STATISTICAL ANALYSIS PLAN

A Phase 1b/2 Study of FT-2102 in Patients with Advanced Solid Tumors and Gliomas with an IDH1 Mutation

Protocol 2102-ONC-102 (NCT03684811)

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LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

Abbreviation	Definition
2-HG	(R)-2-hydroxyglutarate
AE	Adverse event
AFP	Alpha-fetoprotein
α-KG	α-ketoglutarate
ALP	Alkaline phosphatase
ALT (SGPT)	Alanine aminotransferase (serum glutamic pyruvic transaminase)
ANC	Absolute neutrophil count
AST (SGOT)	Aspartate aminotransferase (serum glutamic oxaloacetic transaminase)
ATC	Anatomic therapeutic class
AUC	Area under the concentration versus time curve
AUC_{0-24}	Area under the concentration versus time curve from time 0 to the end of the dosing interval 24 hours later, calculated using linear trapezoid rule
β-HCG	Beta human chorionic gonadotropin
BOR	Best overall response
BQL	Below quantifiable limit
C_{max}	Maximum plasma concentration
C_{min}	Trough plasma concentration, taken 24 hours after dose and prior to subsequent dose
CBC	Complete blood count
CEA	Carcinoembryonic antigen
CI	Confidence interval
cm	Centimeter
CNS	Central nervous system
CR	Complete response
CRF	Case report form
CSF	Cerebrospinal fluid
CSR	Clinical study report
CT	Computed tomography
ctDNA	Circulating tumor DNA
CTCAE	Common Terminology Criteria for Adverse Events
CV	Coefficient of variation
DLT	Dose-limiting toxicity
DNA	Deoxyribonucleic acid
DOR	Duration of response

Abbreviation	Definition
ECOG	Eastern Cooperative Oncology Group
ECG	Electrocardiogram
FDA	Food and Drug Administration
g	Gram
HBC	hepatobiliary cancer
ICH	International Conference on Harmonisation
IDH1	Isocitrate dehydrogenase 1
IDH2	Isocitrate dehydrogenase 2
IHCC	intrahepatic cholangiocarcinoma
IRB	Institutional Review Board
IWG	International Working Group
IV	Intravenous
kg	Kilogram
KM	Kaplan Meier
L	Liter
LDH	Lactic dehydrogenase
m^2	Square meter
MedDRA	Medical Dictionary for Regulatory Activities
mEq	Milliequivalence
mg	Milligram
mL	Milliliter
mm	Millimeter
mm^3	Cubic millimeter
MR	Minor response
MRI	Magnetic resonance imaging
MRS	Magnetic resonance spectroscopy
MTD	Maximum tolerated dose
N	Number
NOS	Not otherwise specified
ORR	Overall response rate
OS	Overall survival
PD	Progressive disease
%	Percent
PFS	Progression-free survival
pH	Hydrogen ion concentration

Abbreviation	Definition
PK	Pharmacokinetic
PR	Partial response
PT	Preferred term
PTT	Partial thromboplastin time
QD	quaque die/ once daily
QOL	Quality of life
QT	Interval between Q and T waves
QTc	Corrected interval between Q and T waves
RBC	Red blood cell (count)
Rel Day	Relative study day
RP2D	Recommended phase 2 dose
RTF	Rich text format
SAE	Serious adverse events
SAP	Statistical analysis plan
SC	Subcutaneous
SD	Stable disease ***or*** Standard deviation
SI	International System of Units
SOC	System organ class
$T_{1/2}$	Half-life
T_{max}	Time to maximum plasma concentration
TT	Treatment termination
TTP	Time to progression
TTR	Time to response
ULN	Upper limit of normal
V_{dss}	Volume of distribution at steady state
WBC	White blood cell (count)
WHO	World Health Organization

1. INTRODUCTION AND OBJECTIVES

1.1. Introduction

Isocitrate dehydrogenase 1 (IDH1) and isocitrate dehydrogenase 2 (IDH2) mutations in cancer result in abnormal hypermethylation of histones and DNA and suppression of normal cellular differentiation. The metabolic enzyme IDH1 catalyzes the oxidative decarboxylation of isocitrate to α-ketoglutarate (α-KG). In both hematologic and solid tumor malignancies, IDH1 mutations lead to aberrant accumulation of (R)-2-hydroxyglutarate (2-HG). 2-HG has been proposed to act as an "oncometabolite" that has pleotropic effects on tumorigenesis. Excess production of 2-HG has been shown to inhibit α-KG-dependent enzymes involved in epigenetic regulation, collagen synthesis, and cell signaling, thereby leading to a block in normal differentiation of progenitor cells and the subsequent development of cancer (Gross et al, 2010; Cairns et al, 2019; Losman et al, 2013). Therefore, inhibition of mutated IDH1 in tumor cells and the concomitant decrease in 2-HG production is expected to restore normal cellular differentiation and provide therapeutic benefit in IDH1-mutated cancers.

The identification of frequent mutations in the IDH1 and IDH2 genes in human cancers including glioma, hepatocellular carcinomas, chondrosarcomas and intrahepatic cholangiocarcinoma (IHCC) has provided novel therapeutic targets in these diseases (Yan et al, 2009; Amary et al, 2011; Wang et al, 2013; Lee et al, 2017). IDH mutation specific inhibitors have been shown to reduce aberrantly elevated levels of the oncometabolite 2-HG, resulting in antitumor efficacy in preclinical models (Rohle et al, 2013; Saha et al, 2014). Clinical investigation in patients with IHCC, gliomas and chondrosarcomas are ongoing with several other IDH1 inhibitors. A comparable IDH1 inhibitor, ivosidenib has published preliminary data regarding clinical activity in gliomas, chondrosarcomas and IHCC (Tap et al, 2016; Ishii et al, 2017; Mellinghoff et al, 2017).

1.2. Study Objectives

This statistical analysis plan (SAP) is designed to outline the methods to be used in the analysis of study data in order to answer the study objectives. Populations for analysis, data handling rules, statistical methods, and formats for data presentation are provided. The statistical analyses and summary tabulations described in this SAP will provide the basis for the results sections of the clinical study report (CSR) for this trial.

This SAP will also outline any differences in the currently planned analytical objectives relative to those planned in the study protocol.

Primary Objectives

Phase 1b: Evaluate the safety and tolerability of FT-2102 as monotherapy and confirm the dose to be further examined in expansion cohorts as monotherapy and combination therapy.

Phase 2: Evaluate the clinical activity of FT-2102 as monotherapy or in combination in patients with glioma, HBC, chondrosarcoma, and IHCC harboring an IDH1 mutation.

Secondary Objectives

Phase 1b:

- Evaluate the PK of FT-2102 as monotherapy and in combination with other anti-cancer agents
- Evaluate the clinical activity of FT-2102 as a single agent or in combination in patients with glioma, HBC, chondrosarcoma, and IHCC harboring an IDH1 mutation

Phase 2:

- Evaluate the safety of FT-2102 administered as monotherapy and in combination with other anti-cancer agents in patients with glioma, HBC, chondrosarcoma, and IHCC harboring an IDH1 mutation
- Evaluate the PK of FT-2102 as monotherapy and in combination with other anti-cancer agents
- Evaluate additional measures of antitumor activity of FT-2102 as monotherapy or in combination with other anti-cancer agents

Exploratory Objectives

- Evaluate potential biomarkers of response, resistance, and/or safety
- Evaluate pharmacodynamic and PK/pharmacodynamic relationship of FT-2102 as monotherapy and in combination with other anti-cancer agents
- Evaluate the biological effects of FT-2102 on tumor tissue, including tumor cells, CSF, immune cells, and vasculature
- Evaluate the biological effects of FT-2102 on tumor tissue, including tumor cells, CSF, immune cells, and vasculature
- Assess IDH1 mutations in ctDNA and correlate with mutations in tumor tissues

- Evaluate the health-related quality of life (QOL)

1.3. Study Endpoints

Primary Endpoint

Phase 1b: DLTs (Safety Lead-in Periods), adverse event (AEs), and safety laboratory values

Phase 2: Objective response rate (ORR), as determined by applicable disease criteria, for disease-specific cohorts

Secondary Endpoints

- AEs, and safety laboratory values (Phase 2)
- ORR (Phase 1b only)
- PFS, defined as the time from the first dose to disease progression as determined by applicable disease criteria or death due to any cause, whichever is sooner
- Time to progression (TTP), defined as the time from start of treatment until disease specified progression
- Duration of response (DOR), defined as the time from the first response to documented disease progression as determined by applicable disease criteria
- OS, defined as the time from the first dose to death due to any cause
- Time to Response (TTR), defined as the time from first dose to first response
- AEs and abnormal laboratory findings
- PK parameters derived from plasma/cerebrospinal fluid (CSF) FT-2102 concentrations

Exploratory Endpoints

- Pharacodynamic and PK/pharmacodynamic in relationship with clinical safety and clinical activity

- Changes in 2-hyroxygluterate (2-HG levels) (pharmacodynamic, biomarker) in plasma and tumor tissue (1H magnetic resonance spectroscopy (MRS) and CSF in intracranial gliomas and tumor biopsies for other tumors)
- Characterization of biological effects of FT-2102 on tumor biopsies
- Cancer-associated mutations and/or genetic alterations
- IDH1 mutation in ctDNA
- Health-related QOL patient-reported questionnaire (EQ5D)

1.4. Study Design

1.4.1. Synopsis of Study Design

This is a multicenter, Phase 1b/2, open-label, multiple-cohort study examining the efficacy and safety of FT-2102 as a single agent or in combination for the treatment of patients with advanced solid tumors and gliomas with IDH1 R132X mutations.

The study is comprised of 5 cohorts, where four cohorts represent different types of solid tumors and one represents gliomas. Within three of the solid tumor and the glioma cohorts, initially FT-2102 will be administered in a single agent regimen. Each cohort is designed as an independent Simon 2-stage study. If, within a cohort, the Simon 2-stage stops either at the interim analysis for futility or if the final analysis fails to accept the alternative hypothesis, dosing with FT-2102 in combination with other therapies (specific to the disease under study) may commence in a new Simon 2-Stage assessment. Cohort 5 is comprised of "other non-central nervous system (CNS) solid tumors" for patients harboring an IDH-R132X mutation (i.e. other solid tumors that do not fit into the first 4 cohorts). This cohort is purely exploratory, and thus is not designed as a Simon 2-stage. There are no plans to administer any combination therapy for patients enrolled into cohort 5; it is designed as a single agent therapy cohort only.

The Phase 1b part of the study is a safety-lead in, 3+3 study design in which the dose of 150 mg BID, which has been selected as the Phase 2 dose in a concurrent study in AML (2102-HEM-101) will be evaluated for safety. Once the Phase 1b portion is complete and the recommended Phase 2 dose (RP2D) has been selected for a cohort, the Phase 2 portion of the study may commence. The RP2D may differ for each cohort. Patients in the Phase 1b portion who were dosed at the RP2D dose level may contribute to the Phase 2 Simon 2-Stage evaluation.

An overview of the study is depicted in Section 12 of the SAP.

1.4.2. Randomization Methodology

N/A; study is open-label.

1.4.3. Stopping Rules and Unblinding

Unblinding is not applicable as study is open label. Several stopping rules apply, as there are Simon 2-Stage study designs within each cohort.

1.4.4. Study Procedures

The schedule of assessments is outlined in the study protocol, Tables 2-8. Refer to the study protocol for these details.

1.4.5. Efficacy, Pharmacokinetic, Pharmacodynamic and Safety Parameters

1.4.5.1. Efficacy Parameters

Objective Response Rate is defined as follows:

- Glioma: the proportion of patients with a best response of CR, PR or MR (LGG)
- HBC: the proportion of patients with a best response of CR or PR
- Chondrosarcoma: the proportion of patients with a best response of CR or PR
- Cholangiocarcinoma: the proportion of patients with a best response of CR or PR

Best overall response (BOR): BOR is the best response achieved by the patient at any time while on study.

Progression Free Survival (PFS): defined as the time from the date of the first dose to the date of disease progression as determined by applicable disease criteria or death due to any cause, whichever is sooner. If a patient withdraws from the study prior to an event occurring, the patient will be censored at the date of the last response evaluation.

Time to Progression (TTP): defined as the time from the date of the first dose to the date of disease progression as determined by applicable disease criteria. If progression does not occur while on study, the patient will be censored at the date of the last response evaluation.

Duration of Response (DOR): defined as the time from the date of the first response to the date of the documented disease progression as determined by applicable disease criteria. If progression does not occur while on study, the patient will be censored at the date of the last response evaluation. This will only be calculated for those patients who have a best response of MR or better.

Overall Survival (OS): defined as the time from the date of the first dose to the date of death due to any cause. If death is not recorded, the patient will be censored at the date of the last known alive.

Time to Response (TTR): defined as the time from the date of first dose to the date of first CR, PR or MR response. This will only be calculated for those patients who have a best response of MR or better.

Best percent change in tumor burden while on study: Maximum percentage reduction or minimum percentage increase at a single time point of the patient's tumor burden post first dose of study drug.

Time on treatment: Time from the date of first FT-2102 dose to the date of the last FT-2102 dose.

Health-related QOL patient-reported questionnaire (EQ5D): Change from baseline for each dimension and overall, number of patients reporting each score for each dimension and overall, and number of patients reporting some problems on each dimension.

1.4.5.2. Pharmacokinetic Parameters

Blood samples for determination of FT-2102 pharmacokinetics are to be collected as outlined in the protocol. Pharmacokinetic parameters to be derived from FT-2102 plasma concentrations collected in Phase 1b (Stage 1) include minimum plasma concentration (C_{min}), maximum plasma concentration (C_{max}), time to maximum plasma concentration (T_{max}), and area under the concentration versus time curve (AUC).

1.4.5.3. Pharmacodynamic Parameters

Pharacodynamic assessments being performed in this study include:

- Changes in 2-hyroxygluterate (2-HG) levels (PD, biomarker) in plasma, urine and tumor tissue (1H magnetic resonance spectroscopy (MRS)) and CSF (if available) in intracranial gliomas and tumor biopsies for other tumors)
- Characterization of biological effects of FT-2102 on tumor biopsies
- Cancer-associated mutations and/or genetic alterations
- IDH1 mutation in ctDNA

1.4.5.4. Safety Parameters

DLTs will be assessed for each dose evaluated in the Phase 1b phase.

The maximum tolerated dose (MTD) will be evaluated.

The RP2D will be determined for each cohort based on both safety and efficacy.

Safety evaluations performed during the study included physical examinations, measurement of vital signs, 12-lead electrocardiograms, clinical laboratory evaluations including hematology, serum chemistry, and urinalysis, and monitoring of adverse events and concomitant medications.

2. PATIENT POPULATION

2.1. Analysis Sets

Dose-Limiting Toxicity-Evaluable Analysis Set

The DLT-Evaluable Analysis Set is defined as all patients in the Safety Lead-in Periods (single- agent FT-2102, combination FT-2102 + 5-azacitidine, combination FT-2102 + GemCis and combination FT-2102 + PD-1 inhibitor) who either experienced a DLT during Cycle 1 or completed at least 75% of the prescribed Cycle 1 dose. This analysis set will be used to assess the tolerability of FT-2102.

Safety Analysis Set

The Safety Analysis Set is defined as all patients who received any amount of study drug(s) (FT-2102 and combination agents, if appropriate).

This analysis set will be the primary analysis set for all safety endpoints, excluding DLT evaluation. Safety analysis will be by cohort and by treatment within cohort if more than 1 dose or dosing combination are initiated for a particular indication cohort.

Response-Evaluable Analysis Set

The Response-Evaluable Analysis Set is defined as all patients with measurable disease at baseline are included in the Safety Analysis Set and had at least 1 post-baseline response assessment or discontinued the treatment phase due to disease progression (including death caused by disease progression) within 8 weeks (+2-week window) of the first dose of study treatment. This analysis set will be the primary analysis set for efficacy endpoints. All response evaluations will be by cohort, and by treatment within cohort if more than 1 doses or dosing combinations are initiated for a particular indication cohort.

Pharmacokinetics Analysis Set

The PK analysis set is defined as patients from Stage 1 who have received at least one dose of FT-2102 and for whom it is possible to calculate at least one primary PK parameter (e.g. C_{max}, AUC_{last}).

Pharmacodynamics Analysis Set

The Pharmacodynamic analysis set is defined as all patients who received at least one dose of FT-2102 and have completed at least one pharmacodynamic assessment.

2.2. Protocol Violations

Major protocol violations, as determined by a de-identified review of the data, may result in the removal of a patient's data from the Response Evaluable population. The Sponsor will be responsible for producing the final protocol violation file (formatted as a Microsoft Excel file), this file will include a description of the protocol violation and clearly identify whether this violation warrants exclusion from the Response Evaluable population. This file will be finalized prior to database lock.

All protocol violations will be presented in a data listing.

3. GENERAL STATISTICAL METHODS

3.1. Sample Size Justification

This study will enroll up to approximately 200 patients.

A single-agent Safety Lead-in Period will be implemented that may enroll approximately 12 patients, which includes approximately 6 patients with glioma and 6 patients with solid tumors. Following successful completion of the Safety Lead-in Period, the study will then enroll 4 disease-specific cohorts examining FT-2102 as either a single agent or in combination. These cohorts include Cohort 1 (glioma) with 16-46 patients; Cohort 2 (HBC) with 21-78 patients; Cohort 3 (chondrosarcoma) with 16-46 patients; and Cohort 4 (IHCC) with 21-78 patients. There will be a fifth cohort of R132X IDH1 mutant solid tumors, non-CNS with up to 6 patients, single-agent only.

Cohort 1a, Cohort 2a, Cohort 3a (single-agent FT-2102)

Cohorts, 1a, 2a and 3a will employ an optimal Simon's 2-Stage design with a 1-sided alpha of 0.025, power of 80%, null hypothesis of 5% and alternative hypothesis of 25%. Stage 1 of these cohorts will evaluate 8 patients for efficacy over 4 treatment cycles; if there are 1 or more responses, Stage 2 will initiate with additional 15 patients. If there are 4 or more responses out of the total 23 patients, the null hypothesis of 5% will be rejected. If there is no response in Stage 1 with single-agent FT-2102, or if the null hypothesis is not rejected at the end of Stage 2, combination therapy may be evaluated.

Cohort 4a (single-agent FT-2102)

Cohort 4a employs an optimal Simon's 2-Stage design with a 1-sided alpha of 0.025, power of 80%, null hypothesis of 8% and alternative hypothesis of 35%. Stage 1 will evaluate 8 patients and if there are 2 or more responses Stage 2 will initiate with additional 14 patients. If there are 5 or more responses out of the total 22 patients, the null hypothesis of 8% will be rejected. If there is 0 or 1 response in Stage 1 with single-agent FT-2102, or if the null hypothesis is not rejected at the end of Stage 2, combination may be evaluated.

Combination Cohorts (1b, 2b, 3b, 4b)

If there is no response in Stage 1 with single-agent FT-2102, combination cohorts may be examined.

Cohort 1b and Cohort 3b

For Cohorts 1b and 3b (combination therapy), an optimal Simon's 2-Stage design will be implemented with a 1-sided alpha of 0.025, 80% power, with a null hypothesis of 5% and alternative hypothesis of 25%. Stage 1 of each cohort will evaluate 8 patients for efficacy over 4 treatment cycles; if there are 1 or more responses, Stage 2 will initiate with

additional 15 patients. If there are 4 or more responses out of the total 23 patients, the null hypothesis of 5% will be rejected.

Cohort 2b

Cohort 2b employs an optimal Simon's 2-Stage design with a 1-sided alpha of 0.025, power of 80%, null hypothesis of 20% and alternative hypothesis of 40%. Stage 1 will evaluate 13 patients for efficacy; if there are 4 or more responses Stage 2 will initiate with an additional 42 patients. If there are 17 or more responses out of the total 55 patients, the null hypothesis of 20% will be rejected.

Cohort 4b

Cohort 4b employs an optimal Simon's 2-Stage design with a 1-sided alpha of 0.025, power of 80%, null hypothesis of 20% and alternative hypothesis of 40%. Stage 1 will evaluate 13 patients and if there are 4 or more responses Stage 2 will initiate with additional 42 patients. If there are 17 or more responses out of the total 55 patients, the null hypothesis of 20% will be rejected.

Cohort 5

Cohort 5, due to the diverse population, this is an exploratory cohort without pre-defined efficacy/futility determinations (n=6).

3.2. General Methods

Data will be summarized in the following groupings:

Group Description	Table Column Header
Cohort 1A: Glioma FT-2102	C1A Glioma SA
Cohort 1B: Glioma FT-2102 + Azacitidine	C1B Glioma Combo
Cohort 1: Glioma	C1 Glioma Overall
Cohort 2A: HBC FT-2102	C2A HBC SA
Cohort 2B: HBC FT-2102 + Nivolumab	C2B HBC Combo
Cohort 2: HBC	C2 HBC Overall
Cohort 3A: Chondrosarcoma FT-2102	C3A Chondro SA
Cohort 3B: Chondrosarcoma FT-2102 + Azacitidine	C3B Chondro Combo

Cohort 3: Chondrosarcoma	C3 Chondro Overall
Cohort 4A: Cholangiocarcinoma FT-2102	C4A Cholangio SA
Cohort 4B: Cholangiocarcinoma FT-2102 + Gemcitibine + Cisplatin	C4B Cholangio Combo
Cohort 4: Cholangiocarcinoma	C4 Cholangio Overall
Cohort 5: Other Solid Tumors FT-2102	C5 Other Tumors SA

All data listings that contain an evaluation date will contain a relative study day (Rel Day). Pre-treatment and on-treatment study days are numbered relative to the day of the first dose of study medication which is designated as Day 1. The preceding day is Day -1, the day before that is Day -2, etc.

All output will be incorporated into Microsoft Word files, sorted and labeled according to the International Conference on Harmonisation (ICH) recommendations, and formatted to the appropriate page size(s).

Tabulations will be produced for appropriate demographic, baseline, efficacy, pharmacokinetic, and safety parameters. For categorical variables, summary tabulations of the number and percentage of patients within each category (with a category for missing data) of the parameter will be presented. For continuous variables, the number of patients, mean, median, standard deviation (SD), minimum, and maximum values will be presented. Time-to-event data will be summarized using Kaplan-Meier methodology using 25^{th}, 50^{th} (median), and 75^{th} percentiles with associated 2-sided 95% confidence intervals, as well as percentage of censored observations. Minimum and maximum values will be presented to the same decimal precision as the raw values, mean and median values to one more, and the standard deviation to two more decimal places that the raw values. And for categorical: all percentages will be presented to one decimal place.

Formal statistical hypothesis testing will be performed on overall response rate with all tests conducted at the 1-sided, 0.025 level of significance. Summary statistics will be presented, as well as confidence intervals on selected parameters, as described in the sections below.

Aside from the primary endpoint of overall response rate, other data analyses are descriptive and will be summarized using descriptive statistics noted above.

Relevant Output

Listing 16.2.0.1 Treatment Codes Applicable to Tables and Listings

3.3. Computing Environment

All descriptive statistical analyses will be performed using SAS statistical software Version 9.3 or higher, unless otherwise noted. Medical history and adverse events will

be coded using the Medical Dictionary for Regulatory Activities (MedDRA) Version 21.0. Concomitant medications and prior therapies will be coded using the World Health Organization (WHO) Drug Dictionary Version Global B3 format March 2018.

3.4. Baseline Definitions

For all analyses, baseline will be defined as the most recent measurement prior to the first administration of study drug.

3.5. Methods of Pooling Data

Data will be pooled for the Phase 1b and Phase 2 patients who are in the EE Population who are dosed at the same level for purposes of the test of the primary endpoint and other efficacy analyses.

Data for each cohort will be pooled for patients within treatment regimen. Data from all study sites and countries will be pooled together.

3.6. Adjustments for Covariates

No formal statistical analyses that adjust for possible covariate effects are planned. Ad hoc analyses examining covariate effects may be performed.

3.7. Multiple Comparisons/Multiplicity

No adjustments to the overall alpha of this study have been made. Each cohort is independent and will be tested with a single primary endpoint at the 1-sided 0.025 level, so the control of false positives is maintained within each cohort.

3.8. Subpopulations

Selected analyses will be performed by subgroup. Some subgroups only apply to selected cohorts. The following subgroups will be examined:

- Gender
- Caucasian vs. other races
- Asian vs. other races (Cohorts 2 and 4 only)
- Baseline ECOG 0/1 vs 2
- Baseline Child-Pugh Score (Cohorts 2 and 4 only)
- Age (18-40, 41-59, ≥60)
- Prior surgery only vs. prior surgery and other anti-cancer therapies

- Number of prior regimens (1, 2, 3, >3)
- Prior IDH1 therapy (yes, no) (combination therapy patients only- Cohort 1b, 2b, 3b, 4b)
- Prior temozolomide (yes, no) (Cohort 1 only)
- Prior procarbazine/CCNU/vincristine (yes, no) (Cohort 1 only)
- Prior radiation therapy (yes, no) (Cohort 1 only)
- Baseline steroids (yes, no) (Cohort 1 only)
- Baseline tumor grade (I or II, III, IV)
- Baseline tumor grade (Stage I, II, or III vs. Stage IV)
- Hepatitis B positive (yes, no) (Cohort 2 only)
- Hepatitis C positive (yes, no) (Cohort 2 only)
- Hepatitis B or C positive (yes, no) (Cohort 2 only)
- Prior gemcitabine-based therapy (yes, no) (Cohorts 2 and 4 only)
- Prior nivolumab or pembrolizumab therapy (yes, no) (Cohort 2)
- Cancer diagnosis (hepatocellular carcinoma, gallbladder carcinoma, IHCC, extrahepatic cholangiocarcinoma, biliary tumor NOS) (Cohort 2 only)
- Glioma diagnosis (Cohort 1 only). Diagnosis subgroupings to be determined based on the data from enrolled patients.
- Chondrosarcoma diagnosis (differentiated, mesenchymal, clear cell, unknown/ other) (Cohort 3 only)
- IDH1 mutation subtype (R132H, R132C, other R132 subtypes)
- Co-mutations. Subgroupings to be determined based on the data from enrolled patients.
- Responder status (best overall response of MR or better vs. non-responder)
- Tumor imaging method (enhancing, non-enhancing). Enhancing = yes if: Screening imaging assessment was performed via T1 MRI post contrast. Otherwise enhancing = no.

3.9. Withdrawals, Dropouts, Loss to Follow-up

Patients who drop out from Phase 1b who are not able to be included in the DLT evaluable population will be replaced to fill the required numbers of patients to evaluate each dose level per the study protocol.

As the sample size for Phase 2 is based on the Response Evaluable Population, if patients drop out before they become evaluable for Response they will be replaced.

3.10. Missing, Unused, and Spurious Data

In general, there will be no substitutions made to accommodate missing data points. All data recorded on the case report form will be included in data listings that will accompany the clinical study report.

Handling of values listed as BLQ for PK and PD data is described in Section 4.4.

Missing partial date of adverse events or concomitant medications will be imputed for purposes of classification as treatment emergent or concomitant, but in data listings the reported date, not the imputed date, will be presented. In cases where a date part is missing, a relday will not be calculated and presented in the listing; the relday will be missing.

Adverse events

When tabulating adverse event data, partial dates will be handled as follows. If the day of the month is missing, the onset day will be set to the first day of the month unless it is the same month and year as study treatment. In this case, in order to conservatively report the event as treatment-emergent, the onset date will be assumed to be the date of treatment. If the onset day and month are both missing, the day and month will be assumed to be January 1, unless the event occurred in the same year as the study treatment. In this case, the event onset will be coded to the day of treatment in order to conservatively report the event as treatment-emergent. A missing onset date will be coded as the day of treatment.

Concomitant medications

For records with a missing medication start and/or stop date, the following procedure will be employed for use in determining whether the medication is prior or concomitant:

- Medication start dates with a missing day and non-missing month will be assumed to occur on the first day of the non-missing month, except for medications occurring in the first month of dosing, in which case the date will be the first day of dosing.

- Medication start dates with missing month will be assumed to occur on the first day of the non-missing year (i.e., January 1), except for medications

occurring in the first year of dosing, in which case the date will be the first day of dosing.

- Medication start year is unknown, the date will not be imputed.
- Medications that are not ongoing and have a medication stop date with a missing day and non-missing month will be assumed to occur on the last day of the non-missing month.
- Medications that are not ongoing and have a medication stop date with a missing month will be assumed to occur on the last day of the non-missing year (ie, December 31).
- Medications that are not ongoing and have a medication stop date with a missing year will be assumed to occur on the first day of dosing.

3.11. Visit Windows

It is expected that all visits should occur according to the protocol schedule. All data will be tabulated per the evaluation visit as recorded on the CRF even if the assessment is outside of the visit window. In data listings, the relative day of all dates will be presented.

3.12. Interim Analyses

Within each cohort, Optimal Simon's 2-Stage designs are employed for both the single agent treatment and also for combination treatment. There are different hypotheses being tested for each cohort, and thus there are different stopping rules for the cohorts, which are described below. All of the following interim analyses are to be conducted on the Response Evaluable Set.

Combination therapy in cohorts 1-4 may also be examined in the event that the single agent cohort passes the futility analysis and the enrollment in the single agent cohort is completed following review by the SRC (below).

<u>Cohort 1a, Cohort 2a, Cohort 3a (single-agent FT-2102)</u>

Cohorts 1a, 2a, and 3a will employ an optimal Simon's 2-Stage design testing a null hypothesis of 5% response versus alternative hypothesis of 25% response. Stage 1 will evaluate 8 patients for efficacy over 4 treatment cycles; if there are 1 or more responses, Stage 2 will initiate with additional 15 patients. If there is no response in Stage 1 with single-agent FT-2102, combination therapy will be evaluated (Cohorts 1b, 2b, 3b).

<u>Cohort 4a (single-agent FT-2102)</u>

Cohort 4a employs an optimal Simon's 2-Stage design testing a null hypothesis of 8% response versus the alternative hypothesis of 35% response. Stage 1 will evaluate 8 patients and if there are 2 or more responses Stage 2 will initiate with additional 14 patients. If there is 0 or 1 response in Stage 1 with single-agent FT-2102, combination therapy will be evaluated (Cohort 4b).

Cohort 1b and Cohort 3b

For Cohorts 1b and 3b (combination therapy), an optimal Simon's 2-Stage design will be implemented to test a null hypothesis of 5% response versus the alternative hypothesis of 25% response. Stage 1 of each cohort will evaluate 8 patients for efficacy over 4 treatment cycles; if there are 1 or more responses, Stage 2 will initiate with additional 15 patients. If there is no response in Stage 1, enrollment will cease, and the null hypothesis will fail to be rejected.

Cohorts 2b and 4b

Cohorts 2b and 4b employ an optimal Simon's 2-Stage design to test a null hypothesis of 20% response versus alternative hypothesis of 40% response. Stage 1 will evaluate 13 patients for efficacy; if there are 4 or more responses Stage 2 will initiate with an additional 42 patients. If there are 3 or fewer responses, enrollment will cease, and the null hypothesis will fail to be rejected.

4. STUDY ANALYSES

4.1. Patient Disposition

Patient disposition will be tabulated and include the number screened, the number treated in total, the number dosed with FT-2102, the number dosed with azacitidine, nivolumab, or gemcitabine/cisplatin, the number in each patient population for analysis, the number of patients who are ongoing in treatment FT-2102 or, if they have ceased treatment with FT-2102, the reason for stopping. The number of patients who are ongoing in the study (whether on treatment or off treatment still in follow up), or if they have ceased study participation the reason for stopping participation in the study. Separate tables will be run for each cohort and within each cohort, tables will be tabulated by single agent therapy and combination therapy.

A by-patient data listing of study disposition information will be presented by cohort and dose level.

Relevant Output

Table 14.1.1	Patient Enrollment and Disposition (Cohort 1)
Table 14.1.1	Patient Enrollment and Disposition (Cohort 2)
Table 14.1.1	Patient Enrollment and Disposition (Cohort 3)
Table 14.1.1	Patient Enrollment and Disposition (Cohort 4)
Table 14.1.1	Patient Enrollment and Disposition (Cohort 5)
Listing 16.2.1.1	Study Completion Status
Listing 16.2.1.2	Pre-Screening Consent
Listing 16.2.1.3	Enrollment
Listing 16.2.2.1	Inclusion and Exclusion Criteria
Listing 16.2.2.2	Protocol Violations
Listing 16.2.3.1	Analysis Sets

4.2. Demographics and Baseline Disease Characteristics

Demographics, baseline characteristics, prior anti-cancer therapies, and IDH1 and other mutation data, will be summarized for each cohort by treatment regimen for the Safety and Response Evaluable Populations using descriptive statistics.

BMI will be calculated as: $\text{weight (kg)} / (\text{height (m)})^2$

Medical history information will be summarized for the Safety Population. Baseline Child-Pugh score and category (A, B, C) will be summarized within the baseline disease characteristics table for Cohorts 2 and 4. Hepatitis B and C status (positive or negative) will also be summarized within the baseline disease characteristics table. No formal statistical comparisons will be performed.

Medical history data will be coded via MedDRA. Prior anti-cancer therapies data will be coded via WHODrug.

In summarization of time since initial cancer diagnosis and months since recurrence, if a partial date is given in the data, month and day will be imputed as January and 01, respectively. Time since cancer diagnosis and months since recurrence will be derived as: informed consent date- date (diagnosis or recurrence) +1.

All demographic and baseline data for each patient will be provided in data listings. Prior radiotherapy and major surgical tumor resections will only be listed; they will not be summarized.

Relevant Output

Table 14.1.2.1a	Demographics and Baseline Characteristics (Cohort 1, Response Evaluable Population)
Table 14.1.2.1b	Demographics and Baseline Characteristics (Cohort 2, Response Evaluable Population)
Table 14.1.2.1c	Demographics and Baseline Characteristics (Cohort 3, Response Evaluable Population)
Table 14.1.2.1d	Demographics and Baseline Characteristics (Cohort 4, Response Evaluable Population)
Table 14.1.2.1e	Demographics and Baseline Characteristics (Cohort 5, Response Evaluable Population)
Table 14.1.2.2a	Demographics and Baseline Characteristics (Cohort 1, Safety Population)
Table 14.1.2.2b	Demographics and Baseline Characteristics (Cohort 2, Safety Population)
Table 14.1.2.2c	Demographics and Baseline Characteristics (Cohort 3, Safety Population)
Table 14.1.2.2d	Demographics and Baseline Characteristics (Cohort 4, Safety Population)
Table 14.1.2.2e	Demographics and Baseline Characteristics (Cohort 5, Safety Population)
Table 14.1.3.1a	Baseline Disease Characteristics (Cohort 1, Response Evaluable Population)
Table 14.1.3.1b	Baseline Disease Characteristics (Cohort 2, Response Evaluable Population)
Table 14.1.3.1c	Baseline Disease Characteristics (Cohort 3, Response Evaluable Population)
Table 14.1.3.1d	Baseline Disease Characteristics (Cohort 4, Response Evaluable Population)

Table 14.1.3.1e	Baseline Disease Characteristics (Cohort 5, Response Evaluable Population)
Table 14.1.3.2a	Baseline Disease Characteristics (Cohort 1, Safety Population)
Table 14.1.3.2b	Baseline Disease Characteristics (Cohort 2, Safety Population)
Table 14.1.3.2c	Baseline Disease Characteristics (Cohort 3, Safety Population)
Table 14.1.3.2d	Baseline Disease Characteristics (Cohort 4, Safety Population)
Table 14.1.3.2e	Baseline Disease Characteristics (Cohort 5, Safety Population)
Table 14.1.4.1a	IDH1 and Other Mutations (Cohort 1, Response Evaluable Population)
Table 14.1.4.1b	IDH1 and Other Mutations (Cohort 2, Response Evaluable Population)
Table 14.1.4.1c	IDH1 and Other Mutations (Cohort 3, Response Evaluable Population)
Table 14.1.4.1d	IDH1 and Other Mutations (Cohort 4, Response Evaluable Population)
Table 14.1.4.1e	IDH1 and Other Mutations (Cohort 5, Response Evaluable Population)
Table 14.1.4.2a	IDH1 and Other Mutations (Cohort 1, Safety Population)
Table 14.1.4.2b	IDH1 and Other Mutations (Cohort 2, Safety Population)
Table 14.1.4.2c	IDH1 and Other Mutations (Cohort 3, Safety Population)
Table 14.1.4.2d	IDH1 and Other Mutations (Cohort 4, Safety Population)
Table 14.1.4.2e	IDH1 and Other Mutations (Cohort 5, Safety Population)
Table 14.1.5.1a	Prior Therapies (Cohort 1, Response Evaluable Population)
Table 14.1.5.1b	Prior Therapies (Cohort 2, Response Evaluable Population)
Table 14.1.5.1c	Prior Therapies (Cohort 3, Response Evaluable Population)
Table 14.1.5.1d	Prior Therapies (Cohort 4, Response Evaluable Population)
Table 14.1.5.1e	Prior Therapies (Cohort 5, Response Evaluable Population)
Table 14.1.5.2a	Prior Therapies (Cohort 1, Safety Population)
Table 14.1.5.2b	Prior Therapies (Cohort 2, Safety Population)
Table 14.1.5.2c	Prior Therapies (Cohort 3, Safety Population)
Table 14.1.5.2d	Prior Therapies (Cohort 4, Safety Population)
Table 14.1.5.2e	Prior Therapies (Cohort 5, Safety Population)
Table 14.1.6a	Medical History (Cohort 1, Safety Population)
Table 14.1.6b	Medical History (Cohort 2, Safety Population)
Table 14.1.6c	Medical History (Cohort 3, Safety Population)

Table 14.1.6d	Medical History (Cohort 4, Safety Population)
Table 14.1.6e	Medical History (Cohort 5, Safety Population)

Listing 16.2.4.1	Demographics and Baseline Information
Listing 16.2.4.2	Baseline Disease Data and Cancer Diagnosis
Listing 16.2.4.3	IDH1 Mutation and Other Mutations
Listing 16.2.4.4	Medical History
Listing 16.2.4.5	Prior Anti-Cancer Therapies
Listing 16.2.4.6	Prior Radiotherapy
Listing 16.2.4.7	Major Surgical Tumor Resections
Listing 16.2.4.8	Child-Pugh Score
Listing 16.2.4.9	Hepatitis B and C
Listing 16.2.4.10	Archival Tumor Tissue

4.3. Efficacy Evaluations

4.3.1. Disease Response and Survival Analyses

In general, efficacy analyses will be conducted using the Response Evaluable population, with the exception of overall survival and the figure of time on treatment, which will be conducted on both the Response Evaluable and the Safety Population.

Best overall response and overall response rate will be summarized by cohort and treatment regimen (single agent or combination therapy) in the disease response assessment table. Disease response assessment will be further examined by subgroups, as described in Section 3.8. PFS, TTP, DOR, and TTR will be summarized by cohort and treatment regimen in another table. OS will be summarized for both the Response Evaluable and the Safety populations.

Time to event endpoints (OS, PFS, DOR) will be expressed as the number of weeks from first dose to the event and will be analyzed using Kaplan-Meier (KM) methods for each cohort. Censoring for each time to event endpoint is defined in Section 1.4.5. The median time to event will be presented along with the 95% confidence intervals, 1st and 3rd quartiles, and minimum and maximum values. The estimated probability of OS and PFS over time will be plotted as KM curves for each cohort and treatment regimen. The probability of survival for each cohort at 3, 6, 9, and 12 months will also be estimated using KM methods.

A plot of time on treatment (aka “swim plot”) will be created for patients in the Safety Population to visualize the time on treatment. The plot will be color coded by best overall response. Time of first response (earliest response assessment where overall response was MR or better) will be annotated on the plot. Patients who are still receiving treatment with FT-2102 will be indicated with arrows at the end of the bar. Patients who are no longer receiving treatment with FT-2102 will have the reason for stopping FT-

2102 treatment annotated at the end of the bar. One plot will be created for each cohort and treatment regimen.

A waterfall plot will be produced for the Response Evaluable population to depict the best percentage change in the total tumor burden while on treatment. One bar will represent each patient, and they will be sorted by maximum percentage to least percentage. Each bar will be color coded by best overall response. One plot will be created for each cohort and treatment regimen. Total tumor burden is calculated as the sum of the longest diameter of each target lesion for RECIST assessments. Total tumor burden is calculated as the sum of the product of the diameters (longest diameter x perpendicular measurement) for all measurable lesions for RANO assessments. If a patient in Cohort 5 is evaluated by Cheson criteria, total tumor burden is calculated as the sum of the product diameters (longest diameter x perpendicular measurement) for all target lesions. Percent change for each follow up assessment is then calculated as the percent increase or decrease in total tumor burden from the screening imaging assessment.

Serum AFP, CA19-9, CEA are biomarkers indicative of response in Cohorts 2 and 4. They are not assessed in other cohorts. These markers will be summarized descriptively for the Response Evaluable population by cohort and visit. Additionally, box and whisker plots will be created for each parameter by cohort, visit, and responder status to compare change in responders vs non-responders over time.

Relevant Output

Table 14.2.1a	Disease Response Assessment Overall and by Subgroup (Cohort 1, Response Evaluable Population)
Table 14.2.1b	Disease Response Assessment Overall and by Subgroup (Cohort 2, Response Evaluable Population)
Table 14.2.1c	Disease Response Assessment Overall and by Subgroup (Cohort 3, Response Evaluable Population)
Table 14.2.1d	Disease Response Assessment Overall and by Subgroup (Cohort 4, Response Evaluable Population)
Table 14.2.1e	Disease Response Assessment Overall and by Subgroup (Cohort 5, Response Evaluable Population)
Figure 14.2.2.1a	Best Percent Change from Baseline in Tumor Burden (Cohort 1 Single Agent, Response Evaluable Population)
Figure 14.2.2.2a	Best Percent Change from Baseline in Tumor Burden (Cohort 1 Combination Therapy, Response Evaluable Population)
Figure 14.2.2.1b	Best Percent Change from Baseline in Tumor Burden (Cohort 2 Single Agent, Response Evaluable Population)
Figure 14.2.2.2b	Best Percent Change from Baseline in Tumor Burden (Cohort 2 Combination Therapy, Response Evaluable Population)

Figure 14.2.5.6c	Kaplan-Meier Plot of Progression Free Survival (Cohort 3, Safety Population)
Figure 14.2.5.6d	Kaplan-Meier Plot of Progression Free Survival (Cohort 4, Safety Population)
Figure 14.2.5.6e	Kaplan-Meier Plot of Progression Free Survival (Cohort 5, Safety Population)
Table 14.2.6a	Serum AFP, CA19-9, CEA (Cohort 2, Response Evaluable Population)
Table 14.2.6b	Serum AFP, CA19-9, CEA (Cohort 4, Response Evaluable Population)
Figure 14.2.7a	Serum AFP, CA19-9, CEA (Cohort 2, Response Evaluable Population)
Figure 14.2.7b	Serum AFP, CA19-9, CEA (Cohort 4, Response Evaluable Population)
Listing 16.2.6.1	Target Lesions (RECIST)
Listing 16.2.6.2	Non-Target and New Lesions (RECIST)
Listing 16.2.6.3	Measurable Lesions (RANO)
Listing 16.2.6.4	Non-Measurable and New Lesions (RANO)
Listing 16.2.6.5	Response Assessment (RECIST)
Listing 16.2.6.6	Response Assessment (RANO and LGG RANO)
Listing 16.2.6.7	Response Assessment (Cheson)
Listing 16.2.6.8	Survival Status
Listing 16.2.6.9	Serum AFP, CA19-9, CEA

4.3.2. Quality of Life Assessment Analysis

The EQ-5D-5L is a validated assessment of the quality of life which consists of five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 5 levels of one's health state: no problems, slight problems, moderate problems, severe problems and extreme problems. The patient indicates his/her health state by selecting the most appropriate statement in each of the five dimensions. This decision results in a 1-digit number that expresses the level selected for that dimension. The digits for the five dimensions can be combined into a 5-digit number that describes the patient's health state.

EQ-5D-5L data will be summarized by nominal visit for the Response Evaluable Population. The number and percentage of patients reporting each score per dimension will be summarized, as well as the number reporting some problems on that dimension (score >1). The change from baseline in the number reporting some problems in each dimension will also be reported (raw and percent change). Furthermore, a stacked bar

chart will be produced to illustrate the EQ-5D-5L values. In the chart, the x axis will represent nominal visit (screening, cycle 3, and end of treatment) and the y axis will represent percentage. Each bar will add to 100% and be color coded to represent the percent of patients reporting each level (1-5) of problems within the dimension for that visit. A table below the figure will show the number of patients contributing data to each visit. A separate chart will be created for each of the dimensions. This figure will be created for each cohort and treatment regimen.

All EQ-5D-5L data will be listed.

Table 14.2.8a	EQ-5D-5L Summary (Cohort 1, Response Evaluable Population)
Table 14.2.8b	EQ-5D-5L Summary (Cohort 2, Response Evaluable Population)
Table 14.2.8c	EQ-5D-5L Summary (Cohort 3, Response Evaluable Population)
Table 14.2.8d	EQ-5D-5L Summary (Cohort 4, Response Evaluable Population)
Table 14.2.8e	EQ-5D-5L Summary (Cohort 5, Response Evaluable Population)
Figure 14.2.9a	EQ-5D-5L Quality of Life Assessment (Cohort 1, Response Evaluable Population)
Figure 14.2.9b	EQ-5D-5L Quality of Life Assessment (Cohort 2, Response Evaluable Population)
Figure 14.2.9c	EQ-5D-5L Quality of Life Assessment (Cohort 3, Response Evaluable Population)
Figure 14.2.9d	EQ-5D-5L Quality of Life Assessment (Cohort 4, Response Evaluable Population)
Figure 14.2.9e	EQ-5D-5L Quality of Life Assessment (Cohort 5, Response Evaluable Population)
Listing 16.2.6.10	EQ5D-5L Quality of Life Assessment

4.4. Pharmacokinetic and Pharmacodynamic Evaluations

Pharmacokinetic analyses will be conducted using the PK population. Pharmacodynamic analyses will be conducted on the 2-HG biomarker using the Pharmacodynamic population.

Evaluation of 2-HG has been done in a number of types of biological samples for this study: plasma, urine, and for glioma patients magnetic resonance spectroscopy (MRS) evaluation of 2-HG in tumor tissue, and cerebral spinal fluid. Each of these types of 2-HG evaluations will be summarized separately; they will not be combined. 2-HG will be summarized for each disease cohort and treatment regimen by actual value, change from baseline, and percent change by nominal visit. In such tables, unscheduled visit results will not be included. Furthermore, 2-HG will also be summarized by subgroup. Percent change from baseline will be plotted in a box plot where the x-axis will represent nominal visit and the y-axis will represent percent change from baseline, and separate boxes will be plotted for sample type (plasma, tumor tissue, CSF, urine). Separate figures will be produced for each cohort.

Pharmacokinetic variables will be calculated from the plasma concentration data using standard non-compartmental methods. The pharmacokinetic variables to be determined are summarized below:

Table 1 Pharmacokinetic Parameters for Analysis

Parameter	Description
AUC_{all}	Area under the concentration versus time curve from Time 0 (pre-dose) to the last quantifiable concentration ; calculated using the linear-log trapezoidal method.
AUC_{tau}	Area under the concentration versus time curve over the dosing interval at steady-state; calculated using the linear-log trapezoidal method.
C_{min}	The trough plasma concentration taken prior to a subsequent dose.
C_{max}	Maximum plasma concentration; the highest concentration observed during a dosage interval.
T_{max}	The time C_{max} was observed.

FT-2102 concentrations below the lower limit of quantitation (LLOQ) will be indicated by BLQ in the listings and will be treated as follows:

- For pre-dose samples prior to the FT-2102 administration: Concentrations that are BLQ or missing will be assigned a numerical value of zero for the calculation of AUC. Any anomalous concentration values observed at pre-dose will be included in the computation of AUC. If the pre-dose concentration is greater than 5% of C_{max}, the data will be evaluated on a case-by-case basis to determine if exclusion of the affected profile is warranted.

For all other BLQ concentrations: Any other BLQ concentrations will be assigned a value of zero if they precede quantifiable samples in the initial portion of the concentration-time profile. A BLQ value that occurs between quantifiable data points, especially prior to C_{max}, will be evaluated to determine if an assigned concentration of zero makes sense, or if exclusion of the data is warranted. Following C_{max}, BLQ values embedded between 2 quantifiable data points will be treated as missing when calculating AUC. If BLQ values occur at the end of the collection interval (after the last quantifiable concentration), these will be set to zero. If consecutive BLQ concentrations are followed by quantifiable concentrations in the terminal portion of the concentration curve, these quantified values will be excluded from the PK analysis by setting them to missing, unless otherwise warranted by the concentration-time profile.

Pharmacokinetic concentration data will be listed by patient including actual sampling times relative to dosing. Plasma concentrations will be summarized by disease cohort, treatment regimen, and nominal visit. The following descriptive statistics will be presented at each nominal time point: n, arithmetic mean, standard deviation, coefficient of variation (CV%), geometric mean, geometric standard deviation, geometric CV%, median, minimum and maximum values.

For each cohort, the individual plasma concentration versus actual time profiles for each patient, as well as the geometric mean plasma concentration versus nominal time profiles will be presented graphically on a linear-linear and log-linear scale.

The following PK parameters will be listed by patient and summarized by disease cohort, and treatment regimen. Descriptive statistics for calculated PK parameters will include: n, arithmetic mean, standard deviation, CV%, geometric mean, median, minimum and maximum values. No descriptive statistics will be presented for an individual PK parameter when fewer than three patients have values for that parameter.

All plasma and CSF (if any) concentration and pharmacodynamic data and the per-patient pharmacokinetic parameters will be displayed in data listings.

Table 14.2.10.1a	Summary of 2-HG, Change from Baseline, and Percent Change from Baseline (Cohort 1, PD Population)
Table 14.2.10.1b	Summary of 2-HG, Change from Baseline, and Percent Change from Baseline (Cohort 2, PD Population)
Table 14.2.10.1c	Summary of 2-HG, Change from Baseline, and Percent Change from Baseline (Cohort 3, PD Population)
Table 14.2.10.1d	Summary of 2-HG, Change from Baseline, and Percent Change from Baseline (Cohort 4, PD Population)
Table 14.2.10.1e	Summary of 2-HG, Change from Baseline, and Percent Change from Baseline (Cohort 5, PD Population)
Table 14.2.10.2a	Summary of 2-HG, Change from Baseline, and Percent Change from Baseline by Subgroup (Cohort 1, PD Population)
Table 14.2.10.2b	Summary of 2-HG, Change from Baseline, and Percent Change from Baseline by Subgroup (Cohort 2, PD Population)
Table 14.2.10.2c	Summary of 2-HG, Change from Baseline, and Percent Change from Baseline by Subgroup (Cohort 3, PD Population)
Table 14.2.10.2d	Summary of 2-HG, Change from Baseline, and Percent Change from Baseline by Subgroup (Cohort 4, PD Population)
Table 14.2.10.2e	Summary of 2-HG, Change from Baseline, and Percent Change from Baseline by Subgroup (Cohort 5, PD Population)
Figure 14.2.11.1a	Boxplot of Plasma 2-HG by Time Point (Cohort 1, PD Population)
Figure 14.2.11.1b	Boxplot of Plasma 2-HG by Time Point (Cohort 2, PD Population)
Figure 14.2.11.1c	Boxplot of Plasma 2-HG by Time Point (Cohort 3, PD Population)
Figure 14.2.11.1d	Boxplot of Plasma 2-HG by Time Point (Cohort 4, PD Population)
Figure 14.2.11.1e	Boxplot of Plasma 2-HG by Time Point (Cohort 5, PD Population)
Figure 14.2.11.2a	Boxplot of Urine 2-HG by Time Point (Cohort 1, PD Population)
Figure 14.2.11.2b	Boxplot of Urine 2-HG by Time Point (Cohort 2, PD Population)
Figure 14.2.11.2c	Boxplot of Urine 2-HG by Time Point (Cohort 3, PD Population)
Figure 14.2.11.2d	Boxplot of Urine 2-HG by Time Point (Cohort 4, PD Population)
Figure 14.2.11.2e	Boxplot of Urine 2-HG by Time Point (Cohort 5, PD Population)

Figure 14.2.14.2a	Geometric Mean FT-2102 Plasma Concentration over Log-Time (Cohort 1, PK Population)
Figure 14.2.14.2b	Geometric Mean FT-2102 Plasma Concentration over Log-Time (Cohort 2, PK Population)
Figure 14.2.14.2c	Geometric Mean FT-2102 Plasma Concentration over Log-Time (Cohort 3, PK Population)
Figure 14.2.14.2d	Geometric Mean FT-2102 Plasma Concentration over Log-Time (Cohort 4, PK Population)
Figure 14.2.14.2e	Geometric Mean FT-2102 Plasma Concentration over Log-Time (Cohort 5, PK Population)
Figure 14.2.15a	FT-2102 Geometric Mean Plasma Concentration over Nominal Time (All Patients on Single Agent Therapy, PK Population)
Figure 14.2.15b	FT-2102 Geometric Mean Plasma Concentration over Nominal Time (Cohort 1, PK Population)
Figure 14.2.15c	FT-2102 Geometric Mean Plasma Concentration over Nominal Time (Cohort 2, PK Population)
Figure 14.2.15d	FT-2102 Geometric Mean Plasma Concentration over Nominal Time (Cohort 3, PK Population)
Figure 14.2.15e	FT-2102 Geometric Mean Plasma Concentration over Nominal Time (Cohort 4, PK Population)
Figure 14.2.15f	FT-2102 Geometric Mean Plasma Concentration over Nominal Time (Cohort 5, PK Population)
Listing 16.2.5.4	Pharmacokinetic Concentrations
Listing 16.2.5.5	Pharmacokinetic Parameters
Listing 16.2.6.11	2-HG MRS Assessments
Listing 16.2.6.12	Archival Tumor Tissue and Tumor Biopsy
Listing 16.2.6.13	Pharmacogenomics Samples

4.5. Safety Analyses

Safety analyses will be conducted using the Safety population. In tables summarizing data by cycle, only cycles with 3 or more patients having data for the cycle will be summarized.

4.5.1. Study Drug Exposure

Study drug exposure will be characterized by duration of exposure, amount of exposure, and percent compliance. Additionally, in the summary table containing duration of exposure, the number of patients and events of the following types will be summarized: dose reduced, dose increased, dose held, drug withdrawn, and non-compliance. These parameters will be calculated over all for the study and summarized by cohort. Amount of exposure and percent compliance will also be calculated by cycle and tabulated. Additionally, these parameters will be listed, along with raw data from the exposure and drug accountability logs.

Duration of FT-2102 Exposure: Duration of study drug exposure to FT-2102 will be calculated as the number of days that patients were administered study drug, as determined below, and will be summarized by treatment group using descriptive statistics.

$$Duration\ of\ Study\ Drug\ Exposure = (Date\ of\ lastdose - Dateoffirstdose) + 1$$

Total assigned dose (mg): For each cycle, the total assigned dose will be calculated for each log line in the FT-2102 administration form as: total assigned dose= (assigned dose*1 (if frequency= QD) or assigned dose*2 if frequency=BID)*number of days comprising the log line (eg. End date-start date+1). To get the total assigned dose for the cycle, the sum of the log lines within the cycle will be calculated. To get the total assigned dose for the study, the sum of the total assigned dose for all cycles will be calculated.

Total dose not taken and not returned (mg): This will be calculated from the drug accountability log. This will be calculated by taking the number of pills dispensed (last cycle)-number of pills returned (this cycle)-doses taken per patient diary (this cycle). That yields the number of pills taken and not returned, to get the dose taken and not returned, multiply the number of pills taken and not returned by the pill strength.

Total dose taken (mg): for each cycle the total dose taken will be calculated based on the drug accountability log. The number of tablets dispensed times the tablet strength (50 or 150 mg) will yield the total dose dispensed and the number of tablets returned times the tablet strength will yield the total dose returned. Total dose taken equals total dose dispensed minus total dose returned minus total dose not taken and not returned. This will be calculated by cycle, and then the sum of all cycles will yield the total dose taken for the study.

Percent compliance: percent compliance will be calculated by cycle and overall for the study. It is calculated as the total assigned dose-total dose taken, divided by total assign

$$\textit{Percent compliance} = \frac{\textit{(total assigned dose – (total assigned dose-total dose taken))}}{\textit{total assigned dose}} * 100$$

For patients receiving combination therapy, the combination drugs are administered via IV or SC. Duration of treatment with combination agents and duration of total treatment including IV therapy and oral therapy (in days) will be presented by treatment group for the Safety and Response Evaluable populations, where duration of treatment is calculated as the end date minus the start date plus 1. Descriptive statistics (both continuous and categorical) will also be presented for the number of doses received for IV therapy. The number of patients who experienced dose interruptions will be tabulated, as well as the reason for the interruption (e.g., adverse event, other reason).

Dosing information for each patient will be presented in a data listing.

Relevant Output

Table 14.2.16.1a	Study Drug Exposure (Cohort 1, Response Evaluable Population)
Table 14.2.16.1b	Study Drug Exposure (Cohort 2, Response Evaluable Population)
Table 14.2.16.1c	Study Drug Exposure (Cohort 3, Response Evaluable Population)
Table 14.2.16.1d	Study Drug Exposure (Cohort 4, Response Evaluable Population)
Table 14.2.16.1e	Study Drug Exposure (Cohort 5, Response Evaluable Population)
Table 14.2.16.2a	Study Drug Exposure (Cohort 1, Safety Population)
Table 14.2.16.2b	Study Drug Exposure (Cohort 2, Safety Population)
Table 14.2.16.2c	Study Drug Exposure (Cohort 3, Safety Population)
Table 14.2.16.2d	Study Drug Exposure (Cohort 4, Safety Population)
Table 14.2.16.2e	Study Drug Exposure (Cohort 5, Safety Population)
Table 14.2.17a	Study Drug Exposure to Azacitidine (Cohort 1, Safety Population)
Table 14.2.17b	Study Drug Exposure to Nivolumab (Cohort 2, Safety Population)
Table 14.2.17c	Study Drug Exposure to Azacitidine (Cohort 3, Safety Population)
Table 14.2.17d	Study Drug Exposure to Gemcitabine and Cisplatin (Cohort 4, Safety Population)
Listing 16.2.5.1	FT-2102 Administration
Listing 16.2.5.2	Drug Accountability
Listing 16.2.5.3	Azacitidine, Nivolumab, Cisplatin, and Gemcitibine Administration

4.5.2. Adverse Events

All AEs will be coded using the MedDRA coding system and displayed in tables and data listings using system organ class (SOC) and preferred term.

Analyses of adverse events will be performed for those events that are considered treatment-emergent. A treatment-emergent adverse event (TEAE) is an AE that begins or worsens in the period from the first dose of study treatment to 28 days after the last dose of study drug. Study drug is defined as FT-2102 or, for patients assigned to receive combination therapy, azacitidine, nivolumab, gemcitabine, or cisplatin.

Adverse events are summarized by patient incidence rates; therefore, in any tabulation, a patient contributes only once to the count for a given adverse event, SOC, or preferred term.

The number and percentage of patients with any treatment-emergent adverse event, with any treatment-emergent adverse event assessed by the Investigator as related to treatment (definite, probable, or possible relationship), and with any serious adverse event will be summarized by treatment group and overall. In these tabulations, each patient will contribute only once (i.e., the most related occurrence or the most intense occurrence) to each of the incidence rates in the descriptive analysis, regardless of the number of episodes.

An additional summary of TEAEs will be produced in which MedDRA PTs are presented, sorted from most frequent to least.

No formal hypothesis-testing analysis of adverse event incidence rates will be performed.

All adverse events gathered in the clinical database, whether treatment emergent or not, will be listed in patient data listings.

By-patient listings also will be provided for the following: patient deaths, serious adverse events, adverse events leading to withdrawal, and dose-limiting toxicities.

Relevant Output

Table 14.3.1.1a	Summary of Treatment-Emergent Adverse Events, Overall and by Dose Group (Cohort 1, Safety Population)
Table 14.3.1.1b	Summary of Treatment-Emergent Adverse Events, Overall and by Dose Group (Cohort 2, Safety Population)
Table 14.3.1.1c	Summary of Treatment-Emergent Adverse Events, Overall and by Dose Group (Cohort 3, Safety Population)
Table 14.3.1.1d	Summary of Treatment-Emergent Adverse Events, Overall and by Dose Group (Cohort 4, Safety Population)
Table 14.3.1.1e	Summary of Treatment-Emergent Adverse Events, Overall and by Dose Group (Cohort 5, Safety Population)
Table 14.3.1.a	Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (All Patients Receiving Single Agent Therapy, Safety Population)

Table 14.3.1.b	Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (All Patients Receiving Combination Therapy, Safety Population)
Table 14.3.1.c	Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (All Patients, Safety Population)
Table 14.3.1.d	Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (Cohort 1, Safety Population)
Table 14.3.1.e	Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (Cohort 2, Safety Population)
Table 14.3.1.2f	Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (Cohort 3, Safety Population)
Table 14.3.1.g	Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (Cohort 4, Safety Population)
Table 14.3.1.h	Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (Cohort 5, Safety Population)
Table 14.3.1.3a	Treatment-Emergent Adverse Events Related to FT-2102 by MedDRA System Organ Class and Preferred Term (Cohort 1, Safety Population)
Table 14.3.1.3b	Treatment-Emergent Adverse Events Related to FT-2102 by MedDRA System Organ Class and Preferred Term (Cohort 2, Safety Population)
Table 14.3.1.3c	Treatment-Emergent Adverse Events Related to FT-2102 by MedDRA System Organ Class and Preferred Term (Cohort 3, Safety Population)
Table 14.3.1.3d	Treatment-Emergent Adverse Events Related to FT-2102 by MedDRA System Organ Class and Preferred Term (Cohort 4, Safety Population)
Table 14.3.1.3e	Treatment-Emergent Adverse Events Related to FT-2102 by MedDRA System Organ Class and Preferred Term (Cohort 5, Safety Population)
Table 14.3.1.4a	Severe Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (Cohort 1, Safety Population)
Table 14.3.1.4b	Severe Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (Cohort 2, Safety Population)
Table 14.3.1.4c	Severe Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (Cohort 3, Safety Population)
Table 14.3.1.4d	Severe Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (Cohort 4, Safety Population)

Table 14.3.1.4e	Severe Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (Cohort 5, Safety Population)
Table 14.3.1.5a	Severe Treatment-Emergent Adverse Events Related to FT-2102 by MedDRA System Organ Class and Preferred Term (Cohort 1, Safety Population)
Table 14.3.1.5b	Severe Treatment-Emergent Adverse Events Related to FT-2102 by MedDRA System Organ Class and Preferred Term (Cohort 2, Safety Population)
Table 14.3.1.5c	Severe Treatment-Emergent Adverse Events Related to FT-2102 by MedDRA System Organ Class and Preferred Term (Cohort 3, Safety Population)
Table 14.3.1.5d	Severe Treatment-Emergent Adverse Events Related to FT-2102 by MedDRA System Organ Class and Preferred Term (Cohort 4, Safety Population)
Table 14.3.1.5e	Severe Treatment-Emergent Adverse Events Related to FT-2102 by MedDRA System Organ Class and Preferred Term (Cohort 5, Safety Population)
Table 14.3.1.6a	TEAEs by MedDRA Preferred Term (Cohort 1, Safety Population)
Table 14.3.1.6b	TEAEs by MedDRA Preferred Term (Cohort 2, Safety Population)
Table 14.3.1.6c	TEAEs by MedDRA Preferred Term (Cohort 3, Safety Population)
Table 14.3.1.6d	TEAEs by MedDRA Preferred Term (Cohort 4, Safety Population)
Table 14.3.1.6e	TEAEs by MedDRA Preferred Term (Cohort 5, Safety Population)
Table 14.3.2.1	Listing of Deaths
Table 14.3.2.2	Listing of Serious Adverse Events
Table 14.3.2.3	Listing of Adverse Events Resulting in Drug Interruptions or Withdrawals
Table 14.3.2.4	Listing of Dose-Limiting Toxicities
Listing 16.2.7.1	Adverse Events by Patient and Verbatim Term
Listing 16.2.7.2	Adverse Events by Patient and MedDRA System Organ Class and Preferred Term
Listing 16.2.7.3	Adverse Events by MedDRA System Organ Class, Preferred Term, Cohort, and Patient

4.5.3. Laboratory Data

Clinical laboratory values (including hematology, coagulation, chemistry, and urinalysis) will be expressed in SI units. CTCAE v 4.03 grading will be applied to laboratory values (for laboratory tests that are graded by CTCAE). In cases where a laboratory reports only hematology differentials in percentage, the absolute values may be derived

programmatically for reporting. The derivation of the absolute value would be calculated by taking the percent of the absolute WBC value.

The actual value and change from baseline to each on-study evaluation will be summarized for each clinical laboratory parameter, including hematology and clinical chemistry. In the event of repeat values, the last non-missing value per study day/time will be used. Unscheduled laboratory draws will not be included in these summaries. Coagulation labs are only drawn pre-treatment, and so will be combined with the hematology table for applicable visits.

Shifts from baseline to worst CTCAE grade experienced on study will be presented. In cases where CTCAE grades may be bi-directional (i.e., sodium, potassium), shifts to highest value and lowest value will be presented. Unscheduled laboratory draws will be included in the consideration of worst value on study.

A separate summary of liver function test abnormalities will be produced, based on the FDA's guidance for industry on drug induced liver injury (June 2009), in addition to the summaries described above. The number and percentage of patients experiencing the following abnormalities will be summarized for the Safety analysis set. A supportive listing of this data will also be produced illustrating which values have received flags applied to this table.

Clinical Laboratory Parameter	Category
ALT	>3 × ULN; >5 × ULN; >10 × ULN; >20 × ULN
AST	>3 × ULN; >5 × ULN; >10 × ULN; >20 × ULN
AST or ALT	>3 × ULN; >5 × ULN; >10 × ULN; >20 × ULN
Total Bilirubin (TBL)	>1.5 × ULN; ≥2 × ULN
ALP	>2.5 × ULN; >5 x ULN
Concurrent AST, ALT and Total Bilirubin	(ALT or AST >3 x ULN) and (TBL >1.5 x ULN); (ALT or AST >3 x ULN) and (TBL >2 x ULN)
Concurrent AST, ALT and Total Bilirubin without ALP abnormality	(ALT or AST >3 x ULN) and (TBL >1.5 x ULN); (ALT or AST >3 x ULN) and (TBL >2 x ULN)
ALT>3 x ULN or AST>3 x ULN with Concurrent report of selected TEAEs during study	(ALT > 3 x ULN) or (AST >3 x ULN and with TEAEs*

*Selected TEAEs include nausea, vomiting, anorexia, abdominal pain, abdominal discomfort, fatigue, jaundice, pruritus, chromaturia, and feces discolored.

Concurrent test values are defined as post-baseline values measured within +/- 7 days of test dates for the related parameters.

All laboratory data will be provided in data listings, and will be flagged with CTCAE grade if applicable, and H or L if above or below the normal limit.

Subset listings will be presented for all abnormal laboratory values and laboratory values with CTCAE severity grade 3 or 4.

Relevant Output

Table 14.3.4.1	Listing of Abnormal Laboratory Values
Table 14.3.4.2	Listing of Laboratory Values with CTCAE Severity ≥Grade 3
Table 14.3.4.3	Listing of Liver Function Tests of Potential Concern
Table 14.3.5.1a	Summary and Change from Baseline for Hematology and Coagulation Parameters by Time Point, Overall and by Dose Group (Cohort 1, Safety Population)
Table 14.3.5.1b	Summary and Change from Baseline for Hematology and Coagulation Parameters by Time Point, Overall and by Dose Group (Cohort 2, Safety Population)
Table 14.3.5.1c	Summary and Change from Baseline for Hematology and Coagulation Parameters by Time Point, Overall and by Dose Group (Cohort 3, Safety Population)
Table 14.3.5.1d	Summary and Change from Baseline for Hematology and Coagulation Parameters by Time Point, Overall and by Dose Group (Cohort 4, Safety Population)
Table 14.3.5.1e	Summary and Change from Baseline for Hematology and Coagulation Parameters by Time Point, Overall and by Dose Group (Cohort 5, Safety Population)
Table 14.3.5.2a	Summary and Change from Baseline for Chemistry Parameters by Time Point, Overall and by Dose Group (Cohort 1, Safety Population)
Table 14.3.5.2b	Summary and Change from Baseline for Chemistry Parameters by Time Point, Overall and by Dose Group (Cohort 2, Safety Population)
Table 14.3.5.2c	Summary and Change from Baseline for Chemistry Parameters by Time Point, Overall and by Dose Group (Cohort 3, Safety Population)
Table 14.3.5.2d	Summary and Change from Baseline for Chemistry Parameters by Time Point, Overall and by Dose Group (Cohort 4, Safety Population)
Table 14.3.5.2e	Summary and Change from Baseline for Chemistry Parameters by Time Point, Overall and by Dose Group (Cohort 5, Safety Population)
Table 14.3.6.1a	Shifts from Baseline to Worst Value on Study in Hematology and Coagulation, Overall and by Dose Group (Cohort 1, Safety Population)

Table 14.3.6.1b	Shifts from Baseline to Worst Value on Study in Hematology and Coagulation, Overall and by Dose Group (Cohort 2, Safety Population)
Table 14.3.6.1c	Shifts from Baseline to Worst Value on Study in Hematology and Coagulation, Overall and by Dose Group (Cohort 3, Safety Population)
Table 14.3.6.1d	Shifts from Baseline to Worst Value on Study in Hematology and Coagulation, Overall and by Dose Group (Cohort 4, Safety Population)
Table 14.3.6.1e	Shifts from Baseline to Worst Value on Study in Hematology and Coagulation, Overall and by Dose Group (Cohort 5, Safety Population)
Table 14.3.6.2a	Shifts from Baseline to Worst Value on Study in Chemistry, Overall and by Dose Group (Cohort 1, Safety Population)
Table 14.3.6.2b	Shifts from Baseline to Worst Value on Study in Chemistry, Overall and by Dose Group (Cohort 2, Safety Population)
Table 14.3.6.2c	Shifts from Baseline to Worst Value on Study in Chemistry, Overall and by Dose Group (Cohort 3, Safety Population)
Table 14.3.6.2d	Shifts from Baseline to Worst Value on Study in Chemistry, Overall and by Dose Group (Cohort 4, Safety Population)
Table 14.3.6.2e	Shifts from Baseline to Worst Value on Study in Chemistry, Overall and by Dose Group (Cohort 5, Safety Population)
Table 14.3.7a	Summary of Liver Function Test Results (All Patients Receiving Single Agent Therapy, Safety Population)
Table 14.3.7b	Summary of Liver Function Test Results (Cohort 1, Safety Population)
Table 14.3.7c	Summary of Liver Function Test Results (Cohort 2, Safety Population)
Table 14.3.7d	Summary of Liver Function Test Results (Cohort 3, Safety Population)
Table 14.3.7e	Summary of Liver Function Test Results (Cohort 4, Safety Population)
Table 14.3.7f	Summary of Liver Function Test Results (Cohort 5, Safety Population)
Listing 16.2.8.1	Laboratory Results: Hematology
Listing 16.2.8.2	Laboratory Results: Chemistry
Listing 16.2.8.3	Laboratory Results: Urinalysis
Listing 16.2.8.4	Laboratory Results: Coagulation
Listing 16.2.8.5	Laboratory Normal Ranges
Listing 16.2.8.6	Laboratory Results: Other Screening Tests and Pregnancy Tests

4.5.4. Vital Signs and Physical Examination

The actual value and change from baseline to each on-study evaluation will be summarized for vital signs.

Vital sign measurements will be presented for each patient in a data listing.

All physical examinations will be presented in a data listing.

Relevant Output

Table 14.3.8a	Summary and Change from Baseline for Vital Signs by Time Point, Overall and by Dose Group (Cohort 1, Safety Population)
Table 14.3.8b	Summary and Change from Baseline for Vital Signs by Time Point, Overall and by Dose Group (Cohort 2, Safety Population)
Table 14.3.8c	Summary and Change from Baseline for Vital Signs by Time Point, Overall and by Dose Group (Cohort 3, Safety Population)
Table 14.3.8d	Summary and Change from Baseline for Vital Signs by Time Point, Overall and by Dose Group (Cohort 4, Safety Population)
Table 14.3.8e	Summary and Change from Baseline for Vital Signs by Time Point, Overall and by Dose Group (Cohort 5, Safety Population)
Listing 16.2.9.1	Vital Signs
Listing 16.2.9.2	Physical Examinations

4.5.5. Electrocardiogram

Electrocardiogram results will be summarized descriptively, including the number and percentage of patients with normal, abnormal, and clinically significant abnormal results at baseline and each study visit.

In addition, the number and percentage of patient experiencing the following events will be tabulated and summarized by baseline QTcF (<450, ≥450 to ≤480, ≥481 to ≤500, ≥501):

Absolute change from baseline in QTcF at any time during study

- >30 to ≤60 msec
- >60 msec

Reaching a value in QTcF at any time during study

- ≥450 to ≤480 msec
- ≥481 to ≤500 msec
- ≥501 msec

A scatter plot will also be produced which plots a single dot for each patient in the Safety set. It will plot the patient's baseline QTcF on the x axis and the maximum post baseline QTcF on the Y axis. Reference lines will be shown at 450 on both axes. Electrocardiogram data for each patient will be provided in a data listing.

Relevant Output

Table 14.3.9a	Electrocardiogram Results (Cohort 1, Safety Population)
Table 14.3.9b	Electrocardiogram Results (Cohort 2, Safety Population)
Table 14.3.9c	Electrocardiogram Results (Cohort 3, Safety Population)
Table 14.3.9d	Electrocardiogram Results (Cohort 4, Safety Population)
Table 14.3.9e	Electrocardiogram Results (Cohort 5, Safety Population)
Table 14.3.10a	QTcF Shifts from Baseline (Single Agent Therapy, Safety Population)
Table 14.3.10b	QTcF Shifts from Baseline (Combination Therapy, Safety Population)
Figure 14.3.10.2a	Maximum Post Baseline QTcF vs Baseline QTcF (Single Agent Therapy, Safety Population)
Figure 14.3.10.2b	Maximum Post Baseline QTcF vs Baseline QTcF (Combination Therapy, Safety Population)
Listing 16.2.9.3	Electrocardiogram Results

4.5.6. Concomitant Medications and Procedures

Concomitant medication is a medication taken during the treatment period. It will be operationally defined as any medication with a start date prior to the date of the first dose of study treatment and continuing after the first dose of study treatment or with a start date between the dates of the first and last dose of study treatment. Any medication with a start date after the date of the last dose of study treatment will not be considered a concomitant medication. Any medication with a start and end date before the first dose of study treatment will be considered a prior medication. Concomitant medications will be coded using the WHO Drug Dictionary. Results will be tabulated by anatomic therapeutic class (ATC) and preferred term.

If there are parts of the start date or stop date of the medication, to determine whether the medication is prior or concomitant, rules described in Section 3.10 will be used.

The concomitant medications will be summarized by ATC classification and PT. For each medication term, the numbers and percentages of patients experiencing a medication with that term. If a patient reports the occurrence of a medication more than once, the medication is only counted once. These will be summarized for the Safety Population.

The use of prior and concomitant medications will be included in a by-patient data listing.

Concomitant procedures experienced while on study will not be summarized; they will be listed.

Systemic steroid use is gathered only for glioma patients as it is part of what is considered for RANO response assessment. This data will not be summarized; it will be listed.

Relevant Output

Table 14.3.11a	Concomitant Medications (Cohort 1, Safety Population)
Table 14.3.11b	Concomitant Medications (Cohort 2, Safety Population)
Table 14.3.11c	Concomitant Medications (Cohort 3, Safety Population)
Table 14.3.11d	Concomitant Medications (Cohort 4, Safety Population)
Table 14.3.11e	Concomitant Medications (Cohort 5, Safety Population)
Listing 16.2.9.4	Prior and Concomitant Medications
Listing 16.2.9.5	Concomitant Procedures
Listing 16.2.9.6	Systemic Steroid Dosing

4.5.7. Performance Status

The ECOG Scale of Performance Status describes a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). All ECOG performance status data will be listed.

Listing 16.2.9.7	ECOG Performance Status

5. EXPLORATORY ANALYSES

Quantification of ctDNA over time will be analyzed in an exploratory fashion. Phamacogenomics will also be analyzed in an exploratory manner. The results of these analyses may be presented in a separate report.

6. CHANGES TO PLANNED ANALYSES

All changes from procedures outlined in the protocol and procedures outlined in this SAP will be summarized in the study report. Decisions to deviate from planned analyses will be documented at the time they are made.

If any modifications in the experimental design, dosages, parameters, patient selection, or any other sections of the protocol are indicated or required, the Investigator will consult with the Sponsor before such changes are instituted. Modifications will be accomplished through formal amendments to this protocol by the Sponsor and approval from the appropriate Institutional Review Board (IRB) or Independent Ethics Committee (IEC).

7. REFERENCES

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8. CLINICAL STUDY REPORT APPENDICES

8.1. Statistical Tables and Figures to be Generated

Disposition/Demographics/Baseline (CSR Table Section 14.1)

Table 14.1.1a	Patient Enrollment and Disposition (Cohort 1)
Table 14.1.1b	Patient Enrollment and Disposition (Cohort 2)
Table 14.1.1c	Patient Enrollment and Disposition (Cohort 3)
Table 14.1.1d	Patient Enrollment and Disposition (Cohort 4)
Table 14.1.1e	Patient Enrollment and Disposition (Cohort 5)
Table 14.1.2.1a	Demographics and Baseline Characteristics (Cohort 1, Response Evaluable Population)
Table 14.1.2.1b	Demographics and Baseline Characteristics (Cohort 2, Response Evaluable Population)
Table 14.1.2.1c	Demographics and Baseline Characteristics (Cohort 3, Response Evaluable Population)
Table 14.1.2.1d	Demographics and Baseline Characteristics (Cohort 4, Response Evaluable Population)
Table 14.1.2.1e	Demographics and Baseline Characteristics (Cohort 5, Response Evaluable Population)
Table 14.1.2.2a	Demographics and Baseline Characteristics (Cohort 1, Safety Population)
Table 14.1.2.2b	Demographics and Baseline Characteristics (Cohort 2, Safety Population)
Table 14.1.2.2c	Demographics and Baseline Characteristics (Cohort 3, Safety Population)
Table 14.1.2.2d	Demographics and Baseline Characteristics (Cohort 4, Safety Population)
Table 14.1.2.2e	Demographics and Baseline Characteristics (Cohort 5, Safety Population)
Table 14.1.3.1	Baseline Disease Characteristics (Cohort 1, Response Evaluable Population)
Table 14.1.3.1b	Baseline Disease Characteristics (Cohort 2, Response Evaluable Population)
Table 14.1.3.1c	Baseline Disease Characteristics (Cohort 3, Response Evaluable Population)
Table 14.1.3.1d	Baseline Disease Characteristics (Cohort 4, Response Evaluable Population)
Table 14.1.3.1e	Baseline Disease Characteristics (Cohort 5, Response Evaluable Population)

Efficacy/Pharmacokinetic Results (CSR Table Section 14.2)

Table 14.2.1a	Disease Response Assessment Overall and by Subgroup (Cohort 1, Response Evaluable Population)
Table 14.2.1b	Disease Response Assessment Overall and by Subgroup (Cohort 2, Response Evaluable Population)
Table 14.2.1c	Disease Response Assessment Overall and by Subgroup (Cohort 3, Response Evaluable Population)
Table 14.2.1d	Disease Response Assessment Overall and by Subgroup (Cohort 4, Response Evaluable Population)
Table 14.2.1e	Disease Response Assessment Overall and by Subgroup (Cohort 5, Response Evaluable Population)
Figure 14.2.2.1a	Maximum Decrease from Baseline in Tumor Burden (Cohort 1 Single Agent, Response Evaluable Population)
Figure 14.2.2.2a	Maximum Decrease from Baseline in Tumor Burden (Cohort 1 Combination Therapy, Response Evaluable Population)
Figure 14.2.2.1b	Maximum Decrease from Baseline in Tumor Burden (Cohort 2 Single Agent, Response Evaluable Population)
Figure 14.2.2.2b	Maximum Decrease from Baseline in Tumor Burden (Cohort 2 Combination Therapy, Response Evaluable Population)
Figure 14.2.2.1c	Maximum Decrease from Baseline in Tumor Burden (Cohort 3 Single Agent, Response Evaluable Population)
Figure 14.2.2.2c	Maximum Decrease from Baseline in Tumor Burden (Cohort 3 Combination Therapy, Response Evaluable Population)
Figure 14.2.2.1d	Maximum Decrease from Baseline in Tumor Burden (Cohort 4 Single Agent, Response Evaluable Population)
Figure 14.2.2.2d	Maximum Decrease from Baseline in Tumor Burden (Cohort 4 Combination Therapy, Response Evaluable Population)
Figure 14.2.2.1e	Maximum Decrease from Baseline in Tumor Burden (Cohort 5, Response Evaluable Population)
Figure 14.2.3.1a	Time on Treatment (Cohort 1 Single Agent, Safety Population)
Figure 14.2.3.2a	Time on Treatment (Cohort 1 Combination Therapy, Safety Population)
Figure 14.2.3.1b	Time on Treatment (Cohort 2 Single Agent, Safety Population)
Figure 14.2.3.2b	Time on Treatment (Cohort 2 Combination Therapy, Safety Population)
Figure 14.2.3.1c	Time on Treatment (Cohort 3 Single Agent, Safety Population)
Figure 14.2.3.2c	Time on Treatment (Cohort 3 Combination Therapy, Safety Population)
Figure 14.2.3.1d	Time on Treatment (Cohort 4 Single Agent, Safety Population)

Table 14.2.8d	EQ-5D-5L Summary (Cohort 4, Response Evaluable Population)
Table 14.2.8e	EQ-5D-5L Summary (Cohort 5, Response Evaluable Population)
Figure 14.2.9a	EQ-5D-5L Quality of Life Assessment (Cohort 1, Response Evaluable Population)
Figure 14.2.9b	EQ-5D-5L Quality of Life Assessment (Cohort 2, Response Evaluable Population)
Figure 14.2.9c	EQ-5D-5L Quality of Life Assessment (Cohort 3, Response Evaluable Population)
Figure 14.2.9d	EQ-5D-5L Quality of Life Assessment (Cohort 4, Response Evaluable Population)
Figure 14.2.9e	EQ-5D-5L Quality of Life Assessment (Cohort 5, Response Evaluable Population)
Table 14.2.10.1a	Summary of 2-HG, Change from Baseline, and Percent Change from Baseline (Cohort 1, PD Population)
Table 14.2.10.1b	Summary of 2-HG, Change from Baseline, and Percent Change from Baseline (Cohort 2, PD Population)
Table 14.2.10.1c	Summary of 2-HG, Change from Baseline, and Percent Change from Baseline (Cohort 3, PD Population)
Table 14.2.10.1d	Summary of 2-HG, Change from Baseline, and Percent Change from Baseline (Cohort 4, PD Population)
Table 14.2.10.1e	Summary of 2-HG, Change from Baseline, and Percent Change from Baseline (Cohort 5, PD Population)
Table 14.2.10.2a	Summary of 2-HG, Change from Baseline, and Percent Change from Baseline by Subgroup (Cohort 1, PD Population)
Table 14.2.10.2b	Summary of 2-HG, Change from Baseline, and Percent Change from Baseline by Subgroup (Cohort 2, PD Population)
Table 14.2.10.2c	Summary of 2-HG, Change from Baseline, and Percent Change from Baseline by Subgroup (Cohort 3, PD Population)
Table 14.2.10.2d	Summary of 2-HG, Change from Baseline, and Percent Change from Baseline by Subgroup (Cohort 4, PD Population)
Table 14.2.10.2e	Summary of 2-HG, Change from Baseline, and Percent Change from Baseline by Subgroup (Cohort 5, PD Population)
Figure 14.2.11.1a	Boxplot of Plasma 2-HG by Time Point (Cohort 1, PD Population)
Figure 14.2.11.1b	Boxplot of Plasma 2-HG by Time Point (Cohort 2, PD Population)
Figure 14.2.11.1c	Boxplot of Plasma 2-HG by Time Point (Cohort 3, PD Population)

Displays of Adverse Events (CSR Section 14.3.1)

Table 14.3.1.1a	Summary of Treatment-Emergent Adverse Events, Overall and by Dose Group (Cohort 1, Safety Population)
Table 14.3.1.1b	Summary of Treatment-Emergent Adverse Events, Overall and by Dose Group (Cohort 2, Safety Population)
Table 14.3.1.1c	Summary of Treatment-Emergent Adverse Events, Overall and by Dose Group (Cohort 3, Safety Population)
Table 14.3.1.1d	Summary of Treatment-Emergent Adverse Events, Overall and by Dose Group (Cohort 4, Safety Population)
Table 14.3.1.1e	Summary of Treatment-Emergent Adverse Events, Overall and by Dose Group (Cohort 5, Safety Population)
Table 14.3.1.a	Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (All Patients Receiving Single Agent Therapy, Safety Population)
Table 14.3.1.b	Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (All Patients Receiving Combination Therapy, Safety Population)
Table 14.3.1.c	Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (All Patients, Safety Population)
Table 14.3.1.d	Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (Cohort 1, Safety Population)
Table 14.3.1.e	Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (Cohort 2, Safety Population)
Table 14.3.1.2f	Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (Cohort 3, Safety Population)
Table 14.3.1.g	Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (Cohort 4, Safety Population)
Table 14.3.1.h	Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (Cohort 5, Safety Population)
Table 14.3.1.3a	Treatment-Emergent Adverse Events Related to FT-2102 by MedDRA System Organ Class and Preferred Term (Cohort 1, Safety Population)
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8.2. Data Listings to be Generated

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Listing 16.2.9.7	ECOG Performance Status

9. TABLE AND FIGURE SHELLS

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Table 14.1.1a

Patient Enrollment and Disposition (Cohort 1)

Disposition	Statistic	Cohort 1A: FT-2102 N (%)	Cohort 1B: FT-2102 + AZA N (%)	Cohort 1: Overall N (%)
Total Number of Patients				
Screened	n	xx	xx	xx
Screen Failures[1]	n (%)	xx (xx)	xx (xx)	xx (xx)
Enrolled[1]	n (%)	xx (xx)	xx (xx)	xx (xx)
Dosed[2]	n (%)	xx (xx)	xx (xx)	xx (xx)
Currently ongoing [3]	n (%)	xx (xx)	xx (xx)	xx (xx)
Discontinued treatment[3]				
Discontinued study participation[3]				
Study Populations[2]				
Safety	n (%)			
DLT Evaluable	n (%)			
Response Evaluable	n (%)			
PK Analysis Set	n (%)			
PD Analysis Set				
Primary Reason for Discontinuation of Treatment[3]	n (%)			
Adverse Event	n (%)			
Death	n (%)			
Withdrew Consent	n (%)			
Lost to Follow-up	n (%)			
Patient Noncompliance	n (%)			
Discontinuation of Study by Sponsor	n (%)			
Protocol Violation	n (%)			
Physician Decision	n (%)			
Protocol Defined Disease Progression				

Primary Reason for Discontinuation of Study Participation[3]	
Death	n (%)
Permanent Withdrawal of Consent	n (%)
Lost to Follow-up	n (%)
Patient Noncompliance/ Protocol Violation(s)	n (%)
Discontinuation of Study by Sponsor	n (%)
Physician Decision	n (%)
Pregnancy	n (%)
Protocol Defined Disease Progression	n (%)
Other	n (%)

[1] Percentage based on the number screened.
[2] Percentage based on the number enrolled.
[3] Percentage based on the number dosed.
Source: Data Listing 16.2.x

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

Programming Note:
Repeat table for Cohorts 2-5.

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Table 14.1.2.1a

Demographics and Baseline Characteristics (Cohort 1, Response Evaluable Population)

Demographics	Statistic	Cohort 1A: FT-2102 (N =)	Cohort 1B: FT-2102 + AZA (N =)	Cohort 1: Overall (N =)
Age at consent (years)	n			
	mean			
	SD			
	median			
	min - max			
Age category (years)				
18-40	n (%)			
41-59	n (%)			
>60	n (%)			
Sex at birth				
Male	n (%)			
Female	n (%)			
Of childbearing potential	n (%)			
Post-menopausal	n (%)			
Sterilized	n (%)			
Race				
American Indian or Alaska Native	n (%)			
Asian	n (%)			
Black or African American	n (%)			
Native Hawaiian or Other Pacific Islander	n (%)			
White	n (%)			
Other	n (%)			
Not Reported				
Ethnicity				
Hispanic				
Not Hispanic				
Not reported	n (%)			

Height (cm)		n
		mean
		SD
		median
		min - max
Weight (kg)		n
		mean
		SD
		median
		min - max
BMI (kg/m^2)		n
		mean
		SD
		median
		min - max
ECOG Score		
	0	n (%)
	1	n (%)
	2	n (%)
	3	n (%)
	4	n (%)
Hepatitis B Status		
Negative		n (%)
Positive		n (%)
Hepatitis C Status		
Negative		n (%)
Positive		n (%)
IDH1 Mutation Subtype		
R132C		n (%)
R132H		n (%)
R132S		n (%)
R132L		n (%)
R132G		n (%)
Other		n (%)
Unknown		n (%)

```
   Programming Note: Repeat for Cohorts 2-5
   Programming Note: Use this shell for 14.1.2.2 (Safety Population)
PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX   DATE: HH:MM/DDMMMYYYY
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Table 14.1.3.1a

Baseline Disease Characteristics (Cohort 1, Response Evaluable Population)

Parameter	Statistic	Cohort 1A: FT-2102 (N =)	Cohort 1B: FT-2102 + AZA (N =)	Cohort 1: Overall (N =)
Current glioma diagnosis				
Diffuse astrocytoma, IDH mutant	n (%)			
Diffuse astrocytoma, NOS	n (%)			
Anaplastic astrocytoma, IDH mutant	n (%)			
Anaplastic astrocytoma, NOS	n (%)			
Glioblastoma, IDH mutant	n (%)			
Glioblastoma, NOS	n (%)			
Oligodendroglioma, IDH mutant	n (%)			
Oligodendroglioma, NOS	n (%)			
Anaplastic oligodendroglioma, IDH-mutant	n (%)			
Anaplastic oligodendroglioma, NOS	n (%)			
Oligoastrocytoma, NOS	n (%)			
Anaplastic oligoastrocytoma, NOS	n (%)			
Pilocytic astrocytoma	n (%)			
Pilomyxoid astrocytoma	n (%)			
Subependymal giant cell astrocytoma	n (%)			
Pleomorphic xanthoastrocytoma	n (%)			
Anaplastic pleomorphic xanthoastrocytoma	n (%)			
Other	n (%)			
Initial glioma diagnosis				
Diffuse astrocytoma, IDH mutant	n (%)			
Diffuse astrocytoma, NOS	n (%)			
Anaplastic astrocytoma, IDH mutant	n (%)			
Anaplastic astrocytoma, NOS	n (%)			
Glioblastoma, IDH mutant	n (%)			
Glioblastoma, NOS	n (%)			
Oligodendroglioma, IDH mutant	n (%)			
Oligodendroglioma, NOS	n (%)			
Anaplastic oligodendroglioma, IDH-mutant	n (%)			
Anaplastic oligodendroglioma, NOS	n (%)			

Oligoastrocytoma, NOS	n (%)
Anaplastic oligoastrocytoma, NOS	n (%)
Pilocytic astrocytoma	n (%)
Pilomyxoid astrocytoma	n (%)
Subependymal giant cell astrocytoma	n (%)
Pleomorphic xanthoastrocytoma	n (%)
Anaplastic pleomorphic xanthoastrocytoma	n (%)
Other	n (%)
Years since initial diagnosis	n
	mean
	SD
	median
	min - max
Grade at initial diagnosis	
I	n (%)
II	n (%)
III	n (%)
IV	n (%)
Months since recurrence	n
	mean
	SD
	median
	min - max
Current grade	
I	n (%)
II	n (%)
III	n (%)
IV	n (%)
Unknown/ NA	n (%)
Baseline steroids	
Yes	n (%)
No	n (%)
Prior therapies	
Surgery only	n (%)
Medication and surgery	n (%)

Number of prior regimens	n
	mean
	SD
	median
	min - max
Prior regimen categories	
1	n (%)
2	n (%)
3	n (%)
>3	n (%)
Prior IDH1 therapy	
Yes	n (%)
No	n (%)
Prior radiation	
Yes	n (%)
No	n (%)
Prior tezolomide	
Yes	n (%)
No	n (%)

Programming note: repeat for 14.1.3.2a (Safety Population)

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Table 14.1.3.1b

Baseline Disease Characteristics (Cohort 2, Response Evaluable Population)

Parameter	Statistic	Cohort 2A: FT-2102 (N =)	Cohort 2B: FT-2102 + Nivolumab (N =)	Cohort 2: Overall (N =)
Hepatobiliary Cancer (HBC) Diagnosis				
Hepatocellular carcinoma	n (%)			
Fibrolamellar	n (%)			
Clear Cell	n (%)			
Other	n (%)			
Gallbladder carcinoma	n (%)			
Intrahepatic cholangiocarcinoma	n (%)			
Extraheptic cholangiocarcinoma	n (%)			
Biliary tumor NOS	n (%)			
Current Stage				
I	n (%)			
IA	n (%)			
IB	n (%)			
IIA	n (%)			
IIB	n (%)			
IIIA	n (%)			
IIIB	n (%)			
IVA	n (%)			
IVB	n (%)			
NA	n (%)			
Grade at Initial Diagnosis				
Gx	n (%)			
G1	n (%)			
G2	n (%)			
G3	n (%)			
G4	n (%)			
Unknown	n (%)			
Not Applicable	n (%)			

Years since initial diagnosis	n
	mean
	SD
	median
	min - max
Months since recurrence	n
	mean
	SD
	median
	min - max
Fibrosis	
F0	n (%)
F1	n (%)
Current TNM Staging: Primary Tumor (T)	
Tx	n (%)
T0	n (%)
Tis	n (%)
T1	n (%)
T2	n (%)
T3	n (%)
T4	n (%)
NA	n (%)
Current TNM Staging: Lymph Node (N)	
Nx	n (%)
N0	n (%)
N1	n (%)
NA	n (%)
Current TNM Staging: Metastasis (M)	
M0	n (%)
M1	n (%)
NA	n (%)
Initial TNM Staging: Primary Tumor (T)	
Tx	n (%)
T0	n (%)
Tis	n (%)

T1	n (%)
T2	n (%)
T3	n (%)
T4	n (%)
NA	n (%)
Initial TNM Staging: Lymph Node (N)	
Nx	n (%)
N0	n (%)
N1	n (%)
NA	n (%)
Initial TNM Staging: Metastasis (M)	
M0	n (%)
M1	n (%)
NA	n (%)
Number of prior regimens	n
	mean
	SD
	median
	min - max
Prior regimen categories	
1	n (%)
2	n (%)
3	n (%)
>3	n (%)
Prior IDH1 therapy	
Yes	n (%)
No	n (%)
Child-Pugh Score	n
	mean
	SD
	median
	min - max
Child-Pugh Category	
A	n (%)
B	n (%)

C	n (%)

Programming note: repeat for 14.1.3.2b (Safety Population)

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Table 14.1.3.1c

Baseline Disease Characteristics (Cohort 3, Response Evaluable Population)

Parameter	Statistic	Cohort 3A: FT-2102 (N =)	Cohort 3B: FT-2102 + AZA (N =)	Cohort 3: Overall (N =)
Chondrosarcoma diagnosis				
Differentiated	n (%)			
Mesenchymal	n (%)			
Clear cell	n (%)			
Unknown	n (%)			
Other	n (%)			
Current Stage				
Tx	n (%)			
T0	n (%)			
T1	n (%)			
T1a	n (%)			
T1b	n (%)			
T2	n (%)			
T2b	n (%)			
T3	n (%)			
T3a	n (%)			
T3b	n (%)			
T4	n (%)			
Stage at initial diagnosis				
Tx	n (%)			
T0	n (%)			
T1	n (%)			
T1a	n (%)			
T1b	n (%)			
T2	n (%)			
T2b	n (%)			
T3	n (%)			
T3a	n (%)			
T3b	n (%)			

T4	n (%)
Current grade	
Gx	n (%)
G1	n (%)
G2	n (%)
G3	n (%)
G4	n (%)
Unknown	n (%)
Not Applicable	n (%)
Grade at Initial Diagnosis	
Gx	n (%)
G1	n (%)
G2	n (%)
G3	n (%)
Unknown	n (%)
Not Applicable	n (%)
Years since initial diagnosis	n
	mean
	SD
	median
	min - max
Months since recurrence	n
	mean
	SD
	median
	min - max
Current TNM Staging: Primary Tumor (T)	
Tx	n (%)
T0	n (%)
T1	n (%)
T1a	n (%)
T1b	n (%)
T2	n (%)
T2a	n (%)
T2b	n (%)
T3	n (%)
T3a	n (%)

```
   T3b                                                  n (%)
   T4                                                   n (%)
   T4a                                                  n (%)
   T4b                                                  n (%)
   NA                                                   n (%)

Current TNM Staging: Lymph Node (N)
   Nx                                                   n (%)
   N0                                                   n (%)
   N1                                                   n (%)
   NA                                                   n (%)

Current TNM Staging: Metastasis (M)
   M0                                                   n (%)
   M1                                                   n (%)
   M1a                                                  n (%)
   M1b                                                  n (%)

Initial TNM Staging: Primary Tumor (T)
   Tx                                                   n (%)
   T0                                                   n (%)
   T1                                                   n (%)
   T1a                                                  n (%)
   T1b                                                  n (%)
   T2                                                   n (%)
   T2a                                                  n (%)
   T2b                                                  n (%)
   T3                                                   n (%)
   T3a                                                  n (%)
   T3b                                                  n (%)
   T4                                                   n (%)
   T4a                                                  n (%)
   T4b                                                  n (%)
   NA                                                   n (%)

Initial TNM Staging: Lymph Node (N)
   Nx                                                   n (%)
   N0                                                   n (%)
   N1                                                   n (%)
   NA                                                   n (%)

Initial TNM Staging: Metastasis (M)
```

M0	n (%)
M1	n (%)
M1a	n (%)
M1b	n (%)
Number of prior regimens	n
	mean
	SD
	median
	min - max
Prior regimen categories	
1	n (%)
2	n (%)
3	n (%)
>3	n (%)
Prior IDH1 therapy	
Yes	n (%)
No	n (%)

Programming note: repeat for 14.1.3.2c (Safety Population)

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Table 14.1.3.1d

Baseline Disease Characteristics (Cohort 4, Response Evaluable Population)

Parameter	Statistic	Cohort 4A: FT-2102 (N =)	Cohort 4B: FT-2102 + GemCis (N =)	Cohort 4: Overall (N =)
Current Stage				
I	n (%)			
IA	n (%)			
IB	n (%)			
IIA	n (%)			
IIB	n (%)			
IIIA	n (%)			
IIIB	n (%)			
IVA	n (%)			
IVB	n (%)			
NA	n (%)			
Initial Stage				
I	n (%)			
IA	n (%)			
IB	n (%)			
IIA	n (%)			
IIB	n (%)			
IIIA	n (%)			
IIIB	n (%)			
IVA	n (%)			
IVB	n (%)			
NA	n (%)			
Current Grade				
Gx	n (%)			
G1	n (%)			
G2	n (%)			
G3	n (%)			
Unknown	n (%)			
Not Applicable	n (%)			

Grade at Initial Diagnosis	
Gx	n (%)
G1	n (%)
G2	n (%)
G3	n (%)
Unknown	n (%)
Not Applicable	n (%)
Years since initial diagnosis	n
	mean
	SD
	median
	min - max
Months since recurrence	n
	mean
	SD
	median
	min - max
Current TNM Staging: Primary Tumor (T)	
Tx	n (%)
T0	n (%)
Tis	n (%)
T1	n (%)
T2	n (%)
T3	n (%)
T4	n (%)
NA	n (%)
Current TNM Staging: Lymph Node (N)	
Nx	n (%)
N0	n (%)
N1	n (%)
NA	n (%)
Current TNM Staging: Metastasis (M)	
M0	n (%)
M1	n (%)
NA	n (%)

Initial TNM Staging: Primary Tumor (T)	
Tx	n (%)
T0	n (%)
Tis	n (%)
T1	n (%)
T2	n (%)
T3	n (%)
T4	n (%)
NA	n (%)
Initial TNM Staging: Lymph Node (N)	
Nx	n (%)
N0	n (%)
N1	n (%)
NA	n (%)
Initial TNM Staging: Metastasis (M)	
M0	n (%)
M1	n (%)
NA	n (%)
Number of prior regimens	n
	mean
	SD
	median
	min - max
Prior regimen categories	
1	n (%)
2	n (%)
3	n (%)
>3	n (%)
Prior IDH1 therapy	
Yes	n (%)
No	n (%)
Child-Pugh Score	n
	mean
	SD
	median
	min - max

Child-Pugh Category	
A	n (%)
B	n (%)
C	n (%)

Programming note: repeat for 14.1.3.2d (Safety Population)

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Table 14.1.3.1e

Baseline Disease Characteristics (Cohort 5, Response Evaluable Population)

Parameter	Statistic	Cohort 5: Overall N (%)
Current Stage		
I	n (%)	
IA	n (%)	
IB	n (%)	
IIA	n (%)	
IIB	n (%)	
IIIA	n (%)	
IIIB	n (%)	
IVA	n (%)	
IVB	n (%)	
NA	n (%)	
Initial Stage		
I	n (%)	
IA	n (%)	
IB	n (%)	
IIA	n (%)	
IIB	n (%)	
IIIA	n (%)	
IIIB	n (%)	
IVA	n (%)	
IVB	n (%)	
NA	n (%)	
Years since initial diagnosis	n	
	mean	
	SD	
	median	
	min - max	
Months since recurrence	n	

	mean
	SD
	median
	min - max
Current TNM Staging: Primary Tumor (T)	
Tx	n (%)
T0	n (%)
Tis	n (%)
T1	n (%)
T2	n (%)
T3	n (%)
T4	n (%)
NA	n (%)
Current TNM Staging: Lymph Node (N)	
Nx	n (%)
N0	n (%)
N1	n (%)
N2	n (%)
N3	n (%)
NA	n (%)
Current TNM Staging: Metastasis (M)	
M0	n (%)
M1	n (%)
NA	n (%)
Initial TNM Staging: Primary Tumor (T)	
Tx	n (%)
T0	n (%)
Tis	n (%)
T1	n (%)
T2	n (%)
T3	n (%)
T4	n (%)
NA	n (%)
Initial TNM Staging: Lymph Node (N)	
Nx	n (%)
N0	n (%)

N1	n (%)
N2	n (%)
N3	n (%)
NA	n (%)
Initial TNM Staging: Metastasis (M)	
M0	n (%)
M1	n (%)
NA	n (%)
Number of prior regimens	n
	mean
	SD
	median
	min - max
Prior regimen categories	
1	n (%)
2	n (%)
3	n (%)
>3	n (%)
Prior IDH1 therapy	
Yes	n (%)
No	n (%)
Child-Pugh Score	n
	mean
	SD
	median
	min - max
Child-Pugh Category	
A	n (%)
B	n (%)
C	n (%)

Programming note: repeat for 14.1.3.2e (Safety Population)

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Table 14.1.4.1a

IDH1 and Other Mutations (Cohort 1, Response Evaluable Population)

Parameter	Statistic	Cohort 1A: FT-2102 (N =)	Cohort 1B: FT-2102 + AZA (N =)	Cohort 1: Overall (N =)
IDH1 Mutation Subtype				
R132C	n (%)			
R132H	n (%)			
R132S	n (%)			
R132L	n (%)			
R132G	n (%)			
Other	n (%)			
Unknown	n (%)			
Other mutations				
ABL1	n (%)			
ABL2	n (%)			
ARID1A	n (%)			
ARID2	n (%)			
AXIN1	n (%)			
(etc.)	n (%)			

Programming notes:

For other mutations show all mutations where at least 1 patient had the mutation. List them in alphabetical order. If a patient notes a mutation in the other, specify field then also show that mutation in this list.

Repeat for Cohorts 2-5
Repeat for 14.1.4.2a-14.1.4.2e (Safety population)

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Table 14.1.5a

Prior Therapies (Cohort 1, Response Evaluable Population)

Parameter	Statistic	Cohort 1A: FT-2102 (N =)	Cohort 1B: FT-2102 + AZA (N =)	Cohort 1: Overall (N =)
Drug class 1	n (%)			
ATC text 1	n (%)			
ATC text 2	n (%)			
ATC text 3	n (%)			
etc.	n (%)			
Drug class 2	n (%)			
ATC text 1	n (%)			
ATC text 2	n (%)			
ATC text 3	n (%)			
etc.	n (%)			

.

Repeat for Cohorts 2-5 (Response Evaluable Population)
Repeat for 14.1.5.2a-e (Safety Population)

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

Note: Prior anti-cancer therapy medications are coded with the WHO Drug version March 2018.

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Table 14.1.6a

Medical History (Cohort 1, Safety Population)

Parameter	Statistic	Cohort 1A: FT-2102 (N =)	Cohort 1B: FT-2102 + AZA (N =)	Cohort 1: Overall (N =)
SOC	n (%)			
PT1	n (%)			
PT2	n (%)			
PT3	n (%)			
etc.	n (%)			
SOC2	n (%)			
PT1	n (%)			
PT2	n (%)			
PT3	n (%)			
etc.	n (%)			

Repeat for Cohorts 2-5

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX | DATE: HH:MM/DDMMMYYYY
Note: Medical Histories are coded with the MedDRA version 21.0.

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Table 14.2.1a

Disease Response Assessment Overall and by Subgroups (Cohort 1, Response Evaluable Population)

Parameter	Statistic	Cohort 1A: FT-2102 (N =)	Cohort 1B: FT-2102 + AZA (N =)	Cohort 1: Overall (N =)
Best overall response	n (%)			
Complete response (CR)	n (%)			
Partial response (PR)	n (%)			
Minor response (MR)	n (%)			
Stable disease (SD)	n (%)			
Progression (PD)	n (%)			
Not evaluable	n (%)			
Overall response rate (ORR)	n (%)			
ORR by subgroups:				
Gender				
Male				
Responder	n (%)			
Non-Responder	n (%)			
Female				
Responder	n (%)			
Non-Responder	n (%)			
Race (Caucasian yes/ no)				
Caucasian				
Responder	n (%)			
Non-Responder	n (%)			
Non-Caucasian				
Responder	n (%)			
Non-Responder	n (%)			
Baseline ECOG				
0/1				
Responder	n (%)			

```
        Non-Responder                                   n (%)
    2
        Responder                                       n (%)
        Non-Responder                                   n (%)

Age Category
    18-40
        Responder                                       n (%)
        Non-Responder                                   n (%)
    41-59
        Responder                                       n (%)
        Non-Responder                                   n (%)
    >=60
        Responder                                       n (%)
        Non-Responder                                   n (%)

Prior therapy
    Surgery only
        Responder                                       n (%)
        Non-Responder                                   n (%)
    Surgery and medication
        Responder                                       n (%)
        Non-Responder                                   n (%)

Number of prior regimens
    1
        Responder                                       n (%)
        Non-Responder                                   n (%)
    2
        Responder                                       n (%)
        Non-Responder                                   n (%)
    3
        Responder                                       n (%)
        Non-Responder                                   n (%)
    >3
        Responder                                       n (%)
        Non-Responder                                   n (%)

Prior IDH1 therapy
    Yes
        Responder                                       n (%)
        Non-Responder                                   n (%)
```

```
    No
        Responder                                   n (%)
        Non-Responder                               n (%)

Prior temozolomide
    Yes
        Responder                                   n (%)
        Non-Responder                               n (%)
    No
        Responder                                   n (%)
        Non-Responder                               n (%)

Prior radiation therapy
    Yes
        Responder                                   n (%)
        Non-Responder                               n (%)
    No
        Responder                                   n (%)
        Non-Responder                               n (%)

Baseline steroids
    Yes
        Responder                                   n (%)
        Non-Responder                               n (%)
    No
        Responder                                   n (%)
        Non-Responder                               n (%)

Baseline tumor grade
    I
        Responder                                   n (%)
        Non-Responder                               n (%)
    II
        Responder                                   n (%)
        Non-Responder                               n (%)
    III
        Responder                                   n (%)
        Non-Responder                               n (%)
    IV
        Responder                                   n (%)
        Non-Responder                               n (%)
```

```
IDH mutation subtype
   R132H
      Responder                                          n (%)
      Non-Responder                                      n (%)
   R132C
      Responder                                          n (%)
      Non-Responder                                      n (%)
   other R132 subtypes
      Responder                                          n (%)
      Non-Responder                                      n (%)
```

Repeat for Cohorts 2-5

Programming note: for cohorts 2 and 4, refer to SAP for cohort-specific subgroups to add to the table, not shown in this shell.
For cohorts 2 and higher, remove MR as a response option.

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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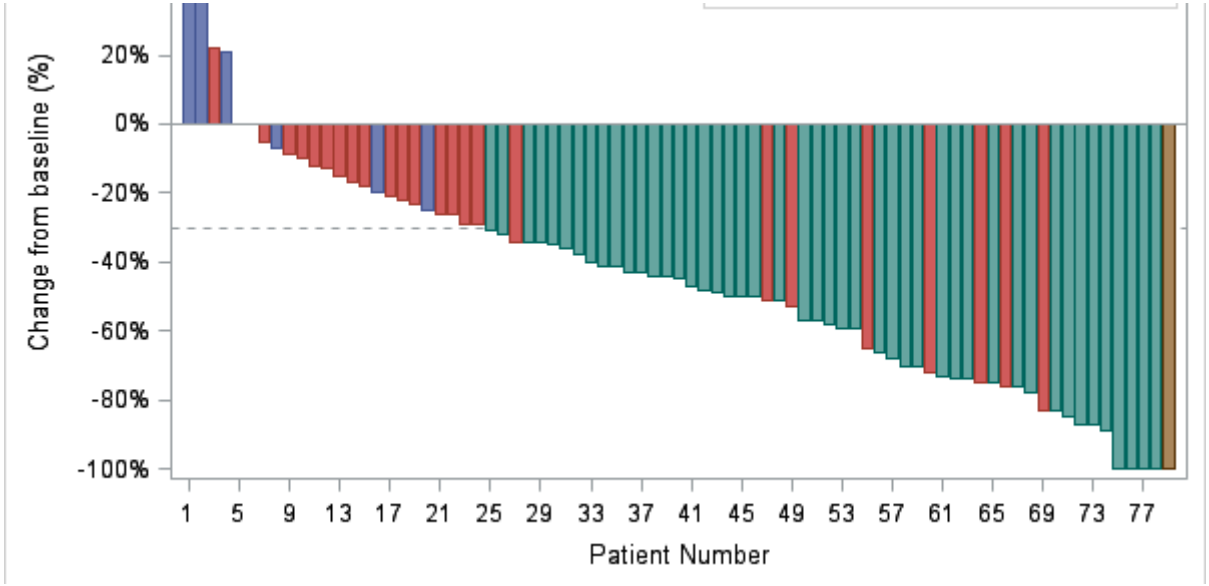
Figure 14.2.2.1a

Best Percent Change from Baseline in Tumor Burden (Cohort 1 Single Agent, Response Evaluable Population)



Note: Baseline is the last imaging assessment performed before the patient's first dose of FT-2102.
Note: Best percent change is defined as maximum percentage reduction or minimum percentage increase at a single time point of the patient's tumor burden post first dose of study drug.

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

Programming note: color code the bars by best overall response
Programming note: Y-axis should be labeled "Maximum Decrease from Baseline (%)"
Programming note: for Cohort 1, reference line should be at -50% for Cohort 1, and -30% for other cohorts.

Programming note: Repeat for 14.2.2.2a-e (Combination Therapy)

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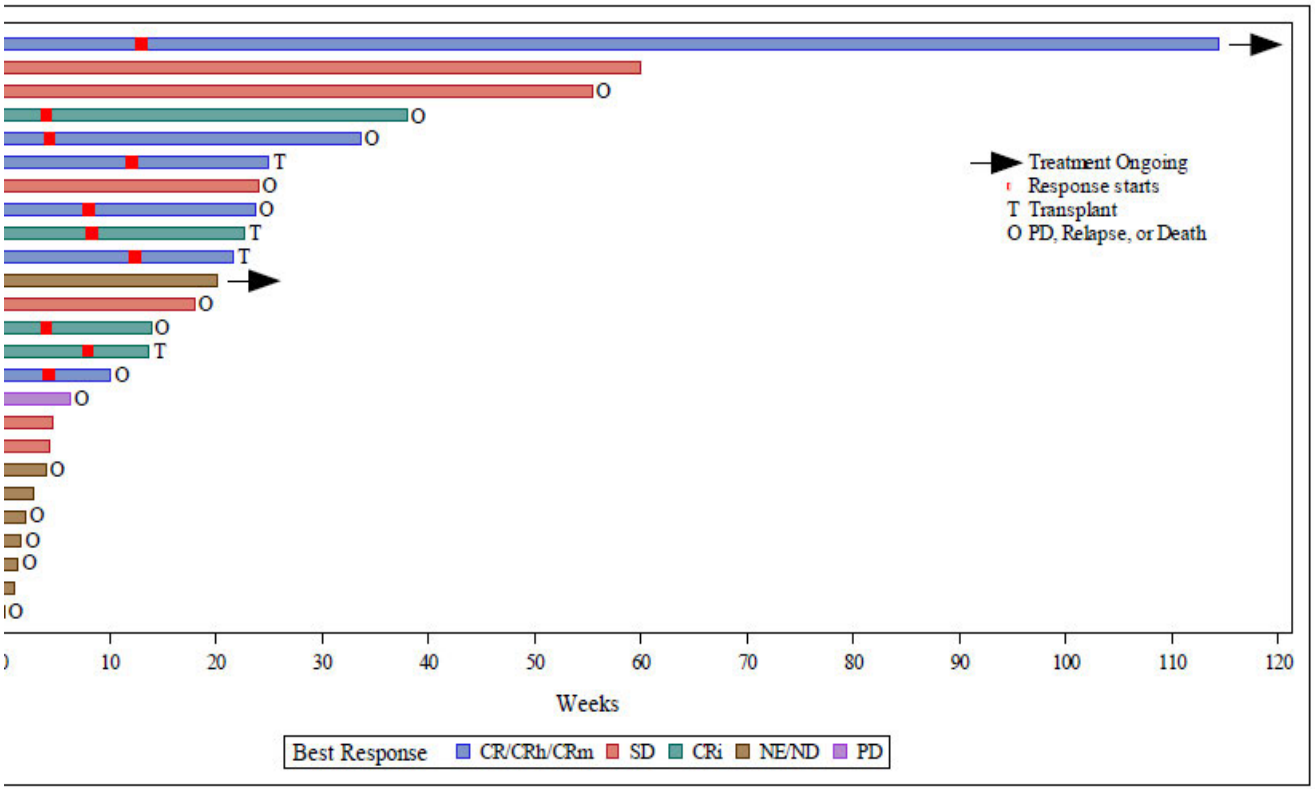
Figure 14.2.3.1a

Time on Treatment (Cohort 1 Single Agent, Safety Population)



Programming note: Repeat for 14.2.3.2a-e (Time on Treatment Combination Therapy)
Programming note: color code by appropriate best overall response criteria, depending on Cohort being summarized. This figure is for example only, the response categories used above are not to be used, follow appropriate disease-based response criteria.

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Table 14.2.4a

Progression Free Survival, Time to Progression, Duration of Response, and Time to Response (Cohort 1, Response Evaluable Population)

Parameter	Statistic	Cohort 1A: FT-2102 (N =)	Cohort 1B: FT-2102 + AZA (N =)	Cohort 1: Overall (N =)
Progression free survival (PFS; weeks)				
Patients with event	n (%)			
Censored Patients	n (%)			
PFS	n			
	median			
	95% CI for median			
	25-75%ile			
	min - max			
Time to progression (TTP; weeks)				
Patients with event	n (%)			
Censored Patients	n (%)			
TTP	n			
	median			
	95% CI for median			
	25-75%ile			
	min - max			
Duration of response (DOR; weeks)				
Patients with event	n (%)			
Censored Patients	n (%)			
DOR	n			
	median			
	95% CI for median			
	25-75%ile			
	min - max			
Time to response (TTR; weeks)				
TTR	n			
	median			
	95% CI for median			

25-75%ile
min - max

Repeat for Cohorts 2-5

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

Note: Progression Free Survival (PFS) is defined as the time from the date of the first dose to the date of disease progression or death, whichever is sooner. Time to Progression (TTP) is defined as the time from the date of the first dose to the date of disease progression. Duration of Response (DOR) is defined as the time from the date of the first CR, PR, or MR response to the date of disease progression. Time to Response (TTR) is defined as the time from the date of first dose to the date of first CR, PR or MR response.

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Table 14.2.5.1

Overall Survival (Response Evaluable Population)

Parameter	Statistic	FT-2102 (N =)	FT-2102 combination (N =)	Overall (N =)
Cohort 1				
Overall survival (weeks)				
Patients with event	n (%)			
Censored Patients	n (%)			
OS	n			
	median			
	95% CI for median			
	25-75%ile			
	min - max			
Event free Rate (95% CI)				
3 months	%(%,%)			
6 months	%(%,%)			
9 months	%(%,%)			
12 months	%(%,%)			
Cohort 2				
Overall survival (weeks)				
Patients with event	n (%)			
Censored Patients	n (%)			
OS	n			
	median			
	95% CI for median			
	25-75%ile			
	min - max			
Event free Rate (95% CI)				
3 months	%(%,%)			
6 months	%(%,%)			
9 months	%(%,%)			
12 months	%(%,%)			
Cohort 3				
Overall survival (weeks)				

Patients with event	n (%)
Censored Patients	n (%)
OS	n
	median
	95% CI for median
	25-75%ile
	min - max
Event free Rate (95% CI)	
3 months	%(%,%)
6 months	%(%,%)
9 months	%(%,%)
12 months	%(%,%)
Cohort 4	
Overall survival (weeks)	
Patients with event	n (%)
Censored Patients	n (%)
OS	n
	median
	95% CI for median
	25-75%ile
	min - max
Event free Rate (95% CI)	
3 months	%(%,%)
6 months	%(%,%)
9 months	%(%,%)
12 months	%(%,%)
Cohort 5	
Overall survival (weeks)	
Patients with event	n (%)
Censored Patients	n (%)
OS	n
	median
	95% CI for median
	25-75%ile
	min - max
Event free Rate (95% CI)	
3 months	%(%,%)
6 months	%(%,%)
9 months	%(%,%)
12 months	%(%,%)

Programming note: repeat for 14.2.5.2 (Safety Population)

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY
Note: Overall Survival (OS) is defined as the time from the date of the first dose to the date of death.

Table 14.2.5.3a

Kaplan-Meier Plot of Overall Survival (Cohort 1, Response Evaluable Population)

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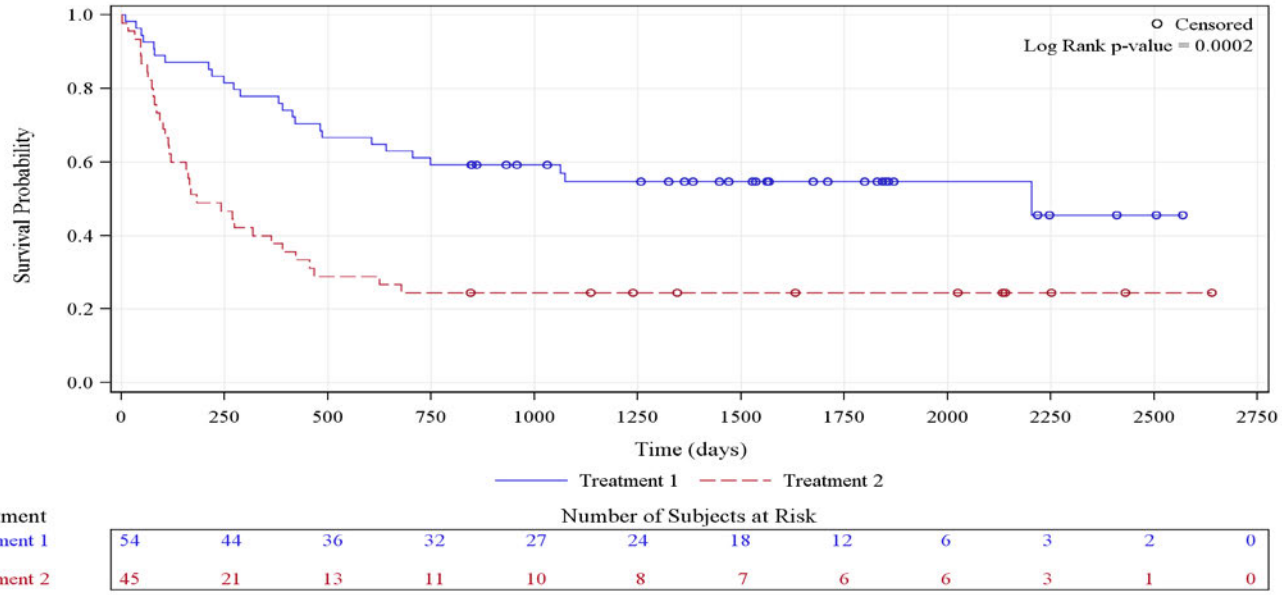
Study: Test

Figure XX
Kaplan-Meier Analysis for Time-to-Event Variable
TEST Population



Treatment	Number of Subjects at Risk											
Treatment 1	54	44	36	32	27	24	18	12	6	3	2	0
Treatment 2	45	21	13	11	10	8	7	6	6	3	1	0

Program: EXAMPLE.sas Run: 25SEP2013 09:40, Dataset: SASHELP.BMT

Note: Overall Survival (OS) is defined as the time from the date of the first dose to the date of death.

Programming note: Present different lines for single agent and combination arms, rather than treatments.
Repeat for cohorts 2-5.
Repeat for 14.2.5.4a-e Overall Survival(Safety Population), 14.2.5.5a-e Progression Free Survival (Response Evaluable Population), 14.2.5.6a-e Progression Free Survival (Safety Population)

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Table 14.2.6a

Serum AFP, CA19-9, and CEA (Cohort 2, Safety Population)

Parameter	Statistic	Cohort 2A: FT-2102 (N =)			Cohort 2B: FT-2102 + AZA (N =)			Cohort 2: Overall (N =)		
		Value	Change from BL	Pct. Chg fr BL	Value	Change from BL	Pct. Chg fr BL	Value	Change from BL	Pct. Chg fr BL
Serum AFP										
Pre-Dose C1	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median	xx	xx	xx	xx	xx	xx	xx	xx	xx
	min -	xx -			xx -			xx -		
	max	xx	xx - xx	xx - xx	xx	xx - xx	xx - xx	xx	xx - xx	xx - xx
C3	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median	xx	xx	xx	xx	xx	xx	xx	xx	xx
	min -	xx -			xx -			xx -		
	max	xx	xx - xx	xx - xx	xx	xx - xx	xx - xx	xx	xx - xx	xx - xx
(continue for all cycles present in data)	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median	xx	xx	xx	xx	xx	xx	xx	xx	xx
	min -	xx -			xx -			xx -		
	max	xx	xx - xx	xx - xx	xx	xx - xx	xx - xx	xx	xx - xx	xx - xx
CA19-9										
Pre-Dose C1	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median	xx	xx	xx	xx	xx	xx	xx	xx	xx
	min -	xx -			xx -			xx -		
	max	xx	xx - xx	xx - xx	xx	xx - xx	xx - xx	xx	xx - xx	xx - xx

C3	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median	xx	xx	xx	xx	xx	xx	xx	xx	xx
	min -	xx -			xx -			xx -		
	max	xx	xx - xx	xx - xx	xx	xx - xx	xx - xx	xx	xx - xx	xx - xx
(continue for all cycles present in data)	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median	xx	xx	xx	xx	xx	xx	xx	xx	xx
	min -	xx -			xx -			xx -		
	max	xx	xx - xx	xx - xx	xx	xx - xx	xx - xx	xx	xx - xx	xx - xx
CEA										
Pre-Dose C1	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median	xx	xx	xx	xx	xx	xx	xx	xx	xx
	min -	xx -			xx -			xx -		
	max	xx	xx - xx	xx - xx	xx	xx - xx	xx - xx	xx	xx - xx	xx - xx
C3	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median	xx	xx	xx	xx	xx	xx	xx	xx	xx
	min -	xx -			xx -			xx -		
	max	xx	xx - xx	xx - xx	xx	xx - xx	xx - xx	xx	xx - xx	xx - xx
(continue for all cycles present in data)	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median	xx	xx	xx	xx	xx	xx	xx	xx	xx
	min -	xx -			xx -			xx -		
	max	xx	xx - xx	xx - xx	xx	xx - xx	xx - xx	xx	xx - xx	xx - xx

Programming note: repeat for Cohort 4

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

Note: BL = baseline.
Note: Baseline is defined as the most recent measurement prior to the first administration of study drug.

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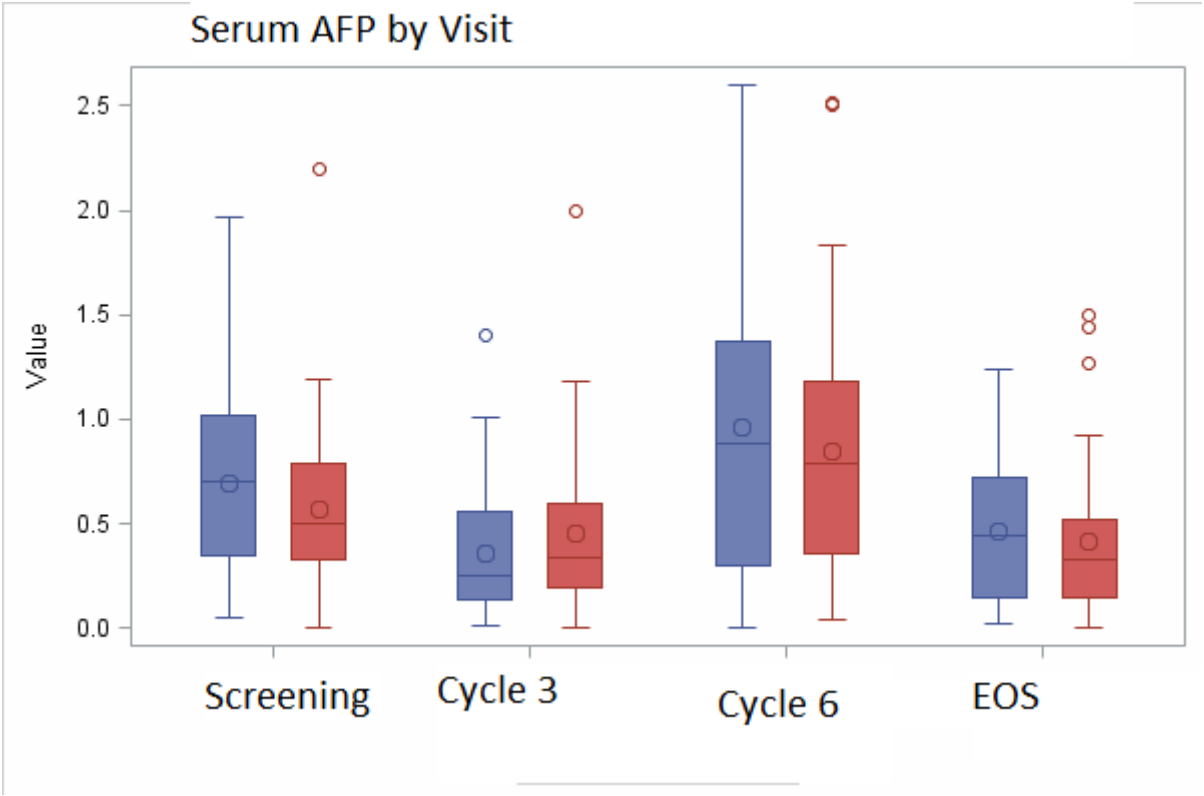
Figure 14.2.7a

Serum AFP, CA19-9, and CEA (Cohort 2, Response Evaluable Population)



Programming note; Different colors indicate single agent and combination therapy. Please include legend indicating this.
Programming note; please include value and unit on Y-axis
Programming note: via proc SGPANEL, matrix to include Serum AFP, CA19-9, and CEA on a single page.

Repeat for Cohort 4

Table 14.2.8a

EQ-5D-5L Summary (Cohort 1, Response Evaluable Set)

Dimension Visit	Level	Statistic	Cohort 1A: FT-2102 (N =)	Cohort 1B: FT-2102 combination (N =)	Cohort 1: Overall (N =)
Mobility					
C1	1 (no problems)	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	2	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	3	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	4	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	5	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Total	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Number reporting some problems	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Change from BL in number reporting some problems	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
C3	1 (no problems)	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	2	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	3	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	4	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	5	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Total	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Number reporting some problems	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Change from BL in number reporting some problems	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Treatment Termination	1 (no problems)	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	2	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

3	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
5	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number reporting some problems	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Change from BL in number reporting some problems	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

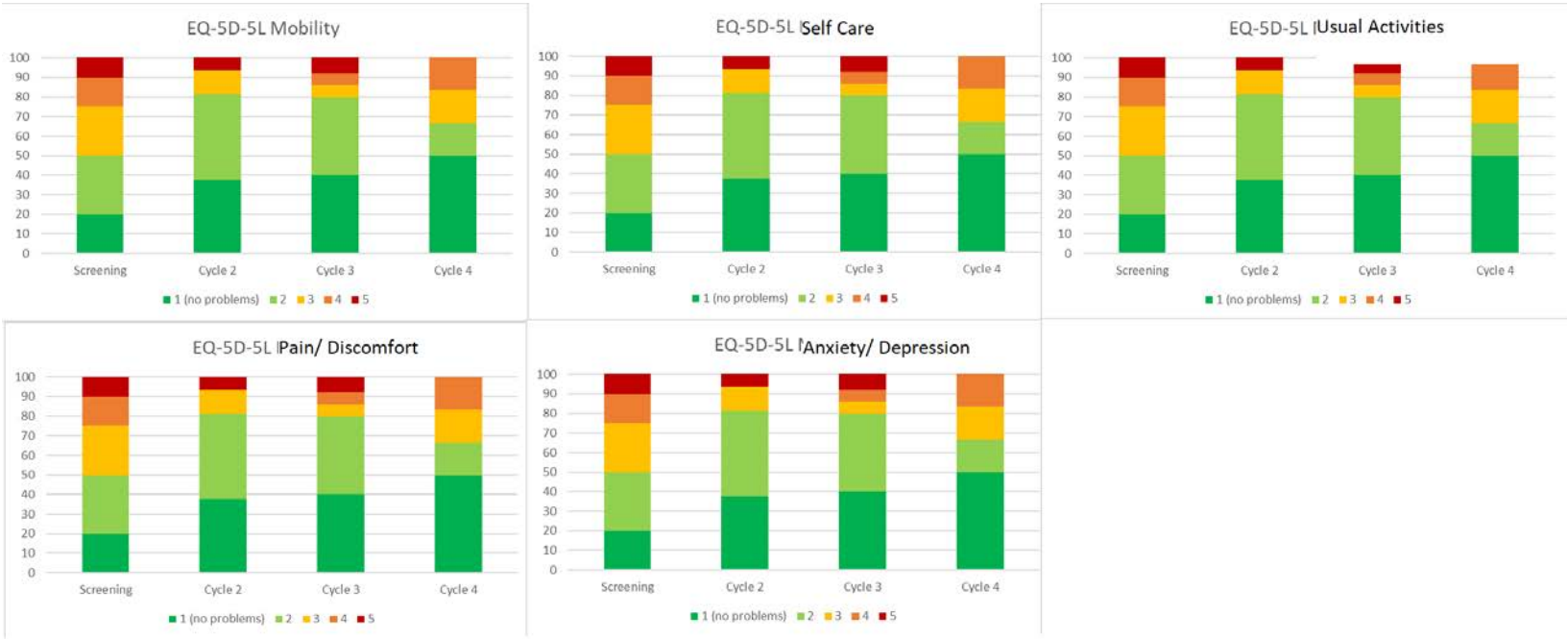
Continue for other EQ-5D dimensions

BL = baseline
Repeat for Cohorts 2-5

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY
Note: Baseline is defined as the most recent measurement prior to the first administration of study drug.
Source: Data Listing 16.2.x

Figure 14.2.9a

EQ-5D-5L Quality of Life Assessment (Cohort 1, Response Evaluable Population)



Programming notes:

TRT will be displayed at the top left of the page, or of each graph that is presented on the page, whichever is most expedient.

Y-axis label is "Percent".

Bars will be shaded as shown in the legend.

All panels (Mobility, Self-care, Usual Activities, Pain/Discomfort and Anxiety/Depression) will be presented in a 2x3 matrix on a single page. (Programmer can use SGPANEL)

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Table 14.2.10.1a

Summary of 2-HG, Change from Baseline, and Percent Change from Baseline (Cohort 1, PD Population)

Parameter	Time Point	Statistic	Cohort 1A: FT-2102 (N =)			Cohort 1B: FT-2102 + AZA (N =)			Cohort 1: Overall (N =)		
			Value	Change from BL	Pct. Chg fr BL	Value	Change from BL	Pct. Chg fr BL	Value	Change from BL	Pct. Chg fr BL
2-HG Plasma											
C1D1	Pre-dose	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
		mean	xx	xx	xx	xx	xx	xx	xx	xx	xx
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		median	xx	xx	xx	xx	xx	xx	xx	xx	xx
		min - max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
	4 hours	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
		mean	xx	xx	xx	xx	xx	xx	xx	xx	xx
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		median	xx	xx	xx	xx	xx	xx	xx	xx	xx
		min - max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
C1D2	Pre-dose	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
		mean	xx	xx	xx	xx	xx	xx	xx	xx	xx
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		median	xx	xx	xx	xx	xx	xx	xx	xx	xx
		min - max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
(continue for all cycle/ days and time points)		n	xx	xx	xx	xx	xx	xx	xx	xx	xx
		mean	xx	xx	xx	xx	xx	xx	xx	xx	xx

	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median	xx	xx	xx	xx	xx	xx	xx	xx	xx
	min - max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
C3	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median	xx	xx	xx	xx	xx	xx	xx	xx	xx
	min - max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
(continue for all cycles present in data)	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median	xx	xx	xx	xx	xx	xx	xx	xx	xx
	min - max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
2-HG CSF (present all days/ times)	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median	xx	xx	xx	xx	xx	xx	xx	xx	xx
	min - max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
2-HG Urine (present all days/ times)	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median	xx	xx	xx	xx	xx	xx	xx	xx	xx

		xx -			xx -			xx -				
	min - max	xx	xx - xx	xx - xx	xx	xx - xx	xx - xx	xx	xx - xx	xx - xx		

BL = Baseline
Programming note: repeat for
Cohorts 2-5

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY
Note: Baseline is defined as the most recent measurement prior to the first administration of study drug.

Table 14.2.10.2a

Summary of 2-HG, Change from Baseline, and Percent Change from Baseline by Subgroup (Cohort 1, PD Population)

Parameter	Time Point	Statistic	Cohort 1A: FT-2102 (N =)			Cohort 1B: FT-2102 + AZA (N =)			Cohort 1: Overall (N =)		
			Value	Change from BL	Pct. Chg fr BL	Value	Change from BL	Pct. Chg fr BL	Value	Change from BL	Pct. Chg fr BL
2-HG Plasma											
C1D1											
Male	Pre-dose	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
		mean	xx	xx	xx	xx	xx	xx	xx	xx	xx
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		median	xx	xx	xx	xx	xx	xx	xx	xx	xx
		min - max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
Female	Pre-dose	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
		mean	xx	xx	xx	xx	xx	xx	xx	xx	xx
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		median	xx	xx	xx	xx	xx	xx	xx	xx	xx
		min - max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
Male	4 hours	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
		mean	xx	xx	xx	xx	xx	xx	xx	xx	xx
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		median	xx	xx	xx	xx	xx	xx	xx	xx	xx
		min - max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
Female	4 hours	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
		mean	xx	xx	xx	xx	xx	xx	xx	xx	xx
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

	median	xx	xx	xx	xx	xx	xx	xx	xx	xx
	min - max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
C1D1										
Predose	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Male	mean	xx	xx	xx	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median	xx	xx	xx	xx	xx	xx	xx	xx	xx
	min - max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
Female	n	xx	xx	xx	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median	xx	xx	xx	xx	xx	xx	xx	xx	xx
	min - max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
etc.										

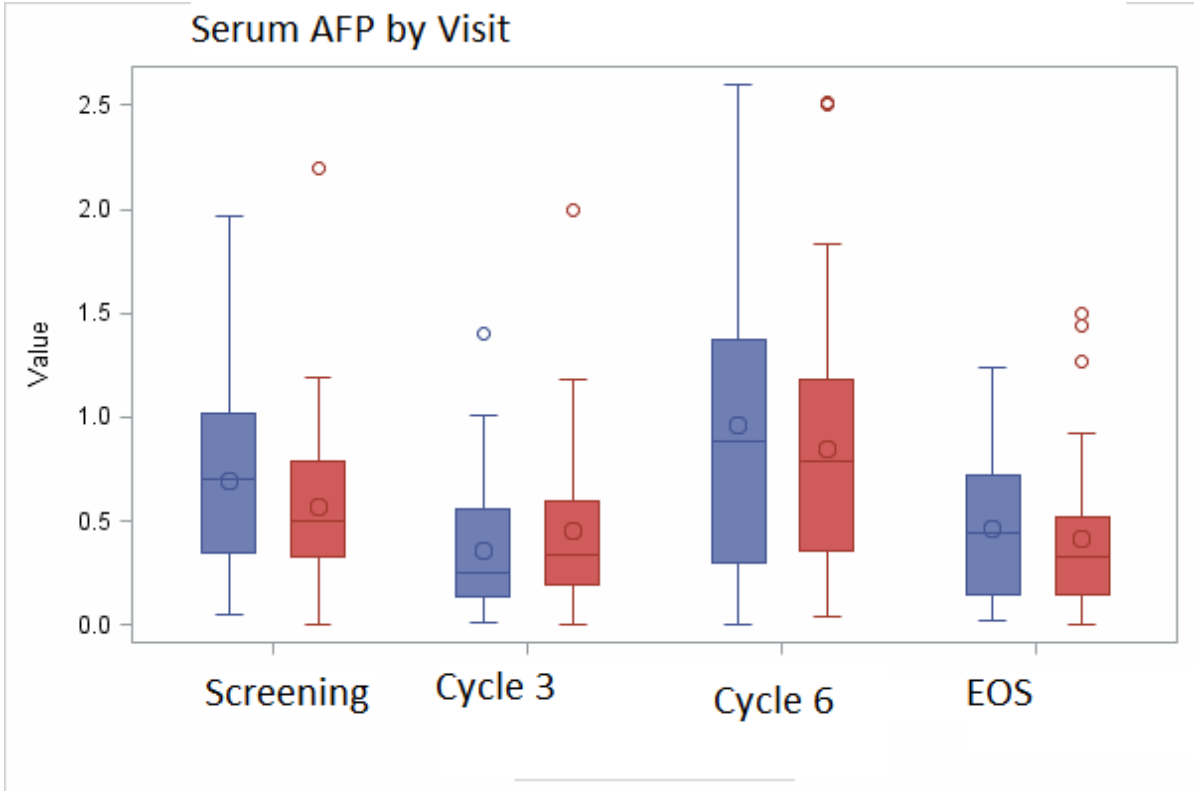
BL = Baseline

Programming note: continue for all subgroups
Programming note: repeat for Cohorts 2-5

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY
Note: Baseline is defined as the most recent measurement prior to the first administration of study drug.

Figure 14.2.11.1a

Plasma 2-HG by Time Point (Cohort 1, PD Population)



Programming note; Different colors indicate single agent and combination therapy. Please include legend indicating this.
Programming note; please include value and unit on Y-axis

Repeat for Cohorts 2-5.
Repeat for Figure 14.2.11.2 Urine 2-HG, Figure 14.2.11.3 MRS 2-HG, and Figure 14.2.11.4 CSF 2-HG

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Table 14.2.12a

Summary of Phamacokinetic Concentration over Time (Cohort 1, Pharmacokinetic Population)

Visit, Time Point	Statistic	Cohort 1A: FT-2102 (N =)	Cohort 1B: FT-2102 + AZA (N =)	Cohort 1: Overall (N =)
Cycle 1, 1 Hour	n			
	mean			
	SD			
	CV (%)			
	Geometric mean			
	Geometric SD			
	median			
	min - max			
Cycle 1, 2 Hours	n			
	mean			
	SD			
	Geometric mean			
	Geometric SD			
	median			
	min - max			
Cycle 1, 4 Hours	n			
	mean			
	SD			
	Geometric mean			
	Geometric SD			
	median			
	min - max			
Etc. for all time points and overall	n			
	mean			
	SD			
	Geometric mean			
	Geometric SD			

```
                                                    median
                                                    min - max



 Repeat for Cohorts 2-5
 )
Programming note: summarize all cycles where n is 3 or more.
```

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Table 14.2.13a

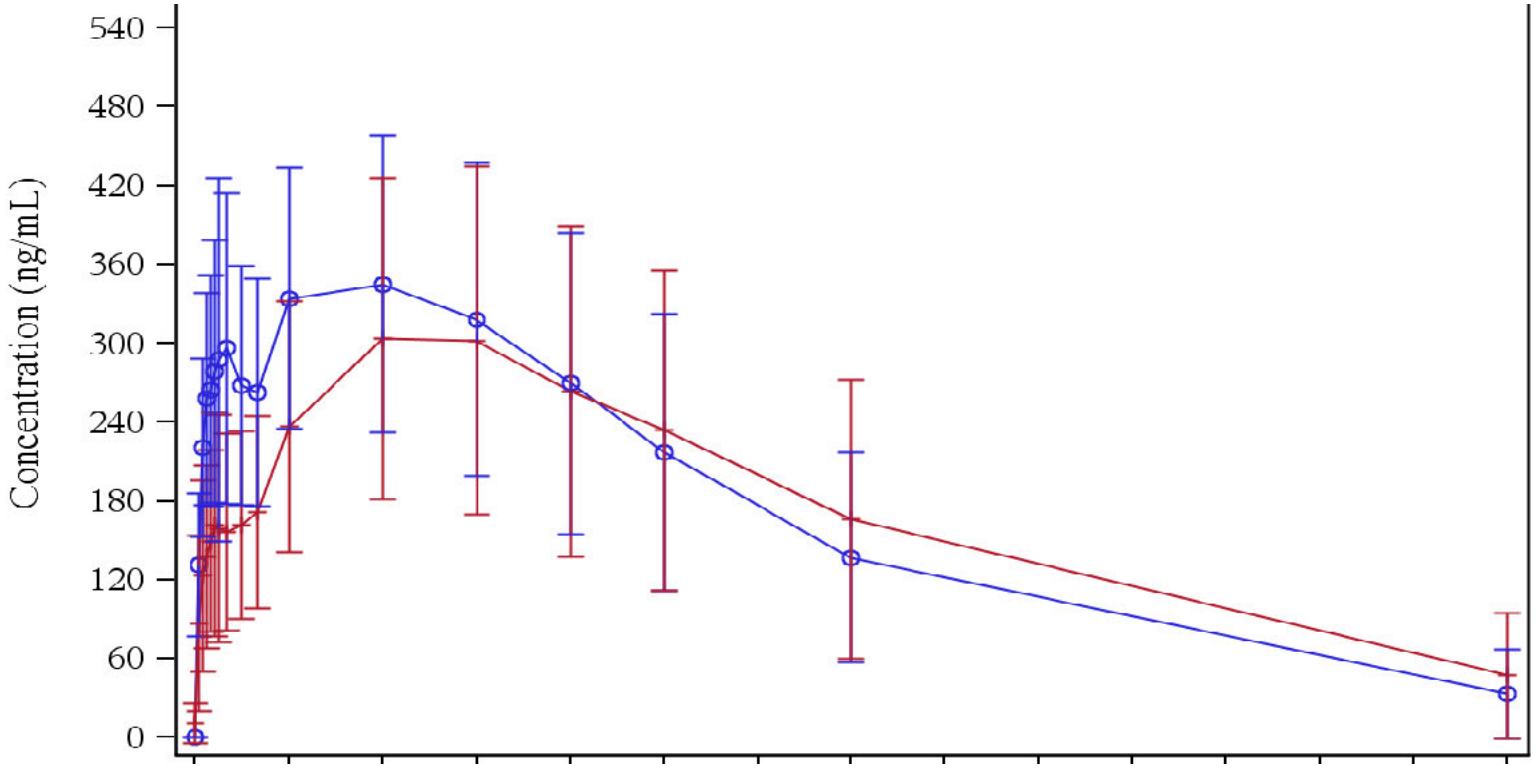
Summary of Phamacokinetic Parameters (All Patients on Single Agent Therapy, Pharmacokinetic Population)

Parameter	Statistic	Cohort 1A: FT-2102 (N =)	Cohort 1B: FT-2102 + AZA (N =)	Cohort 1: Overall (N =)
AUC0-24				
	n			
	mean			
	SD			
	CV (%)			
	Geometric mean			
	Geometric SD			
	median			
	min - max			
	median			
	min - max			
Etc. for all parameters	n			
	mean			
	SD			
	geometric mean			
	geometric SD			
	median			
	min - max			
Repeat for Cohorts 1-5				

)

Programming note: summarize all cycles where n is 3 or more.

Table 14.2.14.1a
Geometric Mean FT-2102 Plasma Concentration over Time (Cohort 1, PK Population)



Note: Only one line is needed. Plot geometric mean and use geometric SD for error bars.

Repeat for:

Figure 14.2.14.1	Cohorts 2-5
Figure 14.2.14.2	FT-2102 Plasma Concentration over Log-Time (Cohort 1, PK Population), but modify x axis so that it is on the log scale.
Figure 14.2.15a-f	FT-2102 Geometric Mean Plasma Concentration over Nominal Time (PK Population)

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Table 14.2.16.1a

Summary of FT-2102 Exposure (Cohort 1)

Visit Parameter	Statistic	Cohort 1A: FT-2102 (N =)	Cohort 1B: FT-2102 + AZA (N =)	Cohort 1: Overall (N =)
Overall				
Duration of FT-2102 exposure (days)	n			
	mean			
	SD			
	median			
	min - max			
Total dose FT-2102 taken (mg)	n			
	mean			
	SD			
	median			
	min - max			
Percent compliance	n			
	mean			
	SD			
	median			
	min - max			
C1				
Duration of FT-2102 exposure (days)	n			
	mean			
	SD			
	median			
	min - max			
Total dose FT-2102 taken (mg)	n			
	mean			
	SD			
	median			
	min - max			

Percent compliance	n
	mean
	SD
	median
	min - max

(etc. Summarize all cycles where there are 3 or more Patients overall).

Repeat for Cohorts 2-5
Repeat for 14.2.16.2 (Safety Population)

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

Table 14.2.17a

Summary of Azacitidine Exposure (Cohort 1, Safety Population)

Visit Parameter	Statistic	Cohort 1B: FT-2102 + AZA (N =)
Overall		
Duration of azacitidine exposure (days)	n	
	mean	
	SD	
	median	
	min - max	
Number of doses of azacitidine	n	
	mean	
	SD	
	median	
	min - max	
Number of patients with azacitidine dose interruptions	n	
	mean	
	SD	
	median	
	min - max	

Reason for interruption	
Adverse Event	n (%)
Other	n (%)

Number of Patients with Dose Modifications	
Dose Reduced	n (%)
Dose Increased	n (%)
Dose Held	n (%)
Dose Withdrawn	n (%)

Repeat for Cohorts 2-4, per appropriate combo drug

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Table 14.3.1.1a

Summary of Adverse Events (Cohort 1, Safety Population)

Parameter	Statistic	Cohort 1A: FT-2102 (N =)	Cohort 1B: FT-2102 + AZA (N =)	Cohort 1: Overall (N =)
Patients with any AE	n (%)			
Patients with any TEAE	n (%)			
Patients with any Grade 3 or greater TEAE	n (%)			
Patients with any Grade 4 or greater TEAE	n (%)			
Patients with any Grade 5 TEAE	n (%)			
Patients with DLT	n (%)			
Patients with SAE	n (%)			
Patients with treatment emergent SAE	n (%)			
Patients with FT-2102 related TEAE	n (%)			
Patients with azacitidine related TEAE	n (%)			
Patients with FT-2102 related treatment emergent SAE	n (%)			
Patients with TEAE related to FT-2102 resulting in dose interruption	n (%)			
Patients with TEAE related to FT-2102 resulting in dose withdrawal	n (%)			
Patients with TEAE related to FT-2102 resulting in dose reduction	n (%)			
Patients with TEAE related to azacitidine resulting in dose interruption	n (%)			
Patients with TEAE related to azacitidine resulting in dose withdrawal	n (%)			
Patients with TEAE related to azacitidine resulting in dose reduction	n (%)			

Repeat for Cohorts 2-5
Programming note: when programming tables for cohorts 2-5, substitute the appropriate combination agent for the cohort. Cohorts 1 & 3 have azacitidine, cohort 2 has nivolumab, cohort 4 has gem/cis, cohort 5 has no combination therapy.

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Table 14.3.1.2a

Treatment Emergent Adverse Events by MedDRA SOC and PT (Cohort 1, Safety Population)

System Organ Class (SOC) Preferred Term (PT)	Statistic	Cohort 1A: FT-2102 (N =)	Cohort 1B: FT-2102 + AZA (N =)	Cohort 1: Overall (N =)
SOC 1	n (%)			
PT 1	n (%)			
PT 2	n (%)			
PT 3	n (%)			
PT 4	n (%)			
etc. for all terms	n (%)			
SOC 2	n (%)			
PT 1	n (%)			
PT 2	n (%)			
PT 3	n (%)			
PT 4	n (%)			
etc. for all terms	n (%)			
etc. for all SOC/ PT				

Repeat for Cohorts 2-5

Programming note: repeat for:
Table 14.3.1.3: Treatment-Emergent Adverse Events Related to FT-2102 by MedDRA System Organ Class and Preferred Term (Safety Population)
Table 14.3.1.4: Severe Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term (Cohort 1, Safety Population)
Table 14.3.1.5: Severe Treatment-Emergent Adverse Events Related to FT-2102 by MedDRA System Organ Class and Preferred Term (Cohort 1, Safety Population)

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX | DATE: HH:MM/DDMMMYYYY
Note: Patients are counted once in each SOC and PT. Adverse Events are coded with the MedDRA version 21.0.

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Table 14.3.1.6a
Treatment Emergent Adverse Events by MedDRA Preferred Term (Cohort 1, Safety Population)

Preferred Term (PT)	Statistic	Cohort 1A: FT-2102 (N =)	Cohort 1B: FT-2102 + AZA (N =)	Cohort 1: Overall (N =)
PT 1	n (%)			
PT 2	n (%)			
PT 3	n (%)			
PT 4	n (%)			
etc. for all terms	n (%)			

Repeat for Cohorts 2-5

Programming note: sort preferred terms from most frequent to least frequent, based on the overall column.

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY
Note: Patients are counted once in each SOC and PT. Adverse Events are coded with the MedDRA version 21.0.

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Table 14.3.2.1

Listing of Deaths (Safety Population)

Cohort	Patient	Date of Last Dose	Date of Death	Rel Day	Primary Cause of Death	AE #

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Table 14.3.2.2

Listing of Serious Adverse Events (Safety Population)

Cohort	Patient	Verbatim Term	Start Date/ Rel Day	Stop Date/ Rel Day	CTCAE Grade/ SAE	Outcome	Relationship to Drug	Action Taken with Study Drug	Other Action Taken
							FT-2102: unrelated Aza: related	FT-2102: None Aza: Drug interrupted	

Programming note: in relationship and action columns, precede the information with the drug name being given in combination with FT-2102.

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

Note: The combination drug is Azacitidine in cohort 1b and 3b, Nivolumab in cohort 2b, and Gemcitibine + Cisplatin in cohort 4b.

[1] Relationship to Drug: None, REM = Remote, POS= Possible, PROB= Probable, DEF= Definite and NA= Not Applicable

[2] Action Taken with Study Drug: None = Dose Not Changed; INT = Dose Interrupted; RED = Dose Reduced; WD = Drug Withdrawn.

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Table 14.3.2.3

Listing of Adverse Events Resulting in Drug Interruptions or Withdrawals (Safety Population)

Cohort	Patient	Verbatim Term	Start Date/ Rel Day	Stop Date/ Rel Day	CTCAE Grade	SAE	Outcome	Relationship to Drug	Action Taken with Study Drug	Other Action Taken
								FT-2102: definite	FT-2102: Drug Withdrawn	

Programming note: in relationship and action columns, precede the information with the drug name being given in combination with FT-2102.

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

Note: The combination drug is Azacitidine in cohort 1b and 3b, Nivolumab in cohort 2b, and Gemcitibine + Cisplatin in cohort 4b.

[1] Relationship to Drug: None, REM = Remote, POS= Possible, PROB= Probable, DEF= Definite and NA= Not Applicable

[2] Action Taken with Study Drug: None = Dose Not Changed; INT = Dose Interrupted; RED = Dose Reduced; WD = Drug Withdrawn.

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Table 14.3.2.4

Listing of Dose Limiting Toxicities (Safety Population)

Cohort	Patient	Verbatim Term	Start Date/ Rel Day	Stop Date/ Rel Day	CTCAE Grade	SAE	Outcome	Relationship to Drug	Action Taken with Study Drug	Other Action Taken
								FT-2102: definite	FT-2102: Drug Withdrawn	

Programming note: in relationship and action columns, precede the information with the drug name being given in combination with FT-2102.

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY
Note: The combination drug is Azacitidine in cohort 1b and 3b, Nivolumab in cohort 2b, and Gemcitibine + Cisplatin in cohort 4b.
[1] Relationship to Drug: None, REM = Remote, POS= Possible, PROB= Probable, DEF= Definite and NA= Not Applicable
[2] Action Taken with Study Drug: None = Dose Not Changed; INT = Dose Interrupted; RED = Dose Reduced; WD = Drug Withdrawn.

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Table 14.3.4.1

Listing of Abnormal Laboratory Values (Safety Population)

Cohort	Patient	Laboratory Category	Test Name	Sample date	Rel Day	Visit Name	Result	Units	LLN	ULN	CTCAE Grade/ Flag	Clinical Significance
		Chemistry										
		Hematology										
		Urine										

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

Programming note: Repeat for table 14.3.4.2 Listing of Laboratory Values with CTCAE Grade 3 or Higher (Safety Population)
Programming note: for CTCAE Grade/ Flag, show CTCAE grade if the lab test is graded via CTCAE criteria. If not, indicate H for above upper limit of normal or L for below lower limit of normal

Table 14.3.4.3

Listing of Liver Function Tests of Potential Concern (Safety Population)

Cohort	Patient	Test Name	Sample date	Rel Day	Visit Name	Result	Units	ULN	Result xULN	CTCAE Grade	Clinical Significance	Concurrent AST, ALT and Total Bilirubin	Concurrent AST, ALT and Total Bilirubin, without ALP abnormality

Programming Note: present data supporting table 14.3.7. Only those lab test results should be presented.

Programming Note: result x ULN should be the derived value (result/ULN) rounded to one decimal.

Programming Note: Concurrent columns should indicate which abnormal results qualified for the "concurrent" flags in table 14.3.7.

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Table 14.3.5.1a

Summary of Hematology and Coagulation Results and Change from Baseline (Cohort 1, Safety Population)

Parameter	Statistic	Cohort 1A: FT-2102 (N =)		Cohort 1B: FT-2102 + AZA (N =)		Cohort 1: Overall (N =)	
		Value	Change from BL	Value	Change from BL	Value	Change from BL
WBC (unit)							
C1D1							
	n	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median						
	n	xx	xx	xx	xx	xx	xx
	min - max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
C1D8	n	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median						
	n	xx	xx	xx	xx	xx	xx
	min - max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
C1D15	n	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median						
	n	xx	xx	xx	xx	xx	xx
	min - max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
C1D22	n	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median						
	n	xx	xx	xx	xx	xx	xx

	min - max	xx - xx	xx - xx	xx	xx - xx	xx	xx - xx
C2D1	n	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	media n	xx	xx	xx	xx	xx	xx
	min - max	xx - xx	xx - xx	xx	xx - xx	xx	xx - xx
(etc for all cycle/ days for the parameter with at least 3 Patients reported in the overall column).	n	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	media n	xx	xx	xx	xx	xx	xx
	min - max	xx - xx	xx - xx	xx	xx - xx	xx	xx - xx
(etc. for all hematology parameters)							

BL = Baseline
Note: Baseline is defined as the most recent measurement prior to the first administration of study drug.

Programming note: repeat for Cohorts 2-5

Programming note: repeat for
Table 14.3.5.2 Chemistry

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Table 14.3.6.1a

Hematology and Coagulation Shifts from Baseline to Worst Value on Study, Overall and by Dose Group (Cohort 1, Safety Population)

Cohort / Parameter	Baseline Grade	Worst Grade on Study: Normal	1	2	3	4	5
Cohort 1A: FT-2102 (N=xx)							
WBC	Normal	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	1	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	2	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	3	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	4	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
RBC	Normal	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	1	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	2	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	3	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	4	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Platelets	Normal	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	1	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	2	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	3	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	4	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
(etc. for all hematology parameters)							
Cohort 1B: FT-2102+AZA (N=xx)							
WBC	Normal	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	1	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	2	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	3	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	4	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
RBC	Normal	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	1	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	2	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	3	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	4	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

Platelets	Normal		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
		1	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
		2	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
		3	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
(etc.)		4	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Cohort 1: Overall (N=xx)								
WBC	Normal		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
		1	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
		2	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
		3	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
		4	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
RBC	Normal		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
		1	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
		2	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
		3	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
		4	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Platelets	Normal		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
		1	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
		2	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
		3	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
(etc.)		4	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

Programming note: repeat for Cohorts 2-5

Programming note: repeat for Table 14.3.6.2 Chemistry Shifts (Safety Population)

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY
Note: Baseline is defined as the most recent measurement prior to the first administration of study drug.

Note: CTCAE v 4.03 is applied to lab values.

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Table 14.3.7a

Summary of Liver Function Tests of Potential Concern (All Patients Receiving Single Agent Therapy, Safety Population)

Parameter	Statistic	Cohort 1A: FT-2102 (N =)	Cohort 2A: FT-2102 (N =)	Cohort 3A: FT-2102 (N =)	Cohort 4A: FT-2102 (N =)	Cohort 5: FT-2102 (N =)	Overall: FT-2102 (N =)
ALT							
ALT >3X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ALT >5X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ALT >10X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ALT >20X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No post-baseline values meet the criteria	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
AST							
AST >3X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
AST >5X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
AST >10X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
AST >20X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No post-baseline values meet the criteria	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
AST,ALT							
AST or ALT >3X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
AST or ALT >5X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
AST or ALT >10X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
AST or ALT >20X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No post-baseline values meet the criteria	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total Bilirubin							
Total Bilirubin >1.5X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total Bilirubin >=2X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No post-baseline values meet the criteria	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ALP							
ALP >2.5X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ALP >5X ULN							

No post-baseline values meet the criteria	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Concurrent AST, ALT and Total Bilirubin*							
(AST or ALT >3X ULN) and Total Bilirubin >1.5X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
(AST or ALT >3X ULN) and Total Bilirubin >2X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No post-baseline values meet the criteria	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Concurrent AST, ALT and Total Bilirubin, without ALP abnormality**							
(AST or ALT >3X ULN) and Total Bilirubin >1.5X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
(AST or ALT >3X ULN) and Total Bilirubin >2X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No post-baseline values meet the criteria	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ALT>3x ULN or AST>3x ULN with CONCURRENT report of selected adverse event(s)***	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

ULN = Upper limit of normal
Note: A Patient may be counted in more than one row.
*Laboratory parameters must be met within +/- 7 days of those parameters to be counted as concurrent.
** ALP must be <2x ULN for all tests drawn within +/- 7 days of the concurrent elevated AST/ALT and Bilirubin.
***Selected adverse events: Nausea, Vomiting, Anorexia, Abdominal pain, Abdominal discomfort, Fatigue, Jaundice, Pruritus, Chromaturia, Faeces discoloured.

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Table 14.3.7b

Summary of Liver Function Tests of Potential Concern (Safety Population)

Parameter	Statistic	Cohort 1A: FT-2102 (N =)	Cohort 1B: FT-2102 + AZA (N =)	Cohort 1: Overall (N =)
ALT				
ALT >3X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ALT >5X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ALT >10X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ALT >20X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No post-baseline values meet the criteria	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
AST				
AST >3X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
AST >5X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
AST >10X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
AST >20X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No post-baseline values meet the criteria	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
AST,ALT				
AST or ALT >3X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
AST or ALT >5X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
AST or ALT >10X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
AST or ALT >20X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No post-baseline values meet the criteria	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total Bilirubin				
Total Bilirubin >1.5X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total Bilirubin >=2X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No post-baseline values meet the criteria	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ALP				
ALP >2.5X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ALP >5X ULN				
No post-baseline values meet the criteria	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Concurrent AST, ALT and Total Bilirubin*				
(AST or ALT >3X ULN) and Total Bilirubin >1.5X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

(AST or ALT >3X ULN) and Total Bilirubin >2X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No post-baseline values meet the criteria	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Concurrent AST, ALT and Total Bilirubin, without ALP abnormality**				
(AST or ALT >3X ULN) and Total Bilirubin >1.5X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
(AST or ALT >3X ULN) and Total Bilirubin >2X ULN	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No post-baseline values meet the criteria	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ALT>3x ULN or AST>3x ULN with CONCURRENT report of selected adverse event(s)***	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

ULN = Upper limit of normal
Note: A Patient may be counted in more than one row.
*Laboratory parameters must be met within +/- 7 days of those parameters to be counted as concurrent.
** ALP must be <2x ULN for all tests drawn within +/- 7 days of the concurrent elevated AST/ALT and Bilirubin.
***Selected adverse events: Nausea, Vomiting, Anorexia, Abdominal pain, Abdominal discomfort, Fatigue, Jaundice, Pruritus, Chromaturia, Faeces discoloured.

Programming note: repeat for cohorts 3-5.

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Table 14.3.8a

Summary of Vital Signs and Change from Baseline by Time Point, Overall and by Dose Group (Cohort 1, Safety Population)

Parameter	Statistic	Cohort 1A: FT-2102 (N =)		Cohort 1B: FT-2102 + AZA (N =)		Cohort 1: Overall (N =)	
		Value	Change from BL	Value	Change from BL	Value	Change from BL
SBP (unit)							
C1D1							
	n	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median	xx	xx	xx	xx	xx	xx
	min - max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
C1D8	n	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median	xx	xx	xx	xx	xx	xx
	min - max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
C1D15	n	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median	xx	xx	xx	xx	xx	xx
	min - max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
C1D22	n	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median	xx	xx	xx	xx	xx	xx
	min - max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
C2D1	n	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median	xx	xx	xx	xx	xx	xx
	min - max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx

(etc for all cycle/ days for the parameter with at least 3 Patients reported in the overall column).	n	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median	xx	xx	xx	xx	xx	xx
	min - max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
(etc. for all vital signs)							

BL = Baseline
Programming note: repeat for Cohorts 2-5

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY
Note: Baseline is defined as the most recent measurement prior to the first administration of study drug.

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Table 14.3.9a

Summary of ECG Results and Change from Baseline (Cohort 1, Safety Population)

Parameter				Cohort 1A: FT-2102 (N =)		Cohort 1B: FT-2102 + AZA (N =)		Cohort 1: Overall (N =)	
Visit	Time Point	Statistic		Value	Change from BL	Value	Change from BL	Value	Change from BL
QRS (unit)									
C1D1									
	Pre-dose	n		xx	xx	xx	xx	xx	xx
		mean		xx	xx	xx	xx	xx	xx
		SD		xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		median		xx	xx	xx	xx	xx	xx
		min - max		xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
	4 hours	n		xx	xx	xx	xx	xx	xx
		mean		xx	xx	xx	xx	xx	xx
		SD		xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		median		xx	xx	xx	xx	xx	xx
		min - max		xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
	8 hours	n		xx	xx	xx	xx	xx	xx
		mean		xx	xx	xx	xx	xx	xx
		SD		xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		median		xx	xx	xx	xx	xx	xx
		min - max		xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
C1D2	Pre-dose	n		xx	xx	xx	xx	xx	xx
		mean		xx	xx	xx	xx	xx	xx
		SD		xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		median		xx	xx	xx	xx	xx	xx
		min - max		xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx

(etc for all cycle/ days/ time points for the parameter with at least 3 Patients reported in the overall column).	n	xx	xx	xx	xx	xx	xx
	mean	xx	xx	xx	xx	xx	xx
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	median	xx	xx	xx	xx	xx	xx
	min - max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
(etc. for all ECG parameters)							

BL = Baseline
Programming note: repeat for Cohorts 2-5

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY
Note: Baseline is defined as the most recent measurement prior to the first administration of study drug.

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Table 14.3.10.1a

QTcF Shifts from Baseline (Single Agent Therapy, Safety Population)

Treatment Group	Baseline Value	Maximum Post-Baseline Value					
		<=450 msec	>450 to <=480 msec	>480 to <=500 msec	>500 msec	>30 to <=60 msec Change from Baseline	>60 msec Change from Baseline
		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Cohort 1 (N=xx)	<=450 msec						
	>450 to <=480 msec						
	>480 to <=500 msec						
	>500 msec						
	Total						
Cohort 2 (N=xx)	<=450 msec						
	>450 to <=480 msec						
	>480 to <=500 msec						
	>500 msec						
	Total						
Cohort 3 (N=xx)	<=450 msec						
	>450 to <=480 msec						
	>480 to <=500 msec						
	>500 msec						
	Total						
Cohort 4 (N=xx)	<=450 msec						
	>450 to <=480 msec						
	>480 to <=500 msec						

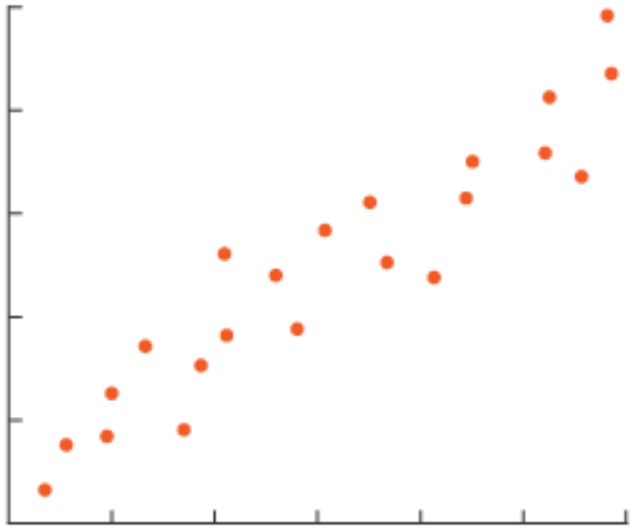
```
                           >500 msec
                               Total

 Cohort 5 (N=xx)           <=450 msec
                  >450 to <=480 msec
                  >480 to <=500 msec
                           >500 msec
                               Total
```

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

Repeat for:
Table 14.3.10.1b QTcF Shifts from Baseline (Combination Therapy, Safety Population)

Figure 14.3.10.2a
Maximum Post Baseline QTcF vs Baseline QTcF (Single Agent Therapy, Safety Population)



Repeat for 14.3.10.2b (Combination Therapy, Safety Population)

Programming notes:

- One axis represents baseline QTcF and the other axis represents maximum post-baseline QTcF. Include unscheduled visits as candidates for maximum.
- Color code the dots by cohort.
- Add reference lines for QTcF of 450, 480, and 500 on both axes.

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Table 14.3.11a
Concomitant Medications (Cohort 1)

Parameter	Statistic	Cohort 1A: FT-2102 (N =)	Cohort 1B: FT-2102 + AZA (N =)	Cohort 1: Overall (N =)
Drug class 1	n (%)			
ATC text 1	n (%)			
ATC text 2	n (%)			
ATC text 3	n (%)			
etc.	n (%)			
Drug class 2	n (%)			
ATC text 1	n (%)			
ATC text 2	n (%)			
ATC text 3	n (%)			
etc.	n (%)			

Repeat for Cohorts 2-5

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX | DATE: HH:MM/DDMMMYYYY

Note: Patients are counted once per drug class and ATC. Concomitant Medications are coded with the WHO Drug version March 2018.

10. DATA LISTING SHELLS

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Listing 16.2.1.1

Study Completion Status

Cohort	Patient	First Dose Date of FT-2102	Last Dose Date of FT-2102	Last Dose Rel Day	Reason for Terminating Treatment	Reason for Terminating Study	Date of Last Contact

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.1.2

Pre-Screening Consent

Cohort	Patient	Pre-Screening Consent	IDH1 Mutation Result	Consent Date for Archival Tumor Tissue	Date of Tissue Collection

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.1.3

Enrollment

Cohort	Patient	Screen Failure	Study Phase and Stage	Safety Lead In	Pharmaco-genomics Consent	Consent for C3 Tumor Tissue Sample

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX | DATE: HH:MM/DDMMMYYYY

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Listing 16.2.2.1

Inclusion and Exclusion Criteria

Cohort	Patient	Informed Consent Date	Protocol Version Consented	Inclusion/ Exclusion Criteria Not Met

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX | DATE: HH:MM/DDMMMYYYY

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Listing 16.2.2.2

Protocol Violations

Cohort	Patient	Violation Severity	Violation Category	Violation Description
		Major		
		Minor		

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX | DATE: HH:MM/DDMMMYYYY

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Listing 16.2.3.1

Analysis Sets

Cohort	Patient	DLT Evaluable Set	Safety Set	Response Evaluable Set	PK Set	PD Set

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.4.1

Demographics and Baseline Information

Cohort	Patient	Age at Consent	Height (cm)	Sex at Birth	Child Bearing Potential	Ethnicity	Race

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.4.2

Baseline Disease Data and Cancer Diagnosis

		Initial					Current					
Cohort	Patient	Diagnosis	Diagnosis Date	Grade	Stage	TNM Stage	Diagnosis	Recurrence Date	Grade	Stage	TNM Stage	Fibrosis

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.4.3

IDH1 and Other Mutations

		IDH Mutation					
Cohort	Patient	Sample Date	Method	Site of Tissue	Result	IDH Mutation	Other Mutations

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX | DATE: HH:MM/DDMMMYYYY

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Listing 16.2.4.4

Medical History

Cohort	Patient	Start Date	Verbatim Term	SOC	PT	CTC Grade	End Date

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

Note: Medical Histories are coded with the MedDRA version 21.0.

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Listing 16.2.4.5

Prior Anti-Cancer Therapies

Cohort	Patient	Regimen	Therapy Name/ WHO Drug Name	Therapy Type/ WHO Drug Class	Start Date/ End Date	Best Response

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

Note: Prior anti-cancer therapy medications are coded with the WHO Drug version March 2018.

Programming notes:

- For Best Response, abbreviate responses as: CR, PR, MR, SD, PD, ND, UN

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Listing 16.2.4.6

Prior Radiotherapy

Cohort	Patient	Type of Radiation	Start Date	End Date	Dose	Unit	Location	Best Response

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

Listing 16.2.4.7

Major Surgical Tumor Resections

Cohort	Patient	Surgical Procedure Description	Location	Procedure Date

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Listing 16.2.4.8

Child Pugh Score

Cohort	Patient	Assessment Date	Total Bilirubin	Serum Albumin	INR	Ascites	Hepatic Encepal-opathy	Child Pugh Score

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.4.9

Hepatitis B and C

					Hepatitis B			Hepatitis C		
Cohort	Patient	Assessment Date	Assessment Time	Method of Assessment	Result	Titer	Unit	Result	Titer	Unit

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

DATE: HH:MM/DDMMMYYYY

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Listing 16.2.4.10

Archival Tumor Tissue

Cohort	Patient	Collection Date	Sample Type	Tissue Site	Was the sample sent to the lab?

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.5.1

FT-2102 Administration

Cohort	Patient	Start Date (Rel Day)	End Date (Rel Day)	Assigned Dose	Frequency	Actual Total Daily Dose	Dose Modification	Reason

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.5.2

FT-2102 Drug Accountability

			Dispensed		Returned		Taken per Pt Diary				
Cohort	Patient	Cycle	50 mg Capsules	150 mg Capsules	50 mg Capsules	150 mg Capsules	50 mg Capsules	150 mg Capsules	Total Dose Taken (mg)	Total Dose Not Taken and Not Returned (mg)	Percent Compliance

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.5.3

Azacitidine, Nivolumab, Cisplatin, and Gemcitabine Administration

Cohort	Patient	Drug	Cycle/ Time Point	Dosing Date (Rel Day)	Start/ Stop Time	Assigned Dose (Unit)/ Route	Prepared Dose (mg)	Volume of Prepared Dose (mL)	Volume Admin-istered (mL)	Dose Modification/ Reason	Interruption/ Reason/ Start Time/ Stop Time
		Azacitidine									
		Nivolumab									
		Cisplatin									
		Gemcitabine									

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX | DATE: HH:MM/DDMMMYYYY

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Listing 16.2.5.4

Pharmacokinetic Concentrations

Cohort	Patient	Visit	Sample Date	Rel Day	Value	Laboratory Comments

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.5.5

Pharmacokinetic Parameters

Cohort	Patient	-	Cmax	Tmax	Thalf	AUC

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.6.1

Target Lesions (RECIST)

Cohort	Patient	Visit	Imaging Date (Rel Day)	Lesion Number	Lesion Location/ Description	Method of Measurement & Contrast	Lesion State	Assessment Result	Longest Diameter (mm)

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.6.2

Non-Target and New Lesions (RECIST)

Cohort	Patient	Visit	Imaging Date (Rel Day)	Lesion Number/ New Lesion	Lesion Location/ Description	Method of Measurement & Contrast	Lesion State	Assessment Result	Longest Diameter/ Short Axis

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.6.3

Measurable Lesions (RANO)

Cohort	Patient	Visit	Imaging Date (Rel Day)	Lesion Number	Lesion Location Category	Location Description	Method of Measurement & MRI Details	Lesion Assessment Result	Longest Diameter (mm)	Perpendicular Measurement (mm)	Lesion Area (mm^2)
					Cerebrum Cerebellum Brainstem Spine Other	Print Location from nodal location or extranodal location and location description fields					

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX | DATE: HH:MM/DDMMMYYYY

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Listing 16.2.6.4

Non-Measurable and New Lesions (RANO)

Cohort	Patient	Visit	Imaging Date (Rel Day)	Lesion Number/ New Lesion	Lesion Location Category	Location Description	Method of Measurement & MRI Details	Lesion Assessment Result	Longest Diameter (mm)	Perpen-dicular Measurement (mm)	Lesion Area (mm^2)
					Cerebrum Cerebellum Brainstem Spine Other	Print Location from nodal location or extranodal location and location description fields					

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.6.5

Response Assessment (RECIST)

Cohort	Patient	Visit	Assessment Date (Rel Day)	Target Lesion Response	Non-Target Lesion Response	New Lesions	Overall Response	Best Overall Response	Progression Date (Rel Day)

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.6.6

Response Assessment (RANO)

Cohort	Patient	Visit	Assessment Date (Rel Day)	Measurable Lesion Response	Non-Measurable Lesion Response	New Lesions	Steroid Status	Clinical Status	Overall Response	Best Overall Response	Progression Date (Rel Day)

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.6.7

Response Assessment (Cheson)

Cohort	Patient	Visit	Assessment Date (Rel Day)	Sum of the Product Diameters (mm^2)	Measurable Lesion Response	Non-Measurable Lesion Response	New Lesions	Overall Response	Best Overall Response	Progression Date (Rel Day)

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.6.8

Survival Status

Cohort	Patient	Date Last Known Alive (Rel Day)	Patient Status at Time of Follow Up	Disease Progression Not Previously Reported?	Treated with Anti-Cancer Therapy for Disease?	Start Date of New Treatment (Rel Day)

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.6.9

Serum AFP, CA-19-9, and CEA

Cohort	Patient	Visit	Date of Sample	Rel Day	Serum AFP Value	CA19-9 Value	CEA Value	Laboratory Comments

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.6.10

EQ-5D-5L Quality of Life Assessment

Cohort	Patient	Visit	Assessment Date (Rel Day)	Mobility	Self Care	Usual Activities	Pain/ Discomfort	Anxiety/ Depression	Your Health Today

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.6.11

2-HG MRS Assessments

Cohort	Patient	Visit	Assessment Date	Rel Day	2-HG Value	Imaging Reader Comments

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.6.12

Archival Tumor Tissue and Biopsy

Cohort	Patient	Visit	Sample Collection Date	Rel Day	Sample Type	Tissue Collection Site	Sample Sent to Lab?

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.6.13

Pharmacogenomics Samples

Cohort	Patient	Visit	Pharmacogenomics Sample Collected?	Sample Date	Rel Day	Sample Time

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.7.1

Adverse Events by Patient and Verbatim Term

Cohort	Patient	Verbatim Term	Preferred Term	Start Date (Rel Day)	Stop Date (Rel Day)	CTCAE Grade	SAE	Outcome	Relationship to Drug[1]	Action Taken with Study Drug[2]	Other Action Taken

Programming Note: Sort by cohort, Patient, start date, and preferred term

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

Note: Adverse Events are coded with the MedDRA version 21.0.
Note:The combination drug is Azacitidine in cohort 1b and 3b, Nivolumab in cohort 2b, and Gemcitibine + Cisplatin in cohort 4b.
[1] Relationship to Drug: None, REM = Remote, POS= Possible, PROB= Probable, DEF= Definite and NA= Not Applicable
[2] Action Taken with Study Drug: None = Dose Not Changed; INT = Dose Interrupted; RED = Dose Reduced; WD = Drug Withdrawn.

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Listing 16.2.7.2

Adverse Events by Patient and MedDRA System Organ Class and Preferred Term

Cohort	Patient	System Organ Class	Preferred Term	Start Date (Rel Day)	Stop Date (Rel Day)	CTCAE Grade	SAE	Outcome	Relationship to Drug[1]	Action Taken with Study Drug[2]	Other Action Taken

Programming Note: Sort by cohort, Patient, system organ class, preferred term, and start date.

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

Note: Adverse Events are coded with the MedDRA version 21.0.

Note:The combination drug is Azacitidine in cohort 1b and 3b, Nivolumab in cohort 2b, and Gemcitibine + Cisplatin in cohort 4b.

[1] Relationship to Drug: None, REM = Remote, POS= Possible, PROB= Probable, DEF= Definite and NA= Not Applicable

[2] Action Taken with Study Drug: None = Dose Not Changed; INT = Dose Interrupted; RED = Dose Reduced; WD = Drug Withdrawn.

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Listing 16.2.7.3

Adverse Events by MedDRA System Organ Class, Preferred Term, Cohort, and Patient

System Organ Class	Preferred Term	Cohort	Patient	Start Date (Rel Day)	Stop Date (Rel Day)	CTCAE Grade	SAE	Outcome	Relationship to Drug[1]	Action Taken with Study Drug[2]	Other Action Taken

Programming Note: Sort by system organ class, preferred term, cohort, Patient, and start date.

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

Note: Adverse Events are coded with the MedDRA version 21.0.

Note:The combination drug is Azacitidine in cohort 1b and 3b, Nivolumab in cohort 2b, and Gemcitibine + Cisplatin in cohort 4b.

[1] Relationship to Drug: None, REM = Remote, POS= Possible, PROB= Probable, DEF= Definite and NA= Not Applicable

[2] Action Taken with Study Drug: None = Dose Not Changed; INT = Dose Interrupted; RED = Dose Reduced; WD = Drug Withdrawn.

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Listing 16.2.8.1

Laboratory Results: Hematology

Cohort	Patient	Test Name	Sample date (Rel Day)	Visit Name	Result	Units	LLN	ULN	CTCAE Grade/ Flag	Clinical Significance

Programming note: for CTCAE Grade/ Flag, show CTCAE grade if the lab test is graded via CTCAE 4.03 criteria. If not, indicate H for above upper limit of normal or L for below lower limit of normal

Programming note: repeat for 16.2.8.2, 16.2.8.3, 16.2.8.4, 16.2.8.6

Programming note: tests that should be in 16.2.8.6 include TSH testing, pregnancy, and Hepatitis B and C testing

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX | DATE: HH:MM/DDMMMYYYY

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Listing 16.2.8.5

Laboratory Normal Ranges

Laboratory Name	Start Date	Stop Date	Gender	Age Category	LLN	ULN

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.9.1

Vital Signs

Cohort	Patient	Visit	Assessment Date (Rel Day)	Assessment Time	Weight (kg)	Temperature (C)	Pulse (beats/min)	Respiratory Rate (breaths/mim)	SBP (mmHg)	DBP (mmHg)

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX | DATE: HH:MM/DDMMMYYYY

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Listing 16.2.9.2

Physical Examination

Cohort	Patient	Visit	Assessment Date	Rel Day	Overall Assessment	If Abnormal, Was Abnormality Present at Screening

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.9.3

Electrocardiogram Results

Cohort	Patient	Visit	Assessment Date (Rel Day)	Time Point	Time of ECG	ECG #	PR	HR	QRS	QT	QTcF	Overall Evaluation/ Clinical Significance	Abnormal, Specify

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.9.4

Prior and Concomitant Medications

Cohort	Patient	Medication	WHO Drug Class	ATC Text	Reason for Medication/ Indication	Dose and Units	Frequency	Route	Start Date (Rel Day)/ Stop Date (Rel Day)	Prior/ Concomitant

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

Note: Prior and Concomitant Medications are coded with the WHO Drug version March 2018.

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Listing 16.2.9.5

Concomitant Procedures

Cohort	Patient	Procedure	Reason for Procedure	Location	Procedure Date	Rel Day

Note: sort by cohort, Patient, and procedure date.

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.9.6

Systemic Steroid Dosing

Cohort	Patient	Medication	WHO Drug Class	ATC Text	Dose and Units	Frequency	Route	Start Date (Rel Day)/ Stop Date (Rel Day)

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

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Listing 16.2.9.7

ECOG Performance Status

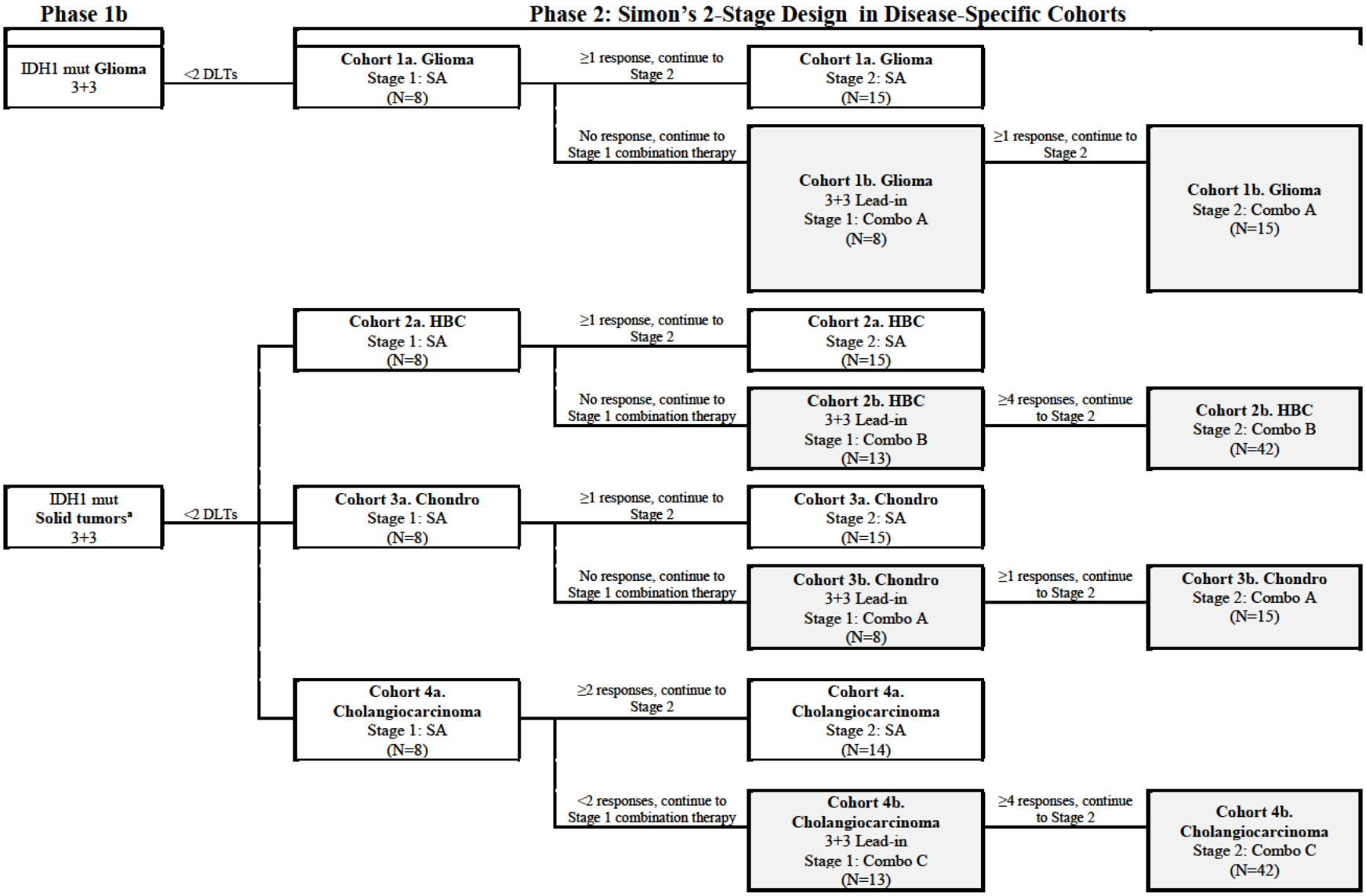
Cohort	Patient	Visit	Assessment Date	Rel Day	ECOG Performance Status

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

11. REVISION HISTORY

Version/ Date	Revisions
1.0/ 05MAR2019	First version
2.0/ 28JUN2019	Update SAP to align with version 3.0 of the protocol. Edit PK analysis details, minor edits/ clarifications to table shells, add QTcF figure, clarify handling of missing date parts, edit criteria for liver function test summary table.

12. STUDY SCHEMATIC


Phase 1b
Phase 2: Simon's 2-Stage Design in Disease-Specific Cohorts
IDH1 mut Glioma
3+3
<2 DLTs
Cohort 1a. Glioma
Stage 1: SA
(N=8)
≥1 response, continue to Stage 2
Cohort 1a. Glioma
Stage 2: SA
(N=15)
No response, continue to Stage 1 combination therapy
Cohort 1b. Glioma
3+3 Lead-in
Stage 1: Combo A
(N=8)
≥1 response, continue to Stage 2
Cohort 1b. Glioma
Stage 2: Combo A
(N=15)
IDH1 mut
Solid tumors[a]
3+3
<2 DLTs
Cohort 2a. HBC
Stage 1: SA
(N=8)
≥1 response, continue to Stage 2
Cohort 2a. HBC
Stage 2: SA
(N=15)
No response, continue to Stage 1 combination therapy
Cohort 2b. HBC
3+3 Lead-in
Stage 1: Combo B
(N=13)
≥4 responses, continue to Stage 2
Cohort 2b. HBC
Stage 2: Combo B
(N=42)
Cohort 3a. Chondro
Stage 1: SA
(N=8)
≥1 response, continue to Stage 2
Cohort 3a. Chondro
Stage 2: SA
(N=15)
No response, continue to Stage 1 combination therapy
Cohort 3b. Chondro
3+3 Lead-in
Stage 1: Combo A
(N=8)
≥1 responses, continue to Stage 2
Cohort 3b. Chondro
Stage 2: Combo A
(N=15)
Cohort 4a. Cholangiocarcinoma
Stage 1: SA
(N=8)
≥2 responses, continue to Stage 2
Cohort 4a. Cholangiocarcinoma
Stage 2: SA
(N=14)
<2 responses, continue to Stage 1 combination therapy
Cohort 4b. Cholangiocarcinoma
3+3 Lead-in
Stage 1: Combo C
(N=13)
≥4 responses, continue to Stage 2
Cohort 4b. Cholangiocarcinoma
Stage 2: Combo C
(N=42)

Combo A=FT-2102 + 5-azacitidine; **Combo B**=FT-2102 + PD-1 inhibitor (nivolumab); **Combo C**=FT-2102 + GemCis; Chondro=chondrosarcoma; DLT=dose limiting toxicity; HBC=hepatobiliary cancer; IHCC=intrahepatic cholangiocarcinoma; mut=mutation; SA=single-agent FT-2102.

Combination therapy in cohorts 1-4 may also be examined in the event that the single agent cohort passes the futility analysis and the enrollment in the single agent cohort is completed **Up to 6 patients with relapsed or refractory non-CNS solid tumors harboring an IDH1 R132X mutation in exploratory Cohort 5a will be treated with single-agent FT-2102.**