Statistical Analysis Plan

Protocol Title: A Randomized, Phase II Study of CX-01 Combined With Standard Induction Therapy for Newly Diagnosed Acute Myeloid Leukemia

Protocol Number: CNTX-CX-01-2015-AML-1 (NCT02873338)

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Cantex Pharmaceuticals, Inc.

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A Randomized, Phase II Study of CX-01 Combined With Standard Induction Therapy for Newly Diagnosed Acute Mycloid Leukemia

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STATISTICAL ANALYSIS PLAN

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APPROVALS

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VERSION HISTORY

Version Number	Version Date	Summary and rational of chane:c(s)

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GLOSSARY OF ABBREVIATIONS

Abbreviation	Definition
AE	Adverse Event
ALT	Alanine Aminotransferase
AML	Acute Myeloid Leukemia
ANC	Absolute Neutrophil Count
AST	Asparlale Aminotransferase
ATC	Anatomical Therapeutic Chemical
AUC	Area Under Curve
BP	Blood Pressure
BUN	Blood Urea Nitrogen
CBC	Complete Blood Count
Cl	Confidence Interval
CR	Complete Remission
CRi	Complete Remission without recovery of neulrophils and/or platelets
CRp	Complete Remission without recovery of platelets
DSMC	Data Safety Monitoring Commillee
ECG	Electrocardiogram
ECOG	Eastern Cooperative Oncology Group
EFS	Event-Free Survival
FU	Follow-Up
INR	International Normalized Ratio
ITT	Intent-To-Treat
IWG	International Working Group
KM	Kaplan-Meier
LDH	Lactate Dehydrogenase
LFS	Leukemia-Free Stale/Survival
MUGA	Multi Gated Acquisition
NCI-CTCAE	National Cancer Institute-Common Terminology Criteria For Adverse Events
NSW	New South Wales
OS	Overall Survival
PK	Phannacokinetic
pp	Per Protocol
PT	Prolhrornbin Time
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SOC	System Organ Class
TBD	To Be Determined
TEAE	Treatment Emergent Adverse Event
USA	United States Of America

STATISTICAL ANALYSIS PLAN AMENDMENT I

NoI applicable

1 SOURCE DOCUMENTS

The Statistical Analysis Plan (SAP) was wriUen based on the following documentation:

Document	Date	Version
Protocol	04 February 2016	1.0
Protocol Amendment 1	16 September 2016	2.0
Protocol Amendment 2	13 January 2017	3.0
eCRF	25 July 2016	1.0
eCRF Amendment	16 August 2017	1.0.4

2 PROTOCOL DETAILS

2.1 Study Objectives

This randomized, phase II study ofCX-01 is designed to assess the effect of adding CX-01 at one of the two different dose levels to standard induction and consolidation therapy for newly diagnosed patients with AML.

2.2 Primary Objectives

The primary objectives are:

- To assess whether 2-0, 3-0 desulfatcd heparin (CX-0 I), administered at any or all studied dose levels in conjunction with standard induction therapy for AML increases the morphologic complete remission (CR) rate based on International Working Group (IWG) criteria.

- To assess the safety and tolerability of CX-01, administered at two studied dose levels in conjunction with standard induction therapy for AML.

2.3 Secondary Objectives

The secondary efficacy objectives are:

To assess whether CX-01, administered at any or all studied dose levels in conjunction with standard induction and consolidation therapy fr)r AML improves:

- Event-free survival (EFS)

- Leukemia-free survival (LFS)

- Overall survival (OS)

- Co111positc CR rate: incidence of CR+ CRi+CRp
- Duration of morphologic CR
- 30-day mortality (in the induction cycle)
- 60-day mortality (in the induction cycle)
- 90-day mortality (in the induction cycle)
- Days until neutropbil recovery to? 1,000/ µL
- Days until platelet recovery to? I 00,()00/ µL

2.4 Exploratory Objectives

The following items are not specified in the protocol but arc still of clinical importance and will be analyzed:

- Duration of composite CR (if present)
- Days until neutrophil recovery to ? 500/ µL
- Days until platelet recovery to? 20,000/ tL

2.5 Overall Study Design

This is an exploratory phase II, open-label, rando111ized, 111ulticcntcr, parallel group trial to dctcr111inc whether there is evidence that the addition of either or both different dose levels of CX-01 to standard induction therapy (idarubicin + cytarabine) and consolidation therapy has an additive therapeutic effect in newly diagnosed AML patients when co111parcd to patients receiving standard induction che111otherapy alone.

To be eligible to participate in the study, patients 111ust meet the following criteria:

I. Newly diagnosed, de novo or secondary, previously untreated AML
2. Age 60 or above
3. Eastern Cooperative Oncology Group (ECOG) performance status of Oto 2
4. Cardiac ejection fraction 45% (asdetermined by echocardiography or multi gated acquisition scan)
5. Adequate hepatic and renal function determined by the following laboratory values:

- Aspartate aminotransferase (AST) or alanine aminotransferase (ALT) <2.5 x upper limit of normal (ULN)

- Bilirubin <2.5 x ULN
- Calculated crcatininc clearance by Cockcrofl Gault forrnula >30 rnL/rnin.

6. Able to provide informed consent and have signed an approved consent forrn that conforms to federal and institutional guidelines.

Patients who meet any of the following criteria will not be eligible to participate in the study:

I. Patients with acute promyclocytic lcukernia based on the presence oft(15; I 7)(q22;q 12) as determined by karyotyping, fluorescence in situ hybridization or polymerase chain reaction
2. Prior chemotherapy for AML (including invcstigational therapy); prior hydroxyurca to control white blood cell count and a single intrathecal administration of cytarabinc for CNS prophylaxis is allowed
3. Prior intensive chemotherapy or stem cell transplantation for treatment of myelodysplastic syndrome (prior treatment with hypornclhylating agents and lenalidomidc arc allowed)
4. Presence of central nervous systcrn leukcrnia
5. Presence of significant active infection that is not controlled in the opinion of the Investigator
6. Presence of significant active bleeding
7. History of severe congestive heart failure or other cardiac disease that contraindicates the use of anthracyclines, including idarubicin
8. Pre-existing liver disease (such as CHILD-Pugh Class B or C liver disease)
9. Renal insufliciency which rnight adversely affect schedule and dose of therapy with cytarabine as well as rnanagcment of tumor lysis syndrome
10. History of drug addiction within the last 6 months
11. Known history of positive Hepatitis 13 surface antigens
12. Known history of positive test for Human lmrnunodeficicncy Virus antibodies
13. Psychiatric or neurologic conditions that could compromise patient safety or compliance, or interfere with the ability to give proper informed consent
14. History of other active malignant disease within the past 3 years, other than cured basal cell carcinoma of the skin, cured in situ carcinoma of the cervix, or localized prostate cancer that has received definitive therapy. Such prostate cancer patients who are receiving hormonal therapy are eligible
15. Patients receiving any form of anticoagulant therapy (heparin flushes for IV catheter permitted)
16. Presence of a known bleeding disorder or coagulation abnorrnality (including but not limited to a PTT >40 seconds) or any condition that requires maintenance of platelet counts at 50,000/"tL or higher
17. Pregnant or breast feeding patients
18. Patients of childbearing potential not using adequate contraception.

Approximately 75 patients will be randomized in a I: I: I ratio to one of the following study treatment groups:

• **Group** I: ldarubicin **+** Cytarabine, OR

• **Group 2:** ldarubicin **+** Cylarabine plus lower dose CX-01 (0.125 mg/kg/hour), OR

• **Group 3:** ldarubicin + Cytarabine plus higher dose CX-0 I (0.25 mg/kg/hour)

Eligible patients who meet the inclusion criteria and do not meet any of the exclusion criteria and have provided informed consent will be enrolled in the study. Each patient will participate in the study for approximately 18 months from the time of informed consent through final study contact, or until they withdraw from the study or the study is terminated by the Sponsor.

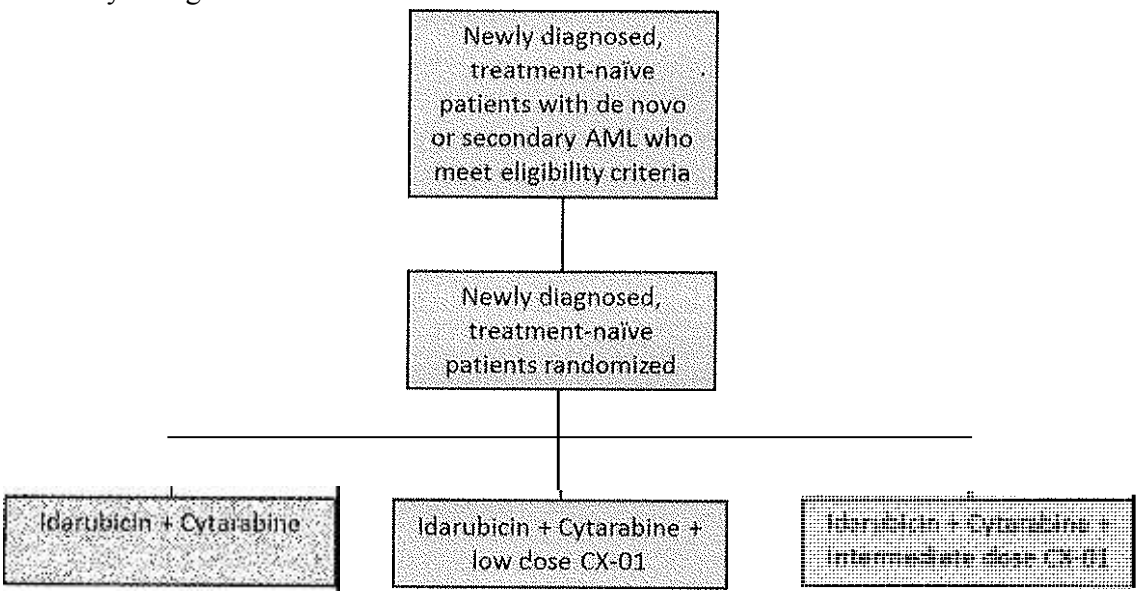
Overall survival data will be collected every 3 months until death or until the end of study by the investigational sites. The end of study will occur approximately 18 months afler the last patient is randomized. Overall survival data will be collected every 3 months until death or until the end of study by the investigational sites. The end of study will occur approximately 18 months afler the last patient is randomized.

A Data and Safety Monitoring Commiltec (DSMC) will meet periodically to review the safety of the study (see Section 6.6.5 of protocol). Details describing the DSMC process and procedures will be outlined in a separate DSMC Charter.

Adverse events (AEs) will be collcctcd from time of informed consent and continue until 30 days after the last study treatment is administered. Longer follow-up and collection of AEs may be required for patients that do not have an absolute neutrophil count (ANC) recovery within 42 days (i.e., until the recovery or the reason for no recovery is diagnosed) after the last induction or consolidation cycle.

A flow diagram of the study design is shown in Figure 2---1.

Figure 2---1 Study Design



Abbreviations: AML=acute mycloid leukemia
Note: It is expected that approximately 90 patients will be screened to identify 75 patients for randomization.

2.6 Sample Size and Power

A total of25 evaluable patients per arm will provide 71.8% power fi:ir each test comparing a dose with control via a Fisher's exact test at I-sided alpha ⁰⁰0.15 to detect a difference between a control proportion 0.55 and an experimental dose proportion 0.80; these tests will be conducted in a fixed sequence: higher dose versus control first and lower dose versus control second, with the second test considered exploratory (failed) if the first test fails.

3 EFFICACY AND SAFETY VARIABLES

3.1 Primary Efficacy Endpoint(s)

The primary endpoint is the rate of patients in each treatment group achieving morphological CR based on IWG criteria during the induction and re-induction phases or the treatment. Morphologic CR is defined as ANC >1000/;tL, platelet count>100,000/µL, <5% blasts in an bone marrow aspirate sample, no blasts with Auer rods, and no evidence of extramedullary disease (sec Appendix A of protocol). Note that a patient is only considered to have achieved morphologic CR if this is documented on or after 21 days from date of randomization and not superseded by a subsequent data entry within 42 days of randomization that indicates treatment failure or progressive disease or persistent disease as indicated by >5% blasts in a bone marrow aspirate sample.

3.2 Secondary Efficacy Endpoints

- Event Free Survival (EFS)
  - Event-free survival (from date of randomization) is measured from the date of randomization until treatment failure (e.g., failure to achieve composite complete morphological remission during the induction or re-induction phase of the study lasting up to 60 days, relapse from CR, or death from any cause, whichever occurs first).

- Leukemia-Free State (LFS)
  - Leukemia-free survival is only assessed in patients who achieve composite CR and is measured from the date ofleukemia-free state until disease relapse or patient death from any cause, whichever occurs first.

- Overall Survival (OS)
  - Overall survival is measured from the date of randomization until death from any cause.

- Composite Complete Remissions (CR) rate
  - Complete remission rate includes CR, (on or after 21 days from date of randomization) and CRi and CRp (either need to be on or after 21 days from date of randomization) as defined by IWG criteria (Appendix A in the protocol) during the induction and re-induction phases of treatment. If a patient achieves a composite CR, but followed by PD or treatment failure from day 21 to 42, then the patient did not achieve a composite CR and should be considered a treatment failure.

- Duration of morphologic CR
  - Duration of morphologic complete response is measured from the achievement of CR to detection of relapse. A relapse is defined as progressive disease or death from clinical disease progression

- Duration of composite CR (if available)
  - Duration of composite complete response is measured from the date of achievement of composite CR to detection of relapse. A relapse is defined as either progressive disease or death from clinical disease progression.

- 30-day, 60-day and 90-day mortality
  - Thirty-day, 60-day, and 90-day mortality are the rate of death during 30 days, 60 days, and 90 days, respectively, from the first day of induction treatment.

- Neutrophil and Platelet Recovery
  - Time to neutrophil recovery (from date of randomization) is measured from the date of randomization until ANC recovers to> 500 and>1000/μL respectively.

- Time to transfusion-independent platelet recovery (from date of randomization) is measured from the date of randomization until the first day that the platelet count recovers to> 20,000 and>100,000/ tL respectively (provided it is not as a consequence of platelet transfi.1sion and provided platelets are then maintained at> 20,000 and >100,000/µL respectively for the five subsequent clays without platelet transfusion).

3.3 Safety Endpoints

Key safety endpoints will be assessed by review of summaries of *A* Es which will include only treatment-emergent AEs (TEAEs), unless otherwise stated. Adverse events will be categorized by System Organ Class (SOC) and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA) dictionary (version 14.1), and will be graded according to NCI-CTCAE version 4.03.

4 PHARMACOKINETIC/PHARMACODYNAMIC VARIABLES

Details to be provided by Biocascade in a separate PK SAP.

5 ANALYSIS POPULATIONS

The analysis sets that will be used for statistical analyses are as follows:

Intent-To-Treat (ITT): This includes all randomized patients. Patients will be analyzed according to the treatment to which they are randomized. The ITT Population will be the primary analysis set for the efficacy variables.

modified-Intent-To-Treat (m!TT): This includes all randomized patients who received at least one dosage of study drug. Patients will be analyzed according to the treatment to which they are randomized.

Per Protocol (PP): Supporting analyses will be conducted on the PP Population, comprising all patients randomized and treated without major protocol deviations during the trial. This population will he documented before final database lock. PP Population will be analyzed according to the treatment lo which they received.

The following are considered protocol deviations for the purpose of identifying the per protocol set:

1. Patients who were subsequently found to be not complying with the inclusion and exclusion criteria
2. Patients who are not compliant with study restrictions (eg. use of prohibited medication (generic drug name) or prohibited treatment therapy)
3. Patients who continued in study but should have been withdrawn according to withdrawal criteria
4. Patients who are not compliant with study drug treatment dose modification or stoppage rules (either temporary or permanent).
5. Patients who took incorrect study drug (CX-01 or other) dose, frequency, timing or method of drug delivery (e.g. subject overdosed with study drug, incomplete study drug administered).

6. Patients who took different study drug than the study drug to which they were randomized.
7. Patients who do not have post baseline data anywhere in the system.

!terns I to 5 are routinely monitored in the study as part of the study monitoring plan.

Safety: All patients who received at least one dose of study treatment. Patients will be included in the analyses according to the treatment they received. The Safety Population will be used in the analyses of all safety endpoints.

6 DATA HANDLING

6.1 Time points and Visit Windows

Day l is defined as the day of randomization visit. Relative days after Day l are calculated as (assessment date···· Day l date)+ l. Relative days prior to Day l arc calculated as (assessment date Day l date). The day prior to Day I is Day -1.

All data will be analyzed using nominal study visits as defined in the Study Schedule and eCRF. No visit windows will he applied for summary and analysis.

In determining the baseline, if assessment on date of randomization is unavailable, then the last scheduled or unscheduled assessment before first study drug/randomization will be used instead.

6.2 Handling of Dropouts or Missing Data (where applicable)

For ITT analysis, patients with partial or missing data to determine morphologic complete remission on the eCRF form will be considered as not having met the criteria morphologic complete remission. For PP analysis and elsewhere, only the complete cases will be analyzed and no missing value imputation will be carried out.

Incomplete AE-rclatcd dates will be handled as follows:

- In cases where:
    - the onset date is completely missing or
    - the onset is in the same year (only the onset year is available) as the start of study treatment or
    - the onset is in the same month and year (only the day is missing) as the start of study treatment or
    - either the onset day or month is missing but the year is not before start of study treatment

  then the onset date will be replaced by the minimum of start of study treatment and AE resolution date.
- In all other cases the missing onset day or onset month will be replaced by first day or January.

- Incomplete stopping dates will be replaced by the last day of the month (if the day is missing only), unless this will result in a date after the date of death. If the imputed date will exceed the date of death, the date of death will be used as the stopping date. No imputation is needed if the event is ongoing.
- In all other cases the incomplete stopping date will not be imputed.

To impute missing day of follow-up dates (such as safety long term follow up) or Disease History, the missing day will be taken as the 15th of the month, as long as month and year is available. In all other cases missing or incomplete dates will not be imputed.

In patient listings, the documented date from cCRF will be reported (e.g. .May2016 in case where the day is missing, but month and year are available).

7 STATISTICAL METHODS

7.1 General Principles

All data processing, summarization and analyses will be performed using the Hosted SAS Environment Version 9.3 (or later) of the SAS'° statistical software package.

Unless specified otherwise, data will be displayed using the following treatment group labels, in the order presented:

- Control,
    - those who are on Idarubicin + Cytarabine therapy only
- Low CX-01,
    - those who are on ldarubicin + Cytarabine + plus lower dose CX-01
- High CX-01,
    - those who are on Idarubicin + Cytarabine + plus higher dose CX-01
- Overall

All data collected will be presented in listings by treatment group, site, subject and visit (where applicable), unless otherwise specified.

Data will be presented in snmmary tables by treatment group, and visit (where applicable). The category "Missing" will be presented if the number missing is greater than zero for at least one treatment group.

Descriptive summary statistics for continuous variables will include the number of subjects (N), mean, standard deviation (SD), median and range.

Descriptive summary statistics for categorical variables (such as gender, race) will include frequency counts and percentages [n (%)]. Unless stated otherwise in the table shells, the denominator for percentage calculations for a particular variable will be the number of subjects with non-missing data.

Dates will be displayed as DDMMMYYYY.

All significance tests will be two-sided and use a 5% significance level except for primary outcome, which is tested at I -sided at 15% level of significance.

7.2 Subject Disposition and Data Sets Analyzed

Subject disposition will be listed and summarized by treatment group and overall and will include the number and percentage of subjects:

- screened;
- randomized;
- randomized and not treated;
- treated;
- available at each study visit (treatment period, 30 day safety follow-up, long term follow-up at every 3 months until approximately 18 months or deaths of all patients, whichever is earlier);
- included in each study population (ITT, PP, Safety).

In addition, the number and percentage of subjects who complete the study and who discontinued early, including a breakdown of the primary reasons as reported in the eCRF for early termination, will be presented for all analysis populations (ITT, PP, Safety). Additional summaries frir safety follow up (reasons for not completing safety follow up) and long term follow up (status of long term follow up, cause of death recorded at long term follow up) will be provided for each treatment arm for the]TT, PP and safety population.

A summary of patient enrollment by site will also be provided by treatment group and overall for the ITT population.

A summary of the reasons for screen failure as well as the number of subjects screened but not randomized will be produced. No other informati,ln for screen failures will be presented.

7.3 Protocol Deviations

All protocol deviations will be listed and summarized by treatment group for the ITT population.

All important protocol deviations leading to exclusion from the PP population (see Section 5) will be listed and summarized by treatment group for the ITT population.

7.4 Demographics and Other Baseline Characteristics

Demographic and baseline characteristics will be listed and summarized by treatment group and overall for all analysis populations (ITT, PP, Safety). Standard descriptive statistics will be presented for the continuous variables of:

- Age at screening (years) [calculated as (informed consent date - date of birth)/365.25 and reported as whole years;
- weight (kg);
- height (cm);
- BMI
- Time since diagnosis
- Baseline blasts in bone marrow(%)
- Baseline LDH

The total counts and percentages of subjects will be presented for the categorical variables of:

- age group (years) (grouped as <70 and 2: 70);
- sex;
- race;
- ethnicity;
- AML type (de novo or secondary);
- Baseline peripheral blasts (Yes/No)
- ECOG performance status
- Time since diagnosis(<= 30 days,> 30 days)

No formal tests of statistical significance will be performed on the demographic and baseline data.

Other baseline measurements, such as bone marrow aspirate/biopsy, pregnancy test result, lab parameters, vital signs, ECG and ECOG, will be summarized by treatment group with the post-baseline measurements.

7.4.1 Medical History

Medical history will be coded using the latest available Medical Dictionary for Regulatory Activities (MedDRA). All medical history will be listed, and the number and percentage of subjects with any medical history will be summarized for some analysis populations (ITT, Safety) by system organ class (SOC) and preferred term (PT) for each treatment group and overall.

7.4.2 Prior, Post treatment (anti AML) and Concomitant Medications

Medications received prior to or concomitantly with treatment will be coded using the WHO Drug Dictionary [March 2016 132 version] Anatomical Therapeutic Chemical (ATC) Classification codes.

Prior, post treatment medications and concomitant medications are defined as follows:

- Concomitant medications are those with a start date on or after the first dose date of study treatment,, or those with a start date before the first dose date of study treatment and a stop date on or after the first dose date of study treatment.
- Prior medications will be defined as non-study medication with a stop date prior to the first dose of study treatment.
- Post treatment medications are those with start date after the last dose of study drug.

Concomitant medications will be further divided according to whether they were started before (both prior and concomitant) or after (concomitant-only) the first dose of treatment.

If a medication cannot be classified as "prior" or "concomitant" after applying imputation rules for missing/incomplete dates, it will be classified as concomitant.

Prior anti-AML treatment medications and concomitant medications will be listed and summarized separately for ITT analysis population. Post treatment medications will be listed only.

The number and percentage of subjects using each medication will be displayed together with the number and percentage of subjects using al least one medication within each therapeutic class (ATC-Level 2), chemical subgroup (ATC-Level 4), and generic term.

7.5 Measurements of Treatment Exposure and Study Drug Usage Rate

Extent of study treatment exposure will be summarized for the entire study treatment period and by cycle. Exposure variables will include duration of study treatment, number of dose reductions, number of treatment delays (interruptions), number of treatment cycles, and dose intensity relative lo dose levels specified in the protocol.

There are three types of treatment cycles: induction cycle, re-induction and consolidation cycles. For each cycle, the exposure for each drug (Jdarubicin, Cytarabine, CX-01) is taken as the sum of duration of drugs for drug taken within that cycle. For drugs that started and ended on the same day, it will be regarded as I day, for drugs that started and ended on differenl days, the duration will be calculated as date of last dose minus date of first dose + 1 day for the period which the drug was administered. Proportion of patients who are exposed to the full expected duration for each component of the study drug will be presented for each cycle.

The study drug usage rate calculation for the induction cycle is as follows, where the expected number of days is the number of days the patients were expected to take the drug, up lo the point of study

discontinuation. If a patient was scheduled to lake 7 days of drug but only took the drug for 5 days because of early withdrawal, then the expected number of days would be 5.

The calculation of BSA will be based on the best possible results for study drug usage (closest to 100% and below) from Mostellar, Dubois and Gehm, formulae as outlined below.

DuBois[I]

BSA $_{(11^2)}$ = 0.007184 x Height(cm) $^{0\ 725}$ x Weight(kg) $^{04\ 25}$

Gehan/2]:

BSA $_{(111^2)}$ =, 0.0235 x lle ight(cm) $^{04\ 2246}$ x Weight(kg) $^{0\ 514\ 56}$

Mostellar/3]:

BSA $_{(11\overset{2}{1})}$ = ([Heigh!(cm) x Wcight(kg)]/ 3600)$^{0\ 5}$

Group I: ldarubicin + Cytarabine

Idarubicin: Actual total dosage per 1112/(12 mg/1112 x expected number of days) [Maximum expected number of days=3]

Cytarabine: Actual total dosage per 1112/(I 00 mg/1112 x expected number of days) [Maximum expected number of days=7]

Group 2: ldarubicin + Cytarabinc + plus lower dose CX-01

Initial CX-01 4 mg/kg, (0 or 100%)

CX-0 I: Actual total dosage per kg/(3 mg/kg/dayx expected number of days) [Maximum expected number of days=7]

ldarnbicin: Actual total dosage per 1112/(12 mg/1112 x expected number of days) [Maximum expected number of days,-3]

Cytarabine: Actual total dosage per 1112/(I 00 mg/1112 x expected number of days) [Maximum expected number of days=7]

Group 3: ldarubicin + Cytarabinc + pins higher dose CX-01

Initial CX-01 4 mg/kg, (0 or 100%)

CXOl: Actual total dosage per kg/(6 mg/kg/dayx expected number of days) [Maximum expected number of days=7]

Idarubicin: Actual total dosage per 1112/(12 mg/1112 x expected number of days) [Maximum expected number of days=3]
Cytarabinc: Actual total dosage per 1112/(100 mg/1112 x expected number of days) [Maximum expected number of days=7]

The study drug usage rate calculation for the re-induction cycle under 5+2 regimen is as follows:

Group 1: ldarubicin + Cytarabinc

Idarubicin: Actual total dosage per 1112/ (12 mg/1112 x expected number of days) [Maximum expected number of days 00 2]
Cytarabine: i\ctual total dosage per 1112/ (I00 mg/1112 x expected number of days) [Maximum expected number of days=5]

Group 2: ldarubicin + Cytarabinc + plus lower dose CX-01

Initial CX-01 4 mg/kg, (0 or 100%)

CXO**1:** Actual total dosage per kg/(3 mg/kg/day x expected number of days) [Maximum expected number of days=S]
Jdarubicin: Actual total dosage per 1112/ (12 mg/1112 x expected number of days) [Maximum expected number of days=2]
Cytarabine: Actual total dosage per 1112/ (100 mg/m2 x expected number of days) [Maximum expected number of days=5]

Group 3: Idarubicin + Cytarabinc + plus higher dose CX-01

Initial CX-01 **4** mg/kg, (0 or 100%)

CXOJ: Actual total dosage per kg/ (6 mg/kg/dayx expected number of days) [Maximum expected number of days=5]
ldarubicin: Actual total dosage per 11121 (12 mg/1112 x expected number of days) [Maximum expected number of days=2]
Cytarabine: Actual total dosage per 1112/ (100 mg/m2 x expected number of days) [Maximum expected number of days=5]

The study drug usage rate calculation for the consolidation cycle is as follows:

Group 1: Cytarabinc

Cytarabine: Actual total dosage per m2/ (2 g/ m2x expected number of days) [Maximum expected number of days=3]

Group 2: Cytarabine + plus lower dose CX-01

Initial CX-01 4 mg/kg, (0 or 100%)

CXOJ: Actual total dosage per kg/(3 mg/kgx expected number of days) [Maximum expected number of days=5]

Cytarabine: Actual total dosage per 1112/(2 g/ rn2x expected number of days) [Maximum expected number of days=3]

Group 3: Cytarabinc + plus higher dose CX-01

Initial CX-01 4 mg/kg, (0 or 100%)

CXOI: Actual total dosage per kg/(6 mg/kgx expected number of days) [Maximum expected number of days-,5]

Cytarabine: Actual total dosage per 11f²/(2 g/ nix expected number of days) [Maximum expected number of days=3]

7.6 Efficacy

7.6.1 Primary Efficacy Analysis

Fisher exact test will be used to compare the proportion of CRs between each dose and control for the ITT population using one sided test at 15% level of significance along with a 70% CI. These tests will be conducted in a fixed sequence: higher dose versus control first and lower dose versus control second, with the second test considered exploratory (failed) if the first test fails.

7.6.2 Secondary Efficacy Analysis

The primary efficacy analysis will be repeated using the PP Population as a supportive analysis along with CRi and composite CR for ITT and PP. Complete response rates and composite complete response rates and confidence intervals will also be reported for key subgroups (De-novo *vs* secondary AML at diagnosis, Age< 70 vs Age 2 70, ECOG performance status:::: 1 vs ECOG performance status =2). The following secondary analyses will be performed on the ITT population. Analyses of EFS, LFS, time to neutrophil and platelet recovery, and OS will be descriptive. Kaplan-Meier (KM) estimates will be used to estimate the survival distribution for each arm and KM plots will be produced to accompany these analyses. 95% Confidence Intervals will be reported for medians and KM estimates. Duration of response will be analyzed using a similar approach; the survival distributions will be estimated as cumulative incidence functions.

M01iality rate at Day 30, Day 60, and Day 90 will be reported using descriptive statistics in a manner similar lo the reporting of the morphologic CR rate. The time to neutrophil and platelet recoveries will be reported using the following descriptive statistics: N, mean, SD, median, minimum, maximum, and the 1st and 3rd quartiles.

7.6.3 Sensitivity Analysis

None.

7.6.4 Subgroup Analysis

Descriptive statistics for the primary efficacy variable (CR) and composite CR and 95% confidence intervals will be provided of the following subgroups for ITT population provided there is suflicient number of patients in total within the subgroup across the treatment arms:

- Age groups (<70 and 2: 70)
- AML at diagnosis (de novo, secondary)
- ECOG performance status (:S 1 Vs ECOG=2)

7.6.5 Exploratory Analysis

Additional efficacy analyses will be performed as exploratory analysis for the following variables, summarized by treatment groups and analyzed in the same way as secondary analyses above.

- Duration of composite CR (if present)
- Days until neutrophil recovery to 2: 500/ LL (from date of randomization and from date of first study drug)
- Days until platelet recovery to 2: 20,000/ LL (from date of randomization and from date of first study drug)

7.7 Safety

7.7.1 Adverse Events

All adverse events (AEs) recorded on the eCRF will he coded using the MedDRA dictionary [Version 14. l] and classified as either pre-treatment AEs or treatment - emergent AEs (TEA Es) as follows:

- Pre-treatment AEs arc events that staii prior to the date of first dose of study treatment.
- Treatment-emergent AEs (TEAEs) arc events with start date and time on or after the date and time of first dose of study treatment (and up to 30 days after date of last dose of treatment) with

start dale prior to the dale of first dose of study treatment whose severity worsens on or after the dale and time of first dose of study treatment.

Assessment of AE severity will be based on the National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE, version 4.0.3).

All AF data will be listed by treatment group including Pre-treatment AEs and TEAEs. The number and percentage of subjects reporting each treatment AE and TEAEs will be summarized for each treatment group and overall, by System Organ Class (SOC) (sorted alphabetically) and Preferred Term **(PT)** (sorted by descending overall total) for Safety populations.

In addition, corresponding listings of serious AEs (SAEs), AEs leading to discontinuation of treatment, AEs causing interruptions from study treatment, AEs causing dose reduction from study treatment and study treatment-related AEs causing dose reductions are provided.

An overview table will summarize the number and percentage of subjects with at least one of the following AEs/TEAEs, where subjects with more than one AEs/TEAE in a particular category are counted only once in that category:

- any AE;
- any TEAEs;
- treatment-related TEAE;
- any AE by maximum NCl-CTCAE grade;treatment-related TEAE by maximum NCJ-CTCAE grade;
- AE leading to treatment interruption;
- treatment- emergent AEs leading lo treatment interruption;
- AF leading to treatment reduction;
- treatment- emergent AEs leading to treatment reduction;
- AE leading lo treatment discontinuation; treatment-emergent AEs leading to discontinuation from the study;
- SAE;
- treatment-emergent SAE;
- SAE leading to death;
- treatment-emergent SAE leading to death;
- SAE leading to treatment discontinuation;

The number and percentage of subjects reporting each TEAE will be summarized by System Organ Class (SOC) and Preferred Term (PT) for the Safety population. Tables will be sorted alphabetically by SOC. !'Ts will be sorted by descending overall total; if the number and percentage are the same for different PTs, the PTs will be listed in alphabetical order (within the SOC). The following summaries will be produced:

- TEAEs by SOC and PT;
- TEAEs by PT;NCI-CTCAE Grade 3 or higher TEAEs by SOC and PT;
- NCI-CTCAE Grade 2 or lower TEAEs by SOC and PT;
- TEAEs related to treatment, by SOC and PT;
- TEAEs by maximum NCl-CTCAE grade, by SOC and PT;
- Treatment--related TEAEs by maximum NCI-CTCAE grade, by SOC and PT;
- TEAEs causing discontinuation from treatment, by CTCAE and worst CTCAE grade;
- TEAEs related lo treatment causing discontinuation from treatment, by CTCAE and worst CTCAE grade;
- Serious TEAEs, by SOC and PT;
- NCI-CTCAE Grade 3 or higher Serious TEAEs, by SOC and PT;
- NCI-CTCAE Grade 2 or lower Serious TEAEs, by SOC and PT;
- Serious TEAEs related lo treatment by CTCAE and worst CTCAE grade;
- TEAEs leading to death, by SOC and PT

In the above summaries, subjects with more than one AE/TEAE within a particular SOC are counted only once for that SOC. Similarly, subjects with more than one AE/TEAE within a particular PT are counted only once for that PT. For summary by maximum severity, subjects with multiple AE/TEAEs within a particular SOC or PT will be counted under the category of their most severe AE/TEAE within that SOC and PT.

7.7.2 Laboratory Evaluations

Clinical laboratory assessments will be summarized using frequency tables, shift tables, and descriptive statistics. Frequency tables and shill tables will be presented by NCI-CTCAE grade. Laboratory variables with no NCI-CTCAE group will be presented in shift tables with respect to normal range. All laboratory variables will be presented in tables of descriptive statistics (mean, SD, etc.) and graphs will be presented for PT/INR, aPTT, anti-factor Xa, fibrinogen, D-dimcr, and platelet count.

7.7.3 Vital Signs and ECOG performance status

Vital signs variables and ECOG performance status will be summarized using descriptive statistics at screening visit and start of consolidation cycle (vital signs only).

7.7.4 Electrocardiograms

Counts and proportion of patients with clinically significant abnormal results at screening and Day 7 will be reported.

7.8 Interim Analysis

A Data Safety Monitoring Committee (DSMC) will be instituted for this study according to a separate DSMC Charter in order to ensure ongoing safety of study subjects.

No other interim analysis is planned.

8 CHANGES FROM PLANNED ANALYSES IN PROTOCOL

A new analysis population m!TT is added as per client request aner the first DSMB meeting.

For primary objective, the time component required (on or after 21 days from date of randomization) for the recognition of morphologic CR is added in the definition.

For secondary objective, the time component required (on or after 21 days from date of randomization) for the recognition of CRi and CRp is added in the definition.

For secondary and exploratory objectives, the following variables are additional to the protocol:

- Duration of composite CR, with the definition of composite CR being clarified as CR or CRi or CRp.
- Days until neutrophil recovery to 2: 500/ ,tL
- Days until platelet recovery to 2: 20,000/ ,tL

For Leukemia-Free State (LFS), the definition is now changed to from date ofleukemia free state, because the protocol definition from date of randomization is not correct.

Repeat ofCRi and composite CR in the same fashion as primary efficacy analysis and addition of composite CR for subgroup analysis.

Compliance is termed as study drug usage rate in the SAP.

Competing risk of death analyses will not be performed.

Post treatment medications will only be listed and not summarized as per client request.

9 DATA ISSUES

Not applicable.

10 REFERENCES

[I] DuBois D, DuBois DF. A formula to estimate the approximate surface area if height and weight be known. Arch Int Med 1916;17:863-71.

12] Gchan EA, George SL. Estimation of human body surface area from height and weight. Cancer Chemothcr Rep 1970;54:225-35.

[3] Mosteller RD. Simplified calculation of body-surface area. N Engl .I Med 1987;3 l 7: I 098.

11 APPENDICES

Appendix I- Schedule of Events

Table 11-1 Induction/Re-induction Cycle Schedule of Study Procedures

Examination	Screen Visit D -28-1	DI	D2	D3	D4	DS	D6	D7	D 8-13	D 14-21	At count recovery & Weekly from D21 until count recovery or D60[15]	Early Term Visit	Safety FU visit (30 days after last dose of treatment)	Long Term FU contact (every 3 month sup to death, or EoS) [16]
Informed consent[1]	X													
Demographic and medical history	X													
Eligibility criteria	X	X												
Randomization		X												
Idarubicin [2]		X	X	X										
Cytarabine[3]		X	X	X	X	X	X	X						
CX-01 Bolus[4]		X												
CX-01[5] continuous infusion		X	X	X	X	X	X	X						
ECOG status	X													
Vital signs (BP,	X													

Table 11 1 Induction/Re-induction Cycle Schedule of Study Procedures

Examination	Screen Visit D -28-1	DI	D2	D3	D4	D5	D6	D7	D 8-13	D 14-21	At count recovery & Weekly from D21 until count recovery or D60[15]	Early Term Visit	Safety FU visit (30 days after last dose of treatment)	Long Term FU contact (every 3 month sup to death, or EoS) [16]
heart rate, height and weight)[6]														
Physical exam	X													
12-lead ECG	X							X						
Echocardiography orMUGAscan	X													
Hematology[7]	X	X	X	X	X	X	X	X	X	X	X	X	X	
Anti-factor Xa, [8 9]	X	X	X	X	X	X	X	X	x9			X		
PT/INR, aPTT[8 10]	X	X	X	X	X	X	X	X	xio	X	X	X	X	
Chemistry [11]	X	X	X	X	X	X	X	X	X	X	X	X	X	
PK sampling[12]				X		X								
AE Assessment	Continuously													
Previous medications	X													
Concomitant medications	continuously													

Table 11-1 Induction/Re-induction Cycle Schedule of Study Procedures

Examination	Screen Visit D -28-1	DI	D2	D3	D4	D5	D6	D7	D 8-13	D 14-21	At count recovery & Weekly from D21 until count recovecy· or D60[15]	Early Term Visit	Safety FU visit (30 days after last dose of treatment)	Long Term FU contact (every 3 month sup to death,or EoS) [16]
Fibrinogen, D-dimer	X										X	X	X	
Serum or urine pregnancy test[13]	X												X	
Bone marrow aspirate/ Biopsy[14]	x14									xi4	x14			
Relapse and survival data														X

Abbreviations: AE=adverse event, ALT=alanine aminotransferase, ANC=absolute neutrophil count, anti-Xa=anti-factor !0a, aPTT=activated partial thromboplastin time, AST=aspartate aminotransferase, BP=blood pressure, BUN=blood urea nitrogen, CBC=complete blood count_ CX-01=2-O, 3-0 desulfated heparin, D=day, ECG=electrocardiogram, ECOG=Eastern Cooperative Oncology Group. EoS=end of study, FU=follow-up, INR=international normalized ratio, IV=intravenous, LDH=lactate dehydrogenase, MUGA=multi gated acquisition. OS=overall survival, PK=pharmacokinetics, PT=prothrombin time, Term=termination.

l. Informed consent must be obtained before any study-related procedures are conducted.

2. Idarubicin administered at a dose of 12 mg/m^2/day by slow (10 to 30 minutes) lV injection/infusion daily on Days 1, 2, and 3.
3. Cytarabine administered at a dose of 100 mg/m^2/day as a continuous 24-hour IV infusion on Days 1-7. Patients who do not achieve leukemia-free state (<5% bone marrow blasts) on bone marrow aspirate performed between Days 14-21 may receive a re-induction cycle with the same regimen ("7 + 3" ± CX-01). Ifin the Investigator's opinion, the patient is not fit to receive full re-induction cycle of"7 + 3" ± CX-01, at the Investigator's discretion the patient may receive "5 + 2" ± CX-01 which is 5 days of cy1arabine (Days 1-5) and 2 days of idarubicin (Days 1 and 2).
4. CX-01 administered at a dose of 4 *mg/kg* as an initial bolus on Day l only, 30 minutes after completion of administration of the first dose of idarubicin.
5. CX-01 administered at a dose of 0.125 or 0.25 mg/kg/hour as a continuous 24-hour IV infusion on Days 1-**7.**
6. Height obtained at Screening only. Actual body weight will be measured at the beginning of each cycle to calculate treatment doses.
7. Hematology **must** include the following: hemoglobin, ANC, and platelets. All other hematology assessments should be performed only if standard of care and/or clinically indicated. Hematology samples will be collected daily until discharge and weekly thereafter until recovery.
8. Note: blood samples for PT/INR, aPTT and anti-Xa levels will be collected 12 hours after the bolus dose ofCX-01.
9. Anti-Xa samples ,vill be collected only on Days 1-8.
10. PT/aPTT will be collected daily on Days 1-8, and on Day 9, Day 1 L and Day 13.
11. Chemistry (and comprehensive metabolic panel) includes BUN, serum creatinine, total bilirubin, ALT, AST, and alkaline phosphatase. Samples will be collected daily until discharge.
12. At selected sites, blood samples for steady-state PK analysis will be collected during the induction cycle from the first six randomized patients assigned to CX-01 on Days 3 and 5 at a single time point.
13. For females of childbearing potential only. All female patients will have a urine pregnancy test at Screening; positive urine tests must be confirmed by a serum pregnancy test.
14. Bone marrow aspirates and/or biopsies are not performed weekly. If the patient's peripheral blood is negative for persistent AML: a bone marrow aspirate and/or biopsy will be performed (once) between Days 14-21 to determine the need for re-induction. Bone marrow biopsy may be necessary if sufficient spicules are not available on aspirate. Bone marrow aspirate at baseline and follow-up should include analysis by flow cy1ometry and cytogenetic analysis. Bone marrow (or peripheral blood if bone marrow is unavailable) should be sent to the institution's local cy1ogenetic laboratory for analysis. For patients with documented CR, confirmatory bone marrow aspirate slides will be submitted to the Sponsor or designee. If count recovery has not occurred by Day 42, a bone marrow aspirate/biopsy will be performed to evaluate disease status, unless presence of persistent AML in peripheral blood.

15. Count recovery is defined as ANC of> 1000/µL and a platelet count>100,000/µL.
16. During long term follovi-up, relapse and survival data will be collected every 3 months until death or until the end of study. The end of study will occur approximately 18 months after the last patient is randomized.

Table 11-2 Consolidation Cycle Schedule of Study Procedures

Examination	I) **1**	I) 2	I) **3**	I) **4**	I) **5**	**Weekly from D6 until count recover** y8
Hematology [1]	X	X	X	X	X	X
PT/lNR, aPTT, and anti-X a[2]	X	X	X	X	X	
Chemistry[3]	X	X	X	X	X	X
Vital signs (BP, heart rate, height and weight)[4]	X					
Cytarabine [5]	X		X		X	
c·X-01 Bolus [6]	X					
CX-01 [7] continuous infusion	X	X	X	X	X	
Concomitant medications	continuously					
Adverse events	continuously					
Bone marrow aspirate/ Biopsy						X9

Abbreviations: aPTr-"activated partial thromboplastin time, anti-Xa=anti-factor IOa, BP$_{00}$ blood pressure; CBC=complcte blood count, D=day, INR=international normalized ratio, PT=prothrombin time.

1. Hematology **must** include the following: hemoglobin, ANC, and platelets. All other hematology assessments should be performed only if standard of care and/or clinically indicated. Hematology samples will be collected daily until discharge and weekly thereafter until recovery.
2. PT/aPTT and anti-Xa blood samples will be collected 12 hours alter the bolus dose of CX-01.
3. Chemistry (and comprehensive metabolic panel) will be collected daily until discharge.
4. Actual body weight will be measured at the beginning of each cycle to calculate treatment doses.
5. Cytarabine administered at a dose of 1.0 g/m^2 over 3 hours, every 12 hours on Days 1, 3, and 5.
6. CX-01 administered at a dose of 4 mg/kg as an initial bolus on Day 1, 30 minutes after completion of the first 3-hour infusion of cytarabinc, followed immediately by a continuous CX-01 24-hour IV infusion.
7. CX-01 administered at a dose of 0.125 or 0.25 mg/kg/hour as a continuous 24-hour IV infusion on Days 1-5 for a total of 120 hours of continuous CX-01 infusion.
8. Count recovery is defined as ANC of> 1000/µL and a platelet count>100,000/ tL.
9. Bone marrow aspirate/biopsy is not done weekly. If the patient's peripheral blood is negative for persistent AML and count recovery has not occurred by Day 42 (of Consolidation cycle), a bone marrow aspirate/biopsy will be done to evaluate disease status.

Appendix 11 - Table, Figure and Listing Shells

The tabk, figure and listing shells and correspondingTable of Contents.are available as a separate file.

TABLES, FIGURES, AND LISTINGS SHELLS

A Randomized, Phase II Study of CX-01 Combined With Standard Induction Therapy for Newly Diagnosed Acute Myeloid Leukemia

TFL Status: Final
TFL Date: 20 I 8-03-08T07:32:05

Study Drug: CX-0 I

Sponsor Reference:
Covance Study No: 00000014620 I

l. INTRODUCTION

The table, figure, and listing (TFL) shells presented in this document arc mock-ups and may be subject to minor format modifications once the actual data are used. The data represented in this document arc used for example purposes only and do not reflect the actual study data captured. The overall contents in any individual TFL shell will not change, although additional tables may be added if necessary, thus changing the table number scheme. Significant changes will be approved by the responsible Covance Clinical Pharmacology project team member and communicated lo the Sponsor.

1.1 General Programming Specifications

All TFLs will follow the following rules:

Papersizc will be A4, with the following margins in Inches:

Landscap			
top	1.5	!en	
bottom	1.73	right	

Portrait			
Top	1.5	!ell	1.5
Bottom	1.5	right	1.23

Every TFL will have a footnote containing program location, name, run date and run time (optional), listing source, the name of the last person who ran the program, and the status of the output: Dry run - Draft-- Final Draft- Final (others as needed)

Dates will be presented in the format yyyy-mm-dd
The presentation order of the statistics will be:
Mean, SD, median, minimum, maximum, N. The abbreviations Med, Min, Max may be used, if necessary.
Rules for significant digits in safoty data tables arc as follows: if the raw value has x decimal places, then the mean and the median will have x decimal places, the standard deviation will have x+I decimal places.

N will be presented as whole numbers.

1.2 Derived Parameters

Individual derived parameters (e.g. pharmacokinetic parameters) and appropriate summary statistics will be reported to three significant figures.

1.3 Tables Summarizing Categorical Data

Tables that summarize categorical data will be created per these specifications:

1. If the number of events is zero, data will be presented as "0".
2. If the categories ofa parameter are ordered, all categories between the maximum possible category and the minimum category will be included, even iftF0 for a given category.
3. If the categories arc not ordered, only those categories for which there is at least one subject represented will be included.
4. A "missing" category will be included for any parameter for which information is missing. This will ensure that the population size totals are consistent across different parameters.

2. TJ:.BLE Cf CC?<)'?SN'IS

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Listing i 6 **2** 30 Physical Examination Results Sater;, Population

3. SECTION 14 TABLES

@	Patient :Sxcludeci from Safety ?o;;;;..:.12::ion
S	Patier.t t̄XC¡_UCE.0. fro2, Ir;c:er,::-to- reat Populatio:1 (ITT)
&	Patient E:zcluded fro:n Per-Protoc:o.:.. Populatio,c
{?.)	Repeat: Visit
{W)	Patient ,:.,Jithdre,-;
; :,	Patient c1isra:1dornized
c'i..	lot Applicable
NC	Not Calculated
ND	Net Do:-1.e
NK	Not K:r:own
?<IR	Not Recorde::i

?aDle :;..4.

Su,c;;;:ary of S::udy Co:;r:pletie>r-, and Withdra·dal

	Cont::-ol		-o·•· rv-o.		:-!igh CX-01		Total	
Patients Screened							xx;,:	
Patie,. s Rando::nized [a]	xxx		xxx		xxx		>:z:-:	xx.x%
?.andom zeC ar,d not tr,::oated [bj	zxx	xx.z%'	:,;;-:x	;-.:x. :,;;-'i.,	xxx	> A >I,	; xx	xz.:--9-
Rar:do'"- zed ar:d -::.reateci lb}	xxz	xz.	::-:zx	x}:. xi·,	xxx	xx.x'ic.)	xxx	x :.z::,
ITT ?op'..<lat en [b	xxx	xx.x>,;	xxx	xx.x%::	:.;xx	xx.x%)	xxx	xx.
?er ?rotoco ?opulation. [bj	x;-:x	xx.x%	xxx	x:-:	;-:xx	xx,	xxx	xz.;-:i;)
Safety Pcµu atio,, [b]	xxx	xx.x°:"	xzx	xx.x ,•	xxx	xx.x0)	xzx	xx.x%)
Completed St:c,.d '.b]	:G{x	xx.:,J,	;,;xx	xx.x	xx}:	;,:x.xco)	',:xx	xx,xS;\
Entered XXX Cy le Jl .c'is!..t [bJ	xxx	xx.x'i	xxx	xx.;	xxx	(xx.x%)	xxx	xx.x ''
repeat :':or a::. visi::s fro2 Dl	xxx	xx.x':1	xx;.-	:<	:u:x	i xx.xS)	xx	(xx.x%)
Primary ?eason fer Ea:-ly Disconti::.uation [c]								
Reasor.	x:c-.:	xx.x':c'	xxx	zx.xrs	x:o:	xx.x'o	xx;,;	xx. x'o)
Reason 2	:o:x	xx.x	zx:,;	xx.	xxx	xx.x'i,;	xxx	xx. x'2)
Reaso:i. 3	xxz	xx.x	xxx	xx.x%)	xxx	xx.;,:S	xxx	(xx.x%)
etc	xxx	:,;::x.x	x;.-;x	:-:x.z'" ·	xxx	xx.x%	:-:xx	xx.z'2)

[a: The den0:r,ir,ator for percentage ca cu ation s !:lase::i er, r1:J.."1lber of patien".:.s sc::::eened.

[b} The der:orr:.inc.tor f-'.}r percentage ca cu a::ion s based er:. n;_i,_-::ber of pat:ier:t:s ra::-:::ciomized ir: each grcc:p.

[c] The denominate::- for percentage ca cu a-:::ion s based c,, the nu."1\De:::: of pa-:::::.e,;ts ;...,ho did r.ot comp.Lete t:"::e study for each gro-c1p.

P.t:09't6:minit1g·:Notes:

'Obtain··reasons £,or :early· di'SC_onti nua:ti()n from. CRF.

Table 2.'<c. .2.2
Surnxo.ary of Wi tC'.dra·,.•al
ITT ?opc1lation

	Co:n-::rol '.N XXX) c	Low CX-Jl (N "" xxx) n (%;	Eigr. cx-o::. 't = :,::xx}	Overal.:. XXX) n (;)
Primary Reason fo.:c Ea.:c::.y Discoc:tinuatio" [aJ				
Reasor;	x;,:x x;.:,	x:-:z X);. Z	xzx xx. x;,,	xxx xx.x
Reason 2	xxx xx. x%'•	xxx xx.	xxz xx.	xxx xx.x
?-.easor: 3	zxx xx. x'1",	xxx xz.x	xxx ;,:z .. ,.	xx;.: xx.x
etc	:-:xx x. x-"'-	xzz xx.:-:'"	xxx xx.	:,:xx xx.x%

[aJ ::i.e denominator for percer:tage ca.'...culatic:-. is based on :nu.:sb,2r of patie:-.::s i:n the vr:,;;n1.'.a-::io:-, set ·,rithin each group.

Pi:o'g_i- ing:·Notes:
_Obtain·.reason·s *foi* -.earl:,/ _discontinua_tiO:ri· fi-o:m CRF.
Program Name: Date Generated: Page x of y
Listing SoJrce:
?,epeat for the fol-2.owir,g displa :s:
Table :':.4. l. 2. 3 Su.Tu"tlary of Wi thdra·,.-a::. PP Population
.;dd:
Footnote: la; "e denominator for :=,ercer,tage calculc.-:::io:-i is based on ;,;;;.sber of patierats t:'le ?? ?opulation set , ithin each groc:p.

Delete:
Footnote: La; The denomir.ator for per:::e::tage calculation is based on n:...:...'Tber of patie,;ts · ::: ,e :::-: Population se::: 1,,,ithi::1 each group.

Table 14. l. 2. 4 SUJ.-:-.mary of \•Ii thdra'.12.l Safet'::/ Population
Add:
Footnote: [aJ The deno;r,inator for percen.-;::age calculatioD is based or. nu.--r.ber of pa.tier.ts .:.:-, :::;-::e Safety Populatior:: set ,...,·it:J.ir. each grou?,

Delete:
Footnote: [aJ The denominator for percentage calcu::.ati.on is based on nu.'T<Der cf pac::ier,ts in ::he Population se:: within each gro;ip.

Table 14.1.2.5

S·u..,--r:Tl',ary 0:: Screen Fai2-11::::es

:='.n,olled Population

	rota.!.-
Patients Sc:reened	xx;-;
?atier,ts Rancio:2..i.2ed [a]	xxx xz . :,!:0)
Patients Screened bu;:: not Randccnized [a;	xx:-: xx . z½
Screen a :.:re :reasor. LbJ	xzx Y:•:.z'i:)
Sc.::::een a :1re reason ,;	xx;-:: z:,:.x',
Screen a ;;.re reason LOJ	xx;-: :,:,:. xS,,
etc	

No e: If a pc. ient has rrrc.ltiple sc.::::een :: ilu::::e easor,s, t'.ne patient is cou:--,ced under each screer: faiL:re reascr:.

la The deno;n nator for perce:1tage calcv. a;::2.or-: s baseci or, nurrcbe!."" of patie:its enrolled.

[b Theder,om nator for percentage calc'..t at.ion s Daseci on the number of patients who got screened bL<:: r.ot rar,cio:.r.iz.eC.

?rogram c'lame: Date Gene::::ated: age of

Listing Source:

Tc.ble ,::. .c.2.6
:::;urr,rrtary of Subject Disposition. - Safe":y ?ollow-up
:::,:- Popula'".:ion

Dispositicr::	:or;.trol (lS co x;,::,:) r,	Low CZ-Ol (J = z:-:z\	(i hx Gl (O;)	Q;rerall (N xxx) n (%)
Safety .:cllc;-.,-,..1p perf,-:,r:;rced	xxx xx.x'o)	xxx xx.x;/	;-: :-:X.X'c	xxx xx.x i·,
Dici not ccrt,plete safe fcllo-,-up	xxx X '..X".')	xxx ;-:x.x" i	xxx x:-:.x<:c·,	xzx xx.x%'.
º rimc.r y ?.eason [aJ				
Rease:,.	x;.:x (::o:.x't)	xxx ;-::-:·,•'i•'	xxx xx.x':i	xxx zx.x%)
Reason	xxx xx. x'Sl	xxx	xxx (X•:.;-:½'	x::–:x xx.xf,)
?.eascn.	x:·c-: xz.	x:o:	xxx ;-:x.x'.;',	xx;,: xx.z%)
	xxx xx. z%)	x;,:x	xzx x:-:.x	xxx xx.z%)
Other	:-:xx zz.x'O	xxx xz. xr-,·;	xxx xx.::--;	xxx xx.x':,,'
Ongoing ;-:i th safety follow-up	x:o: x•:.xG)	: xx zz.	xxx :-:x.x	xxx xx.x%)

The deno.r,i;:atol:' for perce::-ltages ::.s the nwcher cf patien.ts .::.r: the IT';:' Pcp,.:laticr, for each Trec.t:ser:t group.
For [aJ, U·.e Cenominator for percentage calcc.:lation is based 0:1 the *r-,u..,--;.ber* of patients ·,,ho Cici not complete safety follc·,.; '--'P for each group.
Prcgra C1a,ne: :}ate Gene::::ateci: Page x of
L st--i--.g SO"""C"""
Repeat fer the fcllow:cng dis:::,lays:
TabJ.e 10..:.2. 7 Sllic.:7:lary of S\;bject Disposition - Sa'.:ec:y Follow-up ?P ?c:;:;c1latio:1
Add:
Fooc::-iote: The deno:mi:1ator fer perce:1tages is the Cl..hc'..ber cf patier,ts i:1 ::he PP Populat::.on for eac:'. TreatE,ent group.
Delete:
?ootnote: ?he der:omi:cator .:or percen:::ages is t'.'".e n.uillber of patier-.ts in ::he Pop'..:la::ior: for each Treat:;rrent grou.p.

Table 1 . .e:.8 Su.rr.ncary of Sc.:bject Jis;,ositio;-i - Sa::"ety Follo,,'-up Safety Population
.Sdd:
Foo::rwte: '?he deno:;r;i:iator ::er percem:.ai;es is the m.;_,_;1ber of patier,ts ,.., the Safec:y ?cp;..;2.ation for each Treatr:",ent gro,.:p.
Delete:
::'00-::10-ce: ':'he denomiriatcr for perce:-ic:ages is the r:urnber of patients " c::he :TT Pop1.,;.2.ation for eech Treat:nent i;roup.

:'able 14.1.2.9
S T01a:ry of Subject Dispositior:: - Long Te:cr:1 FolJ..o •:-·crp: !':onth X
--""7 Pop--1lation,

Ji s::--o"'	::c:,t:rol = xxx)		:.o'-'.' CX-0.l (N = xz:i(i ,, !%)		High C:.,:-C::. (κ = xxx) n		o·,,rerall ('.')	xxx}
Patients with long te:rrr, fol::.ow-t.:p La)	xzx	xx.xS)	xxx	xz.x%)	:-:;-:x '.		xxz	.--.- .)-·:'
::,ong ter:n follow-up stac.t.:s '.DJ								
Death	x::<	:-:x.xS)	x;-:;-:;	xx.x	xxz	_;.:;-;_;.:;)	xxx	zx.x'i
Ali·,se		xx.x%)	xx;-:	xx.x	x:-.;:x	.:-:x.x\'	:o:x	xz.x';;c
Recu:::-rer::ce	:-::-:;;,;:	x:-::.x":)	;.c-.;:x	x; .x	xxx	Y.X.Z-,	xxx	xx. x'::'
	;--:;-:y	zx.x'c)	xxx	x:,:. x%)	xxx	xx.z -)	xxx	x:o<. x',;
For ;:atients ;,;ho died_. p:::-irr,ary ca.use of dea-.::h [c]								
Res.so::	xxx	xx.x	x;-.;:x	xz.x	xxz	:,:x.z'C	xxz	x;,-:. zs
Reason 2	xT"	x;-:. :(%)	xx:,:	xx.zC	xxx	xx.;-;SC	z;-:x	;,-;x. :;o)
	:,:zx	xx.x%)	xxx	xx.x%	xxx	x:,· .z".,	xxx	xx.x•t'

Foe'.' a the de;:,.o:m nator o::: pe:::-centages is t:'.e ,, "".'<Der cf patie::1.ts in the ITT Populatior. for ea..ch Treat:r,er,t group.
E'er b ".:he denom nator or percentage c2lculatior, is :Jased on r,,,,:.rr.ber of people wi::h recorded long term fol lo·.- ψ status.
E"er c ::he deno:m nator or percentage calcu:ation is based on the rn.uc.ber of patients ,·:10 died.
:c o.....:..n N:.-z.:::: D"...."" s'o""e at""""" Page z of
::,ist::.r.g Source:
Repeat for the follow.ng disc:a,s:
Table "L 1.2.10 Su.mrr.ary o:: Subject Disposi_tio'1 - "-'0:1.g "Ier:rr: Follow-up: l:ionth X ?P Populatio;;
Add:
For ‹ the denorr.inac:or fo:::- percer.tages is the :.c:.cc.ber cf patients in the ?P Population for each TreatG.ent group.
Delete:
:'or [a], the cieT10:minac:o:::- fo:r percentages is the ,, "7.ber cf patier,ts . "ı the Populatior. for eac:1 Treatment grc;.:p.

Table 14.. 2. ScL--:-:mary of Subject Disposition - Lo;-:; Term Follow-up: Moc:th x Safety Populac:ion

F-.dd:

For [aJ, the derwc:-,inator for percer:.tages is the :1;-1,_--:-ber o-: patier,ts .:..r, the Safety ?cpulation for each Treatmer,t g::::-o'..:.p.

Delete:

For [a), t:t:e denomina.tor for percentc:ges is t:1.e nurrber o:'. pat2-e:1ts in the .ITT ?opulat:i.or, for each ':'reat:ne::t g::::-oup.

Table 14.1.2.12
Swill--rsary of Protocol De-v-.:.ations
ITT Populatior,

?rotocol Deviatio:c	:ontrol (N = XXX) n (%)	Low CX-01 (N = XXX} n (%)	High CX-01 {N = xxx) n {%}	Overall (N = xxx) n (%)
At Least l Major !?:rct :col Dev.:.at.:.0:1	xxx (xx.x:;)	xxx xx.:-:%\	xx.z%'.	;:xx x%)
1-:ajor ?r.-otocol De,,iat.-_0:1 l	xxx xx.x%)	xxx x: .:-:t l	;{:,,::{ zx.x%	xzz

etc

Table 14.:.6

Su.i"-<-r.ary of Demograph:.,· ,,,...,. ?opu.lati.on

	:or,trol (N = xxx)	*Lo;-:* CX-01 = xxx.: !'. (%)	Eigh CX-01 {N = ZXX) n	07erc.ll
Age Categories ea.rs n (%)				
N	:-:xz	xxx	xxx	X>-:X
<Category e.g. < 70>	·-::-:;-: :,;x.	xxz XX.X'O	xxx xx.x	xx:•· xx.x
<Cc.tegory 2, e.g. :C: 7C>	xxx xx.	;,:xx xx.xi}	·-:;-:x xx.x	:-:x ·,:x.x
etc.	:o::--: xz.zf,'•	XXX x%)	zxz xx.	zx.x
";ge ;yea.rs)				
n	>-:xx	xzx	x;-;:x	xxx
w.ec.n :_s.6.	xx.x xx. xz'	zx.x xx. xx)	xx xx.xx)	:n:.;,;x (:--:x
medi.C<c:	;c-;:.x	xx.:-:	zx.z	; :;,;. xz
rEin	xx.x	:--:x. x	.x	z
:cc.:-:	:--:x	xx.	:-sx.x	x}:.;-;:x
Ger,der n				
t;	:o:zx	xxx	;-:z)'.	x:,,--
112le	:-:xx X. X'5	;-:xx xx.x½)	xxx x: . x)	;-:;-:x zx. zf,)
Ferne.le	x:-:x xx.:,:	;,:xx x x . x00\	xzx xx.x'i:)	xxx ;,:x. ·Sc'

:.:rote: De::,o::n.inators for percentages are based or, t:'le m:u--:-J.:;er of pat.::_ents ;,·ith r,on-ITcissing dac:a in ec.cr. ?reatme;o,t g::m.ip £or t:'.e relevant -,,a:::iable.

[a] Age is ca:culated as calendar years £:.::om. birth to ir:!forrr-_ed consent

Program :-lame: Date Ge::1erate8.: ?age x o;'.

Listing Source:

'l'a:Cle 14.1.6

SlJ . TfLar:: ,. u.::?. g.. o.l-:-'.v

IT? Populat:.on

	:ontrol (N = xxx)	Lo>·i CX-Gl (N = XXX)	High cx-n:: :::: = :o:x)	Q,;erc.::..l ()i XXXi
BMI (kg/m:)				
n	xxx	::xx	xx:;:	::--:xx
meac \S .d. ·,	x;.:.:.: xx.xx)	xx.x xx. ;.::.x)	x{. xx xx.xx:	xx.xx (xx.xx)
.....d 2"	xx.x	xx.	xx.	.?::< .zx
	xx.x	xx.x	xx.z	xx.xx
rr,ax	xx.x	xx.	xx.x	zx.x;-:
Race Categories				
	:.:xx	xxx	xxz	;.:,o:
<Cac:eg-ory , e.g. Asias>	xxxx xx.x%	:o:x xx.:-	>:xx xx.x)	:-:xx xx.x
<Categcry 2, e.g. Slack>	;c-;x xx.x%	;-:xx xx.x\'·	:•:x>: xx.z l	xxx xx.x
ec:c..	;c-.:x xx.x''::	xxx :.:x.x'o	xxx *X1/.X%)*	:o:x xx.x
Ethnicity r,				
N	xzx	x:-cx	xxx	;,::-o:
<:,Jot 2ispc.:::ic or L2tino>	:.:xz XX.X'S	xxx xx.;,:%/	x:-:x :c,.:-c1•,	:c-:z zx.:,:%)
<Eispa ic or Latino>	xxx xx.x%'.	xxx xx.;.:';	;.:;-:;.: xx.x'':;)	:-.:xz: xx.z%)
etc ..	;,;:xx xx %:<	xxx xx	xx:,: xx. z2,',	xxx xx.:-:%)
Ar L n (%)				
	·o,x	xxz		xxz
<de no·v·o>	*i-<xx* xx.x%)	xxx xx.z>·'	x:-:z ;-:x. x½)	;,:::,:::z xx.x%)
<secor.dary>	:-;xx xx.	x:o: xx.zS·'	x:n: xx.x%:-	xxx xx x%)

I cte: Denc:ninators fo:::: percentages are Cased on the nUJ-:-ibeY of patie:--.ts idtl1 nor.-rr,issir.g data ir: eacr. T::::eatment gro-u.p fc:::: the :::::e l e :. a" t va::::iable.
a: Age is ca.':.c.:lated as calendar ;_:ears frow. birth to .:nformed cor:sen-r

Program Name:

Listing SouYce:

Date Generat.eci:

Table 14.1.6
Summary of Demography
ITT Population

	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]				
		XXX	XXX	XXX
	[illegible]	XXX	XXX	XXX
		XXX	XXX	XXX
		XXX	XXX	XXX
[illegible]				
n	XX	[illegible]	XXX	XX
[illegible]	XX.X	[illegible]	XX.XX	XX.XX
[illegible]	XX.X	[illegible]	XX.X	XX.XX
min	XX.X	[illegible]	XX.X	XX.XX
max	XX.X	[illegible]	XX.X	XX.XX
Height (cm)				
n	[illegible]	[illegible]	[illegible]	[illegible]
mean (SD)	[illegible]	[illegible]	[illegible]	[illegible]
median	[illegible]	[illegible]	[illegible]	[illegible]
min	[illegible]	[illegible]	[illegible]	[illegible]
max	[illegible]	[illegible]	[illegible]	[illegible]
Time since AML [illegible]				
n	XXX	XXX	[illegible]	XXX
[illegible]	XX.X	XX.X	[illegible]	[illegible]
[illegible]	XX.X	XX.X	[illegible]	[illegible]
[illegible]	XX.X	XX.X	[illegible]	[illegible]
[illegible]	XX.X	XX.X	[illegible]	[illegible]

[illegible] are based on the number of patients with non-missing [illegible] each Treatment group [illegible] the relevant variable
[illegible] ears from birth to informed consent

[illegible]

Table 14.1.6
s cr,ar-:,i o:: De:r,ography
-– "Oru:a.-.. .

	:or:-::.:rol (N "' xxx; n (% *i*	ow cx-e:: (fl "' xxx) ::"l ('i;::	High CX–Ol (N "' XXX) r, (%)	o·,·e:rall xxx) n {%)
Tirr,e s:::..nce Al-'!L dia-:;nosis n *If:;*				
	KXX	ZXX	XXX	XXZ
<less o::.· equa.l to 60 days>	:{XX xz.x%'	;en: XZ.}:".i	XXX ZX. X)	xx:.,: XX.?:%)
<gre2.-::.er than 60 days>	;.:XX ×}:. /;}'	xx.x'2'	zxx xx.x%l	:•:zx x:,;:.
Baseline peripheral D:ood blast ao e				
['7	XXX	XXZ	XXX	XXX
'£es	XXX xx.xs·,	xzx zx.>-:'i-'	xzz: zx.x? '	;-:xz: (xx.x9;)
No	XXX xx.x':'s'-	XXX xx.;,::::;	xx;{ xx.x%'.·	xxx xx.x'6)
Baseline blasts i2.. D-::::--ce marrD",.'				
	:,:XX	XZZ	XX:•:	XXX
w.ean ;s.d.	xx.x (xx.z:--'	xx.x (z•:.xx;	xx.xx xx.xx)	xx. xx (xx. x;,:)
:necii2:-::	xx.x	z;c	xx.x	xy.xx
:T,1n	xx.x	:<'.x.	xx.z	*xJ:*
:r:ax	xx.x	xx.x	)OS.	xx.xx
Baseline ;:i				
r,	XXX	XXJ:	XXX	xx;,;
::r:ear. is "	xx.x (xx.	xx.z :-:x::	zx.xx xx.xx)	z;,:.x;,: xx.xx)
:nedia:1	xx.x	×{.×	;-::x.x	xx.xx
rr:::...n	×:{.×	;,::,:.x	xx.x	x;,:.xx
rnax	xx.x	xx.;,:	J:X. X	xx.xx

Note: Deno i::ators *£0:::* percentages are based on the r:.ucc:be::: cf patieuts with no:1-rr,issing data ' each 'Ireat:ciec,t group for ::he relevant: vari2D2.e.
[a) Age is calc;;.la-::.ed as caler:dar year:s f.::-c,rr bi:cth to info:c-rr;ed consen.-::.

Prograr:t ?-iar;,.e:
=-.istir:.g Source:
Repeat for '::.l e foJ.los-, ng displays:

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Page of y

Table 14.1 Summary of Demography of Population

Table 14 Summary of Demography

Table 14. 9
s,.;;.c..,.c\ary of 1,Je:iical History
IT'I ?opulation

	:ontrol (N.= XXX) n (%)		Low CX-01 (N = xxx:) n {%)		High CX-01 (N = xxx) n (%)		Overall (N = xxx) n (%)	
Patie:-.ts Any Med.'"cal histo.:::y?								
No	xxx	:s:;,:. x'C; *i*	xxx	.:-:x.	xxx	xx.x'i	xxx	;,:;,:.
Yes	xxx	:–;.x.x%)	xxx	:,,:x.x	xxx	;,:x.x<"	xxx	xx.z%
Medical E:'..story								
s:;,,-sterr, C-rgar: Class l	xxx	z·,,	xxx	xx.:,:;,;	;,:xx	xx.x'c,,)	xxx	x:,;:. Y'
?r2fA '"Pci. Term l	xxx	:,:z.x%)	xxx	xx. xi)	>:xx	xx.x -.	xxx {	xx.x':C)
c:;-:-,=,ferred Term	xzx	xx.x%}	xxz	xx. x)	xxx	xx.x	xxx	xx.z'o
?referred Term 3	xxx	.x%	xx;,:	x;,;	xxx	xx.x'J	xxx	xx.x'o•
Preferred Term 4	x:-::x		xx>:	xx. x)	xxx	X}:. x;;}	xxx	zx. >>
Syste;:,, Orgar-, Class l	xzx	xx.x'i;,	xxx	x?'..	xxx	xx.x	xxx	xx.
?re:'.erred Term l	x:o:	:-:_:-:_.	xxx	x;,:. -,-'.•.	xxx	xx.;,:	x:-:::x	xx.x2·,
?referred Term 2	xxx	zx.zS)	xxx	xx.x't'	;--;_xx	xx.x	xxx	xx.x"c;
Prefer::ed Terrr,	xxx	zx.z':	xxx	xx.x"s)	xxx	xz.zfj)	xx:-:	z:-:::
?referred Term 4	xxx	xx.z'i;'	xxx	xx. c)	x:o:	zx_z,,	xxx	x .x'c

The der,orr,icator for percentages is ".:he m.:rrber of patients i::i the ITT l?opc.:,la-::ion for each T.:::eatrr,ent g!'."ol.:p

Note: This table co:1t2ir:s CO'-.'.n:::s of patients. a pac:.ien-: had rt.ere than o:-:e r::edical history '.-,i t;'lin a preferred tenr:., ::he patient is coLln-:.:eci only orcce ,-:ithin 2 prefeYred terE. If *a* patient had rr,ore -;:t'.an one ::r;edical '.'",istor:,: within a system orga:1 class, the patient is cc1..::1ted once for each prefer:::ed ter:n aGd 0:-1.ce fo::'.' ,::he sys-::em organ class.

Note: '.edD?A Version used for coding.

Listing Source:
Repeat :'.:or the '::ollow:'..ng displays:

Table 14. l. lO Su.7.rr:.ar· of 1,;edical History Safety Popc1lation

Delete:

Footnote: The de:ior:i.ir,at:cr for percentages is the nurrber of patier.c:s ,,, the IT·: ?cpulatic,"' fer each ?reatffi•'"r:t group

Footnote: r::cte: T :is c:ab2.e co:1tains co·o.nts of patients. :;:fa patier::: had :nore ::han or.s- rr,edical :--listory ·,;ithin a preferred term, the patient is cccm1.:e::i. only cr:ce ·.-:ithin. a p:referred te::::m. ::: a patient had more thar:. one med.ica1 his::or/ withia a sysc:er:-, o::::gan class, the patier.t is cc:.:.nteci once ::':or each prefe:rred c:e::n: an-::":. on.ce for the syste.cc, organ class.

;iote: i:-1:eO:J?..n. Version '..i.sed £0:::: coOir:g.

Table 14. l. 2.1
s,.1,.Tu ,ary of Prior l'-'.eciications-f.'.!'-E,
ITT Population

WHO ATC Level 2 (Therapeutic Cl2ss} Generic Tenn ([a;)	::::cntrcl (N = XXX} n (%)		Lew CX-01 (N = XXX) n {%)		High CX-01 {N = XXX} n (%)		Overall {N = xxx) n (%)	
Patients with prio:::: ;,,2dication,- _cl.l-Jl.	:<:-:x	>:x.:,;:%·,	xzz	xx.x%}	xxx	.-·,:.. x-".,	xx;	·.;,;:, ..
A'!C :Level 2 T rm	;,;:xz	x;,;:_xs:-	xzz	xx.z't,)	xx;-.:	:,-:x. xS"\		x:z. x·c
Ger,eric Med cation	:,;:xx	xx.x·?,,	x;{;,;	xx.x S)	xxx	zx. ;,:%	xxx	x;{. x⁰3
Ger,eric 1•led cat on	z	;-:x.x%)		xx.xi ';:)	xxx	xx.z	xxx	xx.x½
Ger..e::::ic Med ca-;;_ 0:1	xxx	;,;x.;,:	;,;xx	x;,:.x%)	xxx	zx. :,-i•'	:x:>:"	xx.
Ger,eric Med cat on	·-:xx		xzx	zx.x'	xxx	zx. :,,?,',	xx;,:	xx.x%
ATC :.,ev-el 2 T rm 2		xx.xi	xxz	zx.x'o)	zxx	xx. z'.-'	xxx	x>"
Ger,ec:ic Med catio,;_		zx.x·}	zx·,•	xx.x%j	zxx	zx. xS)	xxx	xx.x'i-'
Ge,,e::::ic Med cat on 2	xxz	xx.x%	xxx	xx.x%)	zxx (		:on:	xx.xc•·
Gene.::ic Med cat 0:1	xxx	xx.	xxz	xx.x%	xxx	xx. z"·'	xxx	z.x'.'.
Gene.::ic Med cat on	xxx	xx.z%)	xxx	xx.x"o)	xxx	x:•:.	xxx	,,. .. X ,

The de:wminator for ::> rcentages is the nu.'7ber of patients in t:';.e :::·T Po;:,ulation for each Treatrr,ent g.::oup.
Note: P:;::ior sedicatio;,,s are defined as Eedications take:1 w.:.t:h a sta::::t and s-::.op date prier :::o the first dayof stc:dy Treat:rr,ent.

i,;ote: P. patient Eayhave :.aken :rcore thar:: or.e ::ceCication. Therefore, '.:he SUiL', of nedicatio;-, counts ar.d pe::::cent.ages :na::,,, ;-,c-;: equal tl:',e total counts.
:f a patient had :r,ore than one :meciicaticr: in a c2tegor-y, the patient is cour'.!teC or'.!ce ir. that cates,ory.
'.a] ';J.EC J::::c:g Dictiona::::y (Ver-sior. xx) was used for coding.

Program,,1ing_ :NotEis-:
Note that':thfr first rowwill chan,;;e depen_d_ing 0_ri_·tn-e_··ti t_lE-. If- the ti"t_l-_i _.:l_s'-..:pr_--or_-medi6at:ion:...A.1-1L, -then it i.s·tp_c0;mpute _any--priot: l'ML
medicat-i◊-ris;- If- the title -is concomitant -medi(;ation-At-1L then- the req:u_ired out-put is to compute any- A.ML conccn-sitant :m.edication,
Program Kame: Date Generated: Pcge x of
l;isting Source:
epeat for the followir.g displays:

Table- L1. **I.** ::.3 Su.,,·:;r:iary of 2::::ior Medicatic:r:s-:ior:. **A.ML** ITT ?opulatic,,

?able 14.l._:_:c:
Sur.cr.arv of Cor.cor:--,i tant edica ticns-AML>
I::'T Populatior

WHO - -IC Level 2 ,:Ther<l_)et:tic Class: Ger,eric Te , ([a}'	::ontrol (N = XXX) n {%)		Low CX-01 {N = xxx) n (%)		High CX-01 (N=x=c) n (%)		Overall (N=xxx) n (%)	
Pa::ients with Ccmcc:":ti •,-.ar::.t t1edica-;:io'.7	xzx	xx.x?;.)	xzx	xx.x%)	:-:xx	>:x.x\ ·	zxx	x:>:::.X½'
A C Level 2 Te::::-I:1	x:,	xz.z%)	xxx (	xx.xS)	:•:xx	xx.x',,'	xxz	xz.x%'.
Generic Med.icat on	xxx	xx.z%}	x:-:x	xx. x',)		.z(,	;-:xx	·-··,:. >:';,)
Generic Medioat o:-,	xxx	xx.x%:,	xxx (	xx.x⁰i		xx.x -	?:zx	xx.xi'
Generic c1eCicat on	:-::-:x	(xx.x%\	x:-:x	(xx.x%	xzx	:,x. x		*x;t.* x'ii)
Generic Medicat o;;.	xxx	(xx.}:'z\		zx.x'!c	x:--:;,	xx.	xz:--:	xx.x%)
A':·C :Se·v·el 2 *T* rrr.	:,:xx	xx.x%)	xxx (	xx.		:{.	xxx	:o:.z
Ger.eric 1,1ed cac: on	xxx	:-:):	xxx	xx.x	·•:zx	xx.x	xxx	x.y.x
Generic ("Jed cat on	xzx	:{x.}:%)	:-:zx	(xx.x%)	z:-::-:	xx.;,;	:o:x	;o•:.x
Generic edicatiou	xxx	xx. x%)	xxx	xx.x%	z;-:;.·	X>:.X	zxz	:,x. x?;\
Ger::eric [,Jedicatio;;	xxx	xx.xi;'	xzx	zx.x's	zz:<	xx.;-;%'	xx:{	x}:. x'S)

r:,e denominator for per:cer:tages is the r. T.De,c of patients ir. tr'.e ITT J?opulatior, fer each Treatrr,er..-t gro:.::.p.
Note: Concomitant me,::::::_ca-:ior,s are those ;;it:1 a star-;: date o:1 or after t.he first dose date of Treatr::ie:1t, or t:-wse t,·ith c. start dat.e before the ::"irst dcse date *C-:.:* Treat::nent 2::ci c. stop date or-, or afte:::: the first dose date a:: Treatc:-ie;-,t.

Note: A patient may h2ve taken more tha:c c;;e rr,edicat.icn. The;:-e::"o::::e, t!"le su.,, of rr,eci.icac:ion ccu:1ts ar.d -ercentages :nay T'..Ct eq'...<al the total cour:ts.
If a patient had r::.ore tDan. one :r,edica::ior: .in a category, the patient is cc,,.:.n.ted once in t::J.at catego::"y.
[aJ ;;,;no Drug Dicticna: iVersicn :,::-:) ,,,as ,_;,sed fc>r coding.

Pro9"ramtr,i11:g:Jr:ckes':
Note, that,- the first rowwill change de'pendin;/ On the title. :cf -:t e<_titli::> is, ',Prio:t· -m d.i_cat;i_on-:AML -- ,then ft is l:_6 o)riq:,ute _any _P_i:ibr ?.ML meclicki'tion's-. If the title -is concomitant medication-AHL -then/the r-equired output is -to c_ompute- _any AML concomi:taNt.- medication-.
Program Name: Date Gene::"ated: ?age x of y
Listir:.g Source:
Repeat for the fo:':.lo,-.:i.ng displays:
!able 14.1.14 Sur:-,r:;.ar-· of Concomitant Medicatior.s-non ,ruV;L :: p-.'a-:-ior-

Table 14.1.1S

SLlirh<,ary O:: St'-.:Cy Qrug Usage Ra-::e Ir:ductior, Cycle

ITT Populatior:

		Low CX-01 = xxx)	i-'!igh CX-C)l {N = XXX) Cc (1;)
Inciuc-::.ion Cy-c2.e Compl.::_ar,ce ?.ate ;,	:-::xx	zxx	XXX
Initiel CX-01	xxz xx.:<'!:)	:-:xx XX.X'i',	x :x xx.x
'C'" C'_-,	XXX xx.;-;:'':;	x:..::x xx.x	XXX xz.z
Cy-::.arabine	XXX x;-::. x':	XXX xx.x"i)	xzx xx.x
·:::X-0:	x;-::x x;,·. x':, /	xxx (z:,;.	xxz xx.x

-he der,ominator fer 9-2rcentages is the r.u.,2::er of patiewts ,,:it:'. nor:-rr,issing da-::.a ir, tl'".e ITT ?OfYcllatior, for each Treatr:-,ent g-rc,.::p. Study Dru.g T]sage Rate is defined as percer,tage of patiel".'.ts ,,;i:::::. lCG½ dr·...ig usage '.-:hile en the stud·y.

P:rcjrara,,-rting N6tes:

For:things that -::lo ·.hot apply; inSert e.g. for Idarubicin ·+ CS,tarabibe arir,,. -t-XDl:.artct initial CX0-1 would-riot ·.apply.

?rog::.-an Nar:-,e: Date Generated: Page x cf y

Listing Source:

?.epea:: for the fellowing displays;

:=-0.n e ·'" : .:6 S:..m<l"nac; of Study Drug Usage Rate !nd,.::ct.ion Cycle ;,;;::-:r: Pop'-.:la::ion

_:l_dd:

Footnote: 1.r,e den,.Jc::,ina:.or for per-ceritc.:.ges is tie nLl.a,be::: of. patients ·.,,ith now-:,-.issing data ir, the :-:=r-r Population fer eacr'. Treatnent g.::-cup.

Delete:

Foo-::.:1ote: Tte ::ien-::i::,inator for percer::tages is the "-'-'-'•her of patier,:::.s ;-;ith :'",ori-::n.iss.ing da:::a in the ='=·T ?opulaticr. for eac::L T:.-:eau;ier.t gro,..::p .

Ta;)le · .:1 l. 2-7 S;,;,.,c""ary of Study Dru.g Usage ?..ate ?..e-indvctio:1 (7+3) Cycle Safety Population

Add:

.:'n'1c.no::e: The de:-:.:::r:-.iwator for percentages is L;e :n;.,.,,ber .:,-'_:. pat.ien-::::s ·.,;ith non-'"-iss.ing data in the Safety Fopula-::::io:--, ::or eac'.'". Trea;:.:nent grc-c.1p.

Delete:

Footnote: The der,..Jcc,ina::or for percentages is t:?.e n·c:..,tber of p.?.tiewt;s with :--,on-rr,.i.ssing de.ta .in the :T':' Populati.on fer -:?ac:, Treatment gro;,;.p.

Tab:e 14.l.·'1 sw,s-1.s.r::· of Study Drug Usage Rate Re-inductio::i (5+2; Cycle :11 ?o;n:.lation

Table 14.. lS Su:rcr:-,ac-: of St-:.:.C.y Drc:;g Gs age Rate Consolidation Cycle l Cycle ?opulation

P..dd:

::JcJte to ?rog:::ars--rte . Re:rc,cve Idar:..::bicin. For !1ings that cior.ot appl:). insert "-" e.g. £or::::darubicin + Cytarabine a.::E,, CXOl and initial CXO:. would not apply.

Delete:

::-:icte to ?rogra::-- ,,e;:: For thir.gs tl'.:at do not apply, i;-;sert "-" e.g. for ::::dar-:.:.Oicin + Cytarc.bir,e ar;r,, CXCl and initial CXCl ;,could ;-;o:: c.pply.

Table l4.l.2D S:.:.,c::1ar·· of Study)rug <)sage Rate Ccnsolidatio::i Cycle 2 Cycle I'='T Popc1latio:::.

Add:

No::e to ?rc-g:::ar.,:ne;· Re2ove Idarubic.i.r,. For things that do :wt apply, inse:ct "-" e.g. fey IciaL1bicir, + Cyt.aYabir.e a::.-rr., cxo:. and ini::i2l CXGl would not appl:.'

Dele::e:

Note to ?::.-ogr2rr.:::e:::-: For ::::',ir,-;s t:'.at cio not apply, i:::.se::.-t "-" e.g. for :dar<J.bici:n + Cyt.arabir,e a.:::r,, CZOl and initi2: CXOl woc.:..ld cot app::_y_

Table- 4 l. 21 Su..:.,,ar·- of Stt:.dy Drug *T)sa.ge* Rate Inductic)n Cycle ?? ?opula::io:-,

Add:

Footr::ote: T:'.e cienominator fc:::- perce:-.tages is the nu.mber of patients ;-..·ith ncn-rr,issir,g da-c:a tl-:e ? ? ?op·ulation for sc:a..h T c:::.cc.e" g:::o·_:,,p.

Delete:

Footnote: The cienc-,-:Iinator fo::: percentages is t.he nurrbe;:: of patients ;;it.h :-,cn-missir,g G.at2 in t:-',e ITT Population for each Treatrr,er.t groc.:p.

Tab.le ·4 22 Sc.u,c:r,ar,.· of S::,:.ciy Drc.1-g Usage Rate Re-in:foct.ion (7+3) Cycle P? ?cpc:.lation

Add:

7--.,o:.no,.e: 0.en.....:""-'--o .._ for percentages is the nw-c.ber of patients ,·ith ..... --.iS'-i""9 data the PP Populatio;-1 for, a- : • re-:-7:er.- g-r-01..:p.

Delete:

Foo::note: Tr',e G.e:::omin2tor fer percentages is the 1;.urrbe-r of patients ·,rit:'1 :::on-rnissir-,g cia::a .:.n tr',e ""7·7· Popc.-::lation for each Treatment gro·cp.

Table 14.1.23 SU:.1irr,ar·,· of Study Dr;;,,g Usage Rate ?.e-ind:..::ctio:-i. (5+2) Cycle ?P Populatior.

Add:

Footnote: Tt'.e denominator fc.::- percen::.ages is tt:e r:c1.-r.ber of patients ·.-;ith :-::on-nissir,g data "" t:",e pp ?opulatio:c for each Treatment grc:.1p.

Delete:

Foo::.r,ote: 'E1e ds:. •-..:r.: --ate:::- fo::::- :=,er-cen.tages is t:-:e ::',c.i...-nber cf patients ·;1ith n.'.)r:-r:,issing Cata ::.he IT:- Po:'.'"u'at-i , for each Treat:,rien; grot.:.p.

?able """ . 2% Su.-rmar·,, cf Study Drug Usage ?..ate Cor,solid2tion Cycle Cycle ?P Popu2.a":ion

P.dd:

};ote to ?rogra,rEne.:;,·: Remove :i:daru:Cicir.. For tl'.ings t;:-;at :io not apply, insert"-", e.g. for Idarc:c~c-_, Cytarac_,,e ar-, CXO=. a,1d i,1.:'.tia:.. CXOl >•muld not apply.

Footnote: The deno;ninator for percentages is t::--;e r,-1:-:-bel'." ,:;f patients wi::.h nor, missing data. ::.:-: the ?P Population ::':or eaci: Treatme:-:t grcc:p.

Note: Duratior, of expcsure calcula":eC as (date of las:: dose - date of firs::. dosei + 1.

Delete:

Note to Progra.rm:1er: For ti1ir,gs t:"",a.-::. do not apply, .'...:--:ser:: "-", e.g. for ::darv.bicin + Cy::arai::ine arrc,, CZO: a:-:.d initial CX-'.}1 -.w-:;ld -:".ct a:::,p2.y.

Footnote: The denominator for percentages is the r::.L--:-.t:er of patients ,,,ith :--,-:m-missic1g dat.2 ir: the .,.,,,,,, Popula· icr, for each Trea:::.:nen.:: grot:.p.

St;;:dy Drug :Jsage Rate is defined as percer,tage of pa":ie;--;ts ,rith 100'6 drc:;g usage while c;;. t!"",e s::c:.ciy.

Table 14.1.25 Su,-·nmary of Study Drug Usage Rate Conso.lidation Cycle 2 Cycle PP Pop;;.la.tion

Add:

Note 'c.o ?rograr::c,,er: Remove Idarc:bicir:. For ti'.ings that do not apply, insert "-" e.g. ::or Idart::.bicic "" Cytarab.'.::.ne ar-rr,, CXOl arni initia::. CXOl ·..;ould not apply.

Footnote: The deno:ninato!' for percentages is -::-.he nu,c-.be.::- patients, .. itr. r.cr,-missing data ::_:;. ::l',e ?P Population for eacr. Treatme:::it gx-o'-.lp.

Delete:

:,:ote to Prograr!",me,:: For things ::'.":a:: do :-r.ot apply, insert "-", e.g. for Id&r'-lbicin + Cytara;Jine ar:;-,, cx,::i::.. and i:ritial CXOl would r:o:: apply.

Footnote: Tie deno,nina-cor for per.cectages is the n,.::.,-.ber o:: patie:-r.ts ,,ith nor,-:nissing data i:1 ::he ITT Population fer- each ':'reat:..:ent group.

TaDle l4. 1. 26 Si·nrnary of Study Urug 'Js2ge Rate I:-::ciuctior, Cvcle Safety- Populac:ion

Add:

Footnote: The denor.,inator for _percer::t.ages is ::he nu.rr.ber c,.f patien-:::.s wi-:::-.l', non.-rr:.issing date. -~ ::r.e Sa::'ety ?o;:n..:2-c.t.icr1 fo-r each Trea'c.r:o.eut group.

Delete:

Footnote: The deno:ni:iator for percentages is the nu:-r.ber cf patients with :::o:,-missing date ::.ri -:he ITT ?opulatio:1 for each Treat:nent gro-c;..p.

Tab:ce 14 __2; Sur,t..--nar'/ of S'c:udy Drug Usage ?.ate ?.e-ir,duction !7+3/ Cycle Safety Population
Add:

Foot::io::e: The denominator i'cr per-centages is the nu.'":'l::er of pa-:::ients ,.,-.-;_th :-ion-missing da::a _:_n the Safety Population for eac:-', Treatrc.er.-:: group.

Delete;

Foo:::c.oc:e; :r:e dencminac.or ::"or percen"':ages is the r:u..,--:\ber o;.: patier:;"'.:s ,,ith ;:;on-missing data the :T? Pop'..llaticn for eac:J. Treatme:-,t grou:;::•.

?able 2.4.. 28 Sill:crr-,ar·.- of Study Dr1..;g Usage Rate ?.e-i::.d:J.ctio:1 (5+2;, C: c l e Safety Population
P..dd:

Foctr,ote:_".e derwminator for percentages is the r:ur:-,ber 'Jf pat::.ents ·,rit:h ::-'.or:-:rro.issing da-::a ir: the Safety Popula:::ion fo::: each ' rea::rr,e;;.t group.

Delet:e:

Fc,otnote: ne denu:ninato;:- for percen::ages is the r:,..;;:-,.be:::: of patients -,:i;;:h non-Eissir:;g data ,,., the ITT PopGlatiou ::"or each TreatEer,t g:roup.

Table 29 Su.'"-0-a:::y of Stud;:-· Drug Usage Rate Cor;soli6.ation Cycle Cycle Sa::"ety Pop:..;2.atioc:
Add:

c'<ote to ?::::og::::a;:-t!t.e1:: ?.eEc;te :da:::ubicir:. For things t:'1at do ::-,ct apply, ir:s,:c::::t "-", e.g. .'.:sr Ida.::"Jbicin + Cy::arabine arm, CZOl aud .:.ni..tic.l CXC.l would net a.pp.:.;:-·.

'"oo;;::1cte: T:',e denc::,inatcr for percentages is the :,u:'i'J:,er of patie:r:ts ,.,:it:, r:;on-;r,issi..r:g data in ;;:he Safety Pcpu.:.a'".:icn fo.::: each Treatr::er:t grou)?.

Delete:

Note to ?.:::og.can-;,.er: For things ti-',at do not apply, ir,sert "-", e.g. for Ida::::'..lbicin + c:rta.::abir:;e an:1, C:-'.Ol a::.d :i.:-:itial CXGl ,,oul6. no:: apply.
Foot,:ote: The dencmir:atcr fo:.c percentages is the ;,urnbe;:- cf patier,ts ;.,citi-', r:;on-rc:issing data .'c::-, ::he ITT Population fo::: each TreatE,er:c:: g::::oup.

Table 14_;__3Q SulG.:nary of S-:1.:ciy Drug Usage Rate Consolidation Cycle 2 Cycle Safety ?opulatior,
.;6.d:

Note :::c ?ro:;:::a:r:rr:e1·:: Remove :darubicin. Fo:::: things that do r,ot apply, ir-;se;:"-::: "-" e.g. fo.::: :ci.arubicin + Cytarabi-:-,e arcn, cxc:. ar,d initia.:. CXGl ,,,:ould not apply.

?oct:note: '='he denominator for percentages is tr.e r:;u..,--nl:::er of pa.tients ,·it!'. nor,-rr,issir:.:; de.ta .,,. ::he Safety Pop;,;.latior: for eac:'"l T::::eat,c,er,t group .

Delete:

•lote to ?.cograrr.me;,:; ?or ::hings t:1.at de r:ot apply, ir-:sert "-", e.g. for ::cia.rt:.bicin + Cyta.:::abine arcn, CXOl a,,c i:-,itial CXCl wouid sot app:y. Foo:::no:::e: '::he denc-Einator :i:c.::: pe::::centages is the r,u.7.be:::: of patients, ..;-ith non-,c,issir,g dat2. in the ::r:r Pop'..llatior_ for each T::::eatrr.e0.t group.

Tab::.e 1,G.1.31
S1.1c-;:.,..ary of Treetmen-c Exposu:ce by Cycle
Safety Population

	::or,t:::ol (N = xxx\	Low e>::-Ol (0: = xx;()	;:.,; gh CX-0" { N xzx) o
:nd'.lction Cycle T::::eatr.,e:1.t Ez3x-s·_;_re (Days)			
n	;.:;;;,:	xxx	x;-:x
r:-:ean ı, s . d .)	x>:.x (.:-::-:.xx)	xx.x ;,;y. xx)	xx.xx xx.xx;
mediar,	x.x	xx.x	xx.:,;
Din	xx.;,:	xx.x	xx.x
rrcax	xx.x	xx.x	xx.z
?a.tient with any dosage ::.nterrup'.::io" Proportio;, of patier::ts -",::c ::eek	xxx :,:x. :,:'!:)	;-;xx xx.x;,·1	xxx xx.xS'
Idar,.;bici:r. for less than 3 days Proportion of pat.ients ,,,;-,o toc-k	Y.xx xz. ;,;:\;	xxx xx.x%	xxx
Cytarabine for less t?:an days Proportion of patients o did net take initial CXOl	:s:xx ;.:;;;. :,;%	xx:,;: :-:x.;z;;	xxx zx.x·'1
	xxx (x;:. x"o ·,	xxx xx.	xxx xx.;:'o'
?ro_portion of patients ,-.-:io -::ook CXOl for .:.ess than 7 days	xx xx.x%1	xxx xx.x%)	xxx xx.x-'o;
Proportion of pat::.ents ,,,,-:-.o took less medicatio:r, in terr,, of recr.;.ired du.:::-ation (any of :;: a.rubici:1,			
Cytarabine, initia cx-o::. '3.nd cx-.J::.;	xx xx.x'ol	; xx xx.	;-:xx xz. y;

Ihe denomi,.ator for percen.t2ges is the nu.,--rJJer cf pa.ti.er:.'".:s w::..th :10:1 rr:issir,g- data in the S2fet::,, ?opulation fo::: each '::"reat.ment group.

Note: Durat.:.on of ezpcsure within a period is ca.lcu ateci as ida:::e of las'".: dose - date of :'i:::s--: dose) -"- l for t:'wse d:::ug that ;.;e:::e ad,,i.nistereci across different ciays ar:.ci as .- day for c.hose- dr:..;g a-'.i."niniste:::ed and finished within the sa:ne day. The swc: of these duration expcs;;.re within a. period would form the d0.:-a'..:ion of ezpos,,,re '.-Iit"c.in a cycle.

Table 14.1.31
St'..L-rr,arv of Treat,ner:t :Sxposure by Cycle
Sccfety ?Opcilatior:

	::ontrol	Lo,.,,- CX-Dl (N = xxx:, ('i'.-)	Hig;", CX-Gl \:'1 = xx:s:· {%)
Re-i::1ci1.:ction (7+3) Cycle Treatrr,ent S>:;:-os re :Days'.			
:near, !s.d.)	;-:xx xx.x _z>-1./	xxx ·•:>: :{x.xx:,	xzx xx. x;-:: .xx)
mediar>	xx. :	x:-:.y.	xx.x
L,::_r:	xy. :{	:-:::x.x	xx.x
:nax	xx. x	xx.y	xx.:--;
?a::ie:::·It with any ciosag-e interr-,;.ptio:1 ?rc-por:::ior: of pat:: er,ts whc took	xxx ·•_•.?:	xxx x;s:. x'i'.·	xxx xz. ;{·:,_
ICaru.b.-i_cin :'or less tha:1 3 days ?rop<:;rtio;:-, of pat.i.er:ts ,,.,ho ::ock	xx: >:x. xi)	xzx	xxx xx.
C::rtarabine fo:r less tha:1 7 days ?:roportic:-: of patie:cts s-;hc did not	:-:x;,: xy .z%i	xz:--:	xxx xz.
? a i ti=l rvo1 ?rcpc.:::-ticn of patients ;;to took CXOl	:-:;s:z xx.xs ·,	xx:--: xx.	;-::x:--: z . x, 7 ·
for less than days ?:r::>portion cf patie,1ts whotook .:.ess	:-::xx xx.z,,	xxx xx.	xxx X>:. x%;
medication i::,. terrr.s c f eqciired dureticr, (a::iy of Idarub cir:,			
(':/tc.rabine, initial ext and CX-01)	xxx :•:x.x%)	xxx ;-:z.x'o)	xxx xx.x%'

The denor::inato:::: for 90rcentag-es is t:',e rn..L"CT.be:::: of 9a-::ie:1-:::s -_.,;.th nor: 2issir:g da:::a ir. the Safe::y Popt:.lation fo:::: eacr:! Treat;-r:.ent grou,:::·.

Note: C•uratior. of exposure wit.:-::ir. a period is ca::.c,_;lated as (da ?.::e o:: ':.ast dose - Cate of fi.:::st. dose) + :. fc:::: -::.h8se d::::c1g c.hat ·"·ere c.d,,inistered across diffe=ent days ar.d as 1 day fer tr'.ose drug ad.7ir:istered a:1d fi,,ished withi:1 tl":e same day. The su:n c:' these duratior. expos"Ll.re ·w·it:"lir.

c. pe::'.'iod wc'.lld fo:::-r:, t.he fr0.!.""aticn of exposure witl"".i:1 a cycle.

7able 14.1.31
Sur:unary of T.::::eatrr,ent E:xposure Cy Cycle
Safety Pop"-"lat.ion

	:::or,t.::::ol (N "" xxx)	:...,0'--' CX-01 (N = XXX) n (%/	'-<' gh CX-Oi xxx)
?.e-inductio-r;. 15+2) Cycle T.::::ea-cment E>:poso..:re (Days)			
n	XXX	:u:z	XX>"
:-r,earc (s.d.	X:-:.X ZY..Y.Z)	; Y.. xx.xx)	x.zx x:.-:.xx)
median	xx.x	xx.x	
t.""c:..n		xx.x	x
max	xx.:,.:	xx.:-'	x:-:.x
Pat.ier1t ;,:.:th &n_y dosage ir.::er.::::0p-:.ion ?roport.io:1 of pat:.ent.s ,,:no took	xx;.: xx. x%)	x:-:;-.: :-:::.,:_z:.:;	;_:.:y x:-:
IC.arub.:::.cir:. to.:::: less tt:ar, 2 days P.:::-oportion of pat..1.e;-its ·,-,::to toof:	:,:xx xx.x%}	XXX x,:.xs;	XXX
Cytarabine fo.:::- le:ss -:ta;; 5 days ?.::::opor::ion of pat .er1t.s ,..,r:_o d.id r::ot	:o;:;-; xx.x	XXX xx.)C'.'	XXX XY.z\:
c:.ake i;-iit.ial CXOl ?roportic:n of pat ·.e:-J.t.s ;-,c "'.:oak CXGl	xx.x%\	xx·•· xx.	xx.x xx..x%\
fo.:::: less than S days Proport.ior:. of patc.er,ts ,,,.-io -coo:-: less	'.xx xx.x'b)	xxx :-:x.x'o·,	xx:,: XY
medication in te::'.T.: cf equi.::::ed duration (any cf ::: a.::::ub c1.:i,			
Cytarabir::e, ini ti2. ex- ::. a:::.d CX-Gl)	xxx :-::x.x"c)	XXX x:--:.;.:%'	x;-:::-: x:,;.;-:-"c'

Tt:e der:;ominat.or for percer:::ages is t:"',e nu.r,:cer o:: patients with r:on sissing da::a. in tt:e Safe::/ ?opc.:latior, for eaci Treatment group.

Note: iJuratior, of exposure ·.,:ithin a perioci is calc1..:lated as (date of last dose - Cate cf first ::iose) .,_ l for t.l---.ose drug that: ·.,,er-e ad,"T,ir:is::ered across dif.::e::::en-:: days ar:d as :;_ day .::o::::- tnose dr"...ig ad.--rtinistered a:lci. :'inis ed :.-<ithir, t:'.:e sa:n.e day. The su.--:--, :Jf these d1.;.ratior. expcsu:::e ,.,;ithir: a period :,·ou2.d fc:c-rc'. the dclratior: of ez:posure withir: a cycle.

?rograra Name: Date Generated: Page of y

Lis ting S01..:rce:

Table 2-4.1.31
$;..m',:riary cf Treatment ,:posure by Cycle
Safety Popul tio,,

	- or.t:!'.'ol ʳIJ = :,:x;-:)		O"w· CX-01 \i:S = XXX) n {%i		Big-:"i. CX-01 (N = xxx:· n ('o'	
Cor,soliOation Cycle 1 Tr:-eatrcent Sxposure{Days)						
n	:o::x		zxx		xxx	
mean is.d.'	z;.:.:,:	xx.xx\	x:<.x (xx.xx)		:in:.xx (xx.xx··	
median	;,:,:,,:.:,;		:-:x.		zx.	
in	:-:z.x		xx.x		xx.x	
	xx.x		.x		zz.x	
Pcctient with a:,.y ciosage interruption Proportion of pa::ients who tock	:,::<x	xx.:,,,;•,	:o:x	xx.x;:,·,	xzx	:-:x.x%)
Cytarabine for less t!",arr 3 days Proportion of pac:ients who did :wt	·-:x;.:	xx.'.{',:	xxx	xx.x'?)	;.:zx	·-:x. xt
take ir.itial CXOl ,.opor:-tion of pc.tients ·,;ho took CXOl	:,:;,;x	}G:,x'i_,'		xx.x% i	xxx	xx.xz,;
for less thaw 5 dc.ys ?roportior. of patients whotook less		xx.xi)	xxx	xx.x%	xxx	:,:;,,,
rr.edicac:ion in terms O:'. equired duration (ar.y of I-iar"J.D cin,						
Cytarabine, initial ex- 1 and cx-0:1	'{××	:-:x.xS)	x;oc (xx.x%)		xxx	;.:x.x%)

T:1e denominator for percentages is the n:..1..."°:'her of patie;1ts ,.:it'.', non missing data in ti:.e Safety ?opulatior, fcJY ,22ch Trea:::mec'.t group.

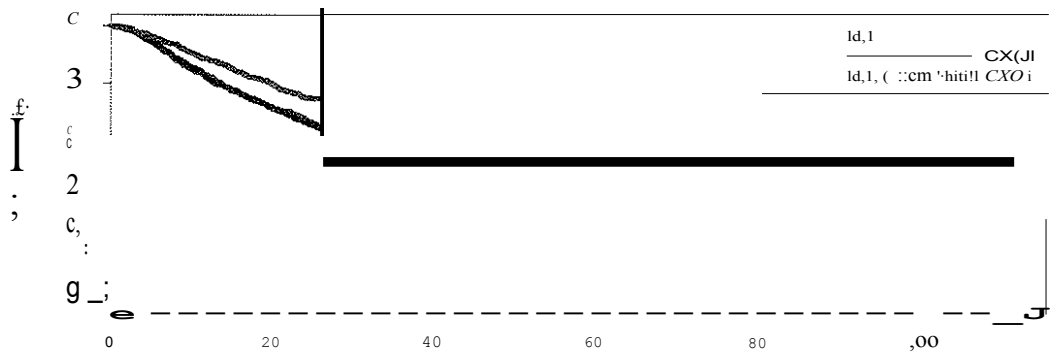
Note: Dur:-ation of expos;..:re within 2 period is calc'..llated as (Gate of last ciose Cate of first: dosej +1 :::.or t.hose drug t:',at ,,:ere ad,c,inistered across differ:-en:: dcys and 2s 1 d2y fer tl1ose drug adc,ir;istered a:.d finished wi·t:':!ir. the same day. Ihe su..:;; of these durc.tior:. exposure witf::ir, a period would form tl":e dura:::io;,. o: e•:pos'-'re wit:::in a cycle.

Table 14.1.31
su.,:rr,ary of Treatr:ient E:.-:posc.:re by Cycle
Safety ?opo_.:.lc.'.:ion

	:or.trol (N "' ;,.:xx) n (%)		Low CX-Cl iN "' xxx;, n (%)		Ei;h CX-Cl {1 = xxxl (%)	
Consolidation Cycle :-r"'-a """"""						
Szposure (Da::is)						
	KXX		%XX		x;-:z	
r:'.ea:r, (s.d. ':	xx.x	x;.,-. ;,.:x;,	xx.x	xx)	;-:x.xx { xx.xx)	
17.edia.,,	xx.x		xx.x		;-:-:.x	
	xx.x		.x		:.-::x:.'-·	
rr.c.x	xx.:.-::		:.-:x.		xx.	
?atie:n:: •,;ith ar,y Gcsage interr,..1pticn Propo.rtior:. of patients who'.:ook	x:,;x	xx. x%)	·-:.-:x	xx.x'.i;	xx;.:	xz.x':,J
Cytara:Oine for less tha,i 3 days ?roportion of pac:.:: er.ts ;;ho did r:ot	xxx	xx.x%)	xxx	:.-;x.xs·,	x:-:;,:	x;-:.
akA i " ia! cxo	xxx	x:.-:.x'c	xxx	xx.x":	x;,:>:	xx.x%l
Proportior:: cf pc:.t:'.ents ;-,;ho took C:;{Ol for less "'c.han 5 days	xxx	xx.x :)	zx:,:	xx.x-?\		xx.x\·:
Proportion of pati.ents whoc:ook .less :r,ed.:..cation ir:. terr:-.s of equired duration (any of :.darub cic, Cytarabine, ini'.:ial CZ- :_ a:1d CX-01)	xxx	xx.	zx:s:	xz.z's)	:o::s:	z.

,.:;e der).cr:;icator for p'C:rcer>.c:ages is t.he m.:.,,cDer of patie:1ts s-:.it;;. r,o:n missir::g da:::a .:.r:: the Sc.fe::::y Populatior. for each Trea-.:::icen-.:: g::-ou;:. :(c-te: Dura.tier;. of exp :-s'...:..re ,,;.ithin a period is calculated as ¹0at e c-f last dose - Gate of first dose: 1 for those drc.:g c.hat ,,-ere adrrdr::.is::.ered a.cross ci.iffe::-e:--.-.:: days ar,d as 1 day for tt:ose drug ad.--:-,i:-:;istered ar,_6. fir.isied ·,:ithi:-: the same day. The SW-'7. cf these du::at.ion exposure wit:h.i:-- 2 perioci. wc;.;.ld f2r2. the du::-aticr, of e;,:pc;sure witr.i::1 a cycle.

Figure 14.2.1
Ove.:::all Sur,rival plot
'<"T' Populatio,,



:".umber at Risk

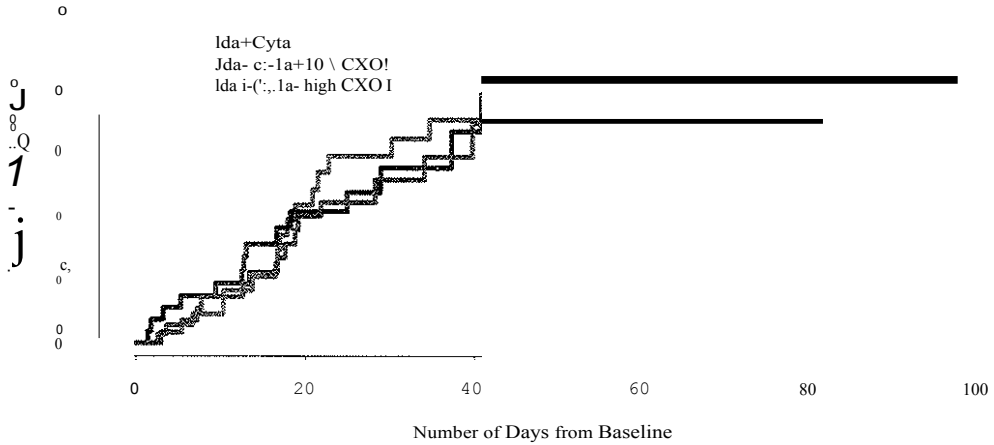
fda···C; -1a	xx	x.x.	;,.ex	xx	:._.::	xx
lda+C;-ta-'-low CX01	xx	xx	xx	xx	xx	xx
lda+Cyta+hig:h cxo l	xx	:.;x		xx	x'<.	

?rogram Name: Date Genera::eci: ?age x of y
!.-isting Source:
Repeat for the following displays:
Figure 14. 2. 2 Overal Survi;ral plot :.'ETT ?opulatior,

Fig"Jre 14.2.3 Overal.'.. Survival p:::.ot ?P ?opc:.latio,,

CIF plo': fo.:::- e-,,en.:: f.:::-ee s;.:::rvival (f:-::orr: date of randc izaticn)

·,·,,,·,,,·· Population



:\"umber at Risk						
lda+Cyta	xx	xx	xx	;;;;;;;	xx	;;;;;
Jda+Cyta+ low CXO I	xx	n..·x	xx	x.·x	xx	xx
!da-.·Cyta+high CXOl	x.x	:,;x	xx	x_;;;	xx	x_-_

Prcgra:r:-, Name:

Da e Gene:ca..::ed;

?age z of

Listir:.g Sou:cce:

Repeat :for t:'"le follm,ing displays:

S,5 3/2 *if* If

Fie:..... 1L.?:::: c::F plot for event f.cee surv·ival ,'.fro:;r: Gate of :::-ar:do:nization/ Q' l?op,tlatio;:,.

Figure "1 2. 5 CIF p:::.ot ::':or lec1ke:aia free s:.1rvival IIT Populatic:•L

Figu;:e 14.2.' CIFpiot. ::':or le:.1kemia free survival ?opulatio::1

Figure J..4.2.8 CIE' plot fer r.eutrophil (>500) recoste:::-y (frmn date of rar.do:r,iz2-:::ion) I':"T Pop:.ila's::ic:i;,.

t=.gure ::.4. 9 CIF :pJ.ot for platelet ">2000C} recovery (from date of rando2ization) I'.:-7 Pop·ula-;:::i:::r Figu:::-e J..4. 2.

lO CIF plc.t £:er ::eu::rophil (>1000) reco-ɹ ɾ ʃ (.fro:2. date of :::a:1ck:2.i::aticr,:, :rT Pop1.1latio"

Figure 14 CIF plc,t £or pla.telet f>l00000; recovery (f.co:.1 date of rar.Co,c,i=a.::icr,) ;:::,opulat::.on

Figur-2 CE' plct :'.or Ye:l.apse rs,orphelogic C?:\ ·"""""" - c;iw.:::a_ ·_

E"igu.re *n.2.~3* CIF plct fey relapse 1c omp c s :::.t e CR) I':'T ?opulatior,

Figl:.:::-e 14.2. "L: CIF plct. ::er relapse 'corr.posi.te CR) *tC'f:"'I* ?cp,..ilation

Table 14.2.1
Primary Outcor:-,e-CR
-,--,.. 0xL'ac '1

	::antral (N = xxx) n (%)	LowCX-01 (N = xxx) n (%)	High CX-01 (N = xxx) n (%)
?..chieved CR	xxx .x ..	:-rnx x. :%)	xzx (x :.z }
versus Ccnt:co:.			
?ropocc:ion Difference		x.xxx	x.xxx
70'o C0Efide0ce Interval [a)		>=.xx, ;;; . >:x:	"z. ;-c-:, x. x;;:
p-vali.:e [b]		.xx:•:	x.xxx

fa] Based or. Exact. Bir,omial (Cloppec: Pearson) Co:-,fiden·::e :Z::1t.e:::7al
[b} One sided ?ishe:r Exact Test
?rcgrar:: Name: Date Ger,erate:""!· ?age x of
Listing Source:
Repeat fer the fo.llm,1i:::.g displays:
Table 14.2.2 -'- rr o-'-i C- tco-.. '"-r:: .. ..-....T nv ..la ::o...

Tab:e 14..c:.3 Prirr,ary Outcocc1e-CR ?? ?opulation

Table 14.2.4 Secondary Outco;ne-C:-ti ITT ?opu.lation
Delete:
Footriote: (a] Based or" Exact Bir,c ,ial (Clopper ?ea:-sor,) Confidence Int er-,al
IbJ One sided Fisher Exact Test

Tab2.e 14.2.5 Secondary Outcome-CRi -lITT Population
Delete:
2'ootnot.e: iaJ 3ased on Exact Bi:-,c:::,ial (Clopper ?earson; Confider::ce ::r::::erval
[b] o e sided Fisher Exac:: Test

Table 14.2.6 Seccnd2.ry Outcome-CRi PP Populc.tio,,
Delete:
Footnote: '.aJ Based on Exact Binomial (Clopper Pea:::soni Confide:c:ce Ir-,::er-val
[bl One side-::i Fisher Sxact Test

Table . 2. Seco:i.dc.ry Ou-::corr,e-Co:;uposite CR ITT ?opv.lation
Delete:
Foot::1ote: '.a2 Based on Exact Binomial {Clopper ?ea:::so:1) Confidence I::",::erva.l
[bJ One sided :!"isher Sxact Test

Table "-'-.2.S Secondc::::::,, Outcome-Co:r,posite CR MITT Popv.lation
Delete:
Footncte: [aJ 3ased 0:1 2:,:ect 3io.o:-nial {Cloppe.c: ?ea:::-so:--,) Confidence ::::n'Cer·val
L.0J One sided ::'isher 2xact Test

Table 14.2.9 Secondary o·c1tco2.e-Co2,posite CR *PP* Pop:J.lat.io:,
Delec:e:
Footno::e: (a] 3ased on :Sxc.ct :Si:cwmial {Clopper ?ea:-so:1) Confidence In-:::e:-va·
\bJ Cne sided Fishe::: Exact Test

?able 14..2.10
Mo.:::-tality Day-30
::::T Population

	:::ontrol {N = xxx) n (%)	Low CX-01 (N = XXX) n (%)	High CX-01 (N = xxx) n (%)
Death by Day 30	zxx x:-::.x'i}	xxx xx.	xxx .};"·
Ve.:::-sus ControJ.			
Propo:::"tio,, Diffe:::ence		x.xxx	7..xxx
95::, Con::'.de:-,ce Inte.rval [a;		[x.xx, x.xx]	xx,
p-value [b]		x.x:-::x	x.x:-:x

[aj Based en Exact Bir.orr_ial !Clopper ?earson) Ccnf:,der..ce Interval
[bj Two sided Fisher Exact Test
?.:::-ogram :';ase: ::a.te Generate- - Pase of y
listing Source:
Repeat for the follo;,·ing displays:
Table 11;. 2. ll Mortality Day-60 rcp"":: "" .:.o"

Table l4. 2 .12 I<lortality Day-SC TIT Population

Table ::_4. 2 .13 :-1crtali ty Da:y--3C: t-'.I'::"T Populatic:-,

Table 14 .14 Mortality Day-60 t-ETT ?opulat.i,..,..,

Table 14.2.15 Mo::::r:.ality Day-90 ME? Population

Table 14. 2. 16 Mortality 8ay-3C PP Population

TabJ.e 14.2.11 Mortality Day-6C PP ?cpulatior,_

able 2.4. 2. l8 Mo::::t:alit:y Day-9G ?P Pop's.:.lat:ion

T2ble H.2.19
Si"T>Ir,ary of O•ierall Survi,,-al
I7I' ?cpulation

	::ont.rol (N = xxx) n (%)	Low CX-01 (N = xxx) n (%)	Hi.gh CX-01 (N = xxx) n (%)
Patients Died	;,:xx xx.x%)	xxx xx.	xxx .:,d)
?atie:1:::s S-cill alive	xxx zx.xS}	xxx zx.x '	xxx xx.xS)
Ti;r,e tc 'Jeath (days)			
⊥ r<' ⊂<c r''' 1	xx. ;		zx.x
95So Cor,f.idence :nterva: for 2-.'.edian [a)	-::-:.x, xxx.xJ	[x:,:y x, xxx.x)	[xzx.x, ;,:xx.x;
25% and 75% (?ercentilesl	xx.:-:}:, :-:x. xx	x:,: :-:x, xx zx	x:-:. xx, ;-:y. ;-:x
Range 'b"	xzz, xxz	:-:,:',:, xx;,	x:-:x, ;-;;;;;;
Vers'-'s Cor,::rol			
?-vc.l;;e (Log-Rank 'lio·S::: ·,		;{. :-:xx	xxx

No e: Den:xninatoYs fo.:.· perce:1t2ges are based on the rn1..7ber of patients ir:. tf;e Pop\1la;::ion
[2. r:cpl2:r:;-t,ieier estior,ates.
[b Inc:·.J.Oi::g censcreC obser7ations.

?:cograr:-, Name: D2c.2 Generated: Page :-: of
Lis tin,; so,.irce:
Repeat for t:--,e following displays:
Tab.le 14.2.20 S·c1,.-r.rr,ary of Cverall Sc:rvival 1.I TT Po,::n:..:;,a::i.on
Add:
FClOt::.cte: Note: De:-wwir,a-::ors for percer-:.tages are baseC on t'.:.e nu.,Tsber of patieu.ts "-, the 11:ITT Popu:ation

Delete:
Foo:::::.o-::e: Note: Deno,:;-,ina-;::o.::-s for percer,tages *c.r-e* based or. the nUEber of ;:;c.tients in t'.ne ITT ?opulation

Table *.2.21-* St:.""TET,ary of Overall Survival PP Popu2-ation
Add:
Foo-:note: Note: Denomina:.::o::s for percer,tages are based on the nUEber of patients ::.n the PP Population

De.lete:
Footnote: Note: DE-nor::cin.-:,tors :t:or percentages are based or. t:le ni_.";_c-r-:ber of patien-ts in the ITT Populatior,

Table 14.2.22
Ssccrr,ary of Overall Sur,ri ᵠ-a l :Ss-::.ima-::.e
ITT Population

Tirr.e Iriterval *(Day;*	or::trol -:::,; = xx.:-:;	Low CX-Dl (.] = xxx} C	nigh CZ-01 (N X>'.X)
0	½z½	;-.:z;-:	xxx
to	;-.:z:,:	xxx	xxz
8 to 13	zxx	xx:-:	xxx
l4 :::c 21	x;-.::,	xzx	;c-:z
to 30	zx:,•	xzx	xxx
31 to 90	xxx	xxx	**xxx**
91 co 120	xxx	;-.:xx	xxx

<cort-:*'"ii"'d>*

Progras Name: D2te Generated: Page x of

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Repeat =or the following displays:

Table ::.4.2.23 SclllLEiar" of c-v-e::-all SurviTal -1 :Ss:::i ace tHTT Pop1..:l2ticr,

Table 14. ~. 24 s,.;..--r£ary of o·verall Su::vival tc.,, :Sstir:-,ate PP PopI.<laticn

T.-c:ble 14. 2. 25

l'i2e tc ve::it Free s·o.rvival - Days

	Cont::ol	Lo;-; CX-01	High cx-c:._
	XXX)	(N ™ z:.,:x:,,	n (
;	XXX	z:-s:x	xx:,
No.::.,"7'.0er of pa::ien::s event free	XXX xx.:,•	XXZ xx.x';;)	::xx x:•:. >:′,
r-:uri.::,er o:: patients cer:sored	zxx xx	XXX XX.X·,	XXX :-:x.
2 ·· I:-"""·:::: "'·.·- e	x;-;:. x	xx.---	.x
;,·ec_a	xx.	xx.	xx.x
75· pe centile	xx.	xx.;.;	xx.x
?ar,ge inclc.,ding ce:1scred ·v·alues \	xxx, ;-:x	xxx, zxx	xxx, ;,;-:x
Ra:-:;ge withO'Jt censored. ·values)	xxx, {;{	xxx, xxx	xxx, x;.:;-.:

Program Ea:r::e: Ja::e Ge:1erated: Page cf y

Lis ti.r.g Source:

Repea:: for the following displays:

'cable 2.26 Time tc Zvent Free Survival - Says LfiTT Pop·c1::.ation

Table 2.27 Time tc Leuk.er:',i.a free Sur:7:.·,,al - Days {::':::-o;-r, rando:;;-;_ization) :TT ?opulat.i:-:in

Add:

::,:ote to P:::ogram.·ne:::: ?.eplace ever.t free „iti"", leukemia free

Table 2.4. 2. 28 Time t:::: Leukerr_ia ree Sur-,,i-.;c.l - Ja.ys (frorcc ::-a:.do:-s.';.;:ation) I•T?':: Pop:ilatio-,

Add:

:1ote to Programmer: Replace evect free v:iti": leukemia f:::-ee

Table .2.29 Ti:ne tc Ne;;trophil ?.eco7e::'.'y \>5CO) - Days (from ::.-and.omizat.ion) :T':: Populatio:1

.A.dci:

i:.:Ote to Prograrr,mer: Replace event free wit.!'. net.::trophil recc-,,e:::y

Table 14.2.30 Ti",e tc platelet Recovery (>20000\ - Days (f:::or:, rar;.dorr,ization) ?opu.latior.
Add:
:,..;ote tc Prograrr.ser: ?..eplace eve:r;t free Ki'".:h platelet reco-,.rery

Table · .--31 :'i::te tc., Neutrophil Recove:-:-y (>l.CCO) - Days ;fro-.:: randomization) ITT Popu2.ation
Add:
:::ote to ?rogrArc.r:10r: Replace event free with neutropf".il recove:::-y

Ta8le 14 Time ts platelet Recovery (>100000) - Days {froz, rar,domizatior::) Pvp,..lo....:.o.-
Acid:
: ate '".::.o P:-:-ogra:;,,,'r,er: ?..eplace evect free \•:.: t:1 platelet recove:-:-v

Table 14.2.33 .t·::::.z,e ::c relapse (duration c::: :rr:orphologic CR) - Days ITT ?opula.c:io:,
Add:
c'.'.iote to Prograr:-.:r,er: ?.eplace ever:t free ._;;ith relapse

Tc.ble :'..4._.34 Tir:,e -::o relapse (du.ratio,, of composite CR) - Days :::T:- Population

Table c 4. 2. 35 Ti::r,e E1:er.t E"ree Survi-:,_,al - Uays (frcn -a..d.---.....; ....o--.; o"") ?P Po9ul2tic::-:

Ta:0}.e l4.2.36 T.:'._r:-,e ::c Leukemia ?ree Survival - Days P? ?opulatio::
Add:
Ncte to Prograrr;:-ner: ?..e;,lace event free with 2-eukemia free

ic.u_;_e 14.2.37 Tirr,e tc- '«:::-t::::-opn Recov-ery (>SGC) Days (:'.::::::-c;n .rando;r:izatior,) ?? ?01>u.lation
Add:
c'iote to ?rogra::cmer: Replace event f.ree ,,;ith neutrcphil recover..

Table 14.2.38 Tic:ie tc platelet Recovery ,'.>2GOGG) - Days (f:::-o:rr: ra::idc:r,izac.ior,) ?? ?op-..,::.atio;1
Add:
·Note to ?rogrArr:.r:-,er: ::Zeplace event free ;d::h platelet :::-ecc;;e:;:-y

Table 14.2.39 Tir;-,e tc- Jei..;trcphi.l Recovery (>1000) - Days {froEt ra.::1domization) ?? ?opi..;la,:ion
Add:
Note to ?rogrArcmer: Replace event free ;-;i::'.", neutrophil reco;ter--.·

Table 14.2.40 Tir.",e to platelet Reco'ter/ {>lOGDGO} Oays *(from* ra:ndornizationl PP ?opulation
Add:
Note to Prog:::-arr;rr-,e::::-: Replace event free 'With platelet recc;terv

Table l4.2.½l Ti::rce tc rel2pse -'.dura-:ion of morphologic CR) - D2ys PP Pop-..;latio;,;.

Add:

Note to Progra2.c--ner: Replace even-:: free **,. ith** relapse

Table· .;. c:..½2 Ii,;;.e tc **relapse** (d:..::rac::ion of corr,pcsite CR) - Days?? Popu2-ation

T2;)le -,i 2 "3
ScJ.bgroup Analysis-CR
:::"c':' ?opulaticc.

	::ontrol (N = XXX) n (%)	Low CX-01 (N = xxx) n (%)	High CX-01 (N = xxx} n (%)
Ageg.::oup: < *!'J*	xxx xx.x°f'	zxx \ xx.x%!	xxx xx.x%)
95 , Confi::ience :::r.t.e.::vc:l	(x.x>: , x.zx·,	\Z.XX , X.xx;,	;x.xx, x.xx)
Age group: 2 c .:,	xxx ·-·x.x-e,	xxx (xx. „':s	xxx (xx.x%:,
95? Confider,ce :::„c.e.::vo.::.	(x.z ;-:.x:-::,	(x.xx , x.zx.)	(x.xx, x.xx)
A1':...: Ve qovo	xxz xx.xS	:-:xz xx.x01	xxx (xx.x%/
95% ConfiCe,1:::-2: :--::.e.::,·:c:	(x.xx , x.xx\	(x.x x.	::;,:.xz , x.xxi
Ai•L: Secorcdary	xxx(xx.x%;	xz:-: *(* xx.xSi	·<xx xx.x%)
95½ Cor::fiO.er::ce ""~e::::,-2	(x.xx , x.xz·:	(x.:o: , x.x:<\	(x.xx , x.xz)
2COG: :::;	xxx x:-:.z'o>	xxz x;-; .x"o'•	xx:-:: (xx.x\i·r
95% ConfiCence :::n-::.e.::val	(x.xx, x.xx:,	(x.xx , x.xx)	(x.xx , x.x:-:l
SCOG: 2	XXX (xx.xS '	xxx (x;-,.x%;	:,;xx ;-o-:.x·t
95% Confidence :rc::e:c,,al	(z.xx , x.xx)	(x.xx , x.xx:,	,:x.zx ;,:.xx)

c:;: is based or: Clopper ?earsor. S:-:act l.....L
?rogra::n r.Jar:;e: ::a-::e Ger,erated: ?age x cf y
Listing Sou.:::-ce:
?..epeat ::or t.he followi.ng displays:
Table- '1. 2. 44 S::.;)g.:::-o:.;p An2lysis-Corq:::osite CR :TT ?op:.:.2.2-:.ior

Table 14.3.1.1.1
Overall Swe.rr,.ary of Ad·,-erse Events
Safe::y ?opu:::.ation

	::ontrol (N = XXX) n (%)		Low CX-01 (N = xxx) n (%)		High CX-01 {N = xxx) n (%)		Overall {N = xxx) n {%)	
Patients with A:t,y Adverse Eve2ts 'ASs)	x::,;x	xx.x%}	xxx	xx.	x:-;:x	:o:.::--·	;,:x;-1	xx.x?s)
Patients ,-,it!l Any T.::eath,ent-Eme:r-gent Adverse Ever:ts (TEAEs)	xzx	xx.x'l;)	xxx	x:-:.z%}	xxx	xx.;-: '	·;;:;;;:,·	:,;x.·,-,
Patients with A,,-_}' AE ty r:-:axirm.1.rr, NC::::-CTCAE g:::-ade								
	xxx	xx.x'ii	xxx	xx.x%)	x<·z	xx. xc:,:		xx.xi)
2	xx:,:	xx.x%	xxx	xx.xS '-	xxx	XX. z l: 1	;,:xx	xz.
3	xzx	xx.x%	xxx	xx.x'i:	xxx	xx.xS	;o::•:	XX.X",; i
	xxx	xx.x%	xxx	xx.xi·,	;,:xx	xz. xli	:,:xx	>D'. :-;:%)
5	xxx	xx.	xxx	xx.x%	xxz	xx.x	x;,:x	x x . z °3;
G:::ade 1 or .c:: Grade 3 or 4								
Grade 3 or above	xxx	xx.z%'	xxx	xx.z't)	:-:xz	xx.x'i:	;,;xx	xx. y>,)
Patients ,,,ith A2yTEAE by axinn. --r:. NCI-CTCl-\.E grade								
1	xxx	xx.x·o	xxx	xx.xi&	zzx	xz.	·,,;}:x	xx.x
2	xxx	xx.x%"	xxx	xx.x:;c	:<xx	>'.Z. X'0 ·,	xxx	xx.x
3	xxx	xx.:s:%	xxx	xx.x%,	;,:xx	xx.x'c'		xz.x
	zxx	xx.:d.	xxx	xx.xi·,	;-:zx	;,:x.	:,;x;-c:	;,:x. x·o i
5	xxx	xx.x%	xxx	xx.x½ '-	xxx	XY. X·}\	x:-:x	xx.
Gradel or 2 Grade 3 er 4								
Grade 3 or above	xxz (	x:-:.z\';)	;,:xx	(xx.:--:%)	xxx	(;,:x.		;,:x.::-: :)

The derwminator f:::,r percentages is t:.-'.e r:cJ..c,ber cf patients in the Safety Populat.::_or,
Cases with s.,.r:kr:.owr, severity ,,:e:::-e assLL-r,ed to be severe.

Program l\a:me: Date Generated: Page of
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'Zable "'1.3.1.
·::::verall S ":W,a:::.-y of Adve::se Events
Safety Popi..;lation

	::antral (N = xxx} n (%)		Low CX-01 (N = xxx) n (%)		High CX-01 (N = xxx) n {%}		Overall (N = XXX) n (%)	
Patients with A:,•:/ A::":s leading to treatr:-,ent inte:-rupti -,	xzx	n.-.. f ..	xxx	xx.x"o	xxxx	xx.x :,	xy'.x	xx. xi)
Patients th Ar::y 7E.n.Es leading to	xxx	xx xo·	xxx	1/.x.	xxxx	xx.x½:,	xxx	Y.>:. x's
Patients w t:-, Any AEs leading -:::o trec.t:.nent -eductinn	xxx	;-;x.x'2	xxx	;,;;-:. >:	xxxx	xx.x'i,)	xx	xx.x,,
Patients with;.-,-, 'I'EAEs leading to	xxx	xx. x:-	x:-sx	xx. x"oi	x:-:x	xx.·,C·'		xx.x%)
Patients with F:.n·· .A.Es leading to trea':.rc:ent disco:-it.i;.;uatior.	xx:-:	s. ,.,	;-;x;-:	xx. x'i\	xxx (	xx.x%}	zzx	·-:.%)
Patier:.ts ·.1i tr: An.,, TE."'.Es leading to treatmer.t C.iscontinua-;::ion	zxx	xx.	xxx	xz. xt;	:,;;,;:x	xz.x%)	;.;;;;;;	xxxSe'
Patients with AnySeve::e Adverse E1;e:;;:.s (SAEs)	xxx	x x . x °	xxx	xx.x';.,)	xzx	xx.x \·-	:-:x:•:	x:-:
Patients with Any Treatmen"t-Emergent Severe Adverse Ev·ents (TES.fl.Es)	xxx	xx .. ,.).\	zxx	xx •.icc	xzx	xx.x%)		xx.
Patier,_ts •.,;i *ti* Any SAEs leading to dea:.h	x:-:x	xx.::s·,	xxx	:•:x.x'i)	;-:xx	xx.;{:±;	xzx	xx.x':o)
Patients •.•:ith A::1y TE:SAEs leading to death	xxx	xx	xxx	xx. x'::)	:-:xx	xx.z;•:;	x}:;-;	xx.x,)
Pa::ien::s with Any S."\Es 1eading to treatment disco:-itinuac:ion	xxx	xx.x	>:x:-:	xx.	xzx	xx.x%)	XX>-:	x:--:. :,;?;)
Pat.ients witr'. .A:-iy TES.AEs leading to -;-_y-;:,atment disco:;.tin.1.;at'.io:,	xxx	xx.xi'	zxz	;.;:;,;_;.;:;)	xxx	xx.x	zxx	xx.x%
Patients with any st·Jd)' drug :-elated -"-Es	xxx	xx.x%l	;-:xx	xx.x'i:)	xxx	xx.x	xxx	xx.x"t
?atienc:s with any study drug related TEAEs	x;,;:s	xx.x%)	xxx	x. ;t)	xxx	xx.x	Y.xx	xx.x%

?he denominator for percer..tages is the nu,.--n.ber of patier.t.s .:,,r, the S2fety Fopulati.cn
Cases -:.,·i th unkr,o,.,n seve::ity were assu.7,ed to be severe.

Table ·," 3
s·cl;JL-r,ary of Treatment related Ad o; er s e Event (Idarubici::-i)
Safety ?cpula-::=ion

	::::ontrol (N = XXX) n (%)		Low CX-01 (N = XXX) n (%)		High CX-01 (N = XXX) n (%)		Overall (N = xxx) n (%)	
Patients '. i .I:iarubicin re:.ated Adverse Ever,ts (AES	:,:xx	xx.x%)	xxx	xx.x ,)	zzx	:,: ;,;':;',	:x	xx.:d)
Patients wi Iciar,ibicin related Treatmer,t-Err:ergec::: Adverse Ever:ts (TEA:'::s)	xxx	Z}:.:-r""	xx'.{	:-.:;,:.	x; x	zx. -,."		xx.x%)
Patie::-,ts wifr, Idarubicirl rela':ed A:S by Zc c A·½"":· '<c - /-•·Cr :: , f' re ,,""								
	xxx	xx.	xzx	x:,;. xSc	xxx	xx.	zxx	zz.z,})
2	xxx	X}:. X""	xxx	:-:x. x>	xxx	xx.	x:-.:x	:-:x. xi'.; l
3	xxx	xx .. ,.;·	xx:,:	x:{	xxx	xx.	:•: ::{	(xx. x% l
4	xxx	xx.x%	:,:x:,:	·−·,.:{'i;'	xxx	x:-:.x'"	xxx	xx.xi)
5	xxx	xx.xi'	;co:	x : .z'c,	:,;xx	:-:x.x?o	xxx	xx.x%)
Grade or 2	xxx	xx.xt;	xxx	xx.	xxz	z'	zxz	xx.x%)
G:rade 3 or	xxx	xx.x%";	xxx	xz. x?;'	xxx	:-.:x_-,-o'"	xxx	zx.
G:rade 3 or abcve	zxx	xx.xi)	xxx	x:,:. x"'·	xxx	:,:x.x% \	xzx	xx.x%)
Patie:1ts wit.h Ici.ar,.;Dicir. rela'.:ed TEA£ b:,/ maximu,.L, NCI-C'.:'C'".E gracie								
	xzx	X}:.x½;	xxx	x·:.>:'.li)	xxx	x;,:. x'i:	xxz	zx.
2	xxx	xx. x::	xxz	:,;x.	xxx	x::,. x'2)	;,;xx	xx.x%)
3	xxx	xx.	xx::-:	xx.::-:''::	xxz	xx.z?'	xxx	xx.x'bl
	xxx	xx.x%'	xxx	xx	xxx	z	xxx	(z:-.:.x";)
5	xxx	xx. x·c	:u:z	xx.x	xxx	xx .x'"	;-::o:	xx.;,;'\)
Grade or 2	;,:xx	xx.xt)	1/.xz	x;-.:.x	xxx	:::,;.	xxx	xz
Grade or 4	x:,:x	xx.:-vo'	xxx	zz.x	xxx	.x:.z	xxx	;,:::, . x-3
Gracie or abcv-e	;,:xx	xx.x·o'	xzx	xx.x	xxx	xx.z	x:-.:x	xx. x'o

Cases with t.:.Ek::-.01-:n se·,:eri ty were assc.:.-r-.ed to be severe.

l_'rograrrirri_ih_g Not.es::
Change, drug na..cH? to, !d2r't:i.bicin related.

Tab2.e 14.3.
Su,,c:t.a:.::y of Treat:.c,er:t related t'.dverse Event (Ida:.::s.,bicir-,)
Safety Populatior.

	::antral (N = xxx) n (%)		Low CX-01 (N = XXX) n (%)		High CX-01 {N = xxx) n (%)		Overall (N = XXX} n (%)	
Patients 1s·i th Idarubicin related _;:::s leading to treatmer;t inte:.::n:.ption	>:x:,:	zz.	xxx	- :>·	xxx	xx.x%)		zx.Y"
Patients ;..·i th Idarubicin re2.ated 7E.;:i..::s leadir,g c:o treatmer:t inte:.::cJ.ptic:-:.	xxx	x:.,:.	xxx	xx.x''o'i	xxx	:-;: -•;: :<"•	;.;;-;):	xx.;,.'i
Patients ·wi tl": Idarubicin ::::elateci ASs leadir,g to t:.::eatmer,t :.::eductior,	xz;,;	:-;:x. x l	xxx	xz. x^{0}	xxz	zx.x½;,	xxx	:-;:x
Patients with Idan:.bicin :.::elated 7EA:Ss leadir,g to treatment r ductior:.	x:.,:;--:	zz.x½	x;--:x	:-:x	xxx	xx.;.:'t '.	x:-:;•:	:;:.x
Patients with Idar'.lbic n related _;:_ss leading to t:.::eatmer.t d scontinuc.tion	;.-:x;c	x:-:	xxx	xl":.;:-.;	xxx	(xx.zf	xxz	}: ,:• :;-:'.6;
P2tients ·,,ith :Cdc.rubic r. relc.ted 'l:S;o.Es lee.ding to t::::eatment ciiscontinu2tior.	z;,:x	•.:':)	xxx	x;.:. :.;:'o	xxx	x:,:.xt.	xxx	z:cx ,,
?atien.ts ,,ri th Idar1;.bicir. ::::e::_ateci Sesrere Adverse Events (SAEs)	zzx		xxx	x:--:. ';)	:-;x>s	zx.x%;	xxx	xx.x":/
?atie1;.ts with Idan;,biciL re2.ated Treatme;;t-E;:ne:rgent Seve:.::e _;c.,.cerse Events {"l'ESAEs)	xxx	zz.x'·	xxx	zx.x%)	xxx	;.:x.	·,:xx	;,:x.x%-·
Patients ·,,·i th IdaruOicin :.::elated SAF.s leading to death	xzx	zz.Y	xxx	xz.	xxx	zx.xt'	zzx	xx.xS:'
Patients ;,·i th Idarubicir, relateci. TESAEs leading to death	xxx	zx. iZ\'-	;;xx	XY.. x?,)	n.t'•	xx.z%'	xxx	xx.x½J
Patier-,ts with Idarci.bic E rela::ed SAEs leading to treat:2ent C scontinuatic-:--,	zxz	xz.x":·:	xxx	xx.	x:-;:x	xx.x't. i	xx;.:	xx.z
Patients ·,,.'c t:r; Idarubic n re:2.2,ted TESAEs leadir,g to treatment d scontinuaticr,	xzx	x	xx,-:	xx.x':o i	xxx	xx.xt'	xxx	zx.x';

Cases ·,-:itf'. \.ln>:no-.-;n severity were assu.c.ed t:o te se'.'ere.

f,rcgi::.a--riroiii.g·- -fbtes:
Cha:n9'e:-dr·u_g -name to· Idar'v.bi:cin· r lated
Program Name: Date Generate::i: ?. ge x of ,,.-
I..isting Sou:.::ce:
Repeat for the following displays:

?able l4.3. 3 Su,.cunary of T::eat:-cent related Aciverse Eve:1t (Cytarabin.e) Safe'.:y P:::ipulatior-i
.i".dd:
No'.:e ':o Prog-rarnmer: Change drug name to Cytarabi::e re:ated

Delete:
Note to Progra:;ru-:;er: Change drug name to Idari.lbici'1 related

Table 14. 3.::.. s,.:rnr::.ary cf Treatment related Adve::se Event {CXOl) Sa::'"e-:: Pcp..:.laticr
.:'.\.dd:
Note -::o ?::og-::amrr,er: C:',ange d:::ug name to CXOl relate...,

Delete:
No.:e -:.c ?rog:::.-a::rcmer: Cf::ange Crug Lame to Ida::·c1bicir. related

Table 14.3. 5 S·c1.rn,--r:a::y o::: Adve:::se Eve:it Cue to ..:.r:Cerl·, ins disease er o:::te.::: dcC'gs *o::* che:r,.icals Safety Po;;mlatio:1
_::i._ctc:
1,Jote to Prograrr -r,e.r: Change dx-ug name to Ur,derlyir:g disease or otf::er d::ugs or chemica2.s related

Delete:
·Jote to P:::-ogram:.--::-ter: Ctange drug ::-iame to Ida:::c:b.'cci.n related

Table 1.4. 3. l. 6
Qveral:i.. Cmlnts of Aci.ve::se Es;er:ts
Sa.:"e::y Populaticr,

	::antral (N = xxx) n (%)	Low CX-01 (N = XXX) n (%}	High CX-01 (N = xxx) n {%)	Overall (N = xxx) n (%)
AES	x.:-:x	xxx	zc'.x	zxx
TE.;;.Es	xzx	:o:x	ZXX	x:o:
SAEs	xx:•:	z:o:	zz:	x%z
TESAEs	z:,:x	xxx	xxx	x:-cx
T::::eatment 1'.'e ated AEs	x;.:x	xxx	xz;,:	x:,:;,:
T::eatsen re a ed TEAEs	xxx	xxx	x:-:x	;,:;,:x
Treat:c,ent re ated SAEs	xxx	xxx	xx :	x c{
'T'reatrr,ent re ated TESAEs	zzx		xxx	xx:,:
AEs leading to treatrr,ent inter::uptio:-,		xxz	xzx	:,:;,:;,:
EAE 2.ead ng to treat-e1t _-te::::r-pt-o-	:--:xx	xxx	xxx	xxx
SAEs leading to treat:r,e:st inte::::ruption	xzx	xxx	xxx	xzx
'iESFEs eaoi'"g to tl'."eat-rre-_ -te:::::up_.._,	xx:-:	xx>:	xxx	xxy.
AEs leadir.g to treat:me:it reci. ctior,	;.-:;,:;,:	xzx	xxx	x:,;x
TE.;;.Es leading to -:reatment rec\'...:ction	y.x:-c	xxx	xxx	x:r:x
SAEs leading to treat:;r,en,:: ::::e'.:: c::ion		:xx	xxx	xxx
'i'ESAEs 2.eading to treatrr,ent reductic-2	x;-:x	xxx	:-:xx	)czx
AEs leaci.ing ".:.o treat.:2en.t ,-.'it.hd::::a1•:al	xxx	:-:xx	xxx	xxx
TEP..Es leading to treatment, ..;::_t:-lcira',,'al	x;,:z	:u:x	xzx	xxx
S.½.Es leading to ':::reatrr.er::: wi. thd::::awal	::--:xx	xxx	xxx	xxx
TESAEs leading to t.:::::eatRent ,,,.:*i* t!'".dra,,;al	xxx	xzx	xxx	xxx

Cases w·i th unKnosir, se,,eri ty ·,.:e:ce assu.,-r,eC. 1:0 be seve::::e.
Progrc.:m Na;-r,e: Date Ge;:ierated: ?age x of y
I.,isting Source:

':'2b:1..e 14.3.1.6
Ove!."2ll CO-:Jr',tS cf Adverse Events
S2::':ety Populaticn

	::antral (N = xxx) n {-%)	Low CX-01 (N = xxx} n {%)	High CX-01 (N = xxx) n (-%)	Overall {N = xxx) n (%)
::-·:::eatrr,er.t related AEs leading to tre2t2ent inte:::::.-uption		xxx	x:-:x	xxx
Trec.tr:ient :::elated TEF>-.Es :eadir::g --.::o ,,,,,,'"2""""P'"t ir-t-"" ...rup1-:. ,,	xx·•·	:-:xx	xx:,-:	xxx
T·:ceatr;ier.t related S.f'.Es leadir::g to treat2ent interruption		:,:z:-:	xxz	xxx
Treatr'.',ent !"elated T S1'.Es 2.eading to treat::-,er,t inte:cruptior:	'o'.x	·.:,:;,:	xzx	xxx
Treat22r,1: related P,Es leading tc treatment ,,,ed.:c-:-.-'o-,,	z:,•··	zxx	xxx	;-o:x
:'re2trr,er.t related TEAEs leadicg --:.o tre2::rr,e,:t red:..:ction	:<;-c;,:	xx:-:	xxx	xxx
Treatc,,enc: related s.n.Es le2ding to ,,,:, :0a,, ,,,,,-.l- r<>j:.:(',7"; cr		zxx	xxx	;,:,,-:x
Treat:;cer,t related TESF-.Es leading to treatcc:er,t x-ed-..:ction	x:•:;,·	;,:x:·:	x:-:z	xzx
Treat:c.ent related AEs leading to treatment ,,,,, :. c:.,l '="'c.l	xx:<	zx:-:	xx:x	;::,-:x
Treatment :::-elated IE.t,,Es l,c?ading to c. ,, ec '-"""'n,,,, :. 1,,hC-'-.awal	x	xxy	xxx	xxx
Treat2e,.t related SAEs leaciicg to t:::-ea.t:.,er,t wit:,ctrawal	:.;	xxx	xxx	;-;:xx
T:::eat:mer.t related TESP,Ss leading to treatrr,ent ·wit:'.'.drawal	;:xx	:-:xx	xxz	xxx

Cases wit:ti unknow::: severity *we*::::*e* ass1..uned to be severe.

?rograrr, Name: :::::ate G,.:merated: :?age x of Y

Listing Source:

Table H.3.l.7

su..,c:nayy of T:-::Ass 8y ;'Jed.D? S System Qyga:1 Class and Fre:'.:, rred Term

Sc.fety ?09ulat:ion

S;/ste::n ():rgar. Class C:e.o.'Fe..reod	::antral (N = xxx) n (%)		Low CX-01 (N = XXX) n (%)		High CX-01 (N = xxx) n {%)		Overall (N = xxx) n {-%)	
?c.::.ients ,,:ith Ar,y TEAI:,	XXX	xx. xi\:,	>:xz	xy.x%)	XZX	xx.	Z>:X	xx.x
Sys···:em Organ Class	x:-;:x	:-:x.X'S	XXX	XX.X'o	:-co:	xz.x	xx;:	xx.
?re erred Terrr,	XXX	xx.x%	xx}:	;.-:z.x½		xx.x	xxx	xx.
2:re erred :e:rm 2	xzz	x:-:.x%	xxx	xx. x;,	xxx	:·:x .z	>:xx	xx.x':>1
P:::-e erred Term 3	x:,:x (xx.xS'		x;-;:z	x:-:.	x:o:	xx.	xx:,;:	xx.x%
ec:c.								
System Orga::, Class	x:,:x	xx.x	x;,;:z	xx.xS)	:,:xx	xx. ; ,'	:,:xz	xx.>'
Preferred Term	xxx	xx.xi	x:o;	x.:,. x",:)	zxx	:G:.;-::'.\	xxx	:-:x.x%
P;::eferred Ter:n	;-:xx	xx.x%	xxx	x.:,•• xS)	:-;:{;,;:	x:-::.	xxx	:,:x.xo)
o.::e- -"r• e.· Tern	xxx	xx.x%	xxx	xY. xS)	zx:-;:	:-:x	xxx	xx.:,;:";\
.. etc.								

te denominator for pe::ce?Ttages is t:he r,u.,c-ber of patienc:s in t:-,e Safety ?opu.latior,

Jote: This table cor,,tc.ircs counts c:f patien::s. :£ a patient experienced more tha::: 0:12 episode of an ad rerse e7er,t, the patient is cosmted only or,ce -within a pre:·erred ter:::i. =t a patient experienced :x.o::e than one adv·erse event ,,;ithin a syste:::-:. organ class, the patie,:_t is counted or.ce for each prefeyr,=C terr.-, anci once for the sysc.em organ class.

Listing Source:

Repeat for ;:be fo2.lo;;ir,g displays:

'I'aO.le 14. 3. l. 9 Sur:1.nar::/ of :1CI-CTCAS G::::ade 3 or higher TE:ASs by EedD?..A Systeo;n Crga,, c:.ass and ?refer::::ed Ter,,n Safety Population

7able 14.3.1.lO S;.1..:ccmary of N:::I-CTc.:..::; Grade 2 or lm•.'er TE.l:..Es by l"ledDRA Syste,,"c Organ Class a2d Preferreci Terr:-; Sa::':ety Pcp-c.12.atior

Delete:

Footnote: The de:1c:nir1ator for 9erce:1tages is the ;-;,.1J.--::-be;:- of patients in the sa:=ety Population

Footnote: Noc:e: ·:: -:.is table contains cm;;r-,ts of patier-,ts. :::: a patient exper1.enced more t!-,ar: 02e e;;:,isccie of ar, adverse event, the patient is ,_____,e0 o,_.' Y o;-;ce witSin a preferred ::ers. a patient experienced mo r t:'.:ar:: one adverse eve:c.c: wic:hir-, a syste::n orga::-:: class, the patient is cou;;.ted once for each prefe:-:-red ter:;,. ar,d o,.ce ::or t:ie syster::, o::::-:;a::i class.

Table .3.. ll Su.,_,1.cw.ry of Treat:nent-?..elated TEP.Es by :,:edDRA System Orgar, c:..ass and Preferreci :e::::- Safet" ?op;_;_lation

TaD:e 14.3.l.... I SU:"".',rn.ary of TESA-2:s/Serio,_;_s ':'EA.'::s b::i 1:,:ec;:::;:;,,, System Orgar. C2.ass ac:d Prefer::::ed '.:-err:, Safet·.· Populatior.

Table 14.3 ....l8 Surr,l;)_ary cf NC!-CTCAE Grace 3 er hi-:;her TSSAE:s/Serio;is TEP-.Es n,, MedD?..l'-. Syster:. C·rgar. Class ar-,d ?:r.eferred Term Sa:'.:ety S1..- Population

Tab2.e 14.3.1.19 ;.rnmary cf NCI-CTCAE: Grade 2 or l.o;,·e::: :::::SAEs/Serious ?EA:;;::s by I•ledD?)l.. Sys,:.er:. c,rgan Class and ?refer:::-ed 7e:::-= Safety Ops.t:;_ac_.o:

Delete:

'foot2ote; The Ce::crr,inator for perce,,tages is the r,Uc-rcber c-f patier:ts in tt-.e Sa:'.:e::y ?opulatj_on

Footnote: t ote: ';:"his table contains cou.nts of patients. ---= a patie2t experier.ceC. nore t:-".a::1 one episode of a,, adverse eve::t, t!"',e patie::::t :;,.s cou::ted only once ,,,itl",ir, a preferred '.::er2. a ;;:,atie"-.: expe:-ie:--:.ced more thar: cne a::iverse ever.t ,,·it:-,i::--, sys-:::e:n or;ar: c.::.ass, tr.e patient is co,.:_ated o:1ce for each ;:,referred ter:c· aI1d ::,;o,ce £or L:.e s_ys-:::erc, organ class.

:able "" 3.1.21 S0.nmary of TEA:::s Lea::iing tc =:ea.tr. c-., l<edD A Syster:-, Orga,, Clccss <rnci. ?re:'.:er.red 'I"errr, Safety Pcpulatior::

'Iable 4.3,_ 8
Su.,-:-z.ary of TEJ:l..:Ss by ?referred Terrr,
Safec:y Pcpula.t.:or,

?refer;:-ed '.i:'er:m	:::ontrol (N = XXX) n (%)	Low CX-01 (N = xxx) n (%)	High CX-01 (N = xxx) n (%)	Overall (N = XXX) n (%)
?at.:ents witt. A:r:y ·_:::,:s_;;;:,	xxx xx.x%)	xxx xx.x ,--	xxx xx.x".s)	x;-:z xx.x?,)
?referred :er:n	xxx ;,:x.;-:(;·:	xxx xx.x:S}	;-:xx xx.x?;)	xxx xx.x".i
Preferred .!:er;:n	:o:x xx.x%)	x:-::--; (:--::-:.x -	x;c: xx x'oi	xxx x:-:.x",
;:...-e ..... "'d .·.c_-	xxx xx.x%)	zxx xx.x°"	:-:xx zy. x'i;c)	xx;-: x:s.x{;
?re erred '!'err:-,	xxx x: . x%)	x:-:x xx.	xx.x'S)	xx:-: x:-:.x%)
Pre erred 1er- 5	xxx (xx.x%)	xxx :-ex.	xx.:-:%)	xxx xx.:--:%)
Pre err:ed ?er::, 6	xxx xx. xs)	zxx :..:x.:--:<:'	XXX xx.x'.3)	xxx zx.
Prefer::::-ed Ter::-, e-:c.	;,;;-:x xx.xi)	xxx xx.x"o)	:·:x;: xx.x%)	xxx zx.zt,)

The Cenc,dn.ator for pe::.-centages is the :r:u..,J::er of patients -c.::-',e Safe-::y Popc.Jlatior:
l ote: This ,:able co,.ta.ins co·.mts of.pa::iem:s. If a patient ezperi.er,ceci :ncre -.:l',a;:; one episode of an adv-erse event, the patient is courcted only once within c. pre:Z:erred t'erm.

I '-7-

\(;
c

\,,,____ '_

?able 14.3.1.12

'°'oo-rt,rr,ary o= ?EAEs by Relationship tc Study Treatment by :"iedD?.P... Systerr, Crgar, ::lass ar.d Preferred Term

Safety· Population

System Organ Class Preferred Te= Relationship to Study Drug	::antral (N = XXX) n (%)	Low CX-01 (N = xxx) n (%)	High CX-01 (N = xxx) n (%)	Overall (N = XXX) n (%)
?atients with J:...ny T:::AE	;.:;,;x xx.z"s	xxx xx.x	zxx xx. ;-d;:	xz;.; ;s:x.x%)
Idarubicin related	;,;xx xx.xS	xxx xx.x	xx;,: xx.x'i	xxx xx.
Cytarab ne relac:ed	xxx z'i	xxx xx.x	:•;,;,;(xz.x'·	;,:xx xY .X's)
CXOl re ated	;,:xx xx.;,:%	xxx xx.x	xxx xx.	:•:xx ;•:x. ;s:::,)
Underly ::i.g disea.se o:: cthe::::- ci.ru;s or chemicals related	;,:xx xx.x's	xxx xx	:•:.:cs: xY .x'i,'	xxx x:-:.x%)
Not Related	xx:.: x;--:::.z:;,·	xxx x:s. x o)	xxx ;,;;-;.:.	xx;, zx . .:•·'·'
System Organ Cl ss l	xx:<'. ×:{. Y""	xzx xx.x%)	;,::--:;(zx.	x;,;.. x':;'
Idarubicin re ated	xxx xx.xii	xzx xx.:,:\'.'	xxx ;{;,;. x'c	:-,.::{;< >:. x ,)
Cyta:cabine re ac.ed	xxx xx.xS:i	xxx xx.x% '-	xxx zx. x⁰₀·:	;-::-,:x xz.x'o)
CXOl releted	>:xx xx.x·s	xxx xx.x'i'-)	x:xx zx.x·3'	xxx xx. x ,
Onderl ir.g disease or ether 0.n.::gs c:c cherr,ical related	xxx xx.x">	xzx xz.x;)	xx;.: xx.x"'.-:	·,:x:•: ;,;x.x'i:)
NotRe ated	x/'.x xx . .,.;,.,	xxx xx.:,:;:;)	x;--:x xz.	xxx xx. :.-:"t)
Preferred TerE l	xz:-' ;{x.z'c	xxx xx.x%)	xx;,: xx.	:·:x.:s:
Idarubicir, related	x:-cx xt)	;.:xx (xx.x%	;:;-,:x x;-,. ;.:" '	x:, :..:x.x%'.
Cytarabine related	x; x xx.x':s'	x)sx xx. x';;	zxx xx.x -	xx;,: :,-:x.x
CXDl related	xxx xx.x":o}	;,:xx (xx. xS:	xxx ;,:x.x';,,;	xx.x
Ur.derlying diseese o.:: other dn.-:gs or chemica.:s related	xxx (xx.x"c'	xzx (zx.x%	x xx.x%,;	xxx xx.x
Not ?.elated	xx:s: xx.xc:,·,	xxx :s:x.x%)	x.:s:x xx.x ::	xxx xx. x%-)
etc	xxx xx.:--:'c\	xxx xx.x%)	;,:xx :-:x.xs;	xx.x%;

The der.ominator for pe:-centages is the :::.L,Tu)er of pat.ie2ts in t:1.e Safety ?op,.-,latiori

Note: This table contair,s cou:ats o:: pati,,,nc:s. 2. patier:t e:-:perienced more '.:.l°',c.n one episode cf a 7-;;:_n_s, the patier,t is CO"..lnted cnly once .,,.,ithi:;1 a preferred te::JT, a:c.d o::ce for c:he system organ class.

?rogra:n Na:r'.e: Dete Ger;.erated: :2age x of

Listing Source:

Table :C.4.3.1.13

SUc.v:-cr.ary of TEA:Ss ;;.,.; :·,Jaxi .,..:..,, IiCI-C':'CAE Severity, System Oz:-gan Class and Preferred :e::::::\
Safety ?opul2-::::ion

Syster::, Crg2:1 Class ?refer::eci Te:::-m l.C-'-.:.*'-'"" .:O .,e,...:c.,j	::ontrol (N = XXX) n (%)		Low CX-01 (N = xxx) n (%)		High CX-01 (N = xxx) n (%)		Overall {N = xxx) n (%)	
?atient.s w:'..t.h Any TEAE	XXX		ZXX	XY.. X':','	XXX	xx. x%'.	:-:xx	X)'.x>)
Overall	XXX	:.;z.·.··		X:,;. X	XXX	xx.xS	:,.x	:,;x.:,;.'.5)
1	X:,;Z	ZX.::--:'·'	ZZX	XX. .X'<;·,	XXX	XX.ZO.:,	XXX	xx. x':c
	X:-:X	X>'.xi'	XZX	ZX. X%1	:S:XX	xx.x%:·		;.;;-:.
3	XX.X	:{x.:r	ZXX	XX.	>:XX	XX.X'2	:c-:z	:•:x.x"1;)
4	XXX	XX.X"	ZX;-::	ZZ. X":)	XXX	xx.;,:%	XXX	XX. X':c
S	XXX	:.;;{.	XXZ	X:-:. x'c)	:-:xx	ZX.X%	XZX	XX. X:-,
Syst.ecc, C::::gan Class l	XXX	ZX.Z	xx:•:		XXX	XX.X' ·,	X:.;:.;	ZX. X'i'
Overall	XXX	:-:X.:,-"	ZXX	X/:.	:-:xx (x%)		XXX	XX.
	XZ;t	xx.	.:-:xx	XX :{-\	:-:xx	x;.·.x'o	XXX	) .. '-
2xxx		:S:X. ·,'C \	XXX	XX.X	XXX	xx.xS;,	ZX:	:-:x);i;-
3xxx		XX.X'c'	XXX	XX. Z	XXX	;O:.X ;	X:-:X	xx. x%
4	X:.;X	ZX.Z'°e\	XZX	XX.X	XXX	X;,;.	:-:xx	XX.X%
S	XXX		;.::xx	XY	;.;xx	xx.x½)	:-:xx	X:-:. X?,;.
?.referred Tercc,	XXX	XX.	X:-0,	::O:.X	XXX	XX..x%)	XXX	XX.X
o,rerall	XXX (x;.;. ;.;-I		XX;{	XX.:-:	XXX	(:{X. ;.:\;;,	:,;xx	X}:. Z
	XXX	:-:::X.X	:,;XX	XX.Y	XXX	XZ. X'.-i	:OZ:-:	XZ.X
2XXX		>D•:.x'±	XXX	XX.X%'	XXX	xx.x'S	XXX	; Z.X
3XXX		XX.X":	XXX	Z:X. X-''	XXX	XX.X%	XX.:-:	XX.X5
▮	XXX	xx.	XXX	XX. X",'	XXX	X:·:.x',	ZXX	XX.X'.';
5	XXX	:-:X.	XZX	XX.XS,	XXX	XX.X%	XX:,:	Z;.:. Z'Si
etc	XXZ	;-:Z.:,;··· -.,	X;-:X	XZ.Z%	XXX	XX.X%1	XX:,:	/;X.Z ;)

':'he denc::-,in2::or fo:::- percentages is the nur:sber 0=:. patients in the Safety Popc.:lation

Ncte: Patients with :r,issir:g "1axi:r,u.Te. se-.cerity are co,.mted in L;.e Jve:::-212- category only. l = t-:rild, 2 = ;:,Joderate, 3 = Severe, 4 = Life Threatening, 5 = Dea".:!",.

Note: This table contains counts of patients. a pa-::::.ent e:-:perienceC more th2:1 or.e episode of ar, adverse evenc., ;:h.e patient is cm.:nted o:1ly· once witLi.n a preferred tern and for ::he episode ,1:.::h ::he r:.a:,:ionc:.c--n seve:::-i::y. If a patient e:<perienced more ::han one acive:::-se eve:1t witi'.in a system organ class, the patient is counted or,ce fo::.· each preferred term ar,d or.ce for the sys ten erg a;,, cl.ass.

?rog:::-am N'ame: Date GeD.era'"c.ed: ?a,;e of

Lis::ing Source:

?.epeat for the fellowing displays:

Tab:..e 14.3.1.::_.:; SLl..'Tu.--::-,a:cy of Treatme::.t-?.elated TEF>,Es by ;:,;aximw,, I c:::-CTCAE Seve:city, Syster:"c O:cgan c::_ass ar,d ?refe:cred Term Safety Popc:.lation Acid:

Note to ?.::::og:carr:!T,e:::: Replace TEAE by T:::-eatne;:i.t-Related TEAE

Table : : .4 .3 .1 .15

,_,_Tu":',ar)" **O=:** ?EAEs Ca,;.siTJ.g Uiscoc,tinuation frorr, S-;:udy Treatrrten.t Dy CTCF-.E and ,rnrst C CAE grade

Safety Pop·c1laticr:.

c::CAE ca tegor""y (alphabetical order)	:-JC: CTCP.i'.; t.ere<, 'a2-p::abetica.l a c.s.. - ,,..i tl-:..:. C?CA:S category:,	T..... "-... C:C::.:, grade	::ontrol (N = xxx) n (%)		Low CX-01 {N = xxx) n (%)		High CX-01 (N = xxx) n (%)		()-,1erall (N = xxx) n (%)	
Nu.-:tber *i>.;)* of subjects										
A2-l C'I·CA:C:: categories	Any	Gracie	x:o:	xx. x'i *i*	xxx	xx.	;,,x;.:		xxx	x:.,s.z,;;
		, .:::a...,	xxx	x-:.x	xxx	:s:x.	zxx	zx	·,:zx	xx.x\'
		Gracie 3	xxx	xx.x ;	xx;-:	;,:x.x',·	xxx	xx.:··".'	xxz	xx.*X'i*
		Grade	x:<x	zx .x	xxx	xz. ·,o.	xxx	xx.x'<S \	xxx	xx. :,s(:
		Gracie	x:,	;.-:x	xxx	;,:z.	xx;,:	.:,d	:{xx	zx.x's
'-- '--A Cc•- go... v	P-.n.y	Grade	;,c,:x	x;,:. x%)	xxx	xz .;-,° ·	xxx	:zx.	c{zx	xx.
		Grade	xxx	*Y.X.*	:•:xx	;-n:.	;,:zx	xx.x-s'	xxz	xy .xf;)
		Gra6e 3	x:o:	*Y.X.*	xxx	xz.x,,·,	xxx	xx.x :)	;,:zx	x:s:.x{,'
		Gl'.aC.e 4	xxx	zx. :,>·-	xxx	xx.x".:,	xxz	zx. ·.·'	;-:zz	xx. x\'i'
		Grade 5	zxx	xx. x'c;	xx;-;:	u:... x'.	xxx	z:,:.Y		xx.x-:,
	c:\ i-:· : CAE ...err:-,..	Gra6e	x;-::x	xx.;,;	xxx	xx.•.,::,	xxx	;,-:x. x:::;	:,:zx	
		C;l'.aCe	xxx	xx.x	xxx	xx.x	xxx	xx.x')	xxx	xx.xi;
		Gracie 3	:-:xx	x;,:.x	xxx	xx.;,-:	xxx	xx.	xxx	zx.x ;)
		Grace 4	xxx	xx.	xxx	x_;.:.x	xxx	xx.x%)	xx:<:	·•·x. xs1
		G:rade 5	xxx	xx. :-:-Z 1	xxx	xx.z"o'.	xxx	:n: . :°0 \	zx;-:	;-:::;-:. x%1

Z::c..

The deno:r.ir.a.toY foY percentages is the nu.,.Llber cf patier,ts in the Safety ?opc:laticn

::ote: Tt.is table contains counts c:f patients. If a pa-;:ient experienced r:.\Orf, than one episode 0f an adverse ever:t, the patient is coc:r,ted onl. once within a prefel'.red ter:r,. a patient expel'.ie::ced r:corF> than one a.dverse event within a syste:r, ol'.gan c2-ass, t 1e patient is coint e d cnce for each preferred ter::I acci. once for the systeB orgar: class.

Table 14.3.1.15

S,.;."cL-n.ary of TE.D,Es Causing :Jisccntinuatior: frort: Study T.reatment n·., CTCAE and worst CTCAE grade Sc.fet ?op:..:.la::ion

	:ontrol (N = xxx) n (%)		Low CX-01 (N = xxx) n (%)		High CX-01 (N = xxx) n {%)		Overall (N = xxx) n {%)	
?atien::s w'._t:h Any AEs leaciing to treatment	xxx	xx.:-cs'	xxx	z:,:. x%'	xxx	zx. xf,)	x:-:x	xz.
Patient.s ,,;ith Specifie::i TEA:Ss .leading to c:.reat2ent	xxx	x:-:. xS',	xxx	xx.z':i	xx:,:	xx.x'-5)		;,:x .x%)
?atie:1ts w.::.th Any AEs leadin9 tc treatment reduct.::.on	xzx	xx. x'c'	xx;-;:	xx.z%	xxx	xx.		;,:x.x\)
?atie::ts ,-,ith Specified TEAEs leading to ':.reatrr,en:: ,.-ed1,;.ct.::.c.:	xzx	xx.:-'"	xxx	zx.:,%)	:-:xx	zx.	zx:,:	x:,;.x::,J
?atier-,ts 1-;ith Any AEs leaC:in;; to treat.me	xzx	xx x:o i	xxx	xx.x'.i;)	xxx	xx.x'o		xx.xs)
Patients c-;i th SpecifieC TE.AES leading to treat:nent ri.is co:,ti:::.:a ti on	xxx	:cs:. x':s':	xx:,:	xx.zSJ	zx:-;:	xx. c\	z{x	xz.:·d;)
Patients -1itD P..ny se,h:cre F-.d·,,erse Svents (SAEs)	xxx	xx. x -.,	/:x;,:	};;:.x'/;)	zxx	i":x. z'S)	z:-:z	XX. X'o i
Patients ·,•:ith Speci-::ied ?reat::r:.en:::-i::merge:-i.t Severe Adverse Events (TESAEs}	xxx	x}:.	xxx	xx.X's)	xxx	xx.	xx:-:	xx.x%)
Patier:ts Any S.AEs leading to death	xxx	x:z. x ; o"	xx:,:	xx. x"o)	xxx	xx.x0)	xxx	xx. x%)
lead.1:.g to death	xzx	z:-: .. ,,,._		;.:x. x'h)	;;xx	;,:x.x%)	z;-:z	X>:. x".,)
Patier:ts ,.;.ith P.:1y SAEs leadi:,:; to treat:r,ent ciiscor'.!tinuation	xx:<:	xx.x'o\	xxz	xx.	xx;-:	xx.x0	zxx	zx.x"o)
?atiects with Specif.::.ed TSSAEs leading to treatment dis ontirn.;ation	%xx	;0 -:. x ŷ 1	xx)'.	x:,;.xS'	:;.:x;z	xx.x':	xxx	:e:x. x%)
Pat e:-i.ts ·,•:ith 2"-Y study Cn:g related AEs	xzx	xx.xi':	zxx	xx.xi	xxx	xz.x%)	xxx	xx.x •'•
Pat e:-i.ts wit:1 any study Cr g :::-elated specified TEAEs	x:-;:x	xx. x° .	xzx	xx.x-\::\	xxx	x;.:.x%)	z,:x	xz.x%]

The der:.orr,::.r:.at:Jr fa;:: per:-centages is t:-.e nuw.ber cf pat.i.ec,ts ir:. the Safety ?opulaticn

<cte; This table contains 20:..::.::its of patients, If a patie:ct experienced :w.ore than one episode 8= an adverse eve:1t, t'.ce pati-2:r:t .::_s counted only o:r:ce ·,;i thin a p:::eferreC ".::erm. a patie'1t experienced ::.ore t:?.ar:. or,e ad·,re:::se ev·er:.t •,;it:,in a system organ class, the patient is coc:.:-,ted once for each preferred ter::., a:i.C. or:.ce for the sys terr, organ class.

Prog::a:s 1\ar:-,e: Date Generated: Page z of

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Table :4.3. 16 Su.--:i.mary of TreatE",ent-Related TSAEs Causing Disco:,-;:::inuat.i.on frorr-, St,.;.dy T:::-eatmer.t Dy CTCAE and wc.::-st C?CAE g.cade Safe-:::y op-,.:a c .... on

TESRE/Series REAPs by CTCAE and

Table 14.3.2.1
Death Listing
Safety Population

Control

Patient/Age/Sex/Race	AML at baseline	[illegible]	Study drug Start Date Day) /End Date (Day)	Last dose (unit)	Date of death
XXXX/38/M/XXX	[illegible]				[illegible]

Programming Notes:
Repeat for each Treatment group
Program Name:
Listing Source:

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Table 1 .3.2.2.1

SG.'\Ena::::; of Labore.to.::·,,- Test Results and Change f:::o:r, Baseline by Visit-3one Marro,..:

Safety Populatior,

3-,..-:v Vi"i_ c	ccr.t:::ol ""XXX) (%)		Lo·..,· CX-01 = ;,:xx)		:iigh CX-Ol 'JJ = x;{x: n		Ove:::all :-:xx1 n	
3aseli'.1<2								
	ĸxx		XXX		x;,:x		XXX	
:mean (s.d.)	;,o:.x	xx.xx)	xx.x	(xx.xx'.	·:-:.xx	(xx.;.:;s:)	xx.;,:z	x:·:.xx)
median	½x.x		zx. -·'				xx.z;,:	
:;:iin	:<X. X		x:, .z		xx.z		xx.xx	
:nax	xx.x		xz. x		.:-:z .x		v-· vv	
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:71.earr (s.c:.:	;-::-:.x	x;-:. xx:,	xx.x (xx.x:{·,		xx.xx	xx. xx',	xx.xx	xx.xx)
cnediar:.	x-:. x		x		;,:x.z		:,:x.	
;:n1..n	x;,:.>-:		x:-:.x		xx.;.:		xx.xx	
max	:,:x.x		xx.x		xx.		x;s.;,o:	
Change £:::o:r, 3aselir,e								
rr	xx;.:		;,::o:.		xxx		;.:xx	
mean (s.d.)	:,:z.z	xx.xx)	xx.x (xx.xx)		xx.x:,:	xx..,.	yy"	xx.:-::-:)
median	;,:z.x		xx.x		xx.x		:-ex.xx	
m.l.n	x'..x		xx.:-:		;-:x.;.:		xx.x:-:	
c2ax	.x		xx.x		:o:.;z		xx.xy.	

[C6ntinti'e fOr;'-rE!maining post-baseline time poin.tS]

:'iote: For cha::-.ge £:::or:i :Jaselice cal,::ulatio2s, this tables 0,.1,, preser,ts :::esults fo::: 9atiects with non-:::;-.iss:.ng data 2t ;:)aseli:1e a::1ci time po.:nt of interest

?rogram Name: Date Generateci: Page x of

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Table 14.3.2.2.1
S:Z'etary of LaDoc:atory Test Resc:.lts ar,d Change frorrc Baseline by \'isit-3one Mar:cow
Safety Pcpe.l a t i or,

Study Visit	:ontrol (N = xx::..,;:.		Low CX-01 (N = XXX)		High CX-02. ,::_,: = xx:.,,·, n (!; 1		Over.3.ll xx;{}	
<\'isi c.>								
Auer rods								
I'.J	,::,;x		xxx		xxx		:,::o:	
Yes	>:x:-:		xy.x	xx.x'.s'	xxx	:c:.x%)	x;-:;,	xx.:,·
:-le	;{;"'.x	Y.X.	xxx	xx.x%	xxx	;-cx.x'"\	:s:x:-::	xx.x":)
Response								
	Y.:•:x		xxx		xxx		x;,:x	
Mo::::-phologi:::: corr.plete rerr,issicr, (C?.)	Y.:<:x	xx.Y.o'	xxx	XX.X'c'	xxx	(zx.	·•:xx	xx.x%;
Co::!:tplete re:nis2ion without reco-ery o-f platelets (CRp;,	xy.x	xx.	xxx	\xx.x	xxx	XX. :-:7c)		xy.x
Complete :::-ecTLission withct:.t ne,.;:::::::-ophi2.s and/or platelets rc?i)	'{xx	;,:x. x't'	:{xx	xx.x	xy.z	x:•:	X>:z	xx.x%
?a::tial emissio:1 {?R)	s:xx	xx.	xzx	);x.x	xx;-:	xx.x ,	'.c{x	z:-:. x';-
Progress ve dis as (PD)	:<:xx	7.x. xi;:	xzx	xx.x	xxx	xx.."'!/,	;-.:xz	
Stable D sease SD	:;;;-:x	.,.. . : 'c	xxx	xx.x	xxx	xx.z%	xxx	xx.;-.:%
Relapse c:crr, C?. C?. /PR	,::s:x	>:x. x'c	x;-.:x	xx.x'o	xxx	xx.x?i	zx:,:	xx.x':,:
In.deter;:n !:ate	,:xx	x :.x:;,•	:-:xx	xx.x\"o)	xxx	xx		x;-.:.
U:iknown	,:zx	xx.xo;;;	:s:xx	xx.x%)	xxx	xx.x%	:,:xx	zx.x% "

[C6nti'nile·. £Or r·emaiii.ihg post-:'ba·s·e1"i -ne tim·e- -pointsj_

:,;ote: *Io:::* char:ge frorr, baseline calculations, -chis tables o::-,l·-· p:::esents :ces;,;.lts for patients ;.:ith non-r:--,issl.:1g data at baseline a.r"d t:i.me point of interest

Table '4 3.2.2.2

Su.'1lc;a:r:::-' of Labo:rato::::-y Tes:: Results and Cl"",ange ::'::::::-:r:. Baseline by Vis.::._t.-:-ie:;r,.atology wi::h CBC Safety ?cpulation

Hematology -;..,;-i t.:l CBC: f.err:ogl.obir, ,: *u:-ii* t)

Study Visit	:ont:col {N = x;•:x) n (%)	LO\•! C, - v. xxxl r,	:.::. g"" r:x-n: (1-, = XXX)	Ove::::-all '.l.(= XXX) c,	
Baseline					
n	xxx	xxx	xx	xxx	
— — · e	xc{.z xx . :z '.	xx.x xy.xx)	x:,:.x>c (xx.x;-.:)		xx.xxj
'<ed.::_ar,	xx.x	xx	xx.x	x:·:	
D1:1	xx.x	xx.x	xx.x	xx.x:-:	
r:-,ax	xx.x	xx.x	:-;;-.:.	;,:;,;.:---·	
<Visit>					
n	xxx	zxx	xz:-:	;-:xz	
r:;ea.n \s .d.	xx.x i xx.xx	xx.x (x;-:.xx:·	xx.xx { xx.xx)	;-.;,:..;-:z	xz.zz)
Dedian	xx.x	xx.:-:	xx.x	:,:z.xx	
r::in	xx.x	xx.x	z}:.;-.:	xx. x;,:	
max	xx.x	x	·'·,:.x	x:-:.xx	
C:J.ar:s:;e from :Sase::.ine					
n	/:xx		xxx	xxx	
r:-,ean (s.d.··	xx.x (xx.xx)	xx.x x:-:.x:-:}	xx. :;,;-.:.. zx)	:-:z.zx	xz.xx)
:-edia'".'	xx.x	:,:x.x	x:·:. x	:,;:z.xx	
XIT1	xx.x	xx.	};;-.:.. z	:,;:;,;.:-:z	
:::ia;.-:	x;-.:.x	xx.x	:( ):	xx.;,o:	

t-t::ont:LnUe £or remaining pos_t_--:baSeline time 'poihtSJ

Note: Fe:::- cha;:-;ge :E:corr: baseline calculaticn.s, this ::ables only presents resul::s :::ol:" patier,ts wi::.r". no,,-r:--.issin:; data at baseline and tirr,e point: of inter:-est rOgr -rimi,hg, Notes,:

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Table 14.3.2.2.3 su..,1Iriery of ::.aboratcry Test Results and Change fron, Baseli:1e by Visit-Coagulation Safety Population

Table 14.3.2.2. S:.;m.r y of Laboratory Tes:: Results and Change from Ease:cine by Visit.-Se:ru!ri. C'.'",emistry Safety ?opulatior:

Table 14.3.2.2.5
Shift. ?able of :,anoYa o::::: ?est Results icm.;.nts:, b:, : -:::_CTC.".E g:::::ade: He"1atology ,,,ith CBC
Safety ?opulatio:-:

HeBatology with CBC: He:r,oglobir,	Control {N = XXX} \·;'erst Occu::-rence	LOK CX-01 = xxz· ____ Worst Occe,::::re:-:,:::(	High CX-0' (N = :-:xx) :·Jo:rst C·cc,1::: -rence
	2 3 '	?J	N 3 '
Change f.::::oc:-, ,,:erst grace to last grade:			
o	xz}: xxx xxx xxx xxx	xx}: xxx xxx ZXY XXZ	xx:{ x;<z xxx :,:;,:x x :>:
-1	XXZxxx xxx x;u: xzx	xxz xzz XXX :,;x:,: :-:z;,;	XXX XXX Z:{x xx;{ xxx
	xx_;.: xxx xxx xxx xxx	:·;:;;,_;.: xxx xx:-· xx: .. x; ';-:	XXX XXX };:,:x ;{:-::{ :,;xx
-3	zxx :co: XXX xxx XXX	x: x xx:,; :-:xx ;,::, x xxx	xxx xxx x:<x XXX XX>:
Only o:1e :c.easure,r,er,t e::c ..	XXX x:,;;:z zxx x}:x xzx	:zxx :-:x:s zx;,: z:,:;,: xxz	xx:< xx:< x:c•: xxx xxz
	xxx :n::z xxz zzx xxx	X>:x xxx xxx x}::, :,:x:{	ZXX XXZ '.{xx xxx xxx
+2	}D:x ;,;xx xxx xxx xxx	:-:zx xx:-.: xxx :•:xx ·,;;,:x	xxx ;::xx XXX :-:-:xx X:<:i:
+3	xx}: zxx xxx xxx :so:x	xxx xxx xxx }:xz _;.:z;-.:	·,:xx %x:% x;-::x :-::xx x:-:x
.Only or,e !1'.easure,:tent etc.	·-:xx zxx xxx xxx xxz	x::-:z xzx xxz xzx }:x	;,; XX>; XXX XX}; XXX

Note: This table p:::ese:1:::s ,,o:::st to last va:Cc;e fro::-:t A?:. ;ia;es, by definitior, Ai'.: is desig:ied to :::ecc:::::d s1nto;,;-ard clinica::. eve:-its, so im:x::o,,e::ne:1ts are usu:ally not reco:::ded tr'£ database, this limi-cation of data is ic;rportar.t for t:'..e i::terp::etatior, of this ::able.

P,r; /gr'.a,ffimin-g Note-s ,

Repei:it "for eaCh lab -parameter

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Table 14.3.,2,6 Shift Tab:Ce of Labora-::o::-y Tes:: Resc.::2.ts (co;,;_nts) by NC: C:TCA-2: grade: Coaq,__;_latic:r, Safety ?opulation

Table 11.3.,.2.7 Shif:: 'table of Lr.borator,- Tes:: ?esc:.lts (counts) by NCI_C:TCA2: grade: Ser T Cherr,istry Safety Pop;.,lation

Table '4.3.2.2.8

Shi£-:: Table of ::.,aborat.ory Tes-:: Resc:lt.s \%) by NC: CTCA -;rrade: Hema-:::olcgy *,:it:I* CBC Safe-:::y ?opulatior,

Eematoiogy with CBC.Hemoglobin	Cor.trol				I.o·,..,· 0:-01				E.igh CX-Gl			
	,:i,.:, = xx:-::				(N = xxx)				'}) "" xxxj			
	Korst GCCT: P r c o				C\o::st Occu::-::-RT:CR				:;-Jors-::: Occ ∅l.r -::enc e			
	l'J		3	4	N		2	3 4			2	3 4
Cha:1:;e frorr, wo.:::st g.:::acie to lase: grade:												
C	;-:xx :-:zx	xxx	zxx	xx;,.:	xxx	xxx	xxx	xxx xxx	XX',: :o:x	xx:;;:	xxx	xxx
	x;-;x xxz	xxx	xxx	;::-:z	xxx	;-;;,;;,;:	:<'.xx	xxx xxx	·,;x;-: xx;,;	;.,;xx	x;.:x	xxx
	xx:-: :-::-:;<	xx;-	xxx	;,:;-:x	xxy	;o:x	x:-:x	xxx xxx	x;,::,; xx:{	xxx	= x;-:	}(xx
-3	xxx xxx	xx:<	xxx	:•:xx	xx;{	xxx	xzx	xxx zxx	xz}; ;-:z:-:	xzx	xxx	xxx
cn.:::..y one :u.easureZ<1er,::: ec:c.	xxx }:xx	xxz	xxx	xxx	xxx	xxx	xxx	x;o: xxx	zxx :<'.:-s::{	xxx	?:x;-.:	xxx
	xxx x:{x	xxx	xx;-:	xzx	xxx	xx;,:	;-o:x	;,:;,:x xxx	:-:xx xx;.-:	xxz	xxx	xxz
	::-o:x xxx	xx;-.:	xx;,.:	xxx	xxx	:{xx	xxx	xxx xxx	zz;.; xz:,;	xxx	xxx	xx:{
..:.3	;.-:;{x	;.-:;-.:;,	x:-:x	x:-::,:	xx:--:	xx:--:	xxx	xxx :<:xx	;o::-; :-:zx	xx;-.:	xxx	xxx
. Oii.:..y one :c.easurezr.en.t etc.	xxx xxz		xxx	;,.:xx	xxx	;-:x:-:	:-::-:z	;--:xx ;,:xx	:-:xx	xxx	xxx	x:,:z

: ote: ihis taCle presents wcrst to last valc,e fro;r, A.S pages, by· definitior>. AE is designed to record ,_;_::tOh'ard cl.irLi.cal eve:r.-'.:s, so irr,proveu,ents are use.ally not recor"cied ir:: the database, t'.'",is limitation of data is irnportar,t for '.:he i::terpreta'".:.io:: of c.r'.is tabl.e.

?:to(Jramming-:ii6:tes::

R€pE:"a'.t fo_r. -iat:h .lab_ -_pa.tB.rneter,_ % fo.i:'- the denominato'r _is _bi!sed on the··t6tal ·wi"t:bin- .each:-·rBC_tarigle ·cell.

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Table "L 3. 9 Shift Table of Laborato::::·,, Test Res'.llts t:-y 1:CCI_CTCAE grade: Coagulation Safety PopcJ.la-:::ior.

ab::.e .3.2.2.10 Shift Table of Laborato:::::i Test Resu.: '".:.s by UCI CTCP..E g::::ade: SerGTc Cf',emistyy Sa:::"ety PopcJ.l.abo::

Table .r.o;.3.2.2.ll
Shi.ft Table cf Laboratory R<csc:lts (co'..lnts) He.satology with C3C:Her:,oglobi::-:
Safet'.f· Popu.lc.tion

Hematology with CBC	Control (N = XXX) Baseline				Low CX-01 (N = xxx) Baseline				High CX-01 (N = xxx) Baseline			
<Visit>												
Lo;,· (L;	xx;-::	XXX	x:,:x	XZX	XXX	xx;,:	x ::<:	XXX	XXX	:,-:x;-:	xxz	;,;:,:x
Nore.al (:;,)	XXX	XXX	XXX	XXX	xxz	:-co-:	x;.;z	;-:x:-::	x;-:x	L:xz	xx:-::	z:-::x
Eigh (1'1)	XXX	XXX	XXX	XXX	x;-.:x	;-::x;-.:			XXX	;,::xx	XXX	x:-::x
Total ·:Tot)	:{XX	XXX		XXX	XXX	XXX	;-.:;sz	:-:::-;;-.:	:,:x;-:		ZXX	XXX
<Visit>												
i,C.-; (I. i	ZXX	XXX	:n:x	:S:XX	XXX	;,;x:,:		XXX	XXX	zx;-::	;-:;,;x	XXX
\:_____1	ZXZ	zz:x	XXX	XXX	xzx	;-::zx	:,;;-::x	: :-:x	XXX	;-::xx	XXX	XXX
Eigh {:-i)	zx:-::	XXX	XXX	XXX	XXX	:-:::xx	XXX	xx:-:	X'.X	XZX	XXX	XXX
Total ,:rot)	XXX	XXX	XXX	XXX	xzx	:-:::xz	zxx	:-::xx	XXX	XXX	XXX	XXX

<_continue for ·an: \risi ts,>

:'late: ?his ;:able or:ly 9Yese:1ts :results for pat.ien.ts with !"lon-rr;issing da;:a a:: base2.ine a:l'.::,. the tirr:e poir::t o:!: ir::terest.
FrOgr-a,.--mr,ing - Not.es:
:R.epeat:):cr. ea'Ch l:ab·-para-n':lt:er
?rog:::artc Na!T!e: iJate Ger::era.ted: ?age ::-: of
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7ab.l.e 14.3.. 2 11 Shift '.ra:Ole of Labo::::ato:::y Results {counts)· Se:::-""-" C:lemistc,-:Albu,,-r,in Safety Pop:;;_laticn

Table 14.3.2.2.14
Shi::'t Table of Laborat:cry Resc2lts {%\: H.e:ri.atclcgy ·,;:'._th 23C:rte::-,og2.o:Ci,.
Safety Population

Hematology with CBC	Control (N = XXX) Baseline e::			Tot	Low CX-01 (N "" XXX} Baseline L	N	H	Tot	High CX-01 (N"" XXX} ---- Baseline 5-:			Tot
<Visit>												
Lo:,:	X:G:	:,:x	xxx	zx;,:	x:-::x	xxx	xxx	xz;.:	:G:x	xz:-;:	xxz	XXX
Nor-ma (Nl	;.;:;.::;;	xxx	xzx	xxx	xx	xxx	xxz	xzx	·,::-:;-;:	z/:x	:-'cxx	xxx
Hic;r'. rt)	xxx	xxx	xxx	xxz	xxx	xxx	xxx	xxx	z:-;:;-;	;,;x;-::	zxx	xxx
Total (Tot)	zxx	x:-:::-:	/:xx	;,:x:-:	xxx	;,:xx	xx:-::	xxx		:,;::,:z	xxx	x: x
<Visit>												
Lo:,· \LJ	xxx	xxz	xz/:	xxx	xxx	xxx	xxx	zxx	x:,	:-:xx	z:-;:x	:-::xx
No::-:rcal (N)	x;o;	xxx		xzx	xxx	zxx	xxx	xxx	;.::,n·			xxx
Higr', (:-i;,	xxx	x:o:	xxx	xxx	xxx	xxx	xzx	xx:-::	;s;:, z	xxx	:s:xx	xxx
To-:::al '.Tot)	;:: ·'.x	xxx	xzz	xx/".	xx:-;:	xxx	xxz	xx:-;:	xxz	xzx	xxx	xxx

<Cont±nue ·,*£6.b* ··all - Vis'its>

:;;oc:e: This table only preser;ts res,ilts ::or patients ;,·it:'. non-:;:.issing data at baseline a:-,d t:-1.e tirr,e poi::-,:: of i;;te;:est.
Progra,_"mm.l'ng··l ot.e·s:c.

R€Pea,t :.Jo,r eaC11: lci.b parameter:, for the denoffiin·atcr is based on tliELtOtaJ.: ¼"ithin each -sq,Ji:;;i'.e cell.

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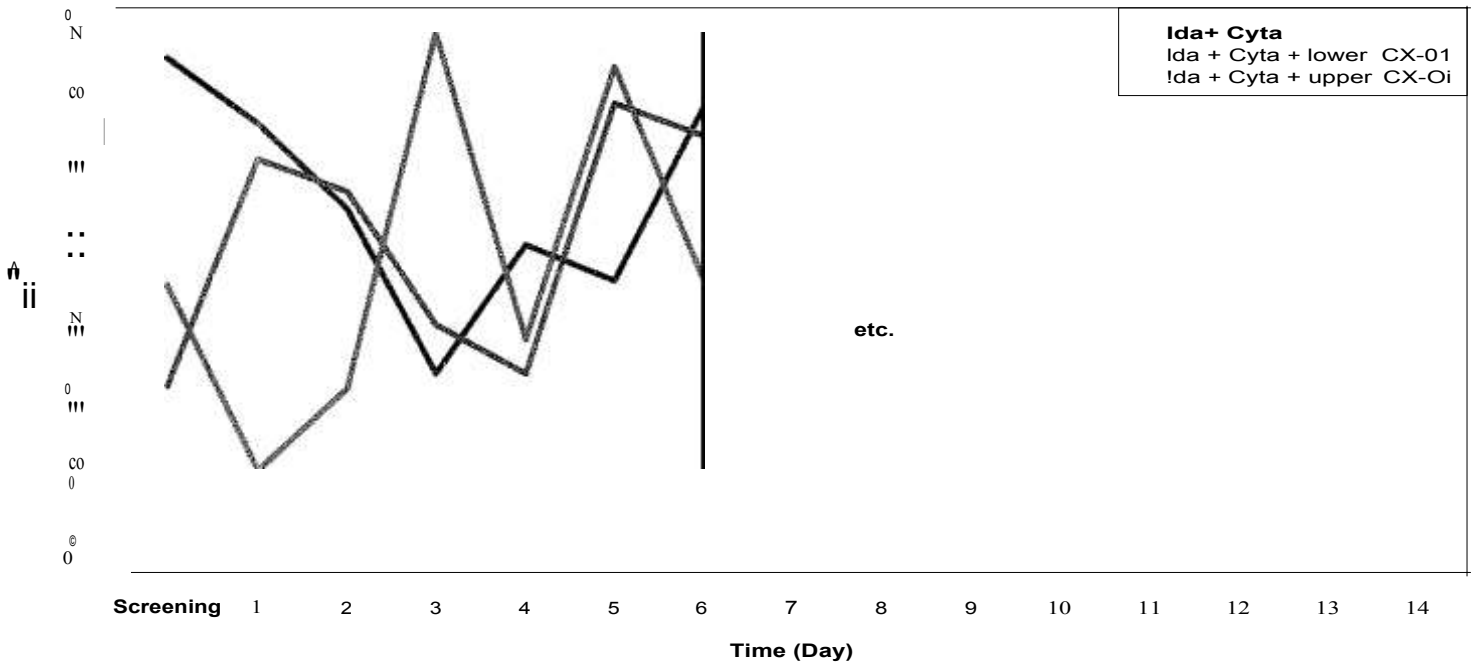
?able l .3.. 2.16 Shift Table of Lal::oratory ?..es;;lts ('i'· · Seruc.I Che:m.istry:Albc1<--::l:i.D sa:::et;/ Pop:.i.latio,,

Figure 14.3.2.2.LI
PT/IN? ove;:;:ir::-,e
Safety ?opc:la;:ion



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epea-:: fol'.: the followi::.g displays:

Figure 14.3.2.2.18 APT'.:.' 0'7@r ti:me Safe-::y POF-Jlation

Figure 14.3.2.2.19 P,nti-factor Xa o·--e,::: -ci:ne Safety Pop,..:lac:io:n

Figure· 3.2.2.20 ?ibrinogen o·ve::: "'.::i",e Safety Pop,_:_laticn D-

Figure 14.3.2.2.21 di:ne:r ove:::- time Safety Popula-cion

Figure 14.3.2.2.22 Platelet coun:: over -::i",e Safety ?opula-::.io:1

Table 14.3.3.1

Summary [illegible] at Screening and Vital Signs at Screening and Start of [illegible]

Safety Population

	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]				
[illegible]				
Weight (kg) [illegible]				
n	[illegible]	XX	[illegible]	XXX
mean (s [illegible]	[illegible]	XX.X	[illegible]	XX.XX
median	[illegible]	XX.X	[illegible]	XX.XX
min		XX.X	[illegible]	XX.XX
max	XX	XX.X	[illegible]	XX.XX
Height (cm) [illegible]				
n	XX	XXX		[illegible]
mean s.d	XX.X	XX.X	[illegible]	[illegible]
median	XX.X	XX.X	[illegible]	[illegible]
min	XX.X	XX.X	[illegible]	[illegible]
max	XX.X	XX.X	[illegible]	[illegible]
Heart Rate (beats/min [illegible]				
n	[illegible]	XXX	XXX	XXX
mean [illegible]	[illegible]	XX.X	[illegible]	XX.XX
median	[illegible]	XX.X	[illegible]	XX.XX
min		XX.X	[illegible]	XX.XX
max		XX.X	[illegible]	XX.XX

[illegible] Generated [illegible]

Summary

SBP (mmHg) Screening:

n	xxx
mean (s.d.)	xx.x (x.x)
median	xx.x
min	xx.x
max	xx.x

DBP (mmHg) (Screening

n	xxx
mean (s.d.)	xx.x (x.x)
median	xx.x
min	xx.x
max	xx.x

Date Generated

Table 14.3.3.1

Su.Tu--nary of 2:COG S-:.:atus at Sc.:::-eening and Vital Signs at Scree?:J.ing ar,d Start *O::.* Cc::1solidation Cyc.:.e Safety ?opulati::Jn

	:cr:trcl = xxx)		:,o'.'-' D'.-01 {l'i = ?:zx: ...,!?.·		High CX-01 (N = XXX} E (;)		Over2ll CJ xx r. :S:,	
Weight i/;g} (Ccnsolidatio:-:: cycle}								
c	xxx		xxx		xxx		xxx	
:,,ean (s.C..)	x.x	}:X.XZ}	·-:x.	xx.xx)	xx.:-:x	xz.:,,;x)	xx.·.-	;,:::;-:.
median	xx.x		xx.x		xx.x		xx.xx	
17,ln	}:X.X		""(,:,:		xx.		xx.xx	
c:iax	x::-:.x		;-:		xx.:,:		;-:x.x:,::	
Height *ter.)* Co:csolida-:.:ion cycle)								
c	:,z:-				xxx		xxx	
,near, (s.d.	xx.}:	zy .xx1	y.z. v	xx.xz}	:;:;, 2x	xx.xx)	xx.xx	·.•,,:.:c-:::;
.:c:edian	xx.		xx.Z		xy..		xx.:-:x	
'.c'.in	xx.z		x:•:. x		:-:x.x		xx.xx	
:max	xx.:,•		xx.;-:		xx.:,::		xx.xx	
Hea.:::--::: ?2.te (beats/min) Cor:solidation cycle}	x::--:x		x::-:x		xxx		xxx	
	xx	::-:x. xx!	:-:-:.,-I	xx.:-::x}	xx.xx	x;-: xx)	zx.zx	x:-::,
::r:.ean (s.d.	xx.		xx.'>'		:o:.x		:x.xx	
.....d: an	;,::,:,x		xx.		zx.x		xx.x:	
Tc,in	xx.		xz.		xx.x		-.-.. xx.	
IT;2x								
SB? (.:1,;c: g) Consolidation cycle)								
	:-:xx		x:-:x		xxx		xxx	
::-::cear. ,:s.d.·	xx.x	x;-:. xx)	xx.	xx.xx}	xx.zx (xx.xx)		xx.xx	x.xx',
s.edia-:1	xz z		xx,'>'		xx.x		xx.xx	
:n.ir,	xy..x		x;,z. x		xx.x		xx.xx	
:2.ax	xx.x		x:-::.		xx.:--		xx.xx	
DBI? (rur:Hg) Co:1solidation cycle)								
n	xzx		xxx		XXX		xxx	
:nean (s.d.	:xx.x	zx.xx)	xx.x	xx.x:-:}	:-:x.xx (xx.xx)		X}:.xx	(xx.xx:,
:median	xz. :{		xx.x		xx.x		xx.xx	
min	xx.x		xz.		xx.x		xx.xx	
max	:x:x.x		xx.x		xx.x		xx.x:,::	

?rograrc, Name: Date Generac:ed: Page x of y

:.,is::ing Sou.::-ce:

Table 1 4. 3. 3 2
Shi::'t of ECG Re s o-ll t s
Safet:y- Population

	::antral {N"" XXX) n (%)		Low CX-01 (N"" xxx) n (%)		High CX-01 (N = XXX) n (%)		Overall (N"" xxx) n {%)	
<Visit>								
	x}		xxx		x:o:		xxx	
:'rorr. r-,ot clinically signi:'icant abno:r;r,al								
res-..,lt at baseline to abr-.ormal and clicically sig:1ific2r.t :-es'.llt	xx>!	xx.x%)	x:c-:	xx.x"'	x:,:x	xx.:{'°"	xzx	;-:z. ;{\;)
?rorr, abnonr:.al and C:inicai::.y signif ca::,t								
res'J t at baseline c;o nc-t clinic2lly sign ficar:t abnormal :resc.1.l''::	xx	xx.x%;,	x:s:x	xx.x%)	x;-:x	="0,	xzz	x:s.Y"'
tl: h-- - g'°"d	xxx	xx.x%)	xxx	xx.x·3:	xxx	x':c\	xxx	XX.X'2

<. Rej;:ieat for all ,visits where ECG performed >

Note: N: ?Jormal; ANCS: A.Dno:rrr,al, Not C:linica.!.. ·., Significant; f'.CS: P-..D:,o:-::mal, Clir,ically Signi:':icant
Prograo:1 :'1ame: Date G12nerated: ?age x of
Listing Source:

Lisc:.i:1g 16.2.1
Subjects Screened

T:reatr.:.ent g:roup: *Treatment*

Site	?atier.t/ Sex/A'.ie	Race	Date of Info:rrr.ed consent	;:... :.....=.,. Reasor; fo:r Scree:-: Fai.'..c.:re
xx	xxx/M/ *4* 5 XXX		D':-ir ...:My\-yy	*Reason*
xx	xxx/F/35	xxx	DD:-.JMMYYYY	***Reasor: 2***
.xx	xxx/M/25	xxx	DDi'lMM'.:"YYY	***Reason***

P·r·o9 -ra.'r.ming Nb:te_S:

Repeat: "for all T-reaL--nent groups: _Sort by Treat_ment ·gr:o_up, ·sfte·. and_pat"ient

Pro-;:ram Name: Date Ge:1e:ra pri· ?age x of

Listing Sou:rce:

Lis::ing 16.2.2
S:.ibject Disposi tic:-.

Treat::ne1;.t group: *Treat:;;e;1t*

Site	?atieEt/ Se:,:/Ale	*?.ace*	Co::::.pleted St;_;_dy	?rimary Reason ::or 'iiiti:drawal	:ate ofWithdrawal Day) '.a]	ate of ast Dose of tudy :'reatmerlt gro-c1p Dal) {a]
xx	xxx/M/ 4	xx2'	'- 0	*Ree.so.,*	C::•Dm,11-:'.YYYY {XX	DmJMMYYYY (xx
x:	xxx/F/3	xxx	:-;0	*Ree.son 2*		DDMMM'iYT:'. (zx
	}:>:X/[•1/2	XXX	Yes	*Reasor:*	(xx	DDt-!M.MYYY:' (xx

[a] ?,elative to the da·, of r2.ndomizatio:1
P:r_og·ra."r,ming:.Notes

R'ep·eat· for. ,all 'f:ceati:ne·nt groups · Sort by T_i:Ji:ci£itte11t·.·gr_oup, site. ind Padent

"·_o__r-•·· ·L-_n-'": Date Generc.teci: ?age x of y

Lis ;::ing Source:

Listing lE.2.3
Sc1bject :reatmer;t Allocation

Site	?atient/Sex/.n.qe	Race	Random:..zed ?reatrr-ar,t Grcc1p	Date cf Rand:::mization
xx	xxz/11/45	*xx;.;*	xz;,-:	DJ11:'".:•'.':...':YY

P_ic,g'ra.-n.7"< _il$_-_:N t -- - _:
-Re,Peat for all tr-eat.c--nent. roups. Sort'b:':i' site- a'nCl patient
Progract, Name: Sate Ge::erated: :?age *x* of y
Listing Source:

Listir,g 16.2.4
?ro"".::ocol Deviat:ions

T:::-eatrr.ent group: *Treatmer:t*

Sit:e	?atie:1t/Sex/Age	Race	P.ny Protocol Deviations?	Date	;:>ro;:ocol Deviatio::1 Catego:::-y	Details of ?:::-ctocol Deviatio:1s
xe:	:..;:/M/4S	xzx	Yes	I):>'eMcJ:YVVY	z;-.:xxxz;s:xxxzxxzx;	x:-:i{XXX:•:xxxxxxxxxx :xx

No-::.e; Jevia;:ions were ider,tified a,:d categorized prior -"""cl da '-"'-.,,,,""s" lock. ?ac:ier,t:s rrcay ha-ve may have more than or,e Deviatic-:-;]..e2.ding to e:-<:clusio:1 fro:c,

Prog:r:a,,"nTili_ri.g ◊Ncit es :

Repea:t..foi all .Treatment··tjio.u:ps·. -sort by ,T:rea:tm .nt:.group, site; and· patient

PYogra;r, l:Jame: Date Ger:erat:ed: Page x of

Listing Sou.rce:

Race

xxx

xxx

Programming Manual

Sort by date and patient

Program Name:

Listing Source:

Listing 16.2.6
Excl;_.;_sior. Criteria

Site	?ac:ie:1t/Sex/AB:e	?..ace	El	E2	E3	:'.-4	E5	6	S7	£8	E9	E1G	::C:ll	cl2	e,13	E14	El5	E16	El7	:'.-18
xy.	;.::x: h-:/45	xxx						Yes												
xx	:xx//35	xxx				Yes														

Prcgratmning N0te's:
Sort- by";_si'te and _patii:=-nt
F c-,.ha,.c ,.:o".e. Date GenerateC.: ?age x of y
Listing So'J.rce:

Listing 16.2.7
Study Pop,;lation

Treatment g.:::-oup: *Treattr:e.,t*

Site	Pc.tie:it/ Sex/A2:e	Race	Completed Study	:T?	!??	So.fet·
xx	x;.;x/:-1/45	xxx	Yes	•-'es	:es	Yes

Listing 16.2.8
Demographics and 3aseline Characteris::ics

Treat::',ent grc·clp: *Treat:nent* ;_

Site	?atient/Sex/.Age	?ace	3MI Cetegory	3'.fi	We.-i.gr,,_ :g) /c•'c"' (CT:',;	SSP /:JBP	Hea:.::t Rate {beats ,?er rr,:-:.n *i*	,.,;,-f'.nicity	Time since F>2.L ç :. ç.....0"'.:'" ("::'ear)	pJ.;l.,	;.;-:-ese """" of 2:-,y r e l e¢a :-.t ...-"'ci:.a' r.: sc ---- ., or ¢::rZi.C"". findirnp	ECOG status	B.aseli,,r-> peri?l":era::. blas::s •;Yes/r.;c'	3aseline 3one Marro:,· blasts
xx	:-:xx/M./4S	x:-:x	xxx	x;-:x	:-:x/:-:;.;	:-cxh:;s:	x>:	xxx	xxx	:Je r,ovo	Yes	:-::-;:-:	xxx	xx:-:

l?ro9"r&lli"ning _rfo't;,_es·
Re'peat f6r a:Ll' T.reatmen·t ·groups. Sort by Trecatm':!i:tt: groUp, site am:l.patient
Prograic, Nar'.'£: Date Genera"::ed: ?ege of
Lis::ing Source:

List:ing 16.2.9
'."iedical History

?reatment group: *Treat,'Tie,-:t*

Site	Pac:ient/Sex/.'".fe	R.a.ce	Systerr: Orga;:-i Code (SOC)/ ?:::-eferred ·Terc'7![a]	Verbati:r,	Date cf Resc:. u:cicn
xx	xz:,:i'i:-i/45	x:-:x	z:xxxxxxxxxx;,:xx:--:xx/ xx:,.:x:,:xxxxxxxxxxxxx:,	xxxxxxxx;,:xxxz:x:-::	JDtfr:t, YY':.."Y.
			zxxxxxxx>:xxxxx:s:xx/ xxxxxxxxxxxxx,-:xxxxx;,:	:-:xxxxxxxxxxxxxxx	
xx	x:-:x	xx:,:	tior:e		

[a} HedDRA Dictionary (Versie,, xz.x) ,-;as used :'.:or coding.
[b] Relati7e to t:'"le da::,- ci: rar.dcrc,ization
'.i?'i.c/gral'l'.niiri'9. Note'.sf
p_e['eat· for.·.a11 ...-T.ceat:ffier-,t groups.· .SO,.rt; by Treatm:ent-·. -9'.i'6_1ipi. i;:'ite.,:• pa·t i€n_t., SOC and preferred te-tm.

Listing 16.2.10
Prior Medication

Treatment group: Treatment 1

Patient/Sex/Age		Dose/Unit/ Frequency/ Route	Indication	Corresponding term for concomitant disease or adverse event	
XXX/M/45	XXXXXXXXXX XXXXXXXXXXXXXX (XXXXXXXXXXX				DD-MMM-YYYY (XX) HH:MM DD-MMM-YYYY (XX) HH:MM /XX
	XXXXXXXXX XXXXXXXXXXXXX (XXXXXXXXXXX		Treatment of Adverse Event		DD-MMM-YYYY (XX)/ DD-MMM-YYYY (XX)/XX
XXX/F/35					

Listing 16.2.ll
Concorr,itant ('Jed.ication

Treatmer.t <;_!?U_F: *Treatxenr:*

Site	?a'.::ie7it/Sex/Age	Rc.ce	T::-ie.:-apeutic Class Cher::ical Subgroup c:2:1;:,r--i *c* Term '.a]	ose/Dr:i:./ .:ut ,.cy/	I,1dicatio:1	Co:rresponding ter:n fo:c cor,co:nitant disease or a::5.s;erse e-,,en:::	Sc;.:;rt Date ¹day_ ₄ IIT,8 Sto9 Date (day/ [bJ '.Cime/ DuratioH (da_:[S)
xx	*xxx/M/45*		xxxxxzxx:-;:x xxxxxxxxxxxxx ¹xxx:-:xxxxzxx:--:l	xx/ur,i *ts/* xx/ xx	ANL		DD:•11-l!-!YYYY (xx) o:;11:-;;wyyy {xx> HB:MM /xx
			xx:-;:xxxxxxx xxY.x) :,:zXXXXXXX (xxxxxxxxxxx) [cj	xx/uni:::s/ *xx/* xx	·J:reat:r,ent o::: P.d,,-erse Sver:t	x:-;:;-:	DDl/,l-lMYY-'!.Y (xx) / 001"11-:MYYVY (XX) */x>:*
xx	xxx/F/3S		No:--.e				

?rogram r:ame:
Listing S01.:rce:

Date Generated:

Page x *cf* Y

Listir:g lE.2.12
?ost Medicaticr,

Treat.rr,er:t group: *Treatment*

Si-ce	?atier,t/Sex/Age	Race	The::apeutic Class C:',esica:C S1.1bgrcup *G"',"""",'" r* -"""" [:o.	Dcse/Dr,it/ Frequer,cy / ?..o;.1te	:n...:.:.c.c ...i..on	Correspcr::di:ig ter:::-: for , o;.co..·' c.2:- dise2se o.:::::- adv-e.:::::-se event	Sta.rt Date (day) Ti::r,e Sc.o;--< *Uac.,:;* :::iay; ID 'T"irr.e/ =:uration (d2}_'S)
x:x:	x:-:x/ U 45	xxx	xxxxxxx:c-:x xxxxxx:,:xxxxxxx '.xxxxxzxxxx:-:x}	xx;':,ni ts/ *xx/* x;,:	."',,ML		c--•"'·c"",,, '.xz·, c.:,,.:-I'--11" Drn,,;1,, '.YY ;v E:i:1·'.M */xx*
			xxxxxxxxxx xxxxxxxxxxxx}:x (zxxxxxxxxxxx) [c]	xx/ur:its/ zx/ xx	Treatment of Adverse Event	x	*O:..hi•.!.'i* r , t \;--::-:;)/ Dc:'.i.'", i -'·<::--:)/xz
xx	xxx/E'/32-		•lone				

a WEO ;)rug Dic-::ior,a:cy (Versior. xx) ·,.,as used for codir.g.
b ?.elative to t:'1e day o-f .:::::-ando,nization r
grt,u\t.t..i_ni;(_Notes·:
·.Repeat fer all Ti€:citme_nt groups. Sort by Tr.eatmE:n:t ."gr 6 up 1 s_ite, patient, ·.s·tai:f date:'<Otnd.d.r:u9, clas·s:,

-isi::ing 16. 2. 3
Stud:i-' Drug Gsage a:1G. 2:zposu:::-e

1reat:rr,ent g:::-oc1p: *Treat;£1en+-*

Site	Patient /Sex/Age	eye.le	Initial ez:-Cl	Id.arc..:.biciD usage rate	Cyta::::abine usage rate	CXGl -_;_sage ra::e	,,.,,,,,atsent Sxpcsu;-:-P '.Jays;	l'J-c.<1.cJ:::er o:t days on a.ar_;:::,~c~-	;JtL""iUJer of days on Cytarabine	N ,cber of da ,s 0'1 CZ-en	Any Dose "to.. :..,.l:-"--'·ens"
xx	xxx/1•1/45	Ind:.J.ction		xxx	xxx	xzx	:".:-:::x	x:,,:x	:-:::zx	zxx	N

P:io r-ir&n_ing Not!!:s.:
Repec.t for all T-ticttmeht _g'rou)?s .. :s·q-_:i:'+,:, ·-oy. _'l',r'e;atm&ri.t -g'±:ouPr-:•:Site· and patient
2-0.: a:u lla:r.c:. Dae. _e"""-"-'--e._:.
Listing Source:

:Sisting 16.2.14
Efficacy pa.::::t

TreatBent g..:-oup: *T:::eatment I*

Site	Patie:-.t /Sex/Age	Race	Achiev·ed C?,? CRi? Cor.,pos:i.te :R?	Dead?	?rirr,ary ca...;se o-f: death	st,,,;dy day of Death	Last study day of fol lot,·-up	sve:1:: T:::-ee?	Study day to which pac:ien:: experiewced e·Jerct free	Leukecnia Tree?	St:_;,dy day to c,·h.i.c::', patient expor:-"-·, leuke"lia .free	?,elapse?	Sts.:.dy day to K:1ich patiecic: experier:ced relapse
xx	xx;-:/l-1I45	xxz	t:/i'i/N	xx	xxx	xx	xx	i(X	xx	xx	xx	xxz	xzx

tro:9":c'ariimi:rl r.·1'Tote_S2:
Repeat for ·a_lJ:. Tieatrhent -;rroups. Sort by Treatn\en'::. -<;rro}.lP -. ,,o.i_te::_and pa,_:ti'e:nt
Prograr;i. t-::ane: Jate Ge:1erated: rege z of y
Listing Sou:.::-ce:

::.,ist::.ng 2.6.2.15
Efficacy pa:::-t 2

Treatzr:.er,t gro·c19: *Treat:nern::*

Site	22::ient /Sex/Age	Race	p.-.-:.-.:.e.ve.-: CR? CR Ccr:',posite C?.?	Dead?	?rirr,ar:,, ca'-lse o:'. de, -:::h	St:,..;dv day of Geatr',	Last sc:i.:.dy day of :Ec-2.lo·.-.:-- ;..*p*	Necc.trophil ?.ecovery?	S':c1dy day "'.::o whic:: patient ex:_::,erienced ne trophil reco,ser.'i	?la-:::elec. Reco-very?	St"..,dy day to whict: patient platelet reccve:::-z
	x;,;x/1•1/45	::xx	Nit-:/::-;	:-::x	xx	xx	xx	xx	:,:x	xx	xx

?r_ogranuni:ri'g Notes-;
Repeat '.for a.l.l T-l::eatmE'nt· grpUps;:;_ Sod: bj. T,ieatment gr-tiuP site· iind patient
?rogram Name: Date Genera-:::ed: ?age ;<: of y
Lis;:ing Source:

List:ir.g 16.2.::_o
AC:verse s-,,en;::s
Safety ?opu.latin7

Treatment g:::ou:e_: *Treat.:ne;;t*

Site	?atier::t /Sex/Age/ ?..ace	Systeccl O:::ga.;,. Class/ Preferreci Ter::rJ Ver:Oati:7, :2J	:::e..:.c. Ucee.e Cc ':'i e S,::q:, Date (day'- '.b) Time/ Juratio::c .da_ys:	c-..a -r>...n E:nergent?	AE is due to :ir::der2-ying dc._sease or ether drs.1gs?	Probcble Sh. .., -:-l-:-g causeci. AS?	Action 'laker; with stuciy dro..:.g [c;	Oc:.tcose	NC ! CTCAE Gracie	SA2
xx	xxx/l•l/45/ xx:-:	xx>:xx:-:x ,::,:;,::zxx:<xxx;.:x x:,:::o:xx:•:xx ,:x;:::,::xxxx/ .:-:xxxx:,:::,:x;-:x;,;:, x:zz/	(xx'> H ;i·/,l•: (xx) E: rv;:;: /xx	No	Yes	Yes,	xxx	Re- solved		: 0
		xxxxxxxx:zzxxxzxxzx xx:o:xxxxxxxxxxxx/ x;,::xxx;-:xxx xx:,::xx:•: /	DJ..Jd•.r v.:., (xx)/ DD)E,JMYYY'i.' (xx) /xx	Yes	No	No	xxx:-:	3'ata:.	5	· ·es
	xxx	xx:-:;.-;xx;, zxxzz:-:x:;,x:-:xx ;,:::,::xxxxxxzx.:-:xx:,:xxx/ xxxxx;-:x.:-:x:{xxx;•:x I	DDMMMYYY·::.· {xx)/ Or.going	Yes	Yes	Yes, o.a.c"• c. ,	zxxx	Re- solved h·ith sequela e	3	Ne

[a} Coded using MedDRA Dictionary (Version xx.xx:
b] Relative tc ::he day of randocnizaL.on

Prog·r,-arorrii:rig,- 1-:foteS:
-Repeat:",.-:£'..or: _all ·'tt,E!at;,,i ht',g_roups, sQ,_i,t>by. T,reatment:, 9'±'(',.ll,fF, -- i:t·e·, _·pai-i,mt',. ·sta_rt ·,da_te .an,a. SOG:
F-or:·•'ACtion· :tak,en·,',', ith ..study,· drug,_ ,-l s.t:, l_l dru_gs: t,ha_t ·app;y;.i_ arae'.ff.:th_ .p·r b:& l·e:_s_t,:u,_dy :drug - ·caused :AE coiu,-un.
:7his 1-is_ting includes:.,a.1_1 ,AEs :_captured i_n the. study,· suc_h as -p_r_e-trea:tm nt..P.Es:-
?r:ogram Na:ne: Date Gener2ted: Page x of
Listing Source:

Repe ': fc-::: the £ollowi::1g disp:ays:

List r.g *2.6. .,'..1.i* Ad,rerse :::venc:s Causir,g Discontir.uat:ion f.:::o:;r,_ Study T.:::-eatmer.t Safety Population
Delete:
:'Jote to Progra.rnmer: Repea'.:. for all T.:::-eatment gro,.,ps. Sort b::,r Treatcc,ent group, site, pac.ient, start dc.te and S:JC.
Fo.:::- Actior: taken with study, drc.;g, list all ciru.g that apply, sa.me ,,,;ith probable study d:rug ca.t:.sed AE colu..,«n.
Note to Prag ammer: This list.:i.r:g includes al ;:..Es ca.pts1red in s;:he study, such a.s pre-t::-:eac:ment AEs.
Footr,ote: :a Coded using t edD?A !)ictionary Ve.:::-sior: :<x.x::--:)
[b] Relati·v·e to he day of rarrdorr,ization

Listing 16 ..c..18 Adve::-:se E;rer,ts ca,.;sir,g Ir,terr,.1ptior. ::rom St:_;dy ':::rea::::-,e::t Safety Po;n,;lation
Delete:
Note to Programrn.er: Repeat fc::: all Treatmer,t gro;.1ps. Sort :0,,.. ?reatc;:e::t groc,.p, site, pc.tier.t, stc.rt date a:..d soc.
?o:r Acc:icr: taker.. v,;ith study, drug, list all cirugs t:'1at apply, sa,,:e \•;ith pro:Oa::)le stud',' d.:::-ug caused AE col:..1...Tfl.!7..
.rote to 2:::cg a.mrner; This listing includes all A:Ss capt,.1red in ::.he study, sc.:ch as pre-treatrr.er,t AEs.
Footr:ote: :a Coded using MeciDRA Dictiona.c" {Ve:::-sic:i ;o:. xxJ
[bJ Relc.ti,,e to he day cf ::-:ar'.dosization

Lis ting *16. . 1.9* Adverse Events :::ausing Dose Reciu.ction £rorn St"J.•:iy ?reat:r,ent Safety ?opu.lat::.on
De2-ete:
l ote to ?:::ogra=e::-:: Repeat for c.ll Treatment gro;;.ps. So:::t by Trea::.;nent group, site, patier.t, start date and so·:::.
For Action ta;:en with study, drug, list all drugs that apply, sa;:;-,e ,,,,,i::h probable study dru.g caused AE colu.:::-..r1.
Note to ?:::cg arr --:-.er: This listing i.ncludes *c.ll.* AEs captu:::ed i::: the study, s...-:.ch as pre-t:::eatment ?.Es. Foctr,,ote:
[a Coded using 1%ciDR.A Dictionary \'.Te:rsi0n xx.xx)
[bJ Relative tc he day of rar-.domization

Listing 16. . *20* Treatmen-c-Re::.ateC Adverse Eve;. s Causing Dose Reductior: :Eron Study Treatment Safety Populatior:.
Delete:
Note tc P:::-og:::::as.-ne:r: ?,epec.t for all Treatment ;-roups. So:rt by ':'reat:ner.c: g:roup, site, patient, stc.:rt date and s-::x.::·.
For P.ction t.-'-"ken ·,;:...th stLldy, drug, list all drugs tr',at apply, s2.ccte with ;,.:roDable study dru.g caused AE colu..--n.n.
Note to Prog a:r-.:ne:r: This listir1g r,cludes c.ll .n.ss capt.c:red in the study, such as pre-treatrn.ent AEs.
Foo.:.ncte: [a Coded using ::--led ?.A ictior,ary (Ve::-:sicc. :<:x.xx)
,o; Relati;re to he day of rando:nizat or;

Listing 16.2.21
Serious Adverse Events

Treat me:::: g:::;o'-'.p: *Treat.:lent*

Site	p-- /Sex/Age/ Race	System Organ C.1.ass/ Preferreci Term/ ··e:cbatir:,	Sta:::t Date (day.\ Tiffie Stop Date (day; [b) Tiffie/ (day_s)	r;o	':'es	Yes, c:2::::- o_,_c	Action Taken wit!'": St.Ll.dy drug	Ou.tcorr,e	NC:-CTCAS Grade
xx	xxx/1•'./45/ xxx	xxx:,;:xz:- x:-:zxxx;,:xxxxx	iJD:":e"J1'1vvvy (z :)				××;,:	Re-solved	,;
		xxxx:o:;,;:x:-:xxxxxvxx/ xxxxxz;,:xxxxx:,::::x/	'-E'..:M"-' (zx)						
			i-i :Mi"'. */xx*						
			DDM11i,1YYT-. (××)/	Yes	r:;c	I'i::::	;-:;,;:zz	:atal	5
		xxxxxxxxxzx:-:>:x:o;:x/	(××) /××						
::--:x	x:-<z	xzz:-:zxx;-...::xzxxzxxx);xx	slDM!-1lr,, *'.:n:)/* Ongoing	Yes	Yes	Yes,	x:-:xx	Re-solved ,-,it , sequela e	3
		xxxxxxxxxxx:s:xxxxx/ x:-::xxxxxxxxx:s:xxx/							

'.aj Coded using Me6DRA Dictiona:::-::· (Vel'."sion xx.xx)
[bi Relative to the day cf l'."ar,dor;-;i::ac.:i.o"

P,rog_r-a.imni,ng _N_oteS:

-?-e_p at- f_or a:11 Treatment· gio1lps. _1fort'"by --_Treatm,mt,_--gr,,9up/--Sf t'e-;_,, _patient, -_st<(:tt -_a<i te_- and, s,ac.

F,oi'·,Action taken with study, drug. list all drugs that ,:apply:-;_--,pame-with pro_bable s,t"lidY dru:g caused' AE colµ:inn.

Program Name: Date Gene::-ated: Page x of y

Listing Source:

Listing 16.2.22
Laboratory FinCings – Bone Marrow
Safety ?op..:.la ion

T:reatmer,t group: *Treat.«ent*

Site	.:::atient' /Sex/;:,.ge /Race,	eye.le	':isit	C"7' e .-" S"' Date (de: [aj	Type of e;,:amination	b.1..as:: in 3one 11arro,,·	.Auer Rods	Respo;:;se
zx	:,,,:..:x/M/ 45 /xxx	Ir,d;_,ct.ion	3aseline	DJ::01-:'.l'-ri·::·yy (l)	::.¡:!	xx	xx	
			x:,x;.:	DD11El::-'.Y'-'...iY (xx·,	Bi:::::_psv	xx	xx	C?
								rO"":;-" "'.-.=. remissionj

[a] Relative tc the day of rando:.,ization
Prdgr:,axb.;nin,j .HOteS:
Rep·eat ·for· ·ail .T.reat!'n,c;nt groups, Soit ·by·_.-r·reatni:::ht group, ·site, p·atien"t: :and. "tris:'3.·-t"-:
Progran Nane: Date Ger,erac:ed;
Listing Sci..:rcf>.

Listing 16.2.23
Laboratory Fir,dings :-',e,T-atology i>.'itl'. C3C
Safety Popula"'.:ion

T:ceat:r,ent group: *Treat:Teer;t*

Site	?atient /Se;z/P..ge /?-ace	Cycle	'hsit	Col2.ection Date !day) [a]	;:.....,, ,S ob:..,	W3C	Platelet Cou:-:t	Neutrcp::ils Absolate Count (ANC'.)	Seg. Nec,trophils ,/3ands c:.....uc- apr.: 's
xx	xxx/'c-1/ 45 /;-:; X	'"ci"-:::--r' ---,,	Baseline	DDMM'.·IYYYY	xx		xx	xx	
			z :xx	nrn1::,1r-:YYYY (xx)	xx	zx	xx	xx	xx

[a] Relative ::.o t:ne Cay of ;:"a:-:cio:mizatiou

Pr'cigrammi:r1g Note _-:-

Repeat-:for al-.l T.reatmefrt groups·, S6it)?Y.' Trea:t:inib:f:.. 9":Coup, site, patiei-rt ·k:Ud 'Visit.

Prograrr:. Kame: Date Generated:

Listir,g- Source:

Listing 16.2.24
Laborato::-y Fir,dir,gs - Coag,..1.latior,
Safet·,, ?opulation

T:::eatment group: *Treat::1eict:*

Site	?atient /Sex/Age /Race	Cycls	VISI"C	:::o.llection Date (day) [a]	An,::i-factor xa	?1'	aP:T	:NR	t ·· ··' 0·vse:-:·.	D-diner
xx	xxx/M/45 /xxx	, na'" : GY.	saselh1e	,,0:,,,:-:u	xx	;n:	xx	x:-:	;-:-;:	:•:x
			X:<XX	1.;C;,;;,-: ffYYY (xx)	xx	xx	xx	xx	x:;:	

'a· Relative to the da:,r ::Jf Yandomizatior,
P:rog'rar!lTtiTlg'-) _O_teS·_:
Repeat Ioc-all· Treatment g·roups. Sort by_. 7-reatm8nt··g:fo_up, site;:_-,pa:t_i&nt-"--arid visit.
?Ycgram Name: Date Generated: Page x of
Lis-::ing Source:

Treat:.,erit 9 £ou_p: *Treat,11ent l*

Site	Patient /Sex/Age /Race	Cycle	Visit	Collectior. Date (day) taJ	A'b·l Zl:"	Tor:al ?:::-otein	Total Bilirubi::-i	Blood Drea Nitrogen	Seru.o-n C.r-eatin -ine	Sodiu.'".l	Pot- assiw-:-,
xx	xxx/?:-5/45 /xxx	Ir:.di..:_ction	Baseline	DD:"1Mll:YYYY ! l)	xx	xx	xx	;,c;x	xx	xx	xx
			xxxx	DDMMNYYYY (}'.X)	xx	:,:x	xx	xx	xx	xx	xx

[a} Relative to the day of rando:Ttiza-::ion

PrOgr·airiJr,.it g· Notes.:

Repeat·. for:·.a11 •'.l'Teat.-nent groups·. •_S6_.rt)i::{,:.Treatmerit group,. :·si-.t.e,. ·patient.-an,ct· vi._S.ft,.

Listing ::._6.2.26
Laboratory Findings Serum Cherr.istry ?art 2
Safety Pop,.::.lation

Treatment 9-ro;i:9: *Treat:,1ent 1*

Site	Patient /Sex/Age / ace	Cycle	\:.'csit	Cate ·:'daJ) [a]	Calciur::	.D..lkaline Phosphatase	::Jric Ac.id	SGOT /AST	SG?T	1DE
xx	xxx/:-1/ 45 /xx:-:		3ase.line	om,n,1t,1YYYY (l)	xx	xx	xx	xx	x:-::	xx
			xxxx	DD1•ltfc'.,JYYYY {xx)	xx	xx	x;,:;	xx	xx	xx

[a] Re.l.ati·v·e to the Cay of randorr:.ization.
P,io_g_timri1in_g_ -Nbt:eS'!
Rei,e"ci't-£0'1'.' :all "freatment groups.-. ·sort by_ Treatment ._grcup_, s-ite", p-2.tient aii.d· visit.
Prograr,, Name: :Jate Generated:
Listing Source:

List in; lE.2.27
i??(listing
Safety ?opulation

T:reat ,er,t g:roup: *Treatment*

Site	Patient/Age/Sex	Visit	Date (d2y) a	PK Parar:sete:r	Pf. value
zx	xzx/xz/F	zx	zz	xx	xx

[a] Re l a t i--ᵉ e to the day cf randor::.ization

Pr,cgr --n,-rcing ·Not_es-::

Repeat .for -all _T_.reat,m'2nt>9'i:oiiP.s-:,,-,t,in't by Treatment- group, -:si_te., patien\::an·a_:v:iSit-.

-i:..... 7... """ 7-- c:

Date Gene:rated:

2age x of

Listing Source:

Listing 16.2.28
Vital Signs
Safety Population

s'reat:;1e:1t group: *T:::eatment*

Site	?atient /Sex/Age /Race	Visi;::	Date Time (day) '.a]	Systolic BP ابا -g:	Diasc:olic 32 :rmn :-tg)	'leart Rate (beat/min)	Weight (kg)	Eeight (cm)
xx	xxx/1-1/4.S /xxx	xx :x:,:xx	JJMMMY.Y.·-:.y HE:ME (xx)	xxx	xxx	xx	xx	xx

[a] Relative to the dc.y of .::ar,dorcization

Pr69'faTiliiling,-Not'e,'s::

1<:epeat £cr_,--E.l1 T.teatment' gl:'o_ups._sOrt by Tie:a:tment:_g,:i.:-Oijp, 'sfre:, pati'-et-it and: vis-it.

List.ir,g 16 2.29
ECG ?,esu ts
Sa::"ety Pope::ation

Treatment group: *Treatme,,t*

s. ::.,tePatient /Sex/Age /?-ace	Visit	.i".ssessnent:: Date Tir;-,.e (da_;[) taJ	ECG _performed?	..Z:..ny clinically sigr,.ificant '"br,or:na2-i t::ies?
xx xxx/t,;/45 /xxx	xxx	DDMMMY HH:YJM xx;·	y,33	Yes
	xx)'.	DDMMMY YY HH:r1M x:-:'	i'io, ?artial refusal	
xx xxx/F/45 /:-:xx	xx:,:	DDMMl·1YY'!."Y H2:t1M (:-:x)	::es	-Jo
	xx}:	DDMMJ'Ł'YYY HE.!"iM (:<:x)	Yes	No

[aJ ?,elative t::o the day of ra'1.do::nizat::icn
PrCi'gri:l.rrtmfn_g_ ·!-:jO;te:s;
R€pe:,i :.:fO:r,:.a_l-_1 .T.reatmE!Ut :g:r_o;jps,.. Sort by .T:ti:-i_Ei-trrient ·group·, :site\ ::t,a:tie:nt_:·a_Il_d :;:'.isi.t::
?:::og:::a:m. Name; Date Ger::erated: ?age x of Y
L..stirrg Sou:::ce:

:ist.'.r1g 16.2.30
?hysica2. Examination ?,esult.s
Safety Population

Treat.me21t. g:::-oup: *Treatment 1*

Site	?atient /Se:-:/Age /Race	Visit	Assessrrcent Date Time (day) [a]	Was done?	Body Syste2. Examined	?esults Normal o Ab""O""""T'2.7?	Specify if J.:..bnormal
x:	X)'.X/M/45 /,-:xx	3aS8line	DDIC:MMYYYY HH:t1!-'I (xx)	Yes	Cardio--,-asc ular	':Jo:::mal	
					RepiratcJr·	Ab:r;orr,al	·,•:•::-:x
					Gastroir,te stinal	?,JC:::-:na;	
					Skin (0-ther t:l.a:1 pri:;;-,.ar site o infect on}	:,Jormal	
					:'luscc.:losh:e let.al	No:::r:2	
					E""'or- ; .. --.,,	'•,:o:::rr,a-	
					Ne·ccrolcgic al	:-Jormal	
					HEEIsT	Jo.::-sal	
					Genitourin ary	No:::mal	
		Wee:-: x	"DEMMYYYY .EE: 111":: (x;-,:)	No	i one		

[a] ?elative to the day of rando:nization

Progr,amtr,i-rig'Jfotes:

-Repeat_-:fcr,_ ll T_r,eatme,nt' - = ups._ 'S◊-r-t::- y/I',f "? rnent -_-group, site pat,ieiit- and ,vi_sit_. ◊-fl- Y_::ptes_e_nt abTlortnal bO'dy s:/stems'. If all body systems are,normal at -a visit;. output '_None'--<-i_n,-,_Body System iTonorw..a:Uti•es-,cc-lurtm. for the visit-.

Listing Source: