Cover Page for Statistical Analysis Plan

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FORMA Therapeutics, Inc.
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Statistical Analysis Plan

Redacted statistical analysis plan
Includes redaction of personal identifiable information only.

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Summary of Changes

Version 1.0	N/A; first version
Version 2.0	Numerous revisions based on regulatory agency interactions. Clarify language, describe imputation of missing data, clarify exposure calculations, edit algorithm for AESI differentiation syndrome, edit transfusion independence analysis, edit censoring rules for time to event endpoints
Version 3.0	Add detail on alpha and beta spend for Phase 2 cohort 1 interim analyses, add sensitivity analysis for the effect of COVID-19 on time to event endpoints. Revise description of AESI analysis.
Version 4.0	Add detail about missing data imputation for QOL assessment. Update definition of BOR. Updates to DS analysis details. Add sensitivity analysis for efficacy.
Version 5.0	Time from diagnosis and time to event end points units changed from weeks to months. Total number of prior regimens received categorical presentation updated. Duration of response definition has been updated to exclude introduction of new anticancer therapy from the events list as per the FDA guidance. Added sensitivity analyses for time to event efficacy end points. Updated analyses for adverse events of special interest: hepatic adverse drug reactions. Clarified that some analyses performed for pivotal IA2 will not be performed for final analysis.

CONTENTS

ABBREVIATIONS

Abbreviation	Definition
AE	adverse event
AESI	adverse event of special interest
ALP	alkaline phosphatase
ALT (SGPT)	alanine transaminase
AML	acute myeloid leukemia
AST (SGOT)	aspartate transaminase
ATC	anatomical therapeutic chemical
AUC	area under the concentration curve
AUC_{last}	AUC up to the last measurable concentration
AUC_{inf}	AUC to infinite time
AUC_{tau}	AUC over the dosing interval
BID	twice daily
CBC	complete blood count
CL/F	total body clearance
C_{max}	maximum plasma concentration
CTCAE	common terminology criteria for adverse events
CR	complete remission
CRh	complete remission with partial hematological recovery
CRi	complete remission with incomplete blood count recovery
DLT	dose-limiting toxicity
DS	differentiation syndrome
eCRF	electronic case report form
EDC	electronic data capture
ECG	Electrocardiogram
ECOG	Eastern Cooperative Oncology Group
2-HG	(R)-2-hydroxyglutarate
HSCT	hematopoietic stem cell transplantation
IDH1	isocitrate dehydrogenase 1
IDH2	isocitrate dehydrogenase 2
IPSS-R	Revised International Prognostic Scoring System
LDAC	low-dose cytarabine
MDS	myelodysplastic syndrome
MED	maximum evaluated dose
MTD	maximum tolerated dose
NCI	National Cancer Institute
PD	Pharmacodynamics
PK	Pharmacokinetics
PT	prothrombin time

PT	preferred term
PTT	partial thromboplastin time
QD	once daily
RFS	relapse free survival
SAP	statistical analysis plan
SA	single agent
SCT	stem cell transplant
SD	stable disease
SMQ	Standardised MedDRA Query
SOC	system organ class
TEAE	treatment emergent adverse event
$t_{1/2}$	terminal elimination half life
T_{max}	time to maximum plasma concentration
VAS	visual analogue scale
Vd/F	volume of distribution
WHO	World Health Organization

I. Introduction

This is a phase 1/2, multicenter, open-label study of FT-2102 as a single agent (SA) and in combination with azacitidine or cytarabine in patients with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS) with an IDH1 mutation.

This Statistical Analysis Plan (SAP) is based on version 5 of Protocol 2102-HEM-101.

This SAP will govern the analysis of data from this study. The plan may be modified until the time of database lock. Any deviations from the analysis plan, including any after the time of database lock, will be documented as such in the study report.

Any protocol-specified statistical analyses for pharmacokinetics (PK), or PK/PD in relationship with clinical safety and clinical activity will be prepared by related function in a separate document.

II. Protocol Objectives

A. Primary

The primary objectives are:

Phase 1

- To determine the maximum tolerated doses (MTDs), the maximum evaluated doses (MEDs), dose-limiting toxicities (DLTs), and the Recommended Phase 2 doses (RP2Ds) of FT-2102 as a single agent in combination with azacitidine, and in combination with cytarabine in patients with AML or MDS harboring an IDH1-R132 mutation.

Phase 2

- To evaluate the antileukemic and antimyelodysplastic activity of FT-2102 as a single agent or in combination with azacitidine in patients with AML or MDS, respectively harboring an IDH1-R132 mutation

B. Secondary

The secondary objectives are:

Phase 1

- To determine the pharmacokinetics (PK) of FT-2102 as a single agent and in combination with azacitidine or cytarabine
- To observe patients for any evidence of antileukemic or antimyelodysplastic activity of FT-2102 as a single agent and in combination with azacitidine or cytarabine

Phase 2

- To confirm the safety of FT-2102 as a single agent and in combination with azacitidine in select patient populations
- To evaluate additional measures of the antileukemic or antimyelodysplastic activity of FT-2102 as a single agent and in combination with azacitidine
- To determine the PK of FT-2102 as a single agent and in combination with azacitidine

C. Exploratory

The exploratory objectives are:

Phase 1 and Phase 2

- To assess on-target activity of FT-2102, as determined by changes in a PD biomarker in plasma
- To determine the frequency of cancer-associated mutations and/or genetic alterations in responding and nonresponding patients
- To evaluate PK/PD and clinical response relationships in each cohort

Phase 2

- To evaluate the health-related quality of life (QOL) of patients receiving FT-2102 as a single agent or in combination with azacitidine

III. Study Endpoints

A. Primary

The primary endpoints are:

Phase 1

- Incidence and severity of adverse events (AEs), clinical laboratory abnormalities, and changes in electrocardiogram (ECG) parameters

Phase 2

- All cohorts except Cohort 2: Complete Response rate (best overall response [BOR] of complete remission (CR)/complete remission with partial hematological recovery (CRh)) as determined by the investigator per disease-specific criteria. Refer to Appendix 6 for AML and Appendix 7 for MDS response criteria in the protocol.
- Cohort 2: Four-month relapse free survival (RFS) rate

B. Secondary

The secondary endpoints are:

Phase 1

- PK parameters derived from FT-2102 concentrations
- Antileukemic or antimyelodysplastic activity as determined by CR, CRh, complete remission with incomplete blood count recovery (CRi), morphologic leukemia-free state (MLFS), Marrow CR, partial remission (PR) and stable disease (SD)

Phase 2

- Evidence of clinical benefit (CRi, MLFS, Marrow CR, Overall Response (OR), Transfusion Independence (TI), Time to Response (TTR), Duration of Response (DOR), event free survival [EFS], RFS, Overall Survival (OS), and other definitions of response, including SD)
- Incidence and severity of adverse events (AEs), clinical laboratory abnormalities and changes in electrocardiogram (ECG) parameters
- PK parameters derived from plasma FT-2102 concentrations

IV. Study Design

A. Design Overview

This Phase 1/2 study will utilize a multicenter, open-label, dose-escalation design, to evaluate the safety, efficacy, PK, and PD of FT-2102 administered orally to patients with AML or MDS. Patients will be given FT-2102 daily (QD or BID) in continuous 28-day cycles, alone or in combination with azacitidine (administered at the dose of 75 mg/m^2 for 7 days IV/SQ per every 28-day cycle) or low-dose cytarabine (LDAC) (administered at the dose of 20 mg BID SC for 10 days every 28-day cycle) until treatment discontinuation.

The study is comprised of 3 stages: a Phase 1 dose-escalation stage, a Phase 1 dose-expansion stage, and a Phase 2 stage. See protocol sections 4.1 and 4.2 for details.

Phase 1 Dose-Escalation Stage

Dose escalation will be initiated using FT-2102 as a single agent in patients with AML or MDS harboring an IDH1-R132 mutation, as determined by local mutation testing. It is planned that doses of 150 and 300 mg FT-2102 QD (Schedule 1) will be tested. Twice-daily (BID) dosing (Schedule 2) and/or dosing with food to improve on bioavailability may be explored when indicated.

The dose-escalation stage will utilize a 3+3 design, whereby three evaluable patients will be treated at each dose level and if a DLT occurs, then the cohort will be expanded to six patients to determine a non-tolerated dose and MTD. For a given cohort, once two or more patients have a DLT, further enrollment/treatment for that cohort will halt, as will dose escalation. The dose level at which two or more of up to six patients have a DLT will be considered to be at least one dose level above the MTD.

The DLT dose level is defined as the lowest dose level at which DLT is experienced in two or more patients within a cohort of six or less patients. The MTD is the highest dose level

that does not meet the DLT dose level definition. The MED is defined as the highest dose level evaluated in the setting when dose escalation is stopped before an MTD is identified.

A dose-limiting toxicity is defined as any AE occurring in Cycle 1 that fulfills one or more of the following criteria. Toxicities will be graded and documented according to the NCI CTCAE, version 4.03 guidelines (see Appendix 3 of protocol):

- Nonhematological Grade 3 or greater toxicity that is unrelated to underlying disease, occurring in Cycle 1 with the following exceptions:
    - Alopecia
    - Grade 3 nausea, vomiting, diarrhea or rash lasting less than 72 hours (with optimal medical management)
    - Grade 3 QTcF prolongation that is < 40 msec increase over baseline in a patient with a bundle branch block (BBB)
    - Grade 3 or 4 toxicity determined to be a sign or symptom of differentiation syndrome that resolves/responds to treatment interventions to < Grade 3 within 7 days
- Any Grade 3 non-hematologic laboratory finding, unrelated to underlying disease, occurring in Cycle 1
- Hematologic Grade 4 toxicity as defined by CTCAE on Day 42, in the absence of disease
- Inability to tolerate a minimum of 75% of FT-2102 scheduled doses during Cycle 1 due to an AE. This applies to patients who have their dose held due to AEs per Section 6.8.1 of protocol.

All patients will be monitored for bone marrow function throughout the study, but these findings may not be considered a DLT unless they fulfill the above criteria.

A DLT is defined within the 28 days of Cycle 1. However, the sponsor will evaluate all safety data, on an ongoing basis, beyond Cycle 1 for determination of an appropriate dose for Phase 2 or later trials.

The dose-escalation portion of the study will allow dose increases of up to 50% between cohorts above the 300 mg total daily dose level until the MTD or an MED is determined. Initiation of Schedule 2 will occur following analysis of PK/PD parameters and clinical observations, and may be independent of an MTD in Schedule 1.

FT-2102 + Azacitidine (Combination) Dose-Escalation

During the course of dose escalation, a parallel escalation arm will be initiated for FT-2102 in combination with azacitidine in patients with AML or MDS harboring an IDH1-R132 mutation. The starting dose of FT-2102 in the combination agent is a dose level at which ≤ Grade 2 toxicities (i.e., no Grade 3 or higher toxicities) were observed when FT-2102 was administered as a single agent. This escalation will also enroll patients on a 3+3 design, whereby three patients will be treated and if one DLT occurs, then the cohort will be expanded to six patients; if more than one DLT occurs, escalation will stop at that dose level (or schedule). FT-2102 will be given orally QD (or BID) in continuous 28-day cycles.

Phase 1 Dose-Expansion Stage

Once the MTD or MED has been identified for the SA or azacitidine combination cohort, up to 14 additional patients will be enrolled in up to 2 expansion cohorts each of SA FT-2102 or in combination with azacitidine to confirm and to further characterize the safety and clinical activity of FT-2102 as a single agent or in combination with azacitidine. From these dose expansion cohorts, a recommended Phase 2 dose (RP2D) of FT-2102 as a single agent or in combination with azacitidine will be selected for subsequent evaluation in Phase 2.

FT-2102 in combination with cytarabine

After dose-expansion is complete for FT-2102 as a single agent and FT-2102 in combination with azacitidine, a cohort of 6 patients with AML harboring IDH1 mutation will be treated with FT-2102 in combination with cytarabine 20 mg BID for 10 days, and then cytarabine will be stopped for 18 days. Starting dose of 150 mg FT-2102 will be given twice daily in accordance with dosing schedule × 28 days out of 28 days. Further dose-escalation of FT-2102 in combination with cytarabine will not occur beyond 150 mg BID.

If > 1 DLTs are observed at the 150 mg BID dose in combination with cytarabine, a lower dose level may be explored.

Recommended Phase 2 Dose

FT-2102 150 mg BID is the RP2D confirmed for single-agent and azacitidine combination treatment.

Phase 2

The Phase 2 portion of the study is comprised of 4 patient cohorts receiving single agent therapy, and 4 patient cohorts receiving combination therapy, defined as follows.

Single-Agent Cohorts:

- Cohort 1 (SA FT-2102): approximately 173 evaluable patients with R/R AML. To account for potential discordance between local and central mutation testing, approximately 190 patients may be enrolled into this cohort.
- Cohort 2 (SA FT-2102): approximately 53 patients with AML in morphologic CR/CRi after prior therapy (+/-hematopoietic stem cell transplantation [HSCT]) with residual IDH1-R132 mutation (> 0.01%) detected in the bone marrow.
- Cohort 3 (SA FT-2102): approximately 20 patients with R/R AML/MDS that have been previously treated with IDH1 inhibitor therapy. Patients who undergo HSCT on-study then relapse post-HSCT are allowed in this cohort.
- Cohort 7 (SA FT-2102): approximately 54 treatment naïve AML patients for whom standard treatments are contraindicated.

Azacitidine Combination Cohorts:

- Cohort 4 (FT-2102 in combination with azacitidine): approximately 20 patients with R/R AML/MDS that are naïve to prior hypomethylating therapy and IDH1 inhibitor therapy.

- Cohort 5 (FT-2102 in combination with azacitidine): approximately 20 patients with R/R AML/MDS that have inadequately responded to or have progressed on prior hypomethylating therapy.
- Cohort 6 (FT-2102 in combination with azacitidine): approximately 44 patients with R/R AML/MDS that have been previously treated with SA IDH1 inhibitor therapy as their last therapy prior to study enrollment. The actual number of patients in this cohort may be larger, since patients from FT-2102 SA cohorts are allowed to enroll in Cohort 6 after their disease progression.
- Cohort 8 (FT-2102 in combination with azacitidine): approximately 28 treatment naïve AML patients who are candidates for azacitidine first line treatment.

Note that for Cohorts 7 and 8, treatment naïve is defined as no prior treatment for AML. Patients may have received a prior treatment for another hematologic malignancy.

The primary analysis will occur when approximately 190 patients in Phase 2 Cohort 1 have completed 6 months of treatment or discontinued study drug.

B. Study Population

The study will include patients with pathologically proven AML or intermediate risk, high risk or very high risk MDS as defined by the World Health Organization (WHO) criteria or Revised International Prognostic Scoring System (IPSS-R) harboring IDH1-R132 mutations, that is either relapsed or refractory to standard therapy, or for whom standard treatments are contraindicated. Patients must have documented IDH1-R132 gene-mutated disease and must be ≥ 18 years of age. See protocol section 4.4 Eligibility Criteria for details.

C. Sample Size

Phase 1

The number of patients who will be enrolled in the dose escalation stage will depend on the number of DLTs observed within each dose cohort. It is anticipated that, at a minimum, doses of 150 mg and 300 mg FT-2102 QD will be tested as a single agent and in combination with azacitidine. If 6 patients are treated at each dose level, approximately 24 patients will be treated in the dose-escalation stage.

During the Phase 1 Dose-Expansion Stage, each of the non-LDAC cohorts would have 14 patients. With 20 patients treated (at least 6 from the dose-escalation stage, 14 from dose-expansion) at the determined MTD/MED there is 90% power of observing adverse events whose true incidence rate is 11% or higher. For the LDAC cohort, the selection of 6 patients is a minor variation of the traditional 3+3 design in order to identify the risk of LDAC for toxicities in more than 17% of patients.

Phase 2

Cohort 1 (patients with R/R AML harboring IDH1-R132 mutations): A group sequential design is planned for this cohort with two interim analyses and a final test. One hundred

seventy-three (173) patients provide 90% power to test the null hypothesis that the true complete response rate (CR + CRh) is 15% or less versus the one-sided alternative hypothesis that the true complete response rate is greater than 15%, assuming a true response rate of 25%, with a 2.5% significance level using a one-sided exact test for a binomial proportion.

Two interim analyses are planned, at approximately 33% and 67% of the information, respectively. O'Brien-Fleming stopping boundaries will be used for both alpha and beta adjustments. At the first interim, if ≤ 6/58 responses are observed (or crude p-value ≥ 0.88), the trial may be stopped early for futility. Interim analysis 1 spends 0 alpha and 0.004 beta. The first interim analysis will be conducted on the full analysis set (FAS) within Phase 2 Cohort 1. At the first interim analysis the study is not intended to stop for efficacy. At the second interim analysis, if ≥ 28/115 responses are observed (or crude p-value is ≤ 0.0057), the trial may stop enrollment for efficacy and if there are 20 or fewer responses (or crude p-value is > 0.2718) the trial will be stopped for futility. Interim analysis 2 spends 0.006 alpha and 0.044 beta. The second interim analysis will be conducted in the efficacy evaluable (EE) analysis set within Phase 2 Cohort 1.

In the event of an early stop for efficacy, all enrolled patients would remain on treatment and their long-term efficacy data, such as, EFS and OS, will continue to be observed.

If the study is not stopped early for efficacy or futility, at least 173 evaluable patients are planned to be enrolled. A one-sided exact test will be performed. If the one-sided p-value is ≤ 0.0245, the null hypothesis (the response rate is ≤ 15%) will be rejected, and the alternative hypothesis that the response rate is > 15% will be accepted. If exactly 173 patients are evaluable, this is equivalent to 36 or more responses observed.

To account for discordance between central and local testing of the IDH1-132 mutation, approximately 190 patients are planned to be enrolled into this cohort.

Cohort 2 (patients with AML with persistent IDH1-R132 mutation + bone marrow demonstrating morphologic CR/CRi after prior therapy +/- HSCT): A Simon optimal two-stage design will be used. The null hypothesis that the true 4-month RFS rate is 80% will be tested against a one-sided alternative. In the first stage, 11 patients will be evaluated. If 9 or fewer of the first 11 patients are relapse-free at 4 months, the study will be stopped. Otherwise, 42 additional patients will be accrued, for a total of 53 patients. The null hypothesis will be rejected if 48 or more of these 53 patients are relapse-free at 4 months. This design yields a 1-sided type I error rate of 0.025 and power of 80% when the true 4-month RFS rate is 94%.

Cohorts 3-5 (patients with AML/MDS harboring IDH1-R132 mutations that are R/R to prior IDH1 inhibitor therapy; or naïve to hypomethylating and IDH1m inhibitor treatments; or R/R to prior hypomethylating therapy): A single-stage design with 20 patients will be used. If 4 or more complete responses are observed in these 20 patients, the lower bound of a one-sided 85% confidence interval based on an exact binomial distribution will be greater than 10%, thus supporting the hypothesis that the true complete response rate is greater than 10%.

Cohort 6 (patients with AML/MDS harboring IDH1-R132 mutations that are R/R to immediately prior SA IDH1 inhibitor therapy): A Simon's optimal two-stage design will be used. The null hypothesis that the true complete response rate is 15% will be tested against a one-sided alternative. In the first stage, 14 patients will be evaluated. If there are 2 or fewer complete responses in the first 14 patients, the study will be stopped. Otherwise, 30 additional patients will be accrued for a total of 44 patients. The null hypothesis will be rejected if 11 or more complete responses are observed in these 44 patients. This design yields a 1-sided type I error rate of 0.05 and power of 80% when the true complete response rate is 32%. The probability that the trial will be stopped at the end of the first stage if the true complete response rate is 10% is 0.65.

Cohort 7 (treatment naïve AML patients for whom standard treatments are contraindicated): A Simon's optimal two-stage design will be used. The null hypothesis that the true complete response rate is 25% will be tested against a one-sided alternative. In the first stage, 17 patients will be evaluated. If there are 5 or fewer complete responses in the first 17 patients, the study will be stopped. Otherwise, 37 additional patients will be accrued for a total of 54 patients. The null hypothesis will be rejected if 20 or more complete responses are observed in these 54 patients. This design yields a 1-sided type I error rate of 0.025 and power of 80% when the true complete response rate is 45%.

Cohort 8 (treatment naïve AML patients who are candidates for azacitidine first line treatment): A Simon's optimal two-stage design will be used. The null hypothesis that the true complete response rate is 25% will be tested against a one-sided alternative. In the first stage, 7 patients will be evaluated. If there are 2 or fewer complete responses in the first 7 patients, the study will be stopped. Otherwise, 21 additional patients will be accrued for a total of 28 patients. The null hypothesis will be rejected if 12 or more complete responses are observed in these 28 patients. This design yields a 1-sided type I error rate of 0.025 and power of 80% when the true complete response rate is 55%.

D. Treatment Randomization

No randomization is planned.

E. Assessment Schedule

See Appendix 1 for a detailed study Schedule of Events, including measurements and evaluations for the entire study period. All planned assessments will be performed predose with the exception of postdose PK/PD sample collection and ECG.

V. Interventions

A. Clinical Trial Material

FT-2102

FT-2102 Capsules are initially presented as two unit strengths, 50 or 150 mg, for oral administration. FT-2102 will be administered as a fixed dose. In case of BID dosing, FT-

2102 should be taken every 12 hours with a minimum of 8 hours between doses. When administered in combination with azacitidine, with the exception of C1D1 and C2D1 (when PK sampling is performed), it is recommended that FT-2102 should be administered first on the days when both FT-2102 and azacitidine are given. The protocol provides additional product details in Section 5.

Following provide dose-escalation schema.

- Single-Agent Dose-Escalation Schema
  1. 150 mg QD
  2. 300 mg QD
  3. 150 mg BID

- Food Effect Cohort
  1. 100 mg QD

- Combination Dose with Azacitidine
  1. FT-2102 150 mg QD and Azacitidine 75 mg/m^2 I.V. or S.C. for 7 days per cycle
  2. FT-2102 150 mg BID and Azacitidine 75 mg/m^2 I.V. or S.C. for 7 days per cycle

- Combination Dose with Cytarabine
  1. FT-2102 150 mg BID and Cytarabine 20 mg BID S.C. for 10 days per cycle

As of Protocol Amendment 3, FT-2102 150 mg BID as SA and in combination with azacitidine will be evaluated in the proposed Phase 2 cohorts. As of Protocol Amendment 5, one patient was enrolled to receive Combination Dose with Cytarabine, after which the cohort was closed. This patient will not be summarized in tables; his data will be contained in listings only.

VI. General Analytical Considerations

A. Definition of Baseline

Unless otherwise specified, the baseline value for each quantity being analyzed is defined as the last non-missing value prior to first dose of study drug. Baseline for ECG parameter is defined as the average of the last three ECG measurements taken prior to first dose of study treatment.
For laboratory data, if a sample was taken on C1D1 that will serve as baseline, even if time of sample draw or time of dosing does not allow for a definitive determination of whether it was drawn prior to first dose.

B. Methods of Pooling Data

Data from all sites will be pooled for tabular summaries. Study center or treatment-by-center interactions will not be included in any statistical analysis. For patients enrolled in Phase 1

of the study, data from multiple dose levels from the dose escalation phase will be pooled together. Dose escalation and dose expansion phase data will be pooled together. See Appendix 3 for the table shell headers.

Phase 2 is comprised of 8 separate cohorts representing different patient populations and so patients enrolled in Phase 2 will be summarized by the cohort in which they are enrolled, and any statistical hypothesis testing will be performed within a cohort.

A single patient enrolled in the Phase 1 treatment arm of FT-2102 + low-dose cytarabine (LDAC) before that arm was closed (removed in the most recent protocol amendment). That patient's data will not be summarized; it will be listed.

C. Missing Data/ Data Imputation

Unless stated otherwise, missing data will not be imputed. However, if there are dates missing for AEs or medications, some intermediate steps may be taken for the determination of being treatment emergent or not. Sections below address such procedures for the handling of those dates in the relevant analyses:

Missing or Partial AE or Medication start or stop date:

For missing or partial start-dates:

1. If the onset date is unknown, then the date will not be imputed and will be assigned a missing value.
2. If the month and day are unknown, then:
    a. If the year matches the year of the first dose date, then impute the month and day of the first dose date.
    b. Otherwise, assign as missing.
3. If the day of the month is unknown, then:
    a. If the month and year match the month and year of the first dose date, then impute the day of the first dose date.
    b. Otherwise, assign as missing.

For partial end-dates:

1. If the year is unknown, then the date will not be imputed and will be assigned a missing value.
2. If the month is unknown, then assign as missing.
3. If the day is unknown, then assign the last day of the month.

Missing Pharmacokinetic (PK) Data:

Missing FT-2102 concentration data in a given profile will not be imputed. Missing samples will be reported as no sample ("NS") and excluded from analysis. The affected

profile(s) will be evaluated whether sufficient FT-2102 concentrations are available to calculate any of the planned PK parameters.

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 predose 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 predose will be included in the computation of AUC. If the predose 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.

Missing Pharmacodynamic (PD) Data:

Missing 2-HG concentration data will not be imputed. Missing samples will be reported as no sample ("NS") and excluded from analysis.

Blast in Hematology and Bone Marrow Blast %:

The CRF captures hematologic blast % data in 2 fields: a numeric percentage and a text field, as some pathology reports note absent or infrequent blasts, but do not quantify the result. If the numerical blast % is missing but the text field says “absent,” or inferior to 1%, 0 will be imputed for blast %. If the blast % is missing but the text field contains any of the following words: isolated, scattered, few, rare, occasional, not enumerated, no value, no total, present, less than 1%, some, then 1% blasts will be imputed. Bone marrow results of “less than 5%” will be imputed as 4.9%.

Hematology Differentials:

If the absolute values for the hematology differentials are missing but results are present in percentages, the absolute value result may be imputed as follows:

Absolute basophils = White blood cells* basophils %

This approach will be taken for all hematology differential parameters.

Missing Quality of Life (QOL) Data:

The imputation will be done according to methodology proposed by Diehr et al. (2007). Data will be imputed for missing assessments of Phase 2 patients and will be performed separately for each of five dimensions and VAS score of the EQ-5D-5L. VAS and each of the dimensions is represented by QOL in the imputation algorithm below. The five domains of EQ-5D-5L responses are ordered categories ranging from "no problems" to "extreme problems." Answers will be converted to a 5-point scale in which 1=no problems and 5= extreme problems. The VAS score of EQ-5D-5L ranges from 0 (worst health) to 100 (best health).

- Compute QOL-transformed (QOLt):
  QOL score will be transformed to the probability that a person will have good QOL next cycle (have domain QOL ≤ 3 next cycle; or have VAS QOL ≥ 80), estimated from his QOL this cycle. All transition pairs (two values of QOL for the same person 1 cycle apart) will be used in the longitudinal data, and the transformation parameters will be estimated from a logistic regression of a binary variable "Good QOL 1 cycle later" on "QOL now." In the longitudinal data for each patient a column with one space for every cycle of that patient's potential follow-up will be created.
  The regression model will be as follows:

  logit (Good QOL 1 cycle later) = a + b*QOL now.

The estimated probability of having good QOL 1 cycle later as a function of current QOL is then:

QOLt = Prob(Good QOL 1 cycle later | QOL) = exp(a+b*QOL)/(1+exp(a+b*QOL)).

- Compute QOL transformed with deaths added (QOLtd):

Set the values of QOLt for the cycles after a patient died to zero. For cycles after death, patients should receive a zero because they have no probability of having good QOL one cycle later.

- Compute QOLtd imputed (QOLtdi):

QOL for cycles when patients were alive but had no QOL data will be imputed from the regression of QOLtd on the logarithm of time from death (or time from the analysis date if still alive).

1) Calculation of time variable Cycle before death/end of follow-up (CBD):
CBD = Cycle before death = cycle minus the integer part of (#days survived/28) + 1.

or

CBD = Cycle before end of follow-up = cycle minus the integer part of (#days on study/28) + 1

Unobserved cycles (e.g. due to missed visit, or time between last observed cycle and death when subject was alive but did not provide data) before deaths or end of follow-up will be imputed.

2) Time variable CBD will be transformed to log form (LCBD) as below:
LCBD=log(absolute value of CBD + 1)

3) A mixed model will be used to predict QOLtdi. The dependent variable is QOLtd; the mixed model will contain random intercept and slope subject effect, and fixed time effect (LCBD). QOLtdi will be predicted at imputed cycles.

- Compute QOLtdi re-transformed to the original scale (QOLback):

This should be done by inverting the logistic regression equation.

$$QOLback = (logit(QOLt) - a)/b = [ln ((QOLt)/(1-QOLt)) - a]/b.$$

- Round imputed values up to the nearest whole number.

Note that no numerical values will be given after death, but "999" flags will be included to indicate cycles when patient was dead.

D. Multiple Study Centers

No stratification by the study centers will be utilized for analyses of efficacy or safety data.

E. Covariate Adjustment in Primary Analysis

Not planned for the primary analysis.

F. Sample Size Reassessment

No sample size reassessment is planned.

G. Interim Analyses

Interim analyses will be performed for the Phase 2 Cohort 1 and in other applicable Phase 2 cohorts that use two-stage designs, at defined timepoints, as outlined in section IV.C.

- Phase 2 Cohort 1: two interim analyses with 33% and 67% of patients' information respectively
- Phase 2 Cohort 2: with first 11 patients evaluable for response
- Phase 2 Cohort 6: with first 14 patients evaluable for response
- Phase 2 Cohort 7: with first 17 patients evaluable for response

- Phase 2 Cohort 8: with first 7 patients evaluable for response

As a result of these analyses, enrollment in a given cohort may be stopped early for futility, or in Cohort 1 for efficacy as well. Interim analyses that meet stopping criteria for futility are binding.

H. Multiple Comparisons

Alpha is controlled for the primary analysis within each Phase 2 cohorts. Corrections for multiple comparisons are not applied for the secondary or exploratory endpoints, as they are descriptive analyses.

I. Analysis Sets

Seven analysis sets are defined for use in various analyses. The following table illustrates the relationship between each analysis set and the analyses. Within an analysis set, the summary table will summarize data within cohorts, as described in Appendix 3. Due to the large number of cohorts in this study (there are eight Phase 2 cohorts), individual cohorts do not have their own analysis set; the result for a hypothesis being tested on a single cohort is found in the summary table for the applicable analysis set, within the table column that describes patients in the applicable cohort.

Analysis Set	Analysis						
	Patient Characteristics	Patient Disposition	Efficacy	Safety	PK	PD	DLT Evaluation
DLT Evaluable Set							X
Safety Analysis Set		X		X			
Efficacy Evaluable Analysis Set	X		X				
Full Analysis Set	X	X	X				
Per Protocol Analysis Set			X				
PK Analysis Set					X		
PD Analysis Set						X	

1. DLT Evaluable Set

All Phase 1 patients who enrolled in the dose escalation cohorts and who have received at least one dose of FT-2102 and completed at least 75% of doses in the first cycle during the DLT evaluation period or have discontinued / interrupted due to adverse events meeting the DLT evaluation criteria. This set will be used for DLT analyses only, unless otherwise specified.

2. Safety Analysis Set

All patients who have received at least one dose of study drug (FT-2102, azacitidine, or cytarabine). All safety analyses will be based on the Safety analysis set unless otherwise specified. Patients will be analyzed under the first dose level received by the patient.

3. Full Analysis Set (FAS)

All patients who were enrolled in the study and have received at least one dose of FT-2102. This analysis set will be used for efficacy analyses and baseline characteristics. Patients will be analyzed under the assigned dose.

4. Efficacy Evaluable (EE) Analysis Set

All patients in Phase 2, Cohort 1 with confirmed IDH1-R132 (by central lab) who have received the first dose of FT-2102 180 days or more prior to the analysis cutoff date. These patients will be included in the analysis set regardless of duration of treatment. This analysis set is the primary analysis set for Phase 2, Cohort 1 efficacy evaluation and early stopping decisions. Patients will be analyzed by assigned dose. Patients who received first dose of FT-2102 less than 180 days prior to the analysis cut off date will not be included in the EE Set, even if they have response assessments recorded. Patients who do not have any response data will be considered to be non-responders if they received the first dose of FT-2102 180 days or more before the analysis cut off date. Analyses based on the EE analysis set will not be produced for the final CSR.

5. Per Protocol (PP) Analysis Set

A subset of patients in the EE analysis set, excluding patients who have protocol violations that could impact the evaluation of the efficacy of FT-2102. Some violations that would result in exclusion from the PP analysis set are: not meeting all inclusion/ exclusion criteria for a particular cohort, having received chemotherapy not per protocol, received starting dose of FT-2102 other than 150 mg BID, not having at least one post-baseline response assessment. The full list of protocol violations will be reviewed on a de-identified basis by the medical, data management, and statistical leads prior to locking the database, and membership in the PP analysis set will be documented and determined based on that review. Analyses based on the PP analysis set will not be produced for the final CSR.

6. PK Analysis Set

All patients for whom it is possible to calculate at least one primary PK parameter (e.g. C_{max}, AUC_{last} and AUC_{inf}) and who do not have any major protocol deviations thought to influence the absorption, distribution, metabolism and excretion of the FT-2102.

PK parameters for patients who discontinue after a single dose of study drug may be presented in the listings but will not be used for summary statistics or any statistical analysis. Data may be excluded from PK analysis (concentrations listed only) if any of the following criteria are fulfilled:

- concomitant medication which could render the plasma concentration-time profile unreliable
- Patient vomits within 2 x the reported median T_{max} for the study drug.

Any data excluded will be discussed in the CSR.

7. PD Analysis Set

All patients who have received at least one dose of FT-2102 and have completed at least one PD assessment. The PD analysis set will be used for PK/PD-related analyses unless otherwise specified.

J. Subgroup Analyses

Data from subgroups of patients in the defined analysis sets will be summarized. The subgroups that may be analyzed include but are not limited to the following:

Subgroup Name	Levels	Additional Details, if applicable
Diagnosis	AML or MDS	
AML Type	Primary AML vs. Secondary AML	Applies only to AML patients
Disease State	Relapsed/Refractory vs. treatment naïve	
AML Cytogenetic Risk Classification	intermediate risk, poor, favorable risk, unknown/missing risk	Applies only to AML patients. Exclude patients with unknown or missing risk classification
IDH1 Mutation Type	R132C, R132H, and [R132L, G, or S]	If central lab result is available, that should be used. Otherwise, mutation type may be taken from CRF.
IDH1 Mutation Confirmed by Central Lab	yes, no	
Age Group	< 65, 65 - < 75, ≥ 75 years	
Sex	male, female	
Region	North America, EU, Asia Pacific	
Race	White vs. other	
Baseline ECOG Performance Score	Grade 0/1, 2	
Number of Prior Regimens	1, 2, ≥ 3	Prior number of regimens
Prior HSCT for AML	yes, no	
Prior Hypomethylating Agents	yes, no	Prior treatment with hypomethylating agents. This will be defined by whether the patient has azacitidine, decitabine, or guandecitabine listed on their prior therapies list.
Prior IDH1 Therapy	yes, no	This includes prior treatment with FT-2102 (if enrolling from one cohort to another), or treatment with ivosidenib. The subgroup is applicable for Phase 2 Cohort 3 patients; and for phase 2 Cohort 6 patients who will be allowed to roll over from Cohort 1 after progressive disease.
Prior FT-2102 Treatment	yes, no	This subgroup is applicable for Phase 2 Cohort 3 patients, whose prior IDH1 inhibitor therapy may have included FT-2102; and for Phase 2 Cohort 6 patients, who will be allowed to roll over from Cohort 1 after progressive disease.
Renal Function	normal, mildly impaired, moderately impaired, severely impaired	Categories of renal function are determined based on baseline creatinine clearance as follows: normal (≥ 90 mL/min), mildly impaired (60 to 89 mL/min), moderately impaired (30 to 59 mL/min), and severely impaired (15 to 29 mL/min). Baseline creatinine clearance is calculated as:

Subgroup Name	Levels	Additional Details, if applicable
		(140 − age) * baseline weight (kg) * (0.85 if female) / (72 * baseline serum creatinine [mg/dL])

K. Data Display Characteristics

Data displays produced for this study will include three types—summary tables, data listings, and figures. Unless stated otherwise, data listings will be produced for all recorded data as well as derived variables. Summary tables will be produced as specified in following sections. Figures will be produced when specified in sections to follow.

Listings will be ordered by phase, treatment (dose and schedule), cohort, patient number, and nominal visit. When expedient, additional levels of ordering hierarchy may reflect subsets of assessments within patient. Data listings will not display patient initials.

Tables will be organized differently based on the purpose of the data analysis being performed: interim safety analyses or formal interim analysis or final analysis. Data snapshots taken for the purpose of safety analysis (regulatory reporting, IB update, etc.) will be organized as outlined in Appendix 3. Table generation for interim futility and efficacy analyses as well as final analyses will be organized as specified in Appendix 3.

The summary statistics displayed will be a function of the type of data associated with the summarized assessment. Unless stated otherwise in relevant sections to follow, continuous data will be summarized with the number of non-missing values, mean, standard deviation, minimum, median, and maximum. Categorical data will be summarized with the number of non-missing values and the numbers of values equal to each of the possible values. Percentages of patients with each of the possible values will be calculated from the number of patients in the corresponding analysis set, unless stated otherwise. Some continuous variables may also be grouped into categorical levels and evaluated in frequency tables.

L. Blinded Review of Data

Not applicable for this study, as it is open label.

VII. Baseline Patient Characteristics and Disposition

A. Disposition

The number of patients enrolled will be summarized, as will the number and percentage of patients in each analysis set. The reason for discontinuation of treatment will be summarized, as will treatment status (ongoing or off-study treatment). The number and percentage of patients who have discontinued from study participation will also be summarized. Percentages of patients who discontinued for each of these reasons will be calculated using the Safety analysis set in the relevant cohort group for the denominator. Disposition will be listed for all subjects in the Safety analysis set.

B. Demographics

Data collected about the following patient characteristics will be summarized in tables for the FAS, EE analysis set, and PP analysis set, and listed for all patients in the FAS:

- Age at time of consent
- Age category (18 -< 40, 40 -< 65, 65 -< 75, 75 -< 85, ≥85 years)
- Sex at Birth (Male, Female)
- Race (American Indian or Alaskan Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, White, Other, Not Reported)
- Ethnicity: Hispanic or Latino origin (Yes, No, Not Reported)
- Height (cm) at baseline
- Weight (kg) at baseline
- BMI at baseline

BMI will be calculated as:

$$\text{BMI (kg/m}^2\text{)} = \text{weight} / (\text{height}/100)^2$$

C. Disease History

Data collected about the following patient characteristics will be summarized in tables for both the FAS (both phases) and the EE analysis set.

Data will be listed for all patients in the FAS.

- AML disease histories (including time from diagnosis to study participation in weeks, AML Type (primary de novo, secondary, transformed MDS, therapy-related, and other), AML disease state (treatment naive, relapsed, refractory), time since relapse (≤12 months or >12 months), and AML WHO Classification).
- MDS disease histories (including time from diagnosis to study participation in weeks, MDS risk category, MDS WHO Classification, disease state (treatment naive, relapsed/ refractory)).

A manual review by Sponsor clinical staff will classify AML patients who are not treatment naïve into the following categories based on their prior therapies: primary refractory, untreated relapse, refractory relapse.

- Primary refractory: patients that enter the study who are refractory to the initial induction treatment.
- Untreated relapse: patients that enter the study who have relapsed after the most recent prior line of therapy
- Refractory relapse: patients that enter the study who have relapsed to a prior line of therapy and then became refractory to an attempt of salvage therapy.

Disease history will be summarized separately for AML and MDS patients. The denominator for percentages will be the number of patients with that disease (AML or MDS).

Time from diagnosis in months will be calculated by subtracting the diagnosis date from the informed consent date, and dividing the number of days by 30.4375, and rounding to one decimal place.

The total number of prior regimens received (based on the prior therapies CRF) will be summarized both by descriptive statistics (mean, standard deviation, median, minimum, maximum) and categorically (number of regimens received: 1, 2, 3, or 4 or more). The site enters regimen number into the CRF (i.e., a single regimen may be comprised of one or more drugs). The maximum regimen number for each patient will be used for tabular summarization of total number of prior regimens.

The number of patients who have received various types of treatment regimens (induction, re-induction, consolidation, salvage, maintenance, autologous HSCT, allogenic HSCT, transplant-DLI, and conditioning) will be tabulated. This information is taken from the prior therapies CRF.

D. Cytogenetics and Molecular Genetics

The following information collected about genetic mutations will be summarized for the FAS (both phases) and for the EE analysis set. The cytogenetics summary will also be produced by subgroup for the following subgroups: disease state (relapsed/refractory vs. treatment naive) for Phase 1 patients only.

Data will be listed for all patients in the FAS. The following data will be summarized separately for AML and MDS patients. The denominator for percentages of patients having a certain mutation will be the number of patients with that disease (AML or MDS).

- Cytogenetic risk classification per CRF
- Cytogenetics per CRF
- Result of central test of IDH1 mutation
- IDH1 mutation type at baseline per CRF
- IDH1 mutation type at baseline per companion diagnostic
- Total number of co-mutations at baseline per CRF
- Incidence of co-mutations at baseline per CRF

E. Baseline Disease Characteristics

The following baseline disease characteristics will be summarized for the FAS for Phase 1 and 2, and for the EE analysis set. Baseline disease characteristics summaries will also be produced by subgroup for the following subgroups for FAS: diagnosis (AML vs. MDS) for all patients; and disease state (relapsed/refractory vs. treatment naive) for Phase 1 patients only.

- ECOG performance status at baseline
- Baseline bone marrow blasts (%): bone marrow aspirate will be used as the primary source. If no aspirate assessment is available, biopsy assessment will be used as default
- Baseline peripheral blood blasts (%)

- Categorical description of baseline values of the following laboratory parameters, as well as descriptive statistics summarizing WBC, ANC, hemoglobin, and platelets:

  - white blood cells (WBC) (< 15×10^9/L, 15 to < 30×10^9/L, ≥ 30×10^9/L),
  - absolute neutrophil count (ANC) (< 0.5×10^9/L, 0.5 to < 1×10^9/L, ≥ 1.0×10^9/L),
  - hemoglobin (< 80 g/L, ≥ 80 g/L),
  - platelet count (<50×10^9/L, ≥ 50×10^9/L),
  - creatinine clearance (< 15 mL/min, 15 to 29 mL/min, 30 to 59 mL/min, 60 to 89 mL/min, ≥ 90 mL/min)

F. Medical and Surgical History

Medical and surgical history will be summarized on the FAS for Phase 1 and 2.

Medical histories will be coded via MedDRA version 19.1 and summarized by SOC and PT. Medical history will be summarized in a separate table from surgical history. Surgical history will be summarized by surgical category, as indicated by the investigator. Data will also be presented in a listing for the FAS.

G. Prior Anti-Cancer Therapies

Prior anti-cancer therapies will be summarized on the FAS for Phase 1 and 2, and for the EE analysis set for Phase 2. Prior anti-cancer therapy summaries will also be produced by subgroup for the following subgroup for FAS: diagnosis (AML vs. MDS).

Prior anti-cancer therapies will be summarized by ATC class and medication name, which will be coded via WHODrug (September 2016 version). Prior anti-AML/MDS therapies will also be presented in a listing for the FAS.

H. Protocol Deviations

Protocol deviations will be summarized as major or minor deviations and by deviation criteria for the Safety analysis set. Protocol deviations will be listed for the FAS, including description and date of deviation. No CRF will be utilized to collect the protocol deviations. They will be provided by clinical operations team prior to database lock. Protocol deviations which have occurred due to COVID-19 will be summarized.

VIII. Safety Analyses

Safety data will be summarized and listed for the Safety analysis set, unless otherwise specified.

A. Exposure

Exposure to the study drug FT-2102 will be characterized via the following parameters:

- Treatment duration in days calculated as (date of last dose of study drug – date of first dose of study drug + 1)
- Total dose taken (mg). Total dose taken will only be calculated for Phase 2 patients, as data in phase 1 were not collected in a manner that allows calculation of total dose.
- The number of cycles of treatment patients received will also be summarized. For phase 1 patients, a patient will be considered to have had a cycle of treatment if they have had one or more doses in a given cycle. For phase 2 patients, the number of cycles of treatment received will be calculated as treatment duration in days divided by 28. This number will then be rounded up to a whole number.
- Number and percentage of patients experiencing dose increases, dose reductions, dose interruptions, drug withdrawals, and reasons for dose modifications or dose interruptions.
- Treatment compliance will be calculated as a percentage (total dose taken divided by total dose prescribed x 100) for Phase 2 patients only

Drug administration data will be presented in data listings including dose modifications and dose interruptions as well as reasons for modifications and interruptions.

Exposure to azacitidine will be summarized as the number of cycles having received azacitidine and the duration of azacitidine dosing. Exposure to cytarabine will be presented in data listing only.

B. Adverse Events

Adverse Events (AEs) will be summarized and recorded from the time of first dose through 28 days after the last dose of study drug, and serious adverse events from the time of informed consent to 28 days after the last dose of study drug. AEs will be coded using the MedDRA dictionary version 19.1, with verbatim terms coded by System Organ Class (SOC) and Preferred Term (PT) and graded via the CTCAE version 4.03. Sponsor coding conventions will be applied during the creation of analysis datasets. Therefore, the raw dataset may reflect a different preferred term than the ADAE data set.

A treatment-emergent AE (TEAE) is an AE that emerges after the first dose of study drug through 28 days post last dose, having been absent pretreatment, that occurred on or after the first dose of study treatment or within 28 days after the last dose, or occurred prior to the first dose and increased in grade during study treatment. If an AE has partial onset date, the imputed onset date as specified in Section VI.C will be used to define TEAE.

The causality of an AE includes related or unrelated. A treatment-related AE is defined as an AE considered “Possibly Related”, “Probably Related”, or “Definitely Related” to the study drug by the investigator. Missing relationship will be treated as unknown and excluded from summary of treatment-related AEs considered to be related; events reported as “Definitely Not Related”, “Probably Not Related”, or “Unlikely” will be considered not related.

If the AE start or stop date is still missing after implementing the rules specified in Section VI.C, the following strategy will be used to determine whether AEs with missing start or stop dates are pre-treatment or treatment-emergent:

1. If the start date and stop date are both missing, the most conservative approach is taken, and the AE is considered to be treatment-emergent.
2. If the start date is missing but the stop date is not missing and is after the day of study dose administration, then the most conservative approach is taken, and the AE is considered to be treatment-emergent.
3. If the start date is missing but the stop date is not missing and is on or before the day of study dose and after the date of signed informed consent, then the AE is considered to be pre-treatment (not TEAE).

The following AE summaries will be produced for both Phase 1 and 2:

- Overall Summary of AEs. This will include the total number of AEs, the total number of TEAEs, the total number of treatment-related TEAEs, and the number of patients with: at least one TEAE, at least one treatment-related TEAE, at least one Grade 3 or higher TEAE, at least one Grade 4 or higher TEAE, at least one treatment-related Grade 3 or higher TEAE, at least one treatment-related Grade 4 or higher TEAE, at least one treatment emergent serious adverse event (TESAE), at least one related TESAE, at least one TEAE that led to study drug discontinuation, at least one TEAE that led to dose modification, and TEAE leading to death.
- Summary of TEAEs by system organ class and preferred term, or by preferred term. For each event term, the numbers and percentages of patients experiencing an AE with that term will be summarized. If a patient reports the occurrence of a particular adverse event more than once, the event is only counted once.
- Summary of TEAEs by system organ class, preferred term, and grade: if a patient has multiple AEs the most severe/ related one will be utilized for the summary. This summary will be presented for a limited subset of patients – total Phase 1 single agent FT-2102 patients; total Phase 1 combination therapy patients; total Phase 2 single agent Cohort 1 patients; total Phase 2 single agent patients overall; and total Phase 2 combination therapy patients. A similar summary of TEAEs will be produced by preferred term and grade.

Summaries by system organ class and preferred term will be sorted alphabetically by system organ class, and alphabetically by preferred term within system organ class. Summaries by preferred term will be sorted in descending frequency per the Overall column for the table.

The table below indicates the types of summaries that will be provided for various sets of TEAEs:

TEAE Set	By SOC and PT	By SOC, PT, and Grade	By PT	By PT and Grade
TEAEs	X	X	X	X
Treatment-related TEAEs	X		X	
TEAEs of G3 or G4	X		X	
Treatment-related TEAEs of G3 or G4	X		X	

TEAE Set	By SOC and PT	By SOC, PT, and Grade	By PT	By PT and Grade
TESAEs	X			
Treatment-related TESAEs	X			
TEAEs leading to withdrawal from study drug	X			
Treatment-related TEAEs leading to withdrawal from study drug	X			
TEAEs leading to dose modification	X			
Treatment-related TEAEs leading to dose modification	X			
TEAEs leading to death	X			
Treatment-related TEAEs leading to death	X			
TEAE of Special Interest	X			

All AEs occurring on study (treatment emergent or not) will be provided in patient data listings. The following additional by-patient listings of AEs (treatment emergent or not) will be provided: all SAEs, all AEs leading to withdrawal of study drug, all AEs leading to dose modification, and all AEs leading to death.

In addition, a listing of all deaths with related information regarding the death will be provided, including AEs leading to death, as well as deaths that are not reported as due to an adverse event.

A summary of DLTs by system organ class and preferred term, and a listing of all AEs that caused a DLT, will be provided for the DLT evaluable set.

Adverse Events of Special Interest (AESI): Hepatotoxic and Gallbladder disorder

Some patients taking FT-2102 have experienced transaminase elevations. As such, summary tables of AEs for hepatotoxicand gallbladder disorders will be created, with tabulations of the number of patients experiencing such events by SOC and PT. Under each PT within each grouping, the time to onset will be summarized descriptively, and time to resolution will be summarized using Kaplan-Meier (KM) methods.

In addition, overall summary table for TEAEs for each AESI group will be created. It will include the number of patients with TEAEs, treatment-related TEAEs, grade 3 or 4 TEAEs, treatment related grade 3 or 4 TEAEs, serious TEAEs, treatment related serious, TEAEs resulting in FT-2102 discontinuation, treatment related TEAEs resulting in FT-2102 discontinuation; TEAEs leading to dose reduction, TEAEs leading to dose hold, treatment related TEAEs leading to dose hold, TEAEs resulting in on-treatment death, treatment related TEAEs resulting in death.

All TEAEs in each group occurring on study will be provided in corresponding patient data listings.

The table below presents preferred terms in each subgroup:

Hepatotoxicity Grouping	Gallbladder disorder Grouping
Alanine aminotransferase increased Aspartate aminotransferase increased Hepatic enzyme increased Hypertransaminasemia Liver function test abnormal Liver function test increased Transaminases increased Hepatitis acute Blood alkaline phosphatase increased Hyperbilirubinemia Blood bilirubin increased	Biliary tract disorder Biliary colic Cholangitis Cholestasis

AESI: Differentiation Syndrome

Differentiation syndrome (DS) is a risk of drugs in this class. While many of the symptoms of differentiation syndrome are non-specific and best judged by the treating clinician, in the spirit of the article by Montesinos et al. (2009), and using methodology outlined by Norsworthy et al. (2020), candidate cases of DS will be summarized. This analysis will be conducted for IA2 only, and not for the final study reporting.

The number of patients with an investigator reported AE of DS will be summarized.

In addition, candidate cases of DS will be summarized based on AE data and also leukocyte count results from the laboratory data set. AE preferred terms will be summarized into categories representing possible symptoms of DS as per the table below, and tabulated by the number of patients experiencing an AE in the category in the first 90 days and 180 days post first dose.

Candidate DS AESI Symptom Category	AE Preferred Terms
Dyspnoea	Acute respiratory distress syndrome Acute respiratory failure Cardiopulmonary failure Cardio-respiratory distress Cough Dyspnoea Dyspnoea exertional Dyspnoea at rest Orthopnea Productive cough Respiratory distress

Pulmonary infiltrates or Pleuropericardial effusion	Acute interstitial pneumonitis Acute lung injury Acute pulmonary oedema Acute respiratory distress syndrome Atypical pneumonia Bilateral pulmonary infiltrates Generalized oedema Interstitial pneumonitis Localized oedema Lower respiratory tract infection Lower respiratory tract inflammation Lung disorder Lung infection Lung infiltration Non-cardiogenic pulmonary oedema Pericardial effusion Pleural effusion Pneumonia Pneumonitis Pneumonitis NOS Pulmonary infiltration NOS Pulmonary congestion Pulmonary oedema Pulmonary toxicity
Kidney injury	Acute kidney injury Anuria Blood creatinine abnormal Blood creatinine increased Cardiorenal syndrome Hepatorenal failure Prerenal failure Renal failure Renal failure acute Renal function test abnormal Renal impairment Renal injury Creatinine value >26.52 µmol/L or >1.5x baseline value in the lab dataset
Hypotension	Hypotension Orthostatic hypotension Blood pressure decreased Blood pressure systolic low Blood pressure diastolic decreased Any systolic blood pressure in vital signs data set < 90 mmHg
Fever	Pyrexia Febrile bone marrow aplasia Febrile neutropenia Temperature in vital signs data set ≥ 38.3˚ C
Weight gain	Capillary leak syndrome Fluid overload

	Fluid retention Generalized oedema Hydraemia Hypervolaemia Oedema Oedema peripheral Weight increased Weight (any value > 5 kg from baseline from vital signs data)

Candidate cases of DS will be identified based on patients having: any 2 or more AESI categories from the table above occurring concomitantly. Concomitant is defined for AESIs as AE start dates within 7 days of each other. Two or more AESI can comprise a DS episode. Repeat DS episodes are separated by > 14 days between the start dates of the AESIs.

The number of patients with candidate cases who have concomitant leukocytosis will be summarized. Concomitant leukocytosis is defined as having AE PT of "Leukocytosis," "Hyperleukocytosis," or "White blood cell count increased," or having laboratory results showing leukocyte count > 10 G/L within 7 days before or after AESI.

Candidate cases will be reviewed by an adjudication committee (details are contained within a separate DS Adjudication Committee charter). Committee members will review the patient cases and adjudicate which cases are DS, and the number of episodes of DS that each patient experienced. The number and percentage of patients who have a committee-adjudicated case of DS will be tabulated.

Of the cases adjudicated as having DS, the following summaries will be presented:

- The number of patients with multiple episodes of DS will be tabulated.
- The number of patients with concomitant leukocytosis will be tabulated.
- The number of patients experiencing severe and moderate DS will be tabulated. If a patient has a reported AE of differentiation syndrome, the severity will be assessed via CTCAE grade, with severe being grade 3/4/5, and moderate being grade 2. If they did not have an investigator-reported AE of differentiation syndrome, then severe is defined as experiencing more than 3 DS AESI categories concomitantly, and moderate is defined as experiencing 2 or 3 DS AESI concomitantly as per Montesinos (2009). These will be tabulated within the first 90 days post first dose, and the first 180 days post first dose.
- The number and percentage of patients reporting at least one DS AESI will be summarized by those occurring during the first 90 and 180 and days post first dose.
- The median time to onset of the DS episode (the first DS AESI for adjudicated cases) will be calculated, along with the 1st and 3rd quartiles of time to onset and the range.
- The number and percentage of patients who also had a best overall response of CR or CRh will be tabulated

A listing will be created to identify patients with DS AESI, presenting all criteria that qualified them for candidate DS.

C. Clinical Laboratory Results

Laboratory test results (including hematology, coagulation, serum chemistry, and urinalysis) and abnormal laboratory values will be presented in data listings. The test results will be presented in SI units. Patients enrolled in Phase 1 of the study use standard laboratory reference ranges to determine normal ranges for CTCAE grades. The standard ranges used are:

- New England Journal of Medicine October 2004
- Oxford Handbook of Clinical Haematology
- Mercy North Hospital Laboratory

Patients enrolled in the Phase 2 portion of the study will have local laboratory normal ranges used for CTCAE grading. If local ranges cannot be obtained, then the standard ranges will be applied.

Hematology differentials will be summarized in absolute values, not percent. If missing, absolute values of hematology differentials will be imputed using percentages as described in Section VI.C. Listings will present percent differentials if reported, and will also present derived absolute values, which will be identified as derived.

Summaries of actual values and changes from baseline will be presented by cohort for each assessment time point, beginning with the screening visit.

Shift tables summarizing the counts and percentages of patients' baseline CTCAE grade vs. their highest CTCAE grade on study will also be displayed for hematology and, serum chemistry, and coagulation.

Summaries of laboratory data by nominal visit will not present unscheduled visits. However, shift tables will include data from unscheduled visits in consideration of the worst value on study. No summaries will be presented when fewer than five patients' data are available at an assessment time point.

Evaluation of liver function tests

A shift table for liver function tests will be produced as described above, presenting shift from baseline to worst post-baseline and shift from baseline to each planned visit. Parameters included in this shift table will be ALT, AST, alkaline phosphatase, total bilirubin, and direct bilirubin.

Scatter plots presenting the maximum ALT by the concomitant total bilirubin, and the maximum AST by the concomitant total bilirubin for each patient on study (i.e., eDISH plots) will be produced. Results without concomitant bilirubin cannot be presented in eDISH plots, so the maximum value of visits which have both ALT and bilirubin (or AST and bilirubin) should be presented.

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.

Flag #	Clinical Laboratory Parameter	Category
1	ALT	>3 × ULN; >5 × ULN; >10 × ULN; >20 × ULN;
2	AST	>3 × ULN; >5 × ULN; >10 × ULN; >20 × ULN
3	AST or ALT	>3 × ULN; >5 × ULN; >10 × ULN; >20 × ULN
4	Total Bilirubin (TBL)	>1.5 × ULN; ≥2 × ULN
5	ALP	>2.5 × ULN; >5 x ULN
6	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);
7	Concurrent AST, ALT, Total Bilirubin, without ALP abnormality	(AST or ALT >3 × ULN) and (TBL >1.5 × ULN) and ALP <2 x ULN; (AST or ALT >3 × ULN) and (TBL >2 × ULN) and ALP <2 x ULN;
8	ALT>3x ULN or AST>3x ULN with concurrent report of selected TEAEs during study*	(ALT >3x ULN) or (AST >3x ULN) and with TEAEs* starting +/- 7 days of the lab sample

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

The flags in the table above are only applied for post-baseline values. For flag #6, if ALT or AST is elevated > 3x ULN, all total bilirubin results within 7 days of the result should be considered. If Flag #6 is applied and ALP is <2x ULN for all samples drawn within +/- 7 days of the AST, ALT, bilirubin sample, then Flag #7 will be applied. Flag #8 requires the adverse event start date to occur within +/- 7 days of an AST/ ALT value exceeding 3x ULN.

D. Vital Signs

Descriptive statistics of actual value and change from baseline value in vital signs (including temperature, pulse, respiration rate, systolic blood pressure, diastolic blood pressure, and weight) will be presented by cohort group for each nominal visit and time point. However, no summaries will be presented when fewer than five patients' data are available at an assessment time point. Summaries by nominal visit will not present unscheduled visits. A vital signs listing will also be provided.

E. Electrocardiogram (ECG)

QTcF and QTcB are calculated automatically in the EDC system using the following formulae:

$$\text{QTcF} = \frac{QT}{RR^{1/3}}$$

$$\text{QTcB} = \frac{QT}{RR^{1/2}}$$

Descriptive statistics of actual value and change from baseline value in ECG parameters (including PR, RR, QRS, QT, QTcB, and QTcF) will be listed by cohort group and time

point. In addition, the summary will include descriptive statistics for the maximum post-baseline value and the minimum post-baseline value. Summaries of data for nominal time points will not include unscheduled visits; summaries of maximum and minimum post-baseline value will include unscheduled visits. The average of the triplicate ECGs at a nominal time point will be used for analysis; values will be rounded to the nearest whole number before assigning to reporting categories. If the triplicate ECGs are not available, the average of ECGs will be calculated using one or two ECGs measured at the same visit. No summaries will be presented when fewer than five patients' data are available at an assessment time point.

In addition, the number and percentage of patient experiencing the following parameters will be tabulated and summarized:

- Change (increase) 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 msec
    - >450 to ≤480 msec
    - >480 to ≤500 msec
    - >500 msec

A shift table summarizing the counts and percentages of patients' baseline QTcF events vs. their maximum post-baseline event will also be presented.

A subset of approximately 30 patients will be consented to 24-hour Holter ECG monitoring for the purposes of the exposure-response modeling the effect of drug exposure on QTcF interval. This model-based analysis will be described in a separate, stand-alone SAP.

A data listing of all ECG values will also be provided, which will list the triplicate values obtained for each timepoint, as well as the derived mean value for each nominal time point.

F. Physical Examination and Pregnancy Test

Physical examination findings and data for pregnancy test will be listed in a patient data listing, but not summarized. The records of abnormal findings prior to or after the first dose of study drug from physical exam will be captured in the medical history CRF and adverse events CRF, respectively.

G. Concomitant Medications

Medications will be coded using the WHO Drug Dictionary version of September 2016, with verbatim terms coded by Anatomical Therapeutic Chemical (ATC) classification and Preferred Term (PT).

To determine whether a medication is a prior or concomitant medication, the imputed non-missing stop date of the medication is used. If this date is on or after the start of first dosing date of study drug, the medication will be defined as concomitant medication; otherwise it will be classified as prior medication.

If the medication stop date is missing, imputation rules specified for AE stop date will be applied. If the medication date is still missing after implementing the rules, the most conservative approach is taken, and the medication is considered to be concomitant.

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 particular medication more than once, the medication is only counted once. These will be summarized for the Safety analysis set.

Concomitant medication is 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.

A data listing of prior and concomitant medications will be provided.

H. ECOG Performance Status

ECOG Performance Status by visit will be summarized in a shift table for the Safety analysis set. The summary will also include shift to worst post-baseline value. Shifts to nominal time points will not include unscheduled visits; the shift to worst post-baseline value will include unscheduled visits. All ECOG scores will be presented in a data listing.

IX. Pharmacokinetic Analyses

Pharmacokinetic analysis will be performed in patients in the PK analysis set, and data will be listed for all patients in the Safety analysis set. Protocol Section 6.4 provides the PK sample collection time points.

Pharmacokinetic concentration data will be listed by patient including actual sampling times relative to dosing. Plasma concentrations will be summarized by phase, treatment (dose, schedule, single agent or combination therapy), cohort, 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.

X. Pharmacodynamic Analyses

Pharmacodynamic analysis will be performed in Phase 1 patients in the PD analysis set, and listed for patients in the Safety analysis set. See Protocol Section 6.5 for the PD assessment time points.

Concentration of 2-HG (including absolute change from baseline and/or percentage change from baseline) will be listed by patient and will be summarized by phase, treatment (dose, schedule, single agent or combination therapy), cohort, 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.

Geometric mean 2-HG concentration versus time profiles and/or geometric mean change from baseline versus time for each cohort will be presented graphically on a linear-linear and/or log-linear scale (as appropriate).

XI. Efficacy Analyses

Efficacy endpoints will be listed for all patients in the FAS, unless otherwise specified. Hematologic parameters evaluated for efficacy will be included in the laboratory listings, and listed for the Safety analysis set.

A. Efficacy Endpoints

Response assessments will be performed through evaluation of clinical findings and bone marrow/peripheral blood cell counts and morphology. Response criteria are derived from the International Working Group (IWG) response criteria for AML (Cheson et al. 2003) and MDS (Cheson et al. 2006) where applicable, and Stein et al. 2017, as outlined in the protocol section 4.3, Appendix 6 and Appendix 7.

Bone marrow for response assessment is required:

- at C2D1 if no peripheral blasts; otherwise, at C3D1, regardless of peripheral blast count;
- at least every 2 cycles (4 to 8 weeks) until morphologic complete remission (CR) is achieved, then up to every 3 cycles (for duration of response assessment) for 12 months after CR achievement, then up to every 6 cycles thereafter;
- when progressive disease is suspected;
- for Phase 2 Cohort 2 only: at C2D1, C4D1, C6D1 and every 6 cycles thereafter.

Response assessment requirements and frequency are the same for all subjects, including those that discontinue treatment due to hematopoietic stem cell transplant (HSCT).

In general, HSCT is not considered an event in time to event analyses. Patients who stop treatment with FT-2102 to have HSCT will continue to be monitored for duration of

response. HSCT is not considered an anti-leukemia therapy for purposes of analyses described herein.

In general, for the purposes of statistical analyses, relapse, progressive disease (PD), or disease progression will be treated interchangeably as being indicative of disease worsening.

AML Response: Following responses for AML will be evaluated by investigator based on the modified Cheson criteria (Cheson et al. 2003). Best overall response for each patient is selected based on the highest category achieved on study from the ordered list in the table below:

Investigator Assessment of AML Response	CR/CRh	Complete Response	Overall Response
Molecular CR (CRm)	√	√	√
Cytogenetic CR (CRc)	√	√	√
Complete Remission (CR)	√	√	√
CR with Partial Hematologic Recovery (CRh)	√		√
CR with incomplete recovery (CRi)			√
Morphologic leukemia-free state (MLFS)			√
Partial Remission (PR)			√
Clinical Benefit			
Stable Disease			
Resistant Disease			
Relapse			
Progressive Disease (PD)			
Not Evaluable			
Not Done			

MDS Response: Response for MDS will be evaluated by investigator based on the response criteria adapted from IWG Response Criteria for MDS (Cheson et al. 2006). Appendix 7 of the protocol provides details.

Investigator Assessment of MDS Response	Complete Response	Overall Response
Complete Remission (CR)	√	√
Marrow CR		√
Partial Remission (PR)		√
Clinical Benefit		
Stable Disease		
Disease Progression (PD)		
Not Evaluable		
Not Done		

CR/CRh rate: The primary efficacy endpoint for AML patients is the CR/CRh rate. It is defined as the proportion of patients who achieve CRm, CRc, CR or CRh, as outlined in the

table for investigator assessment of AML response above. This rate is not calculated for MDS patients.

Complete response rate (CRR): For AML patients, CRR is defined as the proportion of patients who achieve CRm, CRc, or CR at any time while on study. For MDS patients it is defined as the proportion of patients who achieve CR.

Overall response rate (ORR): For AML patients, ORR is defined as the proportion of patients who achieve Molecular CR (CRm), Cytogenetic CR (CRc), Complete Remission (CR), CR with Partial Hematologic Recovery (CRh), CR with incomplete recovery (CRi), Morphologic leukemia-free state (MLFS), or Partial Remission (PR). For MDS patients it is defined as the proportion of patients who achieve Complete Remission (CR), Marrow CR, or Partial Remission (PR).

Best overall response (BOR): BOR is the best response achieved by the patient up to 3 weeks post last dose of study drug or until the introduction of new anticancer therapy, whichever is earlier.

Time to CR/CRh (TTCR/CRh): TTCR/CRh is the time in months between the first dose of study drug and documentation of the CR/CRh for patients who achieve a CR/CRh. This analysis will be performed only on patients who have achieved CR/CRh as a best overall response. Kaplan Meier analyses will not be performed; summary will be descriptive.

Time to complete response (TTCR): TTCR is the time in months between the first dose of study drug and documentation of the CR for patients who achieve a CR. This analysis will be performed only on patients who have achieved CR as a best overall response. Kaplan Meier analyses will not be performed; summary will be descriptive.

Time to response (TTR): TTR is the time in months between the first dose of study drug and documentation of the first overall response for patients who achieve a PR or better. This analysis will be performed only on patients who have achieved PR or better as a best overall response. Kaplan Meier analyses will not be performed; summary will be descriptive. This analysis will not be performed on Phase 2 Cohort 2, as it is not applicable since patients enter the study already in response.

Duration of CR/CRh (DCR/CRh): DCR/CRh is the time in months between documentation of the first CR or CRh until the date of relapse or death, whichever is earlier. Patients will be censored as per Table 1. DCR/CRh will only be calculated for patients who achieve a CR or CRh as the best response.

Duration of complete remission (DCR): DCR is the time in months between documentation of the first CR until the date of relapse or death, whichever is earlier. Patients will be censored as per Table 1. DCR will only be calculated for patients who achieve a CR as the best response.

Duration of overall response (DOR): Duration of overall response will be calculated similarly to DCR but will assess the time in months between documentation of the first response of PR or better until the date of relapse, death, whichever is earlier. Patients will be

censored as per Table 1. This analysis will not be performed on Phase 2 Cohort 2, as it is not applicable since patients enter the study already in response.

Patients who respond and stop FT-2102 to undergo HSCT will continue to be followed until relapse. Duration of response endpoints (DRC/CRh, DCR, DOR) for these patients will encompass time between HSCT and relapse ordeath. For patients with no report of relapse by the end of the follow-up data collection, duration of response (DCR/CRh, DCR, DOR) will be censored as per Table 1.

A separate sensitivity analysis will be conducted for duration of response of Phase 2, Cohort 1 patients, which analyzes duration of response as described above, but for those patients who have enrolled under Phase 2 Cohort 2 due to MRD positivity, the duration of response will be the total duration of response experienced in Cohort 1 and Cohort 2 together.

An additional sensitivity analysis will be performed on DCR/CRh, DCR, and DOR in which HSCT will be handled as the end of response.

Since this study was ongoing during the COVID-19 pandemic, a sensitivity analysis will be performed on OS, DCR, DCR/CRh, and DOR in which patients who have died due to COVID-19 will be censored to assess the effect that COVID-19 had on time to event endpoints.

4-Month Relapse-Free Survival (RFS) Rate: The primary endpoint for Phase 2 Cohort 2 AML patients is the 4-Month RFS rate. This will be evaluated by a Simon 2-Stage design described in Section IV.C, testing the null hypothesis that the 4-month RFS rate is $< 80\%$. It is defined as the proportion of patients in Phase 2 Cohort 2 who have not relapsed or died on or before their 4-month response evaluation. If a patient does not receive a disease response assessment at their 4-month visit but has a subsequent disease response assessment on or after study day 120 that shows non-progression/ non-relapse, they will be evaluated as having achieved 4-month RFS. This rate is not calculated for MDS patients, or for AML patients in any other cohort.

Relapse-Free Survival (RFS): RFS will be calculated for all patients in Phase 2 Cohort 2, who are patients who have achieved a response of CRi or better. It is the time in months between the date of first dose until relapse, start of other (non-protocol study drug) new antileukemia therapy, or death from any cause, whichever occurs first. Hematopoietic stem cell transplant (HSCT) is not considered an event for RFS. For a patient who is responding and experiences none of these events before the end of study follow up, RFS will be censored as per Table 1. The percentage of patients with RFS will be estimated at landmark timepoints.

Event-free survival (EFS): EFS is defined as the time in months between first dose of study drug and disease progression, relapse, death from any cause, treatment failure, or start of other (non-protocol study drug) new antileukemia therapy, whichever occurs first. HSCT is not an event for EFS, and patients experiencing HSCT will continue to be followed until an event occurs. For EFS, treatment failure will be operationally defined as not achieving a best

overall response of CR, CRh, or CRi on study. The date of treatment failure for patients with this event will be the date of the last response assessment while on study.

For a patient with none of these events before the end of study follow-up, EFS will be censored as per Table 1. For patients lost to follow-up prior to any evidence of event, the EFS data will be censored at their last completed assessment date that is SD or better prior to the initiation of anti-cancer therapy.

Overall survival (OS): OS is defined as the time in months from the first dose of study drug until death from any cause. For patients who are not known to have died by the end of study follow-up, OS will be censored on the date the patient was last known to be alive.

Transfusion independence (TI): Patients will be classified as "dependent" or "independent" at baseline within each category of platelets, pRBC, any (i.e., receiving either platelets or pRBC or both) and both (i.e., receiving both platelets and pRBC) if they received a transfusion within 8 weeks prior to the first dose of FT-2102. TI will be defined as patients who experience at least a 28-day or 56-day period during any point on treatment with no transfusion of that type required. For the "both" category, patients who are classified as dependent must have received both a platelet and pRBC transfusion within the 8 weeks prior to baseline, and to be classified post baseline as independent, they must experience a 28 or 56 day minimum duration on study where they did not require a transfusion of either platelets or pRBC.

B. Efficacy Analysis

Any response assessment occurring after the start of alternate anti-cancer therapy will not be included in the analyses using response assessments.

Note that some patients who were assigned to single agent therapy in Phase 1 requested to start combination therapy with azacitidine when a response was not observed on single agent treatment. In such cases, upon beginning dosing with azacitidine (if the patient was assigned to single agent therapy), then response assessments occurring after the first dose of azacitidine will not be included in efficacy analyses. Time to event analyses for such instances will be treated as if the patient has experienced disease progression when azacitidine is initiated.

The overall survival and event-free survival analyses will be based on patients in the FAS. All other efficacy analyses will be based on patients in the EE analysis set as the primary analysis, with selected analyses on the FAS and PP analysis set as supportive. The following table indicates the analysis sets to be analyzed for each endpoint.

Endpoint	Patients Analyzed	Analysis Set		
		EE*	FAS	PP*
CR/CRh Rate, DCR/CRh, TTCR/CRh	AML only	x	x	x
CRR, DCR, TTCR	Each disease group separately	x	x	x
ORR, DOR, TTR	Each disease group separately	x	x	x
Best overall Response	Each disease group separately	x	x	x
4-month RFS Rate	Phase 2 Cohort 2 only		x	
RFS	Phase 2 Cohort 2 only		x	
EFS, OS	All patients combined		x	
TI	All patients combined	x	x	

*EE and PP analyses will only be performed for IA2.

CR/CRh rate will be analyzed for all cohorts except Phase 2 Cohort 2. For Phase 2 Cohort 1, to test the hypothesis that the CR/CRh rate is greater than 15%, a 1-sided exact test for a binomial proportion will be performed. If the exact one-sided p-value is less than 0.0245, the alternative hypothesis will be accepted. This is equivalent to at least 36 CR/CRh responses of 173 EE patients.

For Phase 2, Cohorts 3, 4, and 5 test the hypothesis that the 85% confidence interval for the CR/CRh rate does not include 10%. If there are 5 or more CR/CRh responses of the 20 patients in these cohorts, the 85% confidence interval will be greater than 10%, and the alternative hypothesis that the response rate is greater than 10% will be accepted.

Phase 2 Cohorts 6, 7, and 8 are Simon 2-Stage designs and the primary efficacy endpoint will be evaluated via the number of CR/CRh responses stipulated in the design criteria described in Section IV.C.

The number and proportion of patients achieving CR/CRh response will be reported by cohort from the binomial proportion, along with Clopper-Pearson 95% confidence interval for AML and MDS patients respectively. Appendix 2 provides the SAS code.

For Phase 2 Cohort 1, a sensitivity analysis will be performed on the CR/CRh rate in which Atkinson and Brown confidence intervals will be calculated.

4-Month RFS, BOR, ORR, TI: The proportional endpoints listed here will be summarized as the number and percentage of patients within each category, and will be presented by cohort along with Clopper-Pearson 95% confidence intervals. The 4-month RFS endpoint will be analyzed for Phase 2 Cohort 2 only.

RFS, EFS, OS, TTCR/CRh, TTCR, TTR, DCR/CRh, DCR, DOR: Time to event endpoints listed here will be expressed as the number of months from first dose to the event and will be analyzed using Kaplan-Meier (KM) methods for each cohort, with the exception of TTCR/ CRh, TTCR, and TTR, since these analyses are performed only on the subset of responders and censoring is unnecessary. The analysis will include median, 1st and 3rd quartiles for time calculated using Kaplan-Meier methods, and the 95% confidence interval for the median

calculated using the Brookmeyer-Crowley method. The estimated probability of survival over time for RFS, EFS, OS, DCR/CRh, DCR, and DOR will be plotted as KM curves for Phase 2 Cohort 1, with the exception of RFS, which will be performed for Phase 2 Cohort 2 only. Appendix 2 provides the SAS code.

The survival probability and 95% confidence interval will be estimated at selected landmark timepoints of: 3 months, 6 months, 12 months, and 24 months based on Kaplan-Meier product-limit method and Greenwood's formula. A month will be calculated as time in days divided by 30.4375.

Table 1. Censoring Rules

Case	Censoring Rule
Patient has no post baseline assessments and no date of death recorded	Censor at date of first dose
Patient did not die or experience PD or relapse*	Censor at date of last adequate response assessment (any response assessment that is not "Not Evaluable" or "Not Done")
Patient in Phase 1 started on single agent therapy, but switched to combination therapy	Censor at date of last adequate response assessment prior to the combination therapy

*For patients who discontinue FT-2102 treatment to receive HSCT and remain on study to be followed until documented disease relapse, confirmation of relapse is not required in this situation, and a single occurrence of relapse will be considered as documented "confirmed" relapse in analyses of response.

The following sensitivity analyses of DCR/CRh will be performed with censoring rule variations in EE patients:

1. Patients who undergo HSCT will be censored at the last adequate assessment prior to HSCT
2. Patients who discontinued study treatment due to undocumented progression will be considered as events at the date of last dose
3. Patients with subsequent anti-cancer therapies prior to an event date will be considered to be censored the day before the start of the anti-cancer therapy.
4. Patients with subsequent anti-cancer therapies prior to an event date will be considered as having an event as the start of the anti-cancer therapy.
5. Patients who didn't have an event and are still on treatment will be censored at the last treatment date, otherwise will be censored at the last response assessment.

For DOR and DCR HSCT sensitivity analysis will be performed, where patients who undergo HSCT will be censored at the last adequate assessment prior to HSCT.
The following subgroup analyses will be performed:

- CR/CRh rate, ORR, DCR/CRh – For AML patients in the EE analysis set: AML type (primary or secondary), disease state (relapsed/refractory or treatment naive), AML cytogenetic risk classification, IDH1 mutation type, IDH1 mutation confirmed by

central lab, age group, sex, region, race, baseline ECOG PS, prior HSCT for AML, prior HMA, prior IDH1 therapy, and prior FT-2102 therapy.

- OS, EFS – For AML patients in the FAS analysis set: AML type (primary or secondary), disease state (relapsed/refractory or treatment naive), AML cytogenetic risk classification, IDH1 mutation type, IDH1 mutation confirmed by central lab, age group, sex, region, race, baseline ECOG PS, prior HSCT for AML, prior HMA, prior IDH1 therapy, and prior FT-2102 therapy.

Kaplan Meier plots will not be produced for subgroup analyses.

Transfusion Independence

Transfusion independence will be analyzed as part of the clinical benefit expected from FT-2102. The percentage of patients who are transfusion dependent at baseline will be summarized (overall and by type of blood product of RBC and/or platelets). The proportion of patients who became transfusion independent during any 28-day and 56-day period during treatment will be summarized by best overall response on study. Percentages will be based on the number of patients within the best overall response category.

Swim Lane Plot of Time on Treatment and Duration of Response

A swim lane plot will be created for patients in the FAS population to visualize the time on treatment with FT-2102. Time of first response and time of HSCT will be annotated on the plot. The length of the bar will represent the time (in weeks) on study, including both time on active treatment of FT-2102 and time in follow-up. The bar will be one color during active treatment, and then patients who stop treatment but are still being followed for continuing response will have the bar turn a different color. Patients who are still ongoing (either on treatment with or without response, or off treatment but being actively followed for response) will be indicated with arrows at the end of the bar. Best overall response will be annotated at the end of the bar.

A repeat of the swim lane plot will be done where there is no color coding by on/off treatment status. Rather, the bar will change color if/ when 28 days of transfusion independence is achieved. The length of the bar will represent the time (in weeks) on treatment. Best overall response will be annotated at the end of the bar.

Forest Plot

At IA2, A forest plot will be created for Phase 2 cohort 1 patients in the EE analysis set to present the CR/CRh rate compared across all of the relevant subgroups specified in the section VI.J; the subgroups not applicable to this cohort and excluded from the forest plot are diagnosis, disease state, prior IDH-1 therapy, prior FT-2102 treatment, and renal function. The plot will show the point estimate of each rate with 95% CI.

A similar plot will be created to present ORR for Phase 2 cohort 1 patients in the EE analysis set.

Hematologic Efficacy Analyses

Hematologic efficacy analyses will be performed for IA2 only.

The absolute and percent change in marrow blasts from baseline will be tabulated by visit and maximum post baseline decrease. This table summarizes blasts from either the bone marrow biopsy or bone marrow aspirate form together. At each nominal visit, if there is both a bone marrow biopsy result and a bone marrow aspirate result reported, the aspirate result will be used. Blast results of "less than 5%" will be imputed as 4.9%. No summaries will be presented when fewer than five patients' data are available at an assessment time point.

A waterfall plot will be created for Phase 2 cohort 1 patients in the EE analysis set to present the maximum % decrease in blast % experienced on study.

Line plots showing the mean (+/- SE) bone marrow blasts, ANC count, hematocrit, platelet count will be presented over time on Day 1 for cycles 1-15 for patients in the Phase 2 Cohort 1 FAS and EE analysis set by best response (CR/CRh, non-CR/CRh responders, and non-responders).

Efficacy Profiles

For IA2, For those patients who have a best overall response of PR or better, patient plots of ANC, platelet count, hemoglobin, and bone marrow blasts (analyzed as described above) will be produced for all patients in the Phase 2 Cohort 1 FAS and for patients in the Phase 1 FAS whose starting dose of FT-2102 was 150 mg BID.

C. Quality of Life Analysis

The EQ-5D-5L consists of five dimensions: mobility, self-care, usual activities, pain/ discomfort, and anxiety/depression. Each dimension has 5 levels of 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. Present overall state of health is also to be rated on a vertical visual analogue scale (VAS) from 0 (worst health) to 100 (best health). This assessment was only performed on Phase 2 patients. EQ-5D-5L data will be summarized from the screening visit through cycle 8 for the FAS (Phase 2) and EE analysis sets (Phase 2).

Five domains of EQ-5D-5L

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). Also, the change from baseline in the number reporting some problems in each dimension will be reported (raw and percent change). An additional summary table will be produced that summarizes the EQ-5D-5L data by best response (3 groups: CR/ CRh, Other Responders, Non-Responders). Missing data will be imputed as described in Section VI.C.

A stacked bar chart will be produced to illustrate the domain values. In the chart, the x axis will represent nominal visit (screening, cycle 2, cycle 3, etc.) 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 separate chart will be created for each of the dimensions. This figure will only be created for the

Phase 2, Cohort 1, EE analysis set. The figure will also be produced by best overall response, as described above for the summary table.

VAS score of EQ-5D-5L

The VAS score of overall state of health will be summarized by descriptive statistics (mean, standard deviation, median, Q1, Q3, minimum, maximum) by visit, as well as the number and percentage of patients reporting bad overall state of health (score < 80). An additional summary table will be produced to summarize change from baseline to first response for CR/ CRh and Other Responders, or change from baseline to best score for non-responders, by descriptive statistics by best response (3 groups: CR/ CRh, Other Responders, Non-Responders). Missing data will be imputed as described in Section VI.C.

All EQ-5D-5L data will be listed. In the listing, imputed data will be flagged.

XII. References

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Appendix 1 Schedule of Events

Study Procedures	Pre-screening (Optional)	Screening (D -14 to D1)	Cycle 1									Cycle 2						Cycle 3 and Beyond	End of Treatment[a]	28-day Follow-up[b]	Survival Follow-up
Days			D1	D2	D5 ± 1D	D8 ± 1D	D12 ± 2D	D15 ± 2D	D19 ± 2D	D22 ± 2D	D26 ± 2D	D1 ± 2D	D2 ± 2D	D4 ± 2D	D8 ± 2D	D15 ± 2D	D22 ± 2D	D1 ± 3D	± 7D	+ 7D	q 3 mo
Signed Informed Consent[c]		X[c]																			
Complete Medical History[d]		X																			
Concomitant Medications		X	X	X[e]		X		X		X		X				X		X	X	X	
Height and Weight[f]		X	X									X						X	X		
Vital Signs[g]		X	X			X		X		X		X						X	X		
ECOG PS		X	X									X						X	X		
Physical Examination		X	X			X[h]		X[h]		X[h]		X[h]				X[h]		X[h]	X		
Serum or Urine Pregnancy Test[i]		X	X									X						X	X		
12-lead Electrocardiogram[j]		X	X[i]			X[i]		X[i]		X[i]		X				X[i]		X	X		
Holter Monitoring (Phase 2 only)[k]			X	X								X	X								
Clinical Serum Chemistries[l, m]		X	X		X[n]	X	X[n]	X	X[n]	X	X[n]	X			X[n]	X	X[n]	X	X		
CBC with Differential and Platelet Count[m, o]		X	X		X[n]	X	X[n]	X	X[n]	X	X[n]	X			X[n]	X	X[n]	X	X		
Coagulation Parameters[p]		X										X									
Bone Marrow Aspirate[q]		X										X						X	X		
Urinalysis[m, r]		X	X									X						X	X		
Adverse Event Monitoring		Continuous																		X	
Pharmacokinetics (Peripheral Blood)[s]			X	X		X		X		X		X[t]	X	X		X		X			

Study Procedures	Pre-screening (Optional)	Screening (D -14 to D1)	Cycle 1									Cycle 2						Cycle 3 and Beyond	End of Treatment[a]	28-day Follow-up[b]	Survival Follow-up
Days			**D1**	**D2**	**D5 ± 1D**	**D8 ± 1D**	**D12 ± 2D**	**D15 ± 2D**	**D19 ± 2D**	**D22 ± 2D**	**D26 ± 2D**	**D1 ± 2D**	**D2 ± 2D**	**D4 ± 2D**	**D8 ± 2D**	**D15 ± 2D**	**D22 ± 2D**	**D1 ± 3D**	**± 7D**	**+ 7D**	**q 3 mo**
Pharmacodynamics (Peripheral Blood)[u]	X[v]	X	X	X		X		X		X		X	X	X		X		X			
EQ-5D-5L (Phase 2 only)		X[w]										X						X	X		
Study Drug Diary[x]			X									X						X			
Study Drug Administration[y,z,aa]			Drug will be given in accordance with the dosing schedules for FT-2102, azacitidine and LDAC																		
Survival[bb]																					X

ALT = alanine aminotransferase; ALP = alkaline phosphatase; AST = aspartate aminotransferase; BUN = blood urea nitrogen; C1D1 = Cycle 1 Day 1; C2D1 = Cycle 2 Day 1; Ca = calcium; CBC = complete blood count; Cl = chloride; ECG = electrocardiogram; ECOG PS = Eastern Cooperative Oncology Group performance status; FSH = follicle-stimulating hormone; K = potassium; LDAC = low dose cytarabine; LDH = lactate dehydrogenase; LH = luteinizing hormone; MDS = myelodysplastic syndrome; Mg = magnesium; Na = sodium; PD = pharmacodynamic; PK = pharmacokinetic; PT = prothrombin time; PTT = partial thromboplastin time.

NOTE: All assessments will be conducted predose unless specified otherwise.

[a] End of Treatment visit to be conducted within 7 days of the decision to discontinue treatment. End of Treatment assessments need not be repeated if they were completed within the previous 2 weeks (4 weeks for bone marrow assessments).

[b] 28-day Follow-up visit to be conducted within 28 days (+ 7 days) of last dose for adverse event follow-up and to capture initiation of new therapies (con-medications).

[c] Informed consent must be completed prior to the initiation of any study-specific procedures or assessments. The informed consent process may be completed prior to the Screening Period (i.e., before Day -14) (see Section 6.1.2 of protocol).

[d] Includes complete surgical and cardiac history and complete leukemia or MDS medical history. Complete leukemia or MDS medical history will include applicable treatment history as well as cytogenetic risk categorization at diagnosis by NCCN or ELN guideline.

[e] Only required in patients enrolled in Phase 1 and patients in Phase 2 participating in Holter monitoring.

[f] Height at Screening only.

[g] Includes temperature, blood pressure, pulse rate, and respiratory rate. Prior to dosing on Days 1, 8, 15, and 22 (Cycle 1); Cycle 2 predose on Days 1 and 15 and Cycle 3 and beyond predose on Day 1.

[h] Symptom-directed physical examination due to specific findings or abnormalities.

[i] To be performed on all female patients of childbearing potential and within 72 hr of dosing (Day 1 only of every cycle). At Screening, women aged 55 and under, are not surgically sterile, and who are amenorrheic must have LH, FSH, and estradiol measurements within the postmenopausal range for the

institution, to be considered of nonchildbearing potential. A serum pregnancy test is required at Screening; serum or urine pregnancy tests are allowed for post-Screening visits.

[j] Phase 1: Electrocardiograms will be performed in a supine position in triplicate (within a 10-minute period) predose and at 2 (± 15 minutes), 4 (± 15 minutes), and 8 hr postdose (± 30 minutes) on Cycle 1 Day 1 and Cycle 2 Day 1, and predose at all study visits where indicated. Phase 2: Electrocardiograms will be performed in triplicate (within a 10-minute period) predose on Cycle 1 Day 1 and Cycle 2 Day 1, and at all study visits where indicated. All electrocardiograms will be performed in a supine position.

[k] 24-hour 12-lead continuous Holters will be collected on C1D1 and C2D1 for patients at all centers in the US and select centers ex-US. The Holters should run from approximately 1 hour before dosing until 24 hours (the next day). Patients should remain supine for 10-15 minutes before and 5 minutes after ECG collection. See manual for further guidance on Holter monitoring.

[l] Clinical serum chemistries to include Na, K, Cl, bicarbonate, Mg, Ca, BUN, creatinine, AST, ALT, ALP, albumin, total bilirubin, direct bilirubin (collected only if total bilirubin is abnormal), LDH, glucose, amylase, lipase, uric acid, and thyroid function test (TFT) panel, which includes thyroid-stimulating hormone, free T3, and T4. In addition to the other chemistry panels, TFT panel is to be completed at Screening, C1D1, C2D1, and C3D1, then as clinically indicated.

[m] May be performed from 48 hr (Cycle 2) or 72 hr (Cycle 3 and beyond) prior to Day 1 of a cycle (see Section 6.1 of protocol).

[n] Clinical serum chemistries and CBC with differential and platelet count only at these study visits. May be performed through local laboratory testing.

[o] Includes hemoglobin, hematocrit, platelets, and white blood cell count with differential.

[p] Includes PT and PTT.

[q] Bone marrow aspirate for clinical purposes and research to be done at screening, C2D1 (if no peripheral blasts), C3D1 (if not taken at C2D1), every one to two cycles until CR (not CRi or CRh) and then every two to three cycles until12 months after CR achievement, then at least every 6 cycles afterwards, End of Treatment, and at time of progression/relapse, per Response assessment guidelines (see Section 4.3 of protocol), For Phase 2 Cohort 2, bone marrow should be done at C2D1, C4D1, C6D1 and C12D1 then every 6 cycles thereafter. Refer to the laboratory manual for details of sample collection timing.

- Local IDH confirmation may have occurred > 28 days prior.
- C3D1 to be done on any patient who did not undergo a C2D1 bone marrow aspirate or biopsy.
- Patients who discontinue study treatment for reasons other than treatment failure and have not withdrawn consent from overall study participation, should continue to be followed for disease response assessments until the time of disease progression/relapse or the initiation of a new treatment regimen. Patients who have stopped FT-2102 treatment for HSCT should continue to be followed until disease progression/ relapse. This information should be documented on the appropriate eCRF page

[r] Urinalysis parameters include specific gravity, pH, total protein, protein, glucose, ketones, and blood. Microscopic examinations are to be performed as clinically indicated. For Cycle 3 & beyond and End of Study visit, urinalysis to be performed if clinically indicated.

[s] Blood samples will be collected for measurement of plasma concentrations of FT-2102 (single agent) or FT-2102 + azacitidine (combination agent) Blood will be collected relative to FT-2102 administration as described in Section 6.4 and Table 4 of protocol

[t] A 72-hour wash-out post C2D1 dosing will be requested from all patients participating in the dose-expansion stage. After the C2D1 FT-2102 AM dose, patients will be asked to refrain from taking FT-2102 until the AM of C2D4. PK samples will be collected on C2D2 and C2D4**.

[u] Blood samples will be collected for PD biomarker analysis for single agent FT-2102 and FT-2102/azacitidine combination. Blood will be collected relative to FT-2102 administration as described in Section 6.5 and Table 5 of protocol.

[v] Optional pre-screening blood sample for 2-HG level detection and IDH1 mutation testing (in 2-HG abnormal).

[w] EQ-5D-5L survey can be completed anytime during screening prior to C1D1 dose.

[x] Study drug diary should be distributed by the site to the patient on each cycle day 1, and collected at the next cycle day 1 visit

[y] Single agent (FT-2102): FT-2102 will be given in accordance with dosing schedule × 28 days out of 28 days. On C1D1 only a single dose of FT-2102 is taken.

[z] Combination agent (FT-2102 + azacitidine): azacitidine will be administered via subcutaneous injection or intravenous infusion in combination with oral FT-2102 for 7 days, and then azacitidine will be stopped for 21 days; a 48-hr dose interruption of the azacitidine for weekends or holidays is allowed. On C1D1 and C2D1, azacitidine is to be administered immediately prior to FT-2102 (to enable consistent PK assessments). On all other days and cycles when FT-2102 and azacitidine are co-administered, it is recommended to dose FT-2102 prior to azacitidine.

[aa] Combination FT2102 + cytarabine: cytarabine will be administered at a dose of 20 mg BID subcutaneously (SC) for 10 days every 28-day cycle

[bb] After a patient discontinues study treatment and has completed their last study treatment visit, the study site will contact the patient approximately every 3 months to collect survival data and data pertaining to any other alternative anti-neoplastic therapy the patient begins for up to 12 months from the time of their 1st dose of study drug. Patients who discontinue for reasons other than disease progression or who withdraw consent will continue to be followed for response until progression occurs.

* Not required in Phase 2 unless patient is participating in 24-hour Holter monitoring.

** Not required in Phase

Appendix 2 SAS code for Efficacy Analyses

A. CR/CRh Rate

The SAS® code (SAS Version 9.3 or more current) of the following form will be used for the CR/CRh rate estimate along with confidence interval.

```
proc freq data=DATA_NAME ;
    by COHORT;
    tables OUTCOME / exact binomial (p=0.15);
    weight count;
    exact binomial;
run;
```

Where DATA_NAME is the name of the dataset, COHORT is a vector containing treatment group assignment; OUTCOME is a vector containing the investigator response for each patient.

B. EFS, DOR and OS

The following SAS® code (SAS Version 9.3 or more current) will be used:

```
proc lifetest data=DATA_NAME;
    time OSTIME*CENSOR(1);
    id COHORT;
run;
```

Where DATA_NAME is the name of the dataset, OSTIME is a vector containing the OS measurement for each patient, CENSOR is its respective censoring vector (1=censored, 0=non-censored event), COHORT is a vector containing cohort assignment.

The following SAS® code (SAS Version 9.3 or more current) will be used for OS:

```
proc lifetest data=DATA_NAME plots=(s, ls, lls) intervals=3, 6, 12, 24;
    time OSTIME*CENSOR(1);
    id COHORT;
run;
```

Appendix 3 Column Headings for Analysis Tables

1. Data snapshots taken for the purpose of safety analysis (regulatory reporting, IB update, etc.) will be organized as follows:

	Single Agent			Combination			
Parameter	FT-2102 150 mg BID	Phase 1 FT-2012 Single Agent	Total FT-2102 Single Agent	FT-2102 150 mg BID+ Azacitidine 75 mg/m2	Phase 1 FT-2102 + Azacitidine 75 mg/m^2	Total FT-2102 + Azacitidine 75 mg/m^2	Overall

Note: to be performed on data from both phase 1 and phase 2 patients, regardless of cohort #

2. Table generation for interim futility and efficacy analyses as well as final analyses will be organized as follows:

Phase 1:

Table xxx: Title
xxx Analysis Set, Phase 1

	Single Agent		Combination: Azacitidine 75 mg/m^2		
Parameter	FT-2102 150 mg BID	Total FT-2102	FT-2102 150 mg BID	Total FT-2102	Phase 1 Overall

For Safety Tables:

Phase 2 Single Agent Therapy:

Table xxx: Title
xxx Analysis Set, Phase 2 Single Agent

	FT-2102 150 mg BID					
Parameter	Cohort 1	Cohort 2	Cohort 3	Cohort 7	Phase 2 Single Agent Overall	Ph.1 AML R/R & Ph.2 Cohort 1

Phase 2 Combination Therapy:

Table xxx: Title
xxx Analysis Set, Phase 2 Combination Therapy

	FT-2102 150 mg BID + Azacitidine 75 mg/m^2				
Parameter	Cohort 4	Cohort 5	Cohort 6	Cohort 8	Phase 2 Combination Therapy Overall

For Efficacy Tables:

Phase 2 Single Agent:

Table xxx: Title
xxx Analysis Set, Phase 2 Single Agent

	FT-2102 150 mg BID				
Parameter	Cohort 1	Cohort 2	Cohort 3	Cohort 7	Ph.1 AML R/R & Ph.2 Cohort 1

Phase 2 Combination Therapy:

Table xxx: Title
xxx Analysis Set, Phase 2 Combination Therapy

	FT-2102 150 mg BID + Azacitidine 75 mg/m^2			
Parameter	Cohort 4	Cohort 5	Cohort 6	Cohort 8

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