusion / Exclusion No.	Description
xxx-xx	xx/M	1.0	INCL01	xxxxxxxxxxxx
xxx-xx	xx/M	1.0	EXCL01	xxxxxxxxxxxx
xxx-xx	xx/M	1.0	EXCL02	xxxxxxxxxxxx
xxx-xx	xx/F	1.0	INCL02	xxxxxxxxxxxx

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- List all failed Inclusion / Exclusion criteria as per eCRF.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.1-3 – Patient Disposition
All Patients Set

Basket: Basket 1

Patient ID	Age / Gender	Enrolled	Date of Assignment	Gene/ Codon/ Amino acid change	Completed Screening / Reason	Date of Screening Completion / Discontinuation	Eligible for inclusion?	Rescreened? / Previous patient number
xxx-xx	xx/M	Yes	DDMMMYYYY	BRAF /D594 / Alanine A	Yes	DDMMMYYYY	Yes	No
xxx-xx	xx/F	Yes	DDMMMYYYY	MEK1/MAP2K1 / K601 /Arginine R	No / Physician Decision	DDMMMYYYY	Yes	Yes /xxxxxxx

Note: M=Male, F=Female.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Listing 16.2.1-3 - Patient Disposition
All Patients Set

Basket: Basket 1

Patient ID	Age / Gender	Completed Treatment / Reason	Date of Treatment Discontinuation	Date of Last Study Dose	Completed Study / If no, reason	Date of Completion
xxx-xx	xx/M	Yes	DDMMMYYYY	DDMMMYYYY	Yes	DDMMMYYYY
xxx-xx	xx/F	No/ Progressive Disease	DDMMMYYYY	DDMMMYYYY	No/ xxxxxx	DDMMMYYYY

Note: M=Male, F=Female.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Listing 16.2.2-1 – Analysis Sets
All Patients Set

Basket: Basket 1

Patient ID	Age / Gender	All Patients Set [a]	Full Analysis Set [b]	Stage 1 Analysis Set [c]	Evaluable Analysis Set [d]	PK Analysis Set [e]
xxx-xx	xx/M	Yes	Yes	Yes	Yes	Yes
xxx-xx	xx/F	Yes	Yes	Yes	Yes	Yes

Note: M=Male, F=Female.
[a] Patients who were enrolled regardless of whether they received the study drug or not.
[b] Patients who received at least 1 dose of the study drug.
[c] First 13 patients who have completed at least one cycle of therapy and who have received a minimum of 75% of prescribed study therapy during Cycle 1
[d] Patients who received at least one dose of study drug and have at least one post-treatment study evaluation or who have discontinued therapy prior to the first post-treatment study evaluation due to clinical progressive disease or drug-related adverse events.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.3-1 – Protocol Deviations
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Deviation Category	Summary Term	Deviation Description	Classification	Exclusion from Analysis Sets
xxx-xx	xx/M	Inclusion Criteria …	xxxxxxxxxxxxx	xxxxxxxxxxxxx	Important	Evaluable Analysis Set
xxx-xx	xx/F	Study Assessments …	xxxxxxxxxxxxx	xxxxxxxxxxxxx	Non-Important	Full Analysis Set

Note: M=Male, F=Female.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Categories / Summary Term / Description to match the PDCF.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.4-1 – Demographics and Baseline Characteristics
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Childbearing/ Reproductive Potential	Surgery Name	Date of Surgery/Post-Menopausal	Date of Last Menstrual Period	Race	Ethnicity	Height at Screening (cm)	Weight at Screening (kg)
xxx-xx	xx/M	Surgically Sterile	Vasectomy	DDMMMYYY		White	Hispanic or Latino	xx	xx
xxx-xx	xx/F	Able to Bear Children			DDMMMYYY	Other, xxxx	Not Hispanic or Latino	xx	xx
xxx-xx	xx/F	Sterile – Other Reason, xxxxxx			DDMMMYYY				

Note: M=Male, F=Female.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.4-2 - Smoking History
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Smoking History?	Substance	Usage
xxx-xx	xx/M	Yes	Cigarettes	Former
xxx-xx	xx/F	No		

Note: M=Male, F=Female.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Listing 16.2.4-3 - Disease History
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Cancer Diagnosis	Date of Initial Diagnosis	Time since Initial Diagnosis [a]	Stage at Diagnosis	Method of Diagnosis	Current Stage at Enrollment	Prior Radiation Therapies?
xxx-xx	xx/M	Stomach	DDMMMYYYY	xx	1	Cytological	1	Yes
xxx-xx	xx/F	Other, xxxxx	DDMMMYYYY	xx	2	Histological	4	No

Listing 16.2.4-4 – Medical History and Concomitant Diseases
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Reported Term	System Organ Class	Preferred Term	Start Date (Day) /End Date (Day)	Ongoing	MH or Conc.
xxx-xx	xx/M	xxxxxxxx	xxxxxxxxx	xxxxxxxx	DDMMMYYYY (xx) / DDMMMYYYY (xx)	No	MH
xxx-xx	xx/F	xxxxxxxx	xxxxxxxxx	xxxxxxxx	DDMMMYYYY (xx)	Yes	Conc.

Note: M=Male, F=Female.
MedDRA <vx.x>.
Study day is calculated as (Event Date – Study treatment start date) for dates before Study treatment start date and (Event date – First treatment date + 1) for dates after Study treatment start date.
Medical history (MH): any conditions that started before the first study treatment date and were not ongoing at the first study treatment date.
Concomitant disease (Conc.): any conditions that started before first study treatment administration and were ongoing at first study treatment administration.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.4-5 – Prior Systemic Anti-Cancer Therapies
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Line of Therapy	Name of Therapy	Start Date (Day)	End Date (Day)	Best Overall Response	Date of Best Overall Response	Date of Relapse/ Progression	Reason for Discontinuation
xxx-xx	xx/M	1	xxxxxx	DDMMMYYYY (xx)	DDMMMYYYY (xx)	Stable Disease	DDMMMYYYY	DDMMMYYYY	Intolerance
xxx-xx	xx/M	1	xxxxxx	DDMMMYYYY (xx)	DDMMMYYYY (xx)	Stable Disease	DDMMMYYYY	DDMMMYYYY	Lack of Efficacy
xxx-xx	xx/F	4	xxxxxx	DDMMMYYYY (xx)	DDMMMYYYY (xx)	Partial Response	DDMMMYYYY	DDMMMYYYY	Other, xxxxx

Note: M=Male, F=Female.
Study day is calculated as (Medication Date - Study treatment start date) for dates before Study treatment start date and (Medication date - First treatment date + 1) for dates after Study treatment start date.
Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Data taken from 'Prior Cancer Medications' page.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.4-6 – Prior Radiotherapy Courses
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Site of Radiotherapy	Dose (Unit)	Start Date (Day)	End Date (Day)	Duration (months) [a]
xxx-xx	xx/M	Abdominal Cavity	xxx (xxx)	DDMMMYYYY (xx)	DDMMMYYYY (xx)	xx
xxx-xx	xx/M	Adrenal Gland	xxx (xxx)	DDMMMYYYY (xx)	DDMMMYYYY (xx)	xx
xxx-xx	xx/F	Bile Duct	xxx (xxx)	DDMMMYYYY (xx)	DDMMMYYYY (xx)	xx

Note: M=Male, F=Female.
Study day is calculated as (Medication Date – Study treatment start date) for dates before Study treatment start date and (Medication date – First treatment date + 1) for dates after Study treatment start date.
[a] Duration of radiotherapy calculated as [(end date – start date) + 1] / 30.4375.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Data taken from 'Prior Radiotherapy' page.

Listing 16.2.4-7 – Prior and Concomitant Medications
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Reported Term / Preferred Term / ATC Class	Indication	Start Date (Day)	End Date (Day)	Dose (Units) / Frequency	Route	Medication to treat adverse event? / Adverse Event (ID)	Ongoing	Prior / Conc.
xxx-xx	xx/M	Xxxxxxxxxxx / xxxxxxxxxxxx / xxxxxx	xxxxxx	DDMMMYYYY (xx)	DDMMMYYYY (xx)	xxx (xx) / Daily	Oral	Yes / xxxx (x)	Yes	Conc.
xxx-xx	xx/F	xxxxxxxxxxx/ xxxxxxxxxxxx / xxxxxx	xxxxxx	DDMMMYYYY (xx)	Ongoing	xxx (xx) / Twice per day	Oral, xxxx	No	No	Prior

Note: M=Male, F=Female, ATC=Anatomical Therapeutic Chemical.
WHOHD-B3 <vx.x>.
Study day is calculated as (Medication Date - Study treatment start date) for dates before Study treatment start date and (Medication date - First treatment date + 1) for dates after Study treatment start date.
Prior medication (Prior): any medications whose end date is before the first study treatment date.
Concomitant medication (Conc.): any medication whose start or end date is either the same or after the first dose of study treatment and up to the end of the on-treatment period.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Data taken from 'Prior and Concomitant Medications' page.
- Adverse Event ID taken from collected ID.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.4-8 – On Treatment Radiation
Full Analysis Set

Cohort: Basket 1

Patient ID	Age / Gender	Received Radiation?	Site of Radiotherapy	Dose (Unit)	Start Date (Day)	End Date (Day)
xxx-xx	xx/M	Yes	Abdominal Cavity	xxx (xxx)	DDMMMYYYY (xx)	DDMMMYYYY (xx)
xxx-xx	xx/M	Yes	Adrenal Gland	xxx (xxx)	DDMMMYYYY (xx)	DDMMMYYYY (xx)
xxx-xx	xx/F	No				

Note: M=Male, F=Female.
Study day is calculated as Procedure date – First treatment date + 1.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Data taken from 'On Treatment Radiation' page.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.4-9 – On Treatment Surgery and Medical Procedures
Full Analysis Set

Cohort: Basket 1

Patient ID	Age / Gender	Any Surgeries/ Procedures	Name of Surgery/ Procedure	Indication?	Start Date (Day)	End Date (Day)	Ongoing?
xxx-xx	xx/M	Yes	xxxxxxxxxx	xxxxxxxxxx	DDMMMYYYY (xx)	DDMMMYYYY (xx)	No
xxx-xx	xx/M	Yes	xxxxxxxxxx	xxxxxxxxxx	DDMMMYYYY (xx)	DDMMMYYYY (xx)	Yes
xxx-xx	xx/F	No					

Note: M=Male, F=Female.
Study day is calculated as Procedure date – First treatment date + 1.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Data taken from 'On Treatment Surgery and Medical Procedures' page.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.4-10 – On Treatment Blood Transfusions
Full Analysis Set

Cohort: Basket 1

Patient ID	Age/ Gender	Any blood transfusions	Transfusion ID	Date of Transfusion	Category of Transfusion	Units
xxx-xx	xx/M	Yes	xxxxxxxxxx	DDMMMYYYY (xx)	Platelet transfusion	xx
	xx/M	Yes	xxxxxxxxxx	DDMMMYYYY (xx)	Plasma	xx
xxx-xx	xx/F	No				

Note: M=Male, F=Female.
Study day is calculated as Procedure date – First treatment date + 1.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Data taken from 'On Treatment Blood Transfusions' page.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.4-11 – NGS Data
Full Analysis Set

Cohort: Basket 1

Patient ID	Age/ Gender	Gene / Codon / Amino acid change	Vendor	Date of Report	Report Redacted	Report Uploaded
xxx-xx	xx/M	BRAF /D594 / Alanine A	STRATA	DDMMMYYYY (xx)	Yes	Yes
xxx-xx	xx/F	MEK1/MAP2K1 / K601 /Arginine R	GUARDANT		No	No

Note: M=Male, F=Female.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Listing 16.2.5-1 – Ulixertinib In-clinic Administration
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Treatment Administered?	Dose (mg)	Dose Date and Time (day)
xxx-xx	xx/M	Yes	xxx	DDMMMYYYY hh:mm (xx)
xxx-xx	xx/F	Yes	xxx	DDMMMYYYY hh:mm (xx)
xxx-xx	xx/F	Yes	Xxx	DDMMMYYYY hh:mm (xx)

Note: M=Male, F=Female.
Study day is calculated as Administration date – First treatment date + 1.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Listing 16.2.5-2 – Hydroxychloroquine In-clinic Administration
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Listing 16.2.5-1

Listing 16.2.5-3 – Ulixertinib Interruptions and Adjustments
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Type of Change	Start Date / End Date / Duration (days)	If Adjustment, new dose amount (mg)	Reason for Interruption/Adjustment
xxx-xx	xx/M	Interruption	DDMMMYYYY / DDMMMYYYY / (xx)	xxx	Adverse Event
xxx-xx	xx/F	Adjustment	DDMMMYYYY / DDMMMYYYY / (xx)	xxx	Other, xxxxx
xxx-xx	xx/F				

Note: M=Male, F=Female.
Study day is calculated as Interruption/Change date – First treatment date + 1.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Listing 16.2.5-4 – Hydroxychloroquine Interruptions and Adjustments
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Listing 16.2.5-3

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.5-5 – Ulixertinib Exposure
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Number of cycles received [a]	Duration of exposure (months) [b]	Planned cumulative dose (mg)	Actual cumulative dose received (mg) [c]	Relative dose intensity [d]
xxx-xx	xx/M	xx	xxx	xxx (mg)	xxx (mg)	xxx
xxx-xx	xx/F	xx	xxx	xxx (mg)	xxx (mg)	xxx

Note: M=Male, F=Female.
[a] Number of cycles received = Number of cycles where the patient received at least one dose.
[b] Duration of exposure (months) = (Date of last known treatment dosing with ulixertinib– date of initial dosing with ulixertinib) + 1 / 30.4375.
[c] Actual cumulative dose received (mg) = Sum of [(number of capsules dispensed – number of capsules returned) x 150].
[d] Relative dose intensity = 100 x Actual dose intensity / Planned dose intensity. Actual dose intensity (mg/day) is defined as Actual cumulative dose received (mg) / Duration of exposure (days). Planned dose intensity (mg/day) is defined as Planned cumulative dose (mg) / Duration of exposure (days). Planned cumulative dose is the number of cycles received x number of doses per day x mg prescribed per dose.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Listing 16.2.5-6 – Hydroxychloroquine Exposure
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Listing 16.2.5-5

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.5-7 – Ulixertinib Dispensed
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Mg prescribed per dose	Date Bottles Dispensed (day)	Number of Bottles Dispensed	Lot Number of the bottles dispensed	Different Lot number dispensed to the patient?	Lot number dispensed to patient /No of bottles	Total Number of Capsules Dispensed
xxx-xx	xx/M	xxx	DDMMMYYYY (xx)	xx	xxxx	Yes	Xxxx/XX	xx
xxx-xx	xx/F	xxx	DDMMMYYYY (xx)	xx	xxxx	No		xx

Note: M=Male, F=Female.
Study day is calculated as Dispensed date – First treatment date + 1.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Listing 16.2.5-8 – Hydroxychloroquine Dispensed
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Listing 16.2.5-7

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.5-9 – Ulixertinib Returned
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Cycle	Reason capsules not returned	Date Returned (day)	Patient compliant since last visit? If no, reason	Missed dose related to an adverse event?	Number of Bottles Returned	Lot Number of the bottles returned	Total Number of Capsules Returned
xxx-xx	xx/M	2	Lost	DDMMMYYYY (xx)	Yes	Yes	xx	xxxx	xxx
xxx-xx	xx/F	3	Other, xxxxx	DDMMMYYYY (xx)	No, xxxxx	Yes	xx	xxxx	xxx

Note: M=Male, F=Female.
Study day is calculated as Returned date – First treatment date + 1.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Listing 16.2.5-10 – Hydroxychloroquine Returned
Full Analysis Set

PROGRAMMING NOTES:

- Repeat Listing 16.2.5-9

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.6-1 – Target Lesions
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Visit	Target Lesions at Screening?	Lesion Number	Tumor Type	Organ Site	Method	Date of Scan (Day)	Longest Diameter/ Short-axis (mm)	Sum of Longest Diameter (mm) / Change from baseline / % Change from baseline
xxx-xx	xx/M	Screening	Yes	T01	Primary	Bladder	CT Scan	DDMMMYYYY (xx)	xxx	xxx
		C2D1								
		…								
xxx-xx	xx/F	Screening	Yes	T02	Metastasis	Other, xxxxx	MRI	DDMMMYYYY (xx)	xxx	xxx / xxx / xxx
		…								

Note: M=Male, F=Female.
Study day is calculated as (Scan Date - Study treatment start date) for dates before Study treatment start date and (Scan date - First treatment date + 1) for dates after Study treatment start date.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Sort by Basket, patient ID, visit.

Listing 16.2.6-2 – Non-Target Lesions
Full Analysis Set

Basket: Basket 1

Patient ID	Age/ Gender	Visit	Assessment Performed / Reason	Non-Target Lesions at screening	Lesion Number	Organ Site	Method	Date of Scan (Day)	Result
xxx-xx	xx/M	Screening	Yes	Yes	NT01	Bladder	CT Scan	DDMMMYYYY (xx)	Present
		C2D1	No, xxx						
		…							
xxx-xx	xx/F	Screening	Yes	Yes	NT02	Other, xxxx	MRI	DDMMMYYYY (xx)	Absent (Disappeared)
		…							

Note: M=Male, F=Female.
Study day is calculated as (Scan Date – Study treatment start date) for dates before Study treatment start date and (Scan date – First treatment date + 1) for dates after Study treatment start date.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Sort by Basket, patient ID, visit.

Listing 16.2.6-3 – New Lesions
Full Analysis Set

Basket: Basket 1

Patient ID	Age/ Gender	Visit	Any New Lesions	Lesion Number	Method	Date of Scan (Day)	Organ Site
xxx-xx	xx/M	C2D29	Yes	NL01	CT Scan	DDMMMYYYY (xx)	Abdomen
xxx-xx	xx/F	C2D29	Yes	NL02	Other, xxxx	DDMMMYYYY (xx)	Bone

Note: M=Male, F=Female.
Study day is calculated as Scan date – First treatment date + 1.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.6-4 – Overall Response
Full Analysis Set

Basket: Basket 1

Patient ID	Age/ Gender	Best Overall Response [a]	Assessment Performed/ Reason	Date of Assessment (Day)	Target Lesion Response	Non-Target Lesion Response	New Lesions	Overall Response
xxx-xx	xx/M	CR	Yes	DDMMMYYYY (xx)	CR	CR	Yes	PD
xxx-xx	xx/F	PD	Yes	DDMMMYYYY (xx)	NE	PD	No	NE, xxxx

Note: M=Male, F=Female, CR=Complete Response, Non CR/Non PD=Non Complete Response/Non Progressive Disease, PR=Partial Response, SD=Stable Disease, PD=Progressive Disease, NE=Not Evaluable.
Study day is calculated as Assessment date – First treatment date + 1.
[a] Confirmed best overall response.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

Listing 16.2.6-5 – Progression-Free Survival (PFS)
Full Analysis Set

Basket: Basket 1

Patient ID	Age/ Gender	Treatment Start Date	Date of Last Tumor Assessment	Date of Event/ Censoring	Event / Censoring Reason	PFS (months)
xxx-xx	xx/M	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	Death	xx.x
xxx-xx	xx/F	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	Censored: xxxxx	xx.x

Note: M=Male, F=Female, PFS=Progression-Free Survival.
Event: progressive disease (PD) or death from any cause.
The PFS (in months) is defined as the time from the first ulixertinib dose until the first radiographically documented progression of disease or death from any cause, whichever occurs first.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.6-6 – Survival Status
Full Analysis Set

Basket: Basket 1

Patient ID	Age/ Gender	Completed End of Study?	Any Anti-Cancer Treatment Since End of treatment or Last FUP/ Start Date	Any Tumor Assessment Since End of Study or Last FUP/ Assessment Date/ Overall Response	Survival Status at Follow-Up	Date of Death	Last Known Date Patient Alive [a]
xxx-xx	xx/M	Yes	Yes/ DDMMMYYYY	Yes/ DDMMMYYYY/ Complete Response	Alive		
xxx-xx	xx/F	Yes	No	No	Dead	DDMMMYYYY	

Note: M=Male, F=Female, FUP=Follow-up, CR=Complete Response, Non CR/Non PD=Non Complete Response/Non Progressive Disease, PR=Partial Response, SD=Stable Disease, PD=Progressive Disease, NE=Not Evaluable.
[a] If Survival status at the time of follow-up is unknown.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.6-7 – Duration of Response (DOR)
Full Analysis Set

Basket: Basket 1

Patient ID	Age/ Gender	Best Overall Response [a]	Treatment Start Date	Date of First Response	Date of Last Tumor Assessment	Date of Event / Censoring	Event / Censoring Reason	Duration of Response (months)
xxx-xx	xx/M	CR	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	Death	xx.x
xxx-xx	xx/F	PR	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	Censored: xxxxx	xx.x

Note: M=Male, F=Female, CR=Complete Response, PR=Partial Response, SD=Stable Disease, PD=Progressive Disease, NE=Not Evaluable.
Event: progressive disease (PD) or death from any cause.
This listing includes only patients with response (CR or PR).
Duration of response is the period from the date of initial confirmed PR or CR until the date of first radiographically documented progressive disease or death from any cause.
[a] Confirmed best overall response.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM)

Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.7-1 – Adverse Events
All Patients Set

Basket: Basket 1

Patient ID	Age / Gender	ID	Reported Term	System Organ Class	Preferred Term	Start Date (day)	End Date (day)	TEAE?	SAE?
xxx-xx	xx/M	xx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxx	DDMMMYYYY (xx)	DDMMMYYYY (xx)	Yes	Yes
xxx-xx	xx/F	xx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxx	DDMMMYYYY (xx)	DDMMMYYYY (xx)	No	No

Note: M=Male, F=Female, TEAE=Treatment Emergent Adverse Event, SAE=Serious Adverse Event.
ID as collected in the databased.
MedDRA <vx.x>. NCI CTCAE v5.0.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.7-2 – Treatment-Emergent Adverse Events
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	ID	Reported Term / System Organ Class /Preferred Term	Start Date (Day) / End Date (Day) / Duration (days)	SAE / Seriousness	NCI-CTCAE Grade	Relation Ship to Disease	Relation Ship to Ulixertinib / Hydroxychloroquine	Action Taken with Ulixertinib / Hydroxychloroquine	Medication or Therapies? / Medication Name	Outcome [a]
xxx-xx	xx/M	xx	xxxxxxxx/ xxxxxxxxx/ xxxxxxxxx …	DDMMMYYYY (xx) / DDMMMYYYY (xx) / xx	Yes / Hospitalization	1	Related	Related /Related	Drug Interrupted /Drug Interrupted	Yes /xxxxxxxx, xxxxxxx	Res'd
xxx-xx	xx/F	xx	xxxxxxxx/ xxxxxxxxx/ xxxxxxxxx …	DDMMMYYYY (xx) / DDMMMYYYY (xx) / xx	No	3	Possibly Related	Possibly Related /Related	Drug Interrupted /Drug Interrupted	Yes /xxxxxxxx	Res'd seq, xxxxxx

Note: M=Male, F=Female, TEAE=Treatment Emergent Adverse Event, SAE=Serious Adverse Event.
MedDRA <vx.x>. NCI CTCAE v5.0.
ID as collected in the databased.
Study day is calculated as TEAE date – First treatment date + 1.
[a] Res'd=Resolved, Res'd seq=Recovered/Resolved with sequelae, Ong=Ongoing, Unk=Unknown, Fatal=Fatal.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Sort by Basket, patient ID, ascending Adverse Event Start Date and Reported Term.
- Outcome = "Res'd seq" please specify sequelae.

Listing 16.2.7-3 – Serious Adverse Events
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Listing 16.2.7-2 and include only AEs classified as Serious.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.7-4 – Deaths
All Patients Set

Basket: Basket 1

Patient ID	Age / Gender	Date of Death (Day)	Autopsy Performed? / Date of Autopsy	Primary Cause of Death	Treatment-Emergent Death [a]
xxx-xx	xx/M	DDMMMYYYY (xx)	No	Progressive Disease	Yes
xxx-xx	xx/F	DDMMMYYYY (xx)	Yes /DDMMMYYYY	Adverse Event, xxxxxxx	No

Note: M=Male, F=Female.
[a] A death is considered Treatment-Emergent if occurred after Ulixertinib administration.
Study day is calculated as Death date – First treatment date + 1.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Specify primary cause of death if not PD.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.8-1 – Hematology
Full Analysis Set

Basket: Basket 1

Patient ID	Age/ Gender	Study Visit	Sample Date and Time (Day)	Parameter (Unit)	Result / Reference Range Indicator / CS? [a]	LLN – ULN	CTC Grade	Change from Baseline
xxx-xx	xx/M	Screening	DDMMMYYYY / hh:mm (xx)	RBC (xxx)	xx / L / CS	xx – xx	xx	
				…				
		C1D1	DDMMMYYYY / hh:mm (xx)	RBC (xxx)	xx / L / CS	xx – xx	xx	xx
		…		…				
xxx-xx	xx/F	Screening	DDMMMYYYY / hh:mm (xx)	RBC (xxx)	Not Done			
				…				
		C1D1						
		…						

Note: M=Male, F=Female, L=Low, H=High, ULN=Upper Limit of Normal, LLN=Lower Limit of Normal, CS=Clinically Significant, NCS=Non Clinically Significant.
CTCAE v5.0.
Baseline is the last available assessment prior to first dose of study treatment.
Study day is calculated as (Sample Date – Study treatment start date) for dates before Study treatment start date and (Sample date – First treatment date + 1) for dates after Study treatment start date.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Sort by Basket, patient ID, ascending Sample Date and Time and Parameter.
- Include all hematology parameters.

Listing 16.2.8-2 – Biochemistry
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Listing 16.2-8.1 for all biochemistry parameters.

Listing 16.2.8-3 – Coagulation
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Listing 16.2-8.1 for all coagulation parameters.

Listing 16.2.8-4 – Urinalysis
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Listing 16.2-8.1 for all urinalysis parameters.

Listing 16.2.8-5 – Tumor Markers
Full Analysis Set

PROGRAMMING NOTES:
- Repeat Listing 16.2-8.1 for all tumor marker parameters.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.8-6 – Pregnancy
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Study Visit	Sample Type	Assessment Performed? /Reason	Sample Date (Day)	Result
xxx-xx	xx/F	Screening Baseline	Serum	Yes	DDMMMYYYY (xx)	Positive
xxx-xx	xx/F	Screening	Serum	No /xxxxx		

Note: F=Female.
Baseline is the last available assessment prior to first dose of study treatment.
Study day is calculated as (Sample Date – Study treatment start date) for dates before Study treatment start date and (Sample date – First treatment date + 1) for dates after Study treatment start date.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Sort by Basket, patient ID, visit.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.9-1 – Vital Signs
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Study Visit	Assessment Performed? / Reason	Assessment Date and Time (Day)	Parameter (Unit)	Result/ Reference Range Indicator / CS? [a]	Position	Change from baseline
xxx-xx	xx/M	Screening	Yes	DDMMMYYYY hh:mm (xx)	Systolic Blood Pressure (xxx)	xx / H / CS	Sitting	
					…			
		Baseline	Yes	DDMMMYYYY hh:mm (xx)	Systolic Blood Pressure (xxx)	xx / H / CS	Supine	
		…			…			
xxx-xx	xx/F	Screening	No / xxxxxx			Not Done		
		…						

Note: M=Male, F=Female, L=Low, H=High, VH=Very High, ND=Not Done, CS=Clinically Significant, NCS=Non Clinically Significant.
[a] If status = "Not Done" populate with "Not Done".
* Baseline is the last available assessment prior to first dose of study treatment.
For temperature, Low if < 36.4°C; high if > 37.7°C.
For pulse, Low if < 55bpm; high if 101-150bpm; very high if > 150bpm.
For systolic blood pressure, Low if < 90mmHg; high if 131-160mmHg; very high if >= 161mmHg.
For diastolic blood pressure, Low if < 60mmHg; high if 86-100mmHg; very high if >= 101mmHg.
For Pulse oximetry, Very Low: < 90 %, Low: 90-95 %, Normal: ≥ 95 %.
For Respiratory Rate, Low: < 12 breaths/min, Normal: 12-16 breaths/min, High: > 16 breaths/min.
Study day is calculated as (Assessment Date - Study treatment start date) for dates before Study treatment start date and (Assessment date - First treatment date + 1) for dates after Study treatment start date.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Sort by Basket, patient ID, ascending Assessment Date and Time and Parameter.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.9-2 – Electrocardiogram
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Study Visit	Assessment Performed? / Reason	Assessment Date and Time (Day)	Method/ Position	Parameter (Unit)	Result /CS?	Change from baseline
xxx-xx	xx/M	Screening	Yes	DDMMMYYYY hh:mm (xx)	12 Lead Standard/ Supine	Heart Rate (xxx)	xx /No	
xxx-xx	xx/F	Screening	Yes	DDMMMYYYY hh:mm (xx)	12 Lead Standard/ Supine	Heart Rate (xxx)	xx /Yes	

Note: M=Male, F=Female, L=Low, H=High.
Study day is calculated as (Assessment Date – Study treatment start date) for dates before Study treatment start date and (Assessment date – First treatment date + 1) for dates after Study treatment start date.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Sort by Basket, patient ID, ascending Assessment Date and Time and Parameter.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.9-3 – ECHO
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Assessment Performed? / Reason	Method	Assessment Date (Day)	Parameter (Unit)	Result /CS?
xxx-xx	xx/M	Yes	Echocardiography	DDMMMYYYY (xx)	LVEF (xx)	xx /No

Note: M=Male, F=Female, LVEF=Left Ventricular Ejection Fraction.
Study day is calculated as (Assessment Date – Study treatment start date) for dates before Study treatment start date and (Assessment date – First treatment date + 1) for dates after Study treatment start date.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Sort by Basket, patient ID, ascending Assessment Date and Time.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.9-4 – Physical Examination
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Study Visit	Assessment Performed? / Reason	Assessment Date	Region /Body System	Result /CS? [a]	Abnormal Findings
xxx-xx	xx/M	Screening	Yes	DDMMMYYYY	HEENT	Abnormal/ CS	xxxxxxx
xxx-xx	xx/F	Screening	Yes	DDMMMYYYY	Thorax	Not Done	

Note: M=Male, F=Female, CS=Clinically Significant, NCS=Non Clinically Significant.
[a] If status = "Not Done" populate with "Not Done".

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Sort by Basket, patient ID, visit, Region/body system.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.9-5 – Ophthalmology Exam
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Study Visit	Assessment Performed? / Reason	Assessment Date	Examination Test Name	Any Abnormal Clinically Significant Result?	Eyes Affected	Abnormal Finding
xxx-xx	xx/M	Screening	Yes	DDMMMYYYY	Best-corrected visual acuity …	Yes	Left	xxxxxxxxxxx
xxx-xx	xx/F	Screening	Yes	DDMMMYYYY		Yes	Both	

Note: M=Male, F=Female, CS=Clinically Significant, NCS=Non Clinically Significant.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Sort by Basket, patient ID, visit, examination test name

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.9-6 – ECOG Performance Status
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Study Visit	Assessment Performed? / Reason	Date of Assessment (Day)	ECOG Performance Status [a]
xxx-xx	xx/M	Screening	Yes	DDMMMYYYY (xx)	(0) Fully Active
		Baseline	Yes	DDMMMYYYY (xx)	(0) Fully Active
		…			
xxx-xx	xx/F	Screening	Yes	DDMMMYYYY (xx)	(1) Restricted
		Baseline	No, xxxx		
		…			

Note: M=Male, F=Female.
Baseline is the last available assessment prior to first dose of study treatment.
[a] (0) Fully active, able to carry on all pre-disease performance without restriction
(1) Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work
(2) Ambulatory and capable of all self-care but unable to carry out any work activities
(3) Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
(4) Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
(5) Death
Study day is calculated as (Assessment Date – Study treatment start date) for dates before Study treatment start date and (Assessment date – First treatment date + 1) for dates after Study treatment start date.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Sort by Basket, patient ID, visit, assessment date.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.11-1 – Pharmacokinetic Concentration Data
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Study Visit	Collection Date/Time (Day) / Timepoint	Analyte	Concentration (Unit)
					xxxx (ng/mL)
xxx-xx	xx/M	C1D15	ddmmmyyyy hh:mm (xx) / Pre-dose	BVD-523	
		…			

Note: M=Male, F=Female.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Sort by Basket, patient ID, visit, assessment date and time.

BioMed Valley Discoveries
Protocol: BVD-523-HCQ ('Delivery' / 'Type')
Data extraction date: DDMMMYYYY

Listing 16.2.11-2 – Pharmacokinetic Parameters Data
Full Analysis Set

Basket: Basket 1

Patient ID	Age / Gender	Study Visit	Visit	Analyte	PK Parameter	Result
xxx-xx	xx/M	C1D15	C1D15	BVD-523	AUC	xxxx
		…				

Note: M=Male, F=Female.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Sort by Basket, patient ID, visit and analyte.

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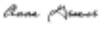
Anna Groover agroover@biomed-valley.com Senior Scientist Security Level: Email, Account Authentication (Required)	Signed by:  Signer Name: Anna Groover Signing Reason: I approve this document Signing Time: 03-Sep-2024 | 08:40 CDT 71380BDD08BC4D289E63FA3831CD4243 Signature Adoption: Pre-selected Style Signature ID: 71380BDD-08BC-4D28-9E63-FA3831CD4243 Using IP Address: 136.37.127.159 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document I approve this document	Sent: 02-Sep-2024 | 16:33 Viewed: 03-Sep-2024 | 14:39 Signed: 03-Sep-2024 | 14:40
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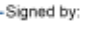
Brent Kreider bkreider@biomed-valley.com President Security Level: Email, Account Authentication (Required)	Signed by:  Signer Name: Brent Kreider Signing Reason: I approve this document Signing Time: 04-Sep-2024 | 08:58 PDT 9FC8BD6421864A9788CCD264914F8A6C Signature Adoption: Pre-selected Style Signature ID: 9FC8BD64-2186-4A97-88CC-D264914F8A6C Using IP Address: 173.197.22.10 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document I approve this document	Sent: 02-Sep-2024 | 16:33 Viewed: 04-Sep-2024 | 16:58 Signed: 04-Sep-2024 | 16:58
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