Werewolf Therapeutics, Inc.

STATISTICAL ANALYSIS PLAN

Protocol Title	:	A Phase 1 (First-In-Human [FIH]), Multi-Site, Dose Escalation and Expansion Study of WTX-330 in Adult Patients with Advanced or Metastatic Solid Tumors or Lymphoma
Protocol Number	:	WTX-330x2101
Compound Number	:	WTX-330
Version	:	V2.0
Effective Date	:	[26Feb2025]

Description:

- The purpose of this Statistical Analysis Plan (SAP) is to describe the planned final analyses and output to be included in the Clinical Study Report (CSR) for Protocol WTX-330x2101.
- Any post-hoc, or unplanned analyses performed to provide results for inclusion in the CSR but not specified in this SAP will be clearly specified in the CSR.

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Version History

This Statistical Analysis Plan (SAP) for study WTX-330x2101 is based on the protocol 02 dated 06 April 2023.

SAP Version	Effective Date	Author	Summary of Changes
0.1	[19Dec2023]	Shuangli Guo	Original version based on the protocol Version Number 02, Dated on 06 April 2023
0.2	[12June2024]	Shuangli Guo	Add summary for Deauville Score
0.3	[21June2024]	Shuangli Guo	Add ASTCT Grade for Cytokine Release Syndrome
1.0	[21June2024]	Shuangli Guo	Accept changes in version 0.3
1.1	[25Feb2025]	Shuangli Guo	Add Free IL-12 PK analysis
2.0	[26Feb2025]	Shuangli Guo	Accept changes in draft 1.1

Table of Contents

1. Summary of Key Protocol Information

Study documents, software, and/or standards on which this version of SAP is based are given in Subsection 15.1. Up-versioning of these documents do not necessarily require an update of this SAP, unless the changes affect the planned analyses or the interpretation of analysis results.

1.1. Changes to the Protocol Defined Statistical Analysis Plan

There is no major changes from the originally planned statistical analysis specified in the protocol v02 dated 06 April 2023, except for the addition of Efficacy Evaluable Analysis Set, Pharmacodynamics Analysis Set, and ADA analysis set.

1.2. Study Objectives and Endpoints

Objectives	Outcome Variables
Primary Objectives and Endpoints for Dose Escalation	
• To determine the MTD and/or recommended dose for expansion (RDE).	• Frequency, severity, and relatedness of treatment-emergent adverse events (TEAEs) and serious adverse events (SAEs), changes in safety laboratory parameters, and DLTs (if observed) for WTX- 330.
Dose Escalation and Expansion (Parts 1 and 2)	
• To further characterize the safety of WTX- 330	• Frequency, severity, and relatedness of TEAEs and SAEs, changes in safety laboratory parameters, and DLTs (if observed) for WTX-330
• To evaluate the anti-tumor activity of WTX-330	• Overall response rate (ORR) (complete response [CR] + partial response [PR]), duration of response (DOR) by Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 and immune-overall response rate (iORR) (immune-complete response [iCR] + immune-partial response [iPR]) by immune-RECIST (iRECIST), or response by Lugano criteria (for lymphoma only)
Secondary Objectives and Endpoints (Parts 1 and 2)	
[redacted]	[redacted]
[redacted]	[redacted]
• To evaluate the immunogenicity of WTX330	• Incidence and titers of ADAs towards WTX-330

Objectives	Outcome Variables
Secondary Objectives and Endpoints (Parts 2)	
• To evaluate the antitumor activity of WTX-330 in patients with relapsed/refractory (r/r) advanced or metastatic malignancies who have progressed on CPIs or who have tumor indications for which CPIs are not approved	• ORR (CR + PR) based on best overall response (BOR) • DOR • Disease control rate at month 3, 6 and 9 • Progression free survival (PFS) per RECIST v1.1 (solid tumor) and iRECIST or Lugano classification (lymphoma; Cheson et al., 2014) assessed by Investigator. • Overall survival (OS)
Exploratory Objectives and Endpoints (Parts 1 and 2)	
[redacted]	[redacted]

1.3. Study Design

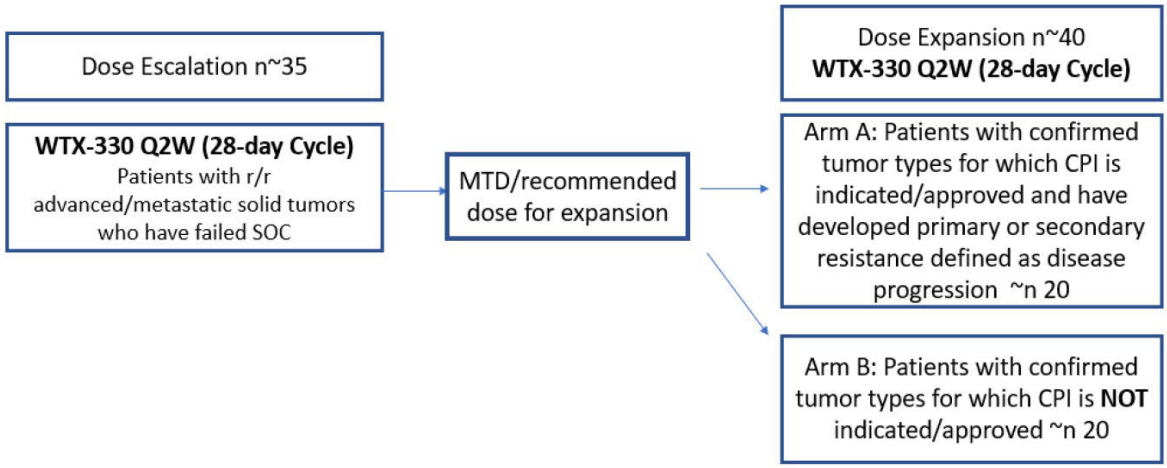
This study is a Phase 1, FIH, multi-site study to determine the safety profile and MTD and/or RDE of WTX-330 in patients with advanced or metastatic solid tumors or lymphomas.

The study consists of a dose escalation part and a dose expansion part. The study design is illustrated in the Figure below.

1.3.1. Dose Escalation – Monotherapy

The dose escalation part of the study will be conducted in patients with relapsed/refractory advanced and/or metastatic solid tumors. Patients with primary CNS malignancies are ineligible. WTX-330 will be administered as a single agent at a dose based on body weight on Days 1 and 15 via IV over 15 minutes (Q2W) of the 28-day treatment cycle (in the absence of infusion-related reactions) at the first and all subsequent infusions. The dose escalation cohorts have been planned as 0.016 mg/kg, 0.032 mg/kg, 0.056 mg/kg, 0.084 mg/kg, 0.126 mg/kg, 0.190 mg/kg, 0.290 mg/kg, and potentially higher than 0.440 mg/kg.

An adaptive 2-parameter BLRM incorporating EWOC will be used during the Dose Escalation (Part 1) to select dose levels and to estimate the MTD (See Protocol Appendix F). Determination of the MTD during dose escalation will be based upon an estimation of the probability of a DLT in Cycle 1 in the dose-determining set (DDS). If the MTD is not reached during dose escalation, the recommended dose for expansion (RDE) will be determined based on review of DLTs, AEs and SAEs, laboratory, PK and PD data by the DEC as the dose with the optimal therapeutic window for WTX-330.



CPI = checkpoint inhibitor; MTD = maximum tolerated dose; Q2W = every 2 weeks; r/r = relapsed/refractory; SOC = standard of care.

1.3.2. Dose Expansion

Once the MTD/RDE is identified from Dose Escalation (Part 1), the Dose Expansion part (Part 2) will open and begin enrollment. Patients will have a confirmed diagnosis of a r/r locally advanced or metastatic solid tumor or lymphoma for which the patient has progressed on or is intolerant of standard therapy, or for whom no standard therapy with proven benefit exists. Dose Expansion will be conducted in 2 arms that will enroll patients based on the following criteria:

- Arm A: Patients with indications for which a CPI is indicated/approved (e.g., cutaneous malignant melanoma, RCC, non-small cell lung cancer [NSCLC], head and neck squamous cell carcinoma [HNSCC], urothelial carcinoma, etc.) who have received a CPI regimen and who demonstrate primary or secondary resistance to CPI therapy.
- Arm B: Patients with tumor types for which CPI therapy is not indicated/approved (e.g., pancreatic cancer, microsatellite-stable [MSS] colorectal carcinoma, castrate-resistant prostate cancer (CRPC), non-Hodgkin lymphoma) and who are CPI naïve. Patients with NHL should have either follicular lymphoma or diffuse large B-cell lymphoma (DLBCL), though other subtypes of NHL such as T-cell lymphomas may be considered after discussion with the Sponsor. All patients with NHL must have received at least 2 prior systemic therapies.

2. Statistical Hypotheses

Hypothesis testing is not preplanned in this study for efficacy endpoints. Confidence intervals may be provided for information purposes only.

3. Sample Size Considerations

The overall sample size for this study is approximately 75 patients between the dose escalation and dose expansion parts of the study and will depend on the observed DLT profiles of WTX-330.

3.1. Dose Escalation Phase

Approximately 30 to 35 patients will be enrolled into the dose escalation part including all dosing groups (0.008 mg/kg (Dose Level -1), 0.016 mg/kg, 0.032 mg/kg, 0.056 mg/kg, 0.084 mg/kg, 0.126 mg/kg, 0.190 mg/kg, 0.290 mg/kg, and potentially higher than 0.440 mg/kg). For the first dose level of WTX-330, at least 1 patient needs to be evaluable. Dose groups will be included in the dose escalation part with 3 to 6 patients in each group.

During dose escalation, additional patients may be enrolled into cohorts at dose levels that have previously been determined to be safe to better understand the safety, tolerability, and PK of WTX-330 before or while proceeding with further dose escalation. Up to 10 patients may be enrolled into an enrichment group. Enrichment groups will enter the DDS and be accounted for in the BLRM for the assessment of DLTs.

The exact sample size cannot be prespecified in advance because it is a dynamic feature of the design. The actual sample size of the dose escalation part of the study will depend upon the underlying dose toxicity profile and variability in actual data realization.

3.2. Dose Expansion Phase

Once the MTD and/or RDE is determined for WTX-330 as a monotherapy in the dose escalation (Part 1), the dose expansion (Part 2) with WTX-330 as a monotherapy will initiate in each of the 2 dose expansion cohorts (Arms A and B; Section 1.3.2). Cohorts of up to 20 patients each are planned for each of the dose expansion arms.

These sample sizes were selected based on practical consideration to confirm safety of WTX-330 for each indication and without formal power calculation.

To show that these sample sizes will also give early evidence on clinical benefit, Table below provides probabilities of declaring success for varying true response rate based on independent Bayesian Beta-binomial models assuming Beta (0.5, 0.5) priors for each expansion arm and declaring success if the posterior probability that the true response rate exceeds 10% is large (at least 90%). This translates to declaring success for an expansion arm if at least 4/20 are observed.

True response rate (%)	**10**	**15**	**20**	**25**	**30**	**40**	**50**	**60**
Probability of declaring success (%)	13.3	35.2	58.9	77.5	89.3	98.4	99.9	100

4. Planned Analyses

4.1. Interim Analyses

Each dose escalation step is considered an interim analysis. The BLRM will be updated with the respective number of subjects treated and the number of DLTs observed in the last cohort. The updated model will then give a statistical recommendation for the next escalation step. In addition, a risk-benefit assessment that includes a comprehensive analysis of safety and available clinical information will be done to decide on the next escalation steps.

After the dose escalation an interim analysis to review the safety data may be performed for this trial. The analyses will be based on a data snapshot. As this trial is of exploratory nature and no inferential statistics are planned, no adjustment for multiple testing will be done.

4.2. Final Analyses

One final planned primary analysis will be performed after the completion of the following sequential steps:

1. All subjects have completed the study as defined in the protocol.
2. All required database cleaning activities have been completed, and final database release and database freeze has been declared by Data Management.

5. Analysis Sets

Analysis Set	Definition / Criteria	Analyses Evaluated
Screened Subjects	All subjects who provided informed consent.	• Disposition
Enrolled Subjects	All subjects who provided informed consent and met all study eligibility criteria as recorded in the eCRF.	• Disposition
Safety Analysis Set	This will include all patients who received at least 1 dose of WTX-330 and had at least 1 post-baseline safety assessment. Safety analyses will in general be descriptive and will be presented in tabular format with the appropriate summary statistics for the Safety Analysis Set. The safety set will be the primary population for all safety related endpoints except determination of the dose-DLT relationship.	• Demographics • Cancer history • Exposure and compliance • Previous and concomitant therapies • Safety evaluations except for DLT
Dose-determining (DDS) Analysis Set	This will include all patients in the safety set who have either (a) experienced a DLT at any time during Cycle 1, or (b) completed Cycle 1 without experiencing a DLT. The DDS, which is the analysis set used for determination of the MTD, will consist of patients who have met the minimum treatment and safety evaluation requirements of the study, and/or who experience a DLT during Cycle 1. The minimum treatment and safety evaluation requirements will have been met if, in Cycle 1, the patient received 75% of assigned study treatment dose, completed the required safety evaluations for Cycle 1, and did not experience a DLT. Patients who do not meet these minimum treatment and safety evaluation requirements will be regarded as ineligible for inclusion in the DDS and will be replaced, if	• DLT events

Analysis Set	Definition / Criteria	Analyses Evaluated
	needed, until the minimum number of patients required for evaluation is reached.	
Efficacy Evaluable Analysis Set	All subjects who receive at least one dose of study drug and with both baseline and post-baseline disease assessment, or all subjects who receive at least one dose of study drug with baseline disease assessment and without post-baseline disease assessment due to death or progression.	• Efficacy: ORR, iORR, DCR, iDCR, PFS, iPFS, DoR, iDoR, OS
Pharmacokinetics (PK) Analysis Set	This will consist of all patients who have received at least 1 dose of study drug and have at least 1 post-dose PK measurement.	• PK
[redacted]		
Anti-Drug Antibody (ADA) Analysis Set	All subjects who received at least 1 dose of WTX-330 and have at least 1 baseline WTX-330 IG sample or at least 1 post-baseline WTX-330 IG sample.	• ADA

Note: Data after withdrawn of ICF will be excluded in analysis.

6. General Considerations and Data Handling Conventions

6.1. Programming Environment

Unless otherwise specified, all analyses will be conducted using SAS® version 9.4 or later.

6.2. Analysis Groups

Unless otherwise specified, the statistical analyses will be presented by dose level in dose escalation phase and by arm in the dose expansion phase for the different analysis sets as defined in Section 5.

6.3. List of Data Display and Handling Appendices

Table 2 Overview of Data Display and Handling Appendices

Component
Appendix 2: Descriptive Statistical Summaries
Appendix 3: Data Display Conventions
Appendix 4: Study Day, Duration, Period, Visit and Analysis Windows
Appendix 5: Derived Data And Definitions
Appendix 6: Premature Withdrawals & Handling of Missing Data

7. Study Conduct and Study Population

7.1. Overview of Planned Analyses of Study Conduct and Study Population

Table 3 Overview of Planned Analyses of Study Conduct & Study Population

	Data Displays Generated		
	Table	Figure	Listing
Study Conduct			
Subject Disposition	Y		Y
Analysis Sets	Y		Y
Protocol Deviations	Y		Y
Demographics and Baseline Disease Characteristics			
Demographics and General Baseline Characteristics (Vital Signs, Body Measurements, Performance Status)	Y		Y
Cancer History & Characteristics	Y		Y
Prior Cancer Therapy	Y		Y
General Medical History by SOC and PT	Y		Y
Prior Non-cancer Therapies and Concomitant Therapies			
Prior Medications by ATC level II and PN	Y		Y
Concomitant Medications ATC level II and PN	Y		
Prior and Concomitant Procedures			Y
Exposure and Compliance			
Study Drug Exposure & Compliance	Y		Y
Infusion Interruptions & Dose Modifications	Y		Y

7.2. Study Conduct

7.2.1. Summary of Analysis Sets

The number and relative frequency of subjects in each analysis set as defined in Section 5 will be descriptively summarized.

- Number of screened subjects (percentage not to be calculated)
- Number of screen failures (percentage not to be calculated)
- Reason for screen failure (percentage not to be calculated, include non 0 categories only)
  - Adverse event
  - Death
  - Failure to meet continuation criteria
  - Logistical problem
  - Met eligibility criteria but not needed
  - Never dosed
  - Other
  - Physician decision
  - Pregnancy
  - Protocol-specified withdrawal criterion met
  - Screen failure
  - Screening not completed

  - Technical problems
  - Withdrawal by parent/guardian
  - Withdrawal by subject
  - Withdrawal of consent
  - COVID-19 Related
- Number of Enrolled Subjects (percentage not to be calculated)
- Safety Analysis Set (percentage not to be calculated)
- Dose-determining (DDS) Analysis Set
- Efficacy Evaluable Analysis Set
- Pharmacokinetics Analysis Set
- [redacted]]
- ADA Analysis Set

Percentages will be calculated with based on the number of subjects in the Safety Analysis Set. Listing will be provided for all Screened Subjects.

7.2.2. Subject Disposition

The number and relative frequency of subjects of the following will be descriptively summarized using Safety Analysis Set:

- Subjects with ongoing or discontinued WTX-330 treatment
- Subjects who ongoing or discontinued the study
- Reasons for WTX-330 discontinuation
  - Adverse Event
  - Death
  - Physician Decision
  - Pregnancy
  - Progressive Disease
    - Radiographic
    - Clinical
  - Study Terminated by Sponsor
  - Withdrawal of ICF
  - Other
- Reasons for end of study
  - Completed study
  - Withdrawal of Consent by Patient
  - Lost to Follow-Up
  - Death
  - Sponsor Terminated by Sponsor
  - COVID-19 Related
  - Other

Percentages will be calculated with based on the number of subjects in the Safety Analysis Set. Disposition of subjects will be provided in a data listing for the Safety Analysis Set.

7.2.3. Protocol Deviations

Protocol Deviation Management Plan (PDMP) version: 1.0 dated on 23Sep22 defined the study specific procedures and responsibilities for managing Protocol Deviations. The document listed the definition of

Bioclinica Deviation Description and Deviation Area, as well the Deviation Category (major vs minor). Subject level protocol deviations will be documented in the Clinical Trial Management System (CTMS).

Deviations from the clinical protocol may include, but are not limited to:

- ICF/Subject Information
- Ineligible Subject Enrolled
- IMP Dose Error
- IMP Other Error
- Prohibited Medication
- Procedure/ Test Not Done
- Procedure/ Test Out of Window
- Procedure/ Test Not Performed per Protocol
- Visit Out of Window
- SAE or AESI Reporting Failure
- Other

The number and percentage of subjects with any protocol deviation, major protocol deviation, or minor protocol deviation will be summarized using the Safety Analysis Set separately.

7.3. Demographics and Baseline Disease Characteristics

Demographic and baseline disease characteristics as specified in detail below will be presented descriptively using the Safety Analysis Set.

7.3.1. Demographics and General Baseline Characteristics

The following baseline characteristics will be descriptively (n, mean, Mean, Standard Deviation, Median, Min, Max) summarized using the Safety Analysis Set:

- Age at informed consent (years)
- Weight (kg) at baseline
- Height (cm) at baseline

The number and percentage of subjects under each of the following baseline characteristics will be summarized using the Safety Analysis Set:

- Sex (Female [with childbearing potential, without childbearing potential], Male)
- Age group (<45, 45 through 65, and ≥65)
- Race (American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, White, Other, and Unknown)
- Ethnicity (Hispanic or Latino, Not Hispanic or Latino, and Unknown)
- Eastern Cooperative Oncology Group (ECOG) performance status (0, 1)

7.3.2. Cancer History

The following cancer history characteristics of solid tumor will be summarized descriptively (n, mean, Mean, Standard Deviation, Median, Min, Max) using the Safety Analysis Set:

- Time since date of initial histopathological diagnosis (months) = (date of first dose - date of initial histopathological diagnosis)/30.4375
- Time since date of most recent disease recurrence/progression (months) = (date of first dose - date of most recent disease recurrence/progression)/30.4375

The number and percentage of subjects with the following primary and metastatic cancer history for solid tumor will be summarized using the Safety Analysis Set:

- Time since date of initial histopathological diagnosis (<12 months, >=12 months - < 24 months, >=24 months - < 36 months, >=36 months)
- Cancer type as recorded in eCRF
- Primary site of solid tumor as recorded in eCRF
- Any pathologic sub-type (Yes, No)
- Stage of solid tumor at initial diagnosis (0, I, II, III, IV)
- Stage of solid tumor at baseline (0, I, II, III, IV)
- Characterization of disease at study entry (locally advanced, metastatic)
- Metastatic site as recorded in eCRF
- Any known genetic mutations (Yes [BRAF, EGFR, HER2, KRAS, KIT, PDGFRA, PIK3CA, NRAS, VHL, Other], No)
- MSI status (Known [MSI-H, MSI-L, MSS dMMR, pMMR] Unknown, Not Applicable)
- TMB Status Known? (No, Not Applicable, Yes [High, Intermediate, Other])
- Tumoral genetic characterization (Yes, No, Not Applicable)

The following cancer history characteristics of lymphoma will be summarized descriptively (n, mean, Mean, Standard Deviation, Median, Min, Max) using the Safety Analysis Set:

- Time since date of diagnosis (months) = (date of first dose - date of initial diagnosis)/30.4375
- Time since date of transformation (months) = (date of first dose - date of transformation)/30.4375

The number and percentage of subjects with the following cancer history for lymphoma will be summarized using the Safety Analysis Set:

- Time since date of diagnosis (<12 months, >=12 months - < 24 months, >=24 months - < 36 months, >=36 months)
- Disease at screening as recorded in eCRF
- Current disease stage (I, IE, II, IIE, II BULKY, III, IV)
- Current Ann Arbor Staging (Stage I, Stage IE, Stage II, Stage IIE, Stage III, Stage IIIE, Stage IIIS, Stage IIIE/S, Stage IV, Not Applicable)
- Bone Marrow Involvement? (Yes, No)

Cancer history characteristics will also be provided in a data listing using the Safety Analysis Set.

7.3.3. Prior Cancer Therapy

Prior cancer therapy information will be summarized using descriptive statistics. Denominators for calculating percentages will be based on the number of subjects in the Safety Analysis Set. Summaries will include the following:

- Any prior anti-cancer therapy
- Type of prior anti-cancer therapy (Surgery, Radiation therapy, Systemic therapy)
- Type of Systemic Therapy (Chemotherapy, Immunotherapy, Hormonal therapy, Targeted therapy, Other)
- Systemic therapy setting (Advance/metastatic, Palliative, Other)
- Best overall response across all prior systemic therapies (CR, PR, SD, PD, NE, NA, Unknown)
- Best overall response from the latest prior systemic therapy (CR, PR, SD, PD, NE, NA, Unknown)
- Reason for stopping treatment in the latest prior systemic therapy (Treatment completed, Progressive disease, Toxicity, Adverse event, Other)
- Number of line of therapies (0, 1, 2, 3, ≥4)

Time since the last prior systemic therapy started (months, date of first dose – start date of the last prior systemic therapy)/30.4375) will be descriptively (n, mean, Mean, Standard Deviation, Median, Min, Max) summarized using the Safety Analysis Set:

Prior systemic anti-cancer medications will be coded according to the latest version of World Health Organization drug dictionary (WHODRUG Global B3 March 2023) and stored with ATC categories and preferred names (PN). A primary ATC category will be selected before DBL based on considerations such as indication, route of administration, and dosage.

The number and percentage of subjects with medication use coded to each primary ATC level 2 category and preferred name (PN) combination will be summarized descriptively using the Safety Analysis Set. If a subject has received more than 1 drug within an ATC class or PN, the subject will be counted only once for this ATC class or PN.

Prior cancer therapy will be reported in data listings using the Safety Analysis Set.

7.3.4. General Medical History

The medical conditions will be coded according to Medical Dictionary for Regulatory Activities (MedDRA 26.0) according to the Data Management Plan.

The number and percentage of subjects with conditions coded to each primary system organ class (SOCs) and preferred terms (PTs) will be summarized descriptively using the Safety Analysis Set. If a subject has more than 1 medical condition within an SOC or PT, the subject will be counted only once for the respective SOC or PT.

Data listings of all medical history records will be provided using the Safety Analysis Set.

7.4. Prior Non-cancer Therapies & Concomitant Therapies

7.4.1. Prior and Concomitant Medications

Prior and concomitant medications will be coded according to the latest version of World Health Organization drug dictionary (WHODRUG Global B3 March 2023) according to the Data Management Plan and stored with ATC categories and preferred names (PN). A primary ATC category will be selected before DBL based on considerations such as indication, route of administration, and dosage. For classification of prior and concomitant use and the imputation of (partial) missing dates, refer to Subsections 15.5 and 15.6. Prior medication is the medication that stopped before the first dose of WTX-330. Concomitant medication is the medication that are used on/after the first dose of WTX-330.

The number and percentage of subjects with medication use coded to each primary ATC level 2 category and preferred name (PN) combination will be summarized descriptively using the Safety Analysis Set as described. If a subject has received more than 1 drug within an ATC class or PN, the subject will be counted only once for this ATC class or PN. For medications with a common PN but being used in different scenarios with different primary ATC level 2 categories, the PN needs to be summarized under all these ATC level categories.

Prior and concomitant medications information will also be provided in a data listing using the Safety Analysis Set.

7.4.2. Prior and Concurrent Procedures

Prior and concomitant procedure information will also be provided in a data listing using the Safety Analysis Set.

7.5. Exposure and Compliance

The following exposure and compliance summaries will be derived for each subject for WTX-330:

- Duration of exposure (weeks) is (the date of last administration of WTX-330 − the date of first administration of WTX-330 + 14)/7.
- Total Planned Dose (mg/kg) is calculated by sum of the individual Planned Dose Level being reported in eCRFs.
- Cumulative Dose (mg/kg) is calculated by sum of the individual Total Dose Administered being reported in eCRFs.
- Treatment compliance (%) is 100*(Cumulative Dose/Total Planned Dose) .
- Average Dose Intensity (mg/kg) /cycle) is calculated by Cumulative Dose / number of treatment cycles started (any amount of the study drug was administered)

The duration of exposure (weeks), number of treatment cycle started, and number of study drug infusions, cumulative Dose, Treatment Compliance and Average Dose Intensity will be summarized using descriptive statistics as numerical variables; percent compliance will also be summarized as a categorical variable (<80%, 80-120%, ≥120%); duration of exposure will also be summarized as a categorical variable (<4 weeks, 4 to <12 weeks, ≥12 weeks).

Additionally, the number and percentage of subjects with 0, 1, 2, or ≥3 WTX-330 infusion interruption events and reason for infusion interruption (Infusion Reaction, Adverse Event other than Infusion Reaction, Other) will be summarized; the number and percentage of subjects with WTX-330 dose adjustment (Dose Missed, Dose Reduced, Dose Discontinued, Dose Interrupted) and reason for WTX-330 dose adjustment (Adverse Event, PI/Sponsor Decision, Other)) will be summarized.

Exposure, dosage, and compliance data will be presented in a data listing.

8. Efficacy Analyses

8.1. Overview of Planned Efficacy Analyses

All analyses of efficacy outcomes will be primarily based on the Efficacy-Evaluable Set.

Table 1 Overview of Planned Efficacy Analyses

	Data Displays Generated		
	Table	Figure	Listing
Target Lesion Size and Individual Assessment			
Spider (line) plot of percent CFB of sum of target lesion diameters (Solid tumors)		Y	Y
Spider (line) plot of percent CFB of sum of the product of the diameters (Lymphomas)			
Waterfall plot of best percent CFB of sum of target lesion diameters (Solid tumors)		Y	
Waterfall plot of best percent CFB of sum of the product of the diameters (Lymphomas)			
Swimming lane plot of individual time point response assessment and time on treatment		Y	
ORR and iORR			
Number and percentages of subjects in each BOR (iBOR) category	Y		Y
ORR (iORR) and 95% Clopper-Pearson interval			

	Data Displays Generated		
	Table	Figure	Listing
CBR and iCBR			
CBR (iCBR) at 3, 6, and 9 months	Y		Y
DOR and iDOR			
Number of responders Number of events Number of censored observations	Y		Y
Kaplan-Meier estimates of survivor function at landmark time points and associated asymptotic 95% CI			
Estimated quartiles of DOR (iDOR) and associated asymptotic 95% CI			
PFS and iPFS			
Number of events Number of censored observations	Y		Y
Kaplan-Meier estimates of survivor function at landmark time points and associated asymptotic 95% CI		Y	
Estimated quartiles of PFS (iPFS) and associated asymptotic 95% CI			
OS			
Number of deaths Number of censored observations	Y		Y
Kaplan-Meier estimates of survivor function at landmark time points and associated asymptotic 95% CI		Y	
Estimated quartiles of OS and associated asymptotic 95% CI			

8.2. Definitions of Efficacy Outcome Variables

Solid tumors

Assessment of solid tumors will be based on RECIST 1.1 and iRECIST during Screening within 28 days of Cycle 1 Day 1. On-study scans should be performed every 8 weeks (±7 days) from Cycle 1 Day 1 for the first 6 cycles and every 12 weeks (±7 days) thereafter. Disease assessments will include radiographic measurements of tumors using computed tomography (CT), magnetic resonance imaging (MRI), or positron emission tomography (PET)/CT. The modality for screening/baseline imaging will be used until progressive disease (PD) per RECIST 1.1 and confirmed progressive disease iRECIST (iCPD) for solid tumor, withdrawal of consent, or initiation of a new anticancer therapy.

Lymphomas

Assessment of lymphomas (NHL) in Dose Expansion Part B will be based on Lugano classification during Screening within 28 days of Cycle 1 Day 1. On-study scans should be performed every 8 weeks (±7 days) from Cycle 1 Day 1 for the first 6 cycles and every 12 weeks (±7 days) thereafter. At Screening, lymphoma patients with FDG-avid disease will undergo fluorodeoxyglucose (FDG) PET/CT imaging. All subsequent disease assessments should also be performed with FDG PET/CT, using the Deauville 5-point scale. The avidity of up to six of the largest dominant nodes, nodal masses and/or extranodal lesions, selected to be clearly measurable in two diameters, should be assessed. Nodes should preferably be from disparate regions of the body and should include, where applicable, mediastinal and retroperitoneal areas. Non-nodal lesions include those in solid organs, the GI tract, cutaneous lesions, or those noted on palpation. Non-measured lesions are any disease not selected as dominant or measurable. For patients with non-FDG-avid or variably FDG-avid tumors, a CT scan of the chest/abdomen/pelvis and any additional known sites of disease will be

performed with IV contrast. The modality for screening/baseline imaging will be used until progressive disease (PD) per Lugano, withdrawal of consent, or initiation of a new anticancer therapy.

8.2.1. Individual Time Point Response

According to RECIST 1.1, the time point response will be evaluated as Complete Response (CR), Partial Response (PR), Stable Disease (SD), Progressive Disease (PD), Not Evaluable (NE). According to iRECIST, the time point response will be evaluated as Immune unconfirmed progressive disease (iUPD), Immune confirmed progressive disease (iCPD), Immune complete response (iCR), Immune partial response (iPR), Immune stable disease (iSD), Not Evaluable (NE). According to Lugano classification, the Lugano (Metabolic/PET-CT Based) time point response will be evaluated as Complete Response (CR), Partial Remission/Response (PR), Stable Disease (SD), and Progressive Disease (PD).

The following RECIST 1.1, iRECIST 1.1, and Lugano time point response(s) will be excluded from derivation of Best Overall Response (BOR), Clinical Benefit Rate (CBR), Duration of Response (DOR), Progression free Survival (PFS), Immuno Best Overall Response (iBOR), Immuno Clinical Benefit Rate (iCBR); Immuno Duration of Response (iDOR), Immuno Progression free Survival (iPFS):

- **All RECIST 1.1, iRECIST 1.1 and Lugano time point response(s) after Antineoplastic therapy (including radiotherapy, surgery and medication) will be excluded**
- **For RECIST 1.1 and Lugano, any time point response(s) after the first PD will be excluded**
- **For iRECIST, any time point response(s) after the first iCPD will be excluded**

8.2.2. Best Overall Response

Best Overall Response (BOR) of each subject per RECIST 1.1 is based on the tumor response among all visits. CR or PR needs to be confirmed in a subsequent assessment at least 28 days apart. Unconfirmed PR or CR will be categorized as SD. See the derivation rules below:

- If a subject has at least 2 CRs at least 28 days apart, and there are no other assessments in between being PR, SD or PD, then the BOR is defined as confirmed CR;
- If a subject has a PR, another CR/PR at least 28 days later, and there are no other assessments in between being SD or PD, then the BOR is defined as confirmed PR;
- For those subjects who do not meet confirmed CR or PR conditions above, if the subject had at least 1 tumor assessment record of CR/PR/SD which is at least 49 days after date of first dose of any study drug, and if the assessment is not preceded by any prior PD, then the BOR is defined as SD;
- For those subjects who do not meet confirmed CR, confirmed PR or SD conditions defined as above, but they have any tumor assessment as PD, their BOR is PD;
- Otherwise, BOR is defined as NE for subjects without any post-baseline tumor assessment data.

Immune Best Overall Response (iBOR) of each subject per iRECIST 1.1 is deleted from all visit responses according to the following sequence: iCR, iPR, iSD, iCPD, iUPD, NE.

Best Overall Response (BOR) of each subject with lymphomas (NHL) per Lugano is seleted from all visit responses according to the following sequence: CR, PR, SD, PD.

The subjects without postbaseline assessment will be categories as NE.

8.2.3. Overall Response Rate

Overall response rate (ORR) per RECIST 1.1 and per Lugano is defined as the proportion of subjects achiving CR or PR of BOR.

Immune Overall response rate (iORR) per iRECIST 1.1 is defined as the proportion of subjects achiving iCR or iPR of iBOR.

8.2.4. Clinical Benefit and Clinical Benefit Rate

Clinical benefit for 3, 6, and 9 months based on RECIST 1.1and Lugano is defined as the subject achiving CR, PR, or SD with duration ≥ 3, 6, and 9 months after the date of first dose, respectively. Duration will be calculated as (the date of last CP/PR/SD, whichever occurs late) – date of first WTX-330 dose + 1)/30.4375.

Immuno Clinical benefit for 3, 6, and 9 months based on iRECIST 1.1 is defined as the subject achiving iCR, iPR, or iSD with duration ≥ 3, 6, and 9 months, respectively. Duration will be calculated as (the date of last iCP/iPR/iSD – date of first WTX-330 dose + 1)/30.4375.

Clinical Benifit Rate (CBR) or Immuno Clinical Benifit Rate (iCBR) is defined as the propotion of subjects achieving clinical benefit, which will be summarized for 3, 6, and 9 months: CBR3, CBR6, CBR9, iCBR3, iCBR6, and iCBR9.

8.2.5. Duration of Response

Duration of response (DOR), reported the subjects achieving confirmed PR or CR per RECIST 1.1, is calculated from the date of first observation of CR or PR to the date of disease progression using RECIST 1.1 criteria or death, whichever occurs first. The subjects without disease progression or death will be censored on the date of last disease assessment. See below for event/censoring rules.

Situation	Date of Event or Censoring	Event or Censoring
** using the derived dataset as descripted in section 8.2.1		
Progression after one or none missing assessment	Date of progression	Event
Death after one or none missing assessment	Date of death	Event
No progression (or death)	Date of last assessment	Censored
Progression or death after two or more missing assessment	Date of last assessment prior to missed assessments	Censored

Duration of response (DOR), reported the subjects achieving CR or PR of BOR per Lugano, is calculated from the date of first observation of CR or PR to the date of disease progression using RECIST 1.1 criteria or death, whichever occurs first. The subjects without disease progression or death will be censored on the date of last disease assessment. See above for event/censoring rules.

Immuno Duration of response (iDOR), reported the subjects achieving iCR or iPR per iRECIST, is calculated from the date of first observation of iCR or iPR to the date of first iUPD that is confirmed in subsequent assessments (iCPD), the date of first iUPD that is not followed any of iSD/iPR/iCR in subsequent assessments, or death, whichever occurs first. The subjects without iUPD/death, or with iUPD being annulled by subsequent assessments (iSD, iPR, iCR) will be censored at the date of last assessment.

8.2.6. Progression-free Survival

Progression-free Survival (PFS) per RECIST1.1 and Lugano is calculated from the date of first WTX-330 dose to the date of disease progression or death, whichever occurs first. The subjects without disease progression or death will be censored on the date of last disease assessment. See event/censoring rules in section 8.2.5.

Immuno Progression-free Survival (iPFS) per iRECIST, is calculated from the date of first WTX-330 dose to the date of first iUPD that is confirmed in subsequent assessments (iCPD), the date of first iUPD that is

not followed any of iSD/iPR/iCR in subsequent assessments, or death, whichever occurs first. The subjects without iUPD/death, or with iUPD being annulled by subsequent assessments (iSD, iPR, iCR) will be censored at the date of last assessment.

Alive subjects without postbaseline assessment will be censored at the date of first WTX-330 dose (day 1).

8.2.7. Overall Survival (OS)

Overall survival (OS) is is calculated from the date of first WTX-330 dose to the date of death. The subjects without death during study will be censored at the date of last known alive.

8.3. Analysis of Efficacy Outcome Variables

8.3.1. Analysis of Target Lesion Sizes and Individual Assessments

For sum of target lesion in solid tumor, longest diameters for non-nodal lesions and short axis for nodal lesions will be added by subject and assessment visit. Assessments after the start of subsequent anticancer therapy will not be included when deriving the change from baseline (CFB) and best (i.e., the minimum of) percent CFB.

For sum of the product of the diameters in Lymphomas, the product of the diameters of each measurable lesion will be added by subject and assessment visit. Assessments after the start of subsequent anticancer therapy will not be included when deriving the change from baseline (CFB) and best (i.e., the minimum of) percent CFB.

A line (spider) plot for the percent CFB of sum of target lesion diameters over time in solid tumor and the percent CFB of sum of the product of the diameters over time in Lymphomas will be made for each subject in escalation part and expansion part.

A waterfall plot for best percent CFB of sum of target lesion diameters in solid tumor best percent CFB of sum of the product of the diameters over time in Lymphomas will be made for each subject in escalation part and expansion part. The plot is restricted to subjects with measurable disease at baseline and at least one valid post-baseline assessment.

Swimming lane plots will be presented for time (month) on treatment, iRECIST response assessments in solid tumor or Lugano response assessments in Lymphomas at all visits, as well as reasons for WTX-330 discontinuation for each subject in escalation part and expansion part.

8.3.2. Analysis of Deuville Scale

Deauville 5-point scale in FDG PET/CT include: score 1 - no uptake; score 2 - uptake < to mediastinum; score 3 - uptake > mediastinum but < liver; score 4 - moderately increased uptake > liver; score 5 – markedly increased uptake and or new lesions (s) likely to be lymphoma; score x - new areas of FDG uptake unlikely to be related to lymphoma. The shift of 5-point scale from baseline to post-baseline at each scheduled visit will be summarized.

8.3.3. Analysis of ORR and iORR

The number and percentage of subjects with BOR per RECIST 1.1, with iBOR per iRECIST, and with BOR per Lugano in each of the response categories will be summarized descriptively. ORR, iORR, and their 2-sided 95% confidence intervals being estimated with Clopper-Pearson method will be presented.

8.3.4. Analysis of CBR and iCBR

The number and percentage of subjects with CBR3, CBR6, CBR9, iCBR3, iCBR6, iCBR9, and their 95% confidence intervals will be estimated with Clopper-Pearson method.

8.3.5. Analysis of Time to Events

Time to event parameters (DoR, iDoR, PFS, iPFS, OS) will be estimated using the Kaplan-Meier method (Kaplan & Meier, 1958). The number and percentage of subjects with events/censored, the 1st quantile (25%), median, 3rd quantile (75%), and their 2-sided 95% confidence interval, event-free rate at 3/6/9/12/15 months and their 2-sided 95% confidence interval will be presented.

Event or censor category of each subject in the summary for DoR, iDoR, PFS, iPFS will be presented. Event categories include progression and death. Censor categories include No progression and death, Progression or death after antineoplastic therapy, Progression or death after two or more missing assessment.

Kaplan-Meier curves for PFS, iPFS and OS of expansion cohorts will be plotted.

8.4. Subgroup Analyses

No subgroup analysis is planned.

9. Safety Analyses

9.1. Overview of Planned Safety Analyses

The Safety Analysis Set will be used to evaluate all safety endpoints unless otherwise specified. In particular, the DLT-Evaluable Analysis Set will be used to evaluate DLT endpoint and to estimate MTD.

Table 2 Overview of Planned Safety Analyses

	Data Displays Generated		
	Table	Figure	Listing
Maximum Tolerated Dose (MTD) and Dose Limiting Toxicity (DLT) Events			
Number and percentage of subjects having experienced DLT events	Y		Y
Adverse Events			
Overview of TEAEs	Y		
All TEAEs	Y		Y
TEAEs related to each study drug	Y		
All Serious TEAEs	Y		
Serious TEAEs related to each study drug	Y		
Grade 3 or higher TEAEs	Y		
Grade 3 or higher TEAEs related to each study drug	Y		
TEAEs leading to any study drug modification	Y		
TEAEs leading to deaths	Y		
TEAEs of Special Interest	Y		
Immune Related Adverse Event (irAE)	Y		Y
Infusion Related Reaction (IRR)	Y		Y
Cytokine Release Syndrome (CRS)	Y		Y
TEAEs leading to any study drug discontinuation	Y		Y
All Serious TEAEs during screening period(s)			Y

	Data Displays Generated		
	Table	Figure	Listing
Primary Cause of Deaths			
On study Deaths	Y		Y
Deaths within 28 days of last administration			
Deaths after 28 days since last administration			
Clinical Safety Laboratory Tests			
Hematology	Y		Y
Clinical Chemistry	Y		Y
Coagulation	Y		Y
Dipstick Urinalysis	Y		Y
ECGs			
Heart Rate (beats/min)	Y		Y
PR Interval (msec)			
QRS Interval (msec)			
QT Interval (msec)			
QTcF Interval (msec) • Highest post-baseline QTcF >450 msec • Highest post-baseline QTcF >480 msec • Highest post-baseline QTcF >500 msec • Maximum CFB of QTcF > 30 msec • Maximum CFB of QTcF > 60 msec			
Overall interpretation & Clinical Significance			Y
Vital Signs & Body Measurements			
Heart Rate (beats/min)	Y		Y
Systolic Blood Pressure (mmHg)			
Diastolic Blood Pressure (mmHg)			
Temperature (°C)			
Other Safety Data Listings			
Physical Examination			Y
ECOG Performance Status			Y
Pregnancies			Y

9.2. MTD and DLT Events

9.2.1. Dose Escalation and Determination of MTD

The dose escalation and determination of the MTD and/or recommended dose will be guided by a BLRM with overdose control (EWOC) (see protocol section 4.1.1, and appendix F). The starting dose and some of the provisional dose levels that could be evaluated during this study are described in protocol Table 1. The doses to be investigated are not limited to the provisional dose level listed in the table. The proposed dose escalation scheme for WTX-330 includes a dose level -1 with a 50% lower dose than the first dose level, in the event that the first dose level is not tolerated. Doses are selected based on patient safety data and are subject to satisfying the EWOC criteria under BLRM. The RDE will be determined by the Dose Escalation Committee (DEC) considering all available data and is not stipulated in this SAP.

9.2.2. DLT Events

The DLT will be listed using the DLT-evaluable set.

9.3. Adverse Events (AEs)

Unless otherwise specified, adverse events will be summarized using frequency tables by System Organ Class (SOC) and Preferred Term (PT).

9.3.1. AE-related Definitions and Derivations

9.3.1.1. Coding and Grading

All adverse events (AEs) will be coded using MedDRA® 26.0 and will be graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) version 5.0 (see Subsection 15.1), except for Cytokine Release Syndrome which will be graded with American Society for Transplantation and Cellular Therapy (ASTCT) Grade.

If severity grading is missing, the event will be graded as severe (Grade 3) unless the event being recorded is leading to life-threatening or death and will be graded accordingly as Grade 4 (life-threatening) or 5 (death).

9.3.1.2. Relatedness Assessment

The investigator will category the relatedness of AE to study drugs as 'Definite,' 'Probable,' 'Possible,' 'Unlikely,' and 'Unrelated.' In safety analyses, 'Definite,' 'Probable,' 'Possible' or missing relationship will be summarized as 'Related,' and other relationship will be treated as 'Unrelated."

9.3.1.3. Treatment Emergent Adverse Events (TEAEs)

A TEAE is defined as an AEs that emerges or worsens (ie increase in CTCAE grade/ASTCT grade) on/after the first WTX-330 dose and within 30 days of the last WTX-330 dose or the start of a new cancer regimen, whichever occurs earlier.

9.3.1.4. TEAEs of Special Interest (AESIs)

TEAEs of special interest (AESIs) include

- >=Grade 2 CRS
- >= Grade 3 Oral Mucositis
- Hy's Law or >= Grade 3 increased ALT or AST

9.3.2. Planned Analysis of Adverse Events

Using the Safety Analysis Set, TEAE summaries will be presented by primary SOC and PT. Summaries will be presented by analysis groups described in Subsection 6.2. Although a PT or SOC may be reported more than once for a subject, each subject will only be counted once within the SOC or PT.

Number and percentage of subjects with the following TEAE categories will be presented in overview TEAE tables. Number and percentage of subjects with the following TEAE categories will be summarized by primary SOC and PT.

- All TEAEs
- TEAEs related to WTX-330
- All Serious TEAEs
- Serious TEAEs related to WTX-330
- Grade 3 or higher TEAEs
- Grade 3 or higher TEAEs related to WTX-330
- TEAEs leading to WTX-330 withdrawn
- WTX-330-related TEAEs leading to WTX-330 withdrawn

- TEAEs leading to WTX-330 modification (including Dose Delayed, Dose Interrupted, Dose Reduced, Infusion Rate Reduced)
- WTX-330-related TEAEs leading to any study drug modification
- TEAEs leading to deaths
- TEAEs of Special Interest
- Immune Related TEAEs
- Infusion Related Reaction
- Cytokine Release Syndrome (CRS)
- DLT

The number and percentage of subjects with TEAEs, TEAEs related to each study drug, Serious TEAEs, Serious TEAEs related to each study drug will also be summarized by PT and/or SOC/PT/Maximum CTCAE/ASTCT Grade.

Subject listing(s) will be provided for subjects with all TEAEs, serious TEAEs, AESIs, Immune Related TEAEs, Infusion Related Reaction, Cytokine Release Syndrome, TEAE leading to death, TEAE leading to drug withdrawn, and TEAE leading to drug modification will be listed. All AEs will also be listed.

9.4. Deaths

The number and percentage of subjects who died on study, within 30 days *after* the last study drug administration day, and beyond 30 days *after* the last study drug administration, as well the number and percentage of subjects who died due to each primary cause will be summarized using the Safety Analysis Set.

Death details as collected in the eCRF will be listed.

9.5. Clinical Safety Laboratory Tests

For laboratory values in the form of <x, ≤x, below lower quantification limit, etc., the value will be imputed as x/2 or half of the lower quantification limit for the purpose of numerical descriptive summary. For laboratory values in the form of >x, ≥x, above upper quantification limit, etc., the value will be imputed as x or upper quantification limit for the purpose of numerical descriptive summary. When such imputation occurs, footnotes will be presented to clarify the imputation rule. The original laboratory values will be presented in data listings.

Hematology tests include Red blood cell (RBC) count, hemoglobin (Hb), hematocrit, mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH); white blood cell (WBC) count and differential count including, absolute lymphocyte count (ALC), and absolute neutrophil count (ANC), leukocytes with differential (manual microscopic review is performed only if WBC count and/or differential values are out of reference range); platelet count.

Clinical chemistry tests include Calcium, magnesium, potassium, sodium, bicarbonate, chloride phosphate, albumin, total blood urea nitrogen (BUN), C-reactive protein (CRP), creatinine, urate, estimated glomerular filtration rate, glucose, Alanine transaminase (ALT), aspartate transaminase (AST), bilirubin, alkaline phosphatase (ALP), lactic acid dehydrogenase (LDH), gamma-glutamyl transferase (GGT), Triiodothyronine (T3), thyroid-stimulating hormone (TSH), thyroxine (T4).

Coagulation laboratory tests Prothrombin time (PT) or International normalized ratio (INR), and Partial thromboplastin time (PTT) or Activated partial thromboplastin time (APTT).

Urinalysis tests include Dipstick (bilirubin, glucose, ketones, leukocytes, nitrite, occult blood, pH, protein, specific gravity, turbidity and colour, and urobilinogen) or microscopy.

The value of hematology tests, coagulation tests, and chemistry tests will be graded with CTCAE 5.0. If a parameter includes both hypo- and hyper- CTCAE grade derivation, hypo- and hyper- will be derived separately. If the baseline is not CTCAE gradable (e.g., AST increase), the baseline measurement will be categorized as low/normal/high according to reference ranges.

- Quantitative laboratory data will be summarized using descriptive statistics (Subsection 15.2) of actual values and changes from baseline to each visit over time.
- Shift of the worst post-baseline CTCAE grade from baseline will be summarized as well.

Some tests (including red blood cells (RBC) count, hematocrit, Chloride, lactic acid dehydrogenase, prothrombin time, etc) with normal range and are not CTCAE gradable. The shift of these tests from baseline low/normal/high to lowest/highest post-baseline will be prepared.

The number and percentage of patients with elevated AST, ALT, total bilirubin, and alkaline phosphatase will be summarized for safety analysis set. Elevations will be summarized as a function of the ULN.

- 3 × ULN, 5 × ULN, 10 × ULN, and 20 × ULN elevations of AST, ALT, and either ALT or AST.
- >1.5 × ULN and >2 × ULN elevations of Total bilirubin.
- Any elevations of ALP >1.5 × ULN.
- Elevation of ALT/AST (>3 × ULN) accompanied by Total bilirubin (>1.5 × ULN, >2 × ULN).

A separate listing will also be provided for all hematology, coagulation, clinical chemistry (including thyroid function tests) and urinalysis. Laboratory values that are outside the normal range will also be flagged in the data listings, along with corresponding normal ranges. Any out-of-range values that are identified by the investigator as being clinically significant will also be shown in the data listing.

For all NCI-CTCAE programmatically gradable laboratory tests, separate listings will be provided for all Grade 3 or higher abnormal lab results (in either direction) together with corresponding baseline results.

9.6. Electrocardiograms (ECG)

For triplicate ECG measurements, the mean of all assessments at each scheduled time point will be used for descriptive summarization purpose; however, all ECG measurements will be provided in data listings.

Local-read ECG data will be listed overall and a separate listing for any clinically significant finding in ECG values will be provided.

Absolute and CFB values for PR Interval, QT Interval, QTcF, QRS Duration and HR will be summarized descriptively by visit and by dose level in escalation phase and by arm in expansion phase. QTcF will be calculated with $QT/(RR)^{1/3}$.

The frequency and percentage of subjects will be tabulated descriptively for the following:

- Highest post-baseline QTcF >450 msec
- Highest post-baseline QTcF >480 msec
- Highest post-baseline QTcF >500 msec
- Maximum CFB of QTcF > 30 msec
- Maximum CFB of QTcF > 60 msec

9.7. Vital Signs and Body Measurements

The absolute values of vital sign and body measurements (including weight, systolic blood pressure, diastolic blood pressure, HR, and temperature) and the CFB measurements will be summarized descriptively for each analysis group over scheduled time points (visits) as defined in Subsection 6.2.

The number and percentage of patients with the following notably abnormal vital signs and body measurements will be presented by visit:

- Clinically notable elevated values:
  - Systolic BP: ≥ 180 mmHg and an increase ≥ 20 mmHg from baseline
  - Diastolic BP: ≥ 105 mmHg and an increase ≥ 15 mmHg from baseline
  - Weight: Increase of ≥ 10% from baseline
  - Heart rate: ≥ 120 bpm with an increase of ≥ 15 bpm from baseline
  - Temperature: > 38° C
- Clinically notable decrease values:
  - Systolic BP: ≤90 mmHg and a decrease ≥ 20 mmHg from baseline
  - Diastolic BP: ≤ 50 mmHg and a decrease ≥ 15 mmHg from baseline
  - Weight: decrease of ≥ 10% from baseline
  - Heart rate: ≤ 50 bpm and a decrease ≥ 15 bpm from baseline
  - Temperature: < 35° C

Vital signs will be provided in a data listing by subject using the Safety Analysis Set.

9.8. Physical Examination

Any clinically significant findings at Screening should be reported on the Medical History; otherwise, new/worsened clinically significant findings should be reported as Adverse Events.

All physical examination data will be listed.

9.9. ECOG Performance Status

ECOG performance status will be provided in a data listing.

9.10. Pregnancies

Pregnancy test results will be provided in a data listing using the Safety Analysis Set.

10. Pharmacokinetics

10.1. Schedule for PK Sampling

On Cycle 1 Day 1~ Day 8 and Cycle 2 Day 1 ~ Day 8 of Dose Escalation, the samples will be collected at Pre-dose, Immediately after (±5 minutes) WTX-330 infusion, 4 hours (±30 minutes) post start of WTX-330 infusion, 8 hours (±30 minutes) post start of WTX-330 infusion, 24 hours (±2 hours) post start of WTX-330 infusion, 48 hours (±2 hours) post start of WTX-330 infusion, 168 hours (±4 hours) post start of WTX-330 Infusion. On other visits, the samples will be collected at Pre-dose, Immediately after (±5 minutes) WTX-330 infusion. On Dose Expansion, the samples will be collected at Pre-dose, Immediately after (±5 minutes) WTX-330 infusion.

10.2. Pharmacokinetic Parameters

Plasma concentrations of WTX-330 and free IL-12 will be determined with a validated bioanalytical assay. PK parameters for WTX-330 and free IL-12 at Cycle 1 and Cycle 2 of Dose Escalation will be calculated from plasma concentrations using noncompartmental analyses: C_{max}, T_{max}, $t½$, AUC_{0-14d}.

10.3. Analysis of Pharmacokinetic Parameters

The PK Analysis Set will be used for summaries of all PK data.

WTX-330 and free IL-12 plasma concentrations will be summarized by visit and dose cohort (n, mean, geometric mean, standard deviation, coefficient of variation, median, Min and Max).

C_{max}, T_{max}, t½, $AUC_{0\text{-}14d}$ at Cycle 1 and Cycle 2 will be summarized with descriptive sctatistics (n, mean, geometric mean, standard deviation, coefficient of variation, median, Min and Max). T_{max} will be summarized with descriptive statistics (n, mean, standard deviation, median, Min and Max).

Plots of mean WTX-330 and free IL-12 plasma concentrations versus time will be generated by dose group and phase in linear and semi-logarithmic form. Individual plasma concentrations versus time graphs will also be provided.

11. Anti-Drug Antibody (ADA)

ADA Samples will be collected at pre-dose on each schedule and unscheduled visit.

Anti-drug antibody (ADA) data of WTX-330 will be provided in listing. ADA will be summarized in tabular by visit under the following categories:

- N (%) of patients with ADA at baseline (i.e. ADA detectable in the Cycle 1 Day 1 pre-dose sample)
- N (%) of patients with post-dose ADA (i.e. ADA detectable in any pre-dose sample from Cycle 1 Day 15 and later)
- N (%) of patients with treatment-induced ADA, defined as those patients with no ADA at baseline and one or more post-treatment (Cycle 1 Day 15 and later) ADA-positive sample.
- N (%) of patients with treatment-boosted ADA, defined as patients with a positive baseline ADA result who had one or more post-treatment (Cycle 1 Day 15 and later) ADA result with a higher titer than that of the baseline ADA sample.
- N (%) of patients with treatment-unaffected ADA, defined as patients with a positive baseline ADA result who had post-treatment (Cycle 1 Day 15 and later) ADA result with a lower titer than that of the baseline ADA sample.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

13. Multiplicity

No formal hypothesis testing will be performed on efficacy and safety endpoints.

14. References

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15. Appendices

15.1. Appendix 1: Referenced Study Documents, Software and Standards

Document, Software, or Standard	Version / Date
Protocol	Amendment V02 / 06 April 2023
Electronic Case Report Form (eCRF)	V3.0 30JUN2023
SAS® Software	9.4
National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE)	5.0 / 27NOV2017
Medical Dictionary for Regulatory Activities (MedDRA®)	26 or higher / latest version at database lock (DBL)
World Health Organization Drug Dictionary (WHODrug)	B3 Global / latest version at DBL (March 2023 or later)
Response Evaluation Criteria in Solid Tumours (RECIST)	1.1 / 2009
Immune-Response Evaluation Criteria in Solid Tumors (iRECIST)	2017
Lugano classification	2014

15.2. Appendix 2: Descriptive Statistical Summaries

Descriptive Statistical Summaries

Numerical Data

Numerical variables will be summarized using descriptive statistics, displaying

- the number of subjects in the analysis group,
- the number of subjects with data,
- sample mean,
- sample standard deviation (calculated as the square root of an unbiased variance estimate),
- sample median,
- minimum (min) and
- maximum (max).

Categorical Data

- Categorical variables will be summarized by using frequency counts and percentages.
- The number of subjects with missing values will be displayed.
- Unless otherwise specified, the denominators used for calculating sample proportions will be the number of subjects in the analysis group (Subsection 6.2) of the specified statistical analysis set (or a subset of the statistical analysis set under use).
- For select ordinal categorical variables, cumulative counts and cumulative percentages may be presented, if appropriate.

15.3. Appendix 3: Data Display Conventions

Data Display Conventions

Precision

Data Display Conventions

- Numeric data will be reported at the precision collected on the eCRF.
- The reported precision from non-eCRF sources will follow the same principles as described below but may be adjusted to a clinically interpretable number of decimal places (dp).
- Means and medians will be presented by 1 additional decimal place, and standard deviation will be presented by 2 additional decimal places than the standard presentation level of the respective data. Minimum and maximum values will be presented using the same number of decimal places as the original data. Standard errors and CI limits will be presented by 1 additional decimal place than corresponding point estimates.
- If not otherwise stated, percentages will be presented to 1 decimal place. However, if the percentage (or estimated proportion) is 100% exactly, no decimal place will be shown, whereas presented as 100.0% implies that the percentage is in the half-open interval [99.95%, 100.0%).
- Reasonable number of dps will be adjusted for proper presentation and interpretation. The maximum number of decimal places reported shall be 4 for any summary statistic, unless otherwise stated.

Default Presentation Precision

Name	Description	Decimal Place (dp)
N	Number of Subjects in the Treatment Group	Always 0 decimal.
n	Number of Subjects with Non-Missing Values	Always 0 decimal.
%	Percentage	1 decimal for categorical data
Mean	Arithmetical Mean	1 more decimal than original data
StdDev	Standard Deviation	2 more decimal than original data
Median	Median	1 more decimal than original data
Min.	Minimum	Same as original data
Max.	Maximum	Same as original data
SE	Standard Error	1 more decimal than the corresponding point estimate
CI	Confidence Interval	1 more decimal Than the corresponding point estimate
P value	P value	3 significant digits

Rounding Rules

- In general, explicit rounding will only occur when presenting data but not when analyzing data. Thus, data in recorded in the Analysis Data Sets (e.g., ADaM data sets) will not be rounded.
- By default, presented data will be rounded to the nearest required presentation precision, with a "round ties to even" tie-breaking rule according to IEEE 754-2019.
- When presenting CIs, the lower interval limit will always be rounded down and the upper interval limit will always be rounded up in order preserve the claimed (exact or asymptotic) confidence level. When either limit is outside of the parameter space (e.g., below 0 or above 1 for proportions), the interval will be truncated at the boundary of the parameter space.

Zero Count Presentation

- For descriptive summaries, if the number of subjects in a category is 0, then percentage will not be displayed, and only a count of 0 will be shown.
- However, structural zeros (e.g., when the count is deemed to be 0 before obtaining actual data), missing data or inapplicable/unevaluable summaries will be presented as −, NA or NE (not applicable or not evaluable, respectively).

Data Display Conventions

Sorting in Displays

- In data listings, data records will be sorted by study phase (escalation vs expansion), therapy (monotherapy vs combination therapy), dose level / arm, site, and subject, and when appropriate by visit, scheduled time point or other identifiers for sequence or type of observation.
- In descriptive summaries involving categorical variables only, e.g., summaries of
  - medical history by SOC and PT,
  - medications by ATC category and PN, and
  - adverse events by SOC and PT,

  the categories and sub-categories will be presented by decreasing frequency using sorting variables in the following preference order:

  1. Total count (irrespective of whether the total column is shown or not)
  2. Count from higher dose level for escalation part or from higher arm code for expansion part (D > C > B > A)
  3. Alphabetical order of the category label

  Sorting variables with lower preference will only be used if ties remain using sorting variables with higher preference.

15.4. Appendix 4: Study Day, Duration, Period, Visit and Analysis Windows

Study Day, Duration, Period, Visit and Analysis Windows

Study Day

For each study subject, Day 1 is defined as the date corresponding to the first administration of any study drug.

Study days after Day 1 are calculated as the number of days from Day 1:

- Study Day = Date of interest – Date of Day 1 + 1, if the date of interest is on or after date of Day 1;
- Study Day = Assessment date – Date of Day 1, if the assessment date is prior to Day 1.
- Study Day is set to missing if the date of interest is missing.

Time Unit and Duration

- Unless otherwise specified, day is the primary time unit for derived time and duration.
- Derived time units include
  1. Week = 7 days
  2. Month = 30.4375 days,
  3. (Gregorian) Year = 365.25 days = 12 months.

  Thus, 1 month and 4 weeks are considered different.
- Unless otherwise specified, duration of time is defined from the starting day through the ending day, inclusive of both boundary days.

Study Periods

- Screening period: beginning on the day of informed consent, or Study Day −28, whichever is latest, and ending on Day −1

Study Day, Duration, Period, Visit and Analysis Windows
• Treatment period: beginning on Study Day 1 and ending on the last day of the End of Treatment (EoT) visit. In case that the EoT visit is missed for any reason, the treatment period will end on the 28th day since the last dose of any study drug. • Safety follow-up period: 30-day safety follow-up period since the first day after the treatment period and or study discontinuation date, whichever occurs first. • Unless otherwise specified, events in the screening period are considered as pre-treatment, events in the treatment period and safety follow-up period are considered as on-treatment.
Time Points and Assessment Windows
• Subject visits will be presented according to the nominal visit and/or time points as obtained on the eCRF. • Unscheduled visits will be included in subject data listing but will not be presented in descriptive summary tables, except for deriving time to event (TTE) variables or otherwise specified.

15.5. Appendix 5: Derived Data And Definitions

Derived Data And Definitions
Baseline & Change From Baseline

• The baseline is defined to be the last non-missing value prior to the first WTX-330 dose.
  ○ For assessments performed on Day 1, if the time of the day is missing but scheduled time point is recorded as pre-dose, the assessment may be considered the baseline assessment for the respective study procedures.
• Change from Baseline (CFB) = Post-baseline Assessment – Baseline Assessment.
  ○ CFB will be set to missing if corresponding post-baseline assessment or the baseline assessment is missing
• Percent CFB = 100 × (CFB / Baseline Assessment) %, with the following exceptions:
  ○ If both CFB and baseline assessment are 0, the corresponding percent CFB will be set to 0.
  ○ If baseline assessment is 0 or missing but the CFB is non-zero, the percent CFB will be set to missing.

Age
Age at informed consent will be calculated from the date of birth to the date of informed consent.
Prior and Concomitant Medications, Procedures, and Medical Conditions
• Prior medications – all medications that ended before Day 1. • Concomitant medications – all non-study drug medications used on/after day 1. • Prior and concomitant procedures are defined analogously.

Derived Data And Definitions
● If the start and/or end dates are partially recorded or missing completely, refer to Subsection 15.6 for the determination of prior vs concomitant status.

15.6. Appendix 6: Premature Withdrawals & Handling of Missing Data

Premature Withdrawals & Handling of Missing Data

Premature Withdrawals

During the dose escalation phase, if a subject in Cycle 1 discontinues, holds, or modifies WTX-330 dose for a reason other than a DLT as reviewed by DEC and is not followed for safety for a minimum of 28 days, the subject may be replaced.

For the Dose Expansion Phase, subjects will be replaced if they do not have at least one post-baseline efficacy assessment and did not discontinue due to clinical progression.

Handling of Missing or Partial Dates

In the presence of missing or partial dates, the determination of "prior" and "concomitant" status for non-study drug medications, and TEAE will follow the rules below:

Partial start date for Adverse Event, partial start date for Medications, and partial date of diagnosis

- if month and day are missing, and the year is the same as the year of first WTX-330 dose, then assign the date of first WTX-330 dose as start date; else assign Jan 1st of the year.
- if only the day is missing, and the month and year are same as the month and year of first WTX-330 dose, then assign the date of first WTX-330 dose as AE start date; else assign 1st day of the month.
- Compare the imputed date with the date of last known alive/contact; if the imputed date is later than the date of last known alive/contact, then assign the date of last known alive/contact as AE start date.

Partial end date for Adverse Event, and partial end date for Medications:

- Assign DEC 31st of the year if both Month and Day are missing.
- Assign last day of the month if only Day is missing.
- Assign 'ongoing' if Year, Month and Day are missing.
- Compare the imputed date with the date of last known alive/contact; if the imputed date is later than the date of last known alive/contact, then assign the date of last known alive/contact as AE end date.

The data listings will report original data instead of the imputed date. The imputed date will be used to categorized TEAE, Prior/Concomitant Medication.

15.7. Appendix 7: List of Abbreviations

Abbreviation	Description
ADA	Anti-drug antibody
ADaM	Analysis Data Model
AE	Adverse event
AESI	Adverse event of special interest
ALT	Alanine aminotransferase
ALP	Alkaline phosphatase
AST	Aspartate aminotransferase
ATC	Anatomical Therapeutic Chemical
BOR	Best overall response
CD	Cluster of differentiation
CFB	Change from baseline
CI	Confidence interval
COVID-19	Coronavirus Disease 2019
CR	Complete response
CRP	C-reactive protein
CRS	Cytokine release syndrome
CSR	Clinical Study Report
DLT	Dose-limiting toxicity
dMMR	Deficient mismatch repair
DoR	Duration of response
ECG	Electrocardiogram
ECOG	Eastern Cooperative Oncology Group
eCRF	Electronic Case Report Form
eGFR	Estimated glomerular filtration rate
EoT	End of Treatment
iBOR	Immune-best overall response
iCBR	Immune-clinical benefit rate
ICH	International Council for Harmonisation
IL	Interleukin
iCPD	Immune-confirmed progressive disease

Abbreviation	Description
iCR	Immune-complete response
iDoR	Immune-duration of response
IFN	Interferon
IL	Interleukin
IL-2R	Interleukin-2 receptor
iORR	Immune-overall response rate
iPFS	Immune-progression-free survival
iPR	Immune-partial response
iRECIST	Immune-Response Evaluation Criteria in Solid Tumors
iSD	Immune-stable disease
iUPD	Immune-unconfirmed progressive disease
LDH	Lactic acid dehydrogenase
Max.	Maximum
MedDRA	Medical Dictionary for Regulatory Activities
Min.	Minimum
MMR	Mismatch repair
mRCC	Metastatic renal cell carcinoma
MSI	Microsatellite instability
MSI-H	MSI-High
MSI-L	MSI-Low
MSS	Microsatellite stable
MTD	Maximum tolerated dose
NCI-CTCAE	National Cancer Institute Common Terminology Criteria for Adverse Events
NE	Not evaluable
NK (cells)	Natural killer (cells)
ORR	Overall response rate
OS	Overall survival
PD	Progressive disease
PFS	Progression-free survival
PK	Pharmacokinetic(s)
pMMR	Proficient mismatch repair

Abbreviation	Description
PN	Preferred name
PR (except for PR interval)	Partial response
PT	Preferred term
PTT	Partial thromboplastin time
QTc	QT interval corrected for heart rate
QTcF	QT interval corrected for heart rate using Fridericia's formula
RECIST	Response Evaluation Criteria in Solid Tumors
SAE	Serious adverse events
SAP	Statistical Analysis Plan
SD	Stable disease
SOC	System organ class
StdDev	Standard deviation
TEAE	Treatment-emergent adverse event
TNF	Tumor necrosis factor
TTE	Time to event
ULN	Upper limit of normal
WHODrug	World Health Organization Drug Dictionary

Werewolf Therapeutics, Inc.

A Phase 1 (First-In-Human [FIH]), Multi-Site, Dose Escalation and Expansion Study of WTX-330 in Adult Patients with Advanced or Metastatic Solid Tumors or Lymphoma

TFL Shells

Author: Shuangli Guo

SAP Version: 2.0

Table Shell Version: 2.0

Caidya Code: WWT21330

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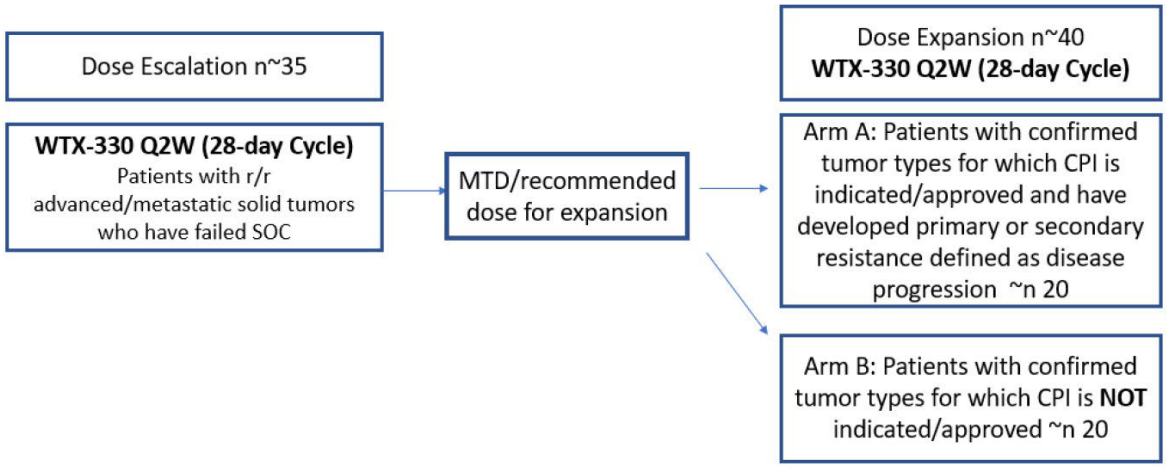
Approval and Signature Page

Approved by:

Name, Institution, and Job Title	Signature	Date
Shuangli Guo Senior Manager Biostatistics Caidya	Signed by: Shuangli Guo Signer Name: Shuangli Guo Signing Reason: I am the author of this document Signing Time: 26-Feb-2025 | 7:28:54 PM GMT 3F1277AD321D4048BF564AE5BED08E47	26-Feb-2025
Oliver Schonborn-Kellenberger Biostatistician Werewolf Therapeutics, Inc.	Signiert von: Oliver Schönborn-Kellenberger Name des Unterzeichners: Oliver Schönborn-Kellenberger Signiergrund: Ich genehmige dieses Dokument Signierzeit: 26-Feb-2025 | 7:59:53 PM GMT 988B94B1FDA24A35AEB8361DCA46EBF3	26-Feb-2025

Format and Ordering of Treatment Groups

The study includes Dose Escalation and Dose Expansion as the strategy below.



CPI = checkpoint inhibitor; MTD = maximum tolerated dose; Q2W = every 2 weeks; r/r = relapsed/refractory; SOC = standard of care.

Disposition, demographic, baseline characteristics, disease history, efficacy, and safety summaries will be presented as follows.

Dose Escalation will be presented by dose level – **additional columns will be added if more dose levels/schedules are tested**:

	WTX-330 0.016 mg/kg	WTX-330 0.032 mg/kg	WTX-330 0.056 mg/kg	WTX-330 0.084 mg/kg	WTX-330 0.126 mg/kg	WTX-330 0.190 mg/kg	WTX-330 0.290 mg/kg	WTX-330 0.XXX mg/kg	Total

Dose Expansion will be presented by Arm:

	Arm A	Arm B	Total

Note: Arm A = Patients with indications for which a CPI is indicated/approved; Arm B = Patients with tumor types for which CPI therapy is not indicated/approved.

Overall response rate (ORR) and immune-overall response rate (iORR) in Dose Expansion will be further summarized by indication

	Arm A				Arm B			
	RCC	NSCLC	HNSCC	XXXXX	CC	FL	DLBCL	YYYYY

Note: Arm A = Patients with indications for which a CPI is indicated/approved; Arm B = Patients with tumor types for which CPI therapy is not indicated/approved.
Note: RCC = Renal Cell Carcinoma; NSCLC = Non-small Cell Lung Cancer; HNSCC = Head and Neck Squamous Cell Carcinoma; XXXXX = __; CC = Colorectal Carcinoma; FL = Follicular Lymphoma; DLBCL = Diffuse Large B-cell Lymphoma; YYYYY = __.

Column headers will be updated according to the indication in Arm A and B.

General Display Conventions

Summary tables and subject data listings will be in landscape format. Table titles will be centered.

Sorting Conventions
For AE and MH summaries, Primary SOCs and PTs will be ordered by descending count in overall Total (last column in table display). Other summaries will follow table shells layout.

Display of Continuous Statistics
Means and medians will be shown to one more decimal place, and the standard deviation will be shown to two more decimal places than the source data values. In cases where variables are derived and have floating point values (no fixed number of decimal places), an appropriate level of precision will be determined based on the context.

Statistics that cannot be derived will be shown as a dash ("-") in summary tables.

Two-Sided confidence intervals are displayed with a format such as "(xx.x, xx.x)." If a confidence interval cannot be produced due to insufficient data, then a dash ("-") will be shown in place of the entire confidence interval.

Display of Percentages
The following conventions apply for percentages:

- Percentages will be displayed to one decimal place unless otherwise specified
- No percentage will be shown if the corresponding count is 0
- Percentages that are exactly equal to 100% will be displayed as "100%"
- Percentages that round down to 0.0% will be displayed as "<0.1%"
- Percentages that round up to 100.0% will be displayed as ">99.9%"

Percentages are shown in parentheses after the corresponding count such as "25 (5.2%)" where extra spaces are included after the left parenthesis to ensure that decimal places for all percentages align within the same column.

Display of P-Values
Unless otherwise noted, p-values will be displayed as follows:

- P-values between 0.0001 and 0.9999 will be displayed in the format "0.xxxx"
- P-values that are exactly equal to 1 will be displayed as "1.0000"
- P-values <0.0001 will be displayed as "<0.0001"
- P-values >0.9999 and not exactly equal to 1 will be displayed as ">0.9999"

P-values that are descriptive and not associated with a formal test of hypothesis will not be flagged based on statistical significance. The following note will be shown in the table:

```
Note: P-values are for descriptive purposes and are not evaluated for statistical
significance.
```

Unless otherwise noted, p-values that are statistically significant will be flagged with an asterisk. The table footnote is dependent on the setting, but the following example footnote is appropriate for many settings:

```
* Statistically significant at the 0.05 level.
```

Display of Dates in Subject Data Listings
Dates will be shown in one of the following formats:

- YYYYMMDD for complete dates
- YYYYMM for dates with only a month and year
- YYYY for dates with only a year

Partial dates are not imputed for subject data listings even if such dates are imputed for statistical algorithms. Relative day (if shown) is only derived for complete dates.

Dates will be shown in ISO8601 format as follows:

- DDMMMYYYY for complete dates
- MMMYYYY for dates with only a month and year
- YYYY for dates with only a year

Partial dates are not imputed for subject data listings even if such dates are imputed for statistical algorithms. Relative day (if shown) is only derived for complete dates.

Display of Missing Values in Subject Data Listings
For subject data listings, missing numeric values will be shown as a dash ("-"). Missing character values will be shown as blanks.

Modification History

Version	Date	Author	Changes from Previous Version
0.1	19Dec2023	Shuangli Guo	N/A – First Version
0.2	12Jun2024	Shuangli Guo	Add shift tables for Deauville Scale
0.3	21Jun2024	Shuangli Guo	Update footnote in TEAE table based on Werewolf's comments, correct typos
1.0	21Jun2024	Shuangli Guo	Accept changes in version 0.3
1.1	18Feb2025	Shuangli Guo	Correct Typo Select the TFLs for aCSR based on WW request
1.2	25Feb2025	Shuangli Guo	Correct Typo Add TFLs for free IL-12 PK summary
2.0	26Feb2025	Shuangli Guo	Accept changes/WW edits in draft 1.2

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Table Shells

14.1 Study Population and Baseline

Table 14.1.1.1
Summary of Analysis Set - Dose Escalation
Screened Subjects

	WTX-330 0.016 mg/kg (N=x)	WTX-330 0.032 mg/kg (N=x)	WTX-330 0.056 mg/kg (N=x)	WTX-330 0.084 mg/kg (N=x)	WTX-330 0.126 mg/kg (N=x)	WTX-330 0.190 mg/kg (N=x)	WTX-330 0.290 mg/kg (N=x)	WTX-330 0.XXX mg/kg (N=x)	Total (N=xx)
Screened subjects									XXX
Screen failure									XX
Enrolled subjects, n	x	x	x	x	x	x	x	x	xx
Safety analysis set, n	x	x	x	x	x	x	x	x	xx
Dose-determining analysis set, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Efficacy evaluable analysis set, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Pharmacokinetics analysis set, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Pharmacodynamics analysis set - Cytokines, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Pharmacodynamics analysis set - Peripheral Immune Cells, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Anti-drug antibody analysis set, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)

Note: See SAP section 5 for the definition of each analysis set.
Note: N is the number of subjects in Safety Analysis Set. It is the denominator for the percentage.

Table 14.1.1.2.1
Summary of Analysis Set – Dose Expansion
Screened Subjects

	Arm A (N=XX)	Arm B (N=XX)	Total (N=XX)
Screened subjects	xx	xx	xx
Screen failure	xx	xx	xx
Enrolled subjects, n	xx	xx	xx
Safety analysis set, n	xx	xx	xx
Efficacy evaluable analysis set, n(%)	XX(XX.X)	XX(XX.X)	XX(XX.X)
Pharmacokinetics analysis set, n(%)	XX(XX.X)	XX(XX.X)	XX(XX.X)
[redacted]			
Anti-drug antibody analysis set, n(%)	XX(XX.X)	XX(XX.X)	XX(XX.X)

Note: Arm A = Patients with indications for which a CPI is indicated/approved; Arm B = Patients with tumor types for which CPI therapy is not indicated/approved.
Note: See SAP section 5 for the definition of each analysis set.
Note: N is the number of subjects in Safety Analysis Set. It is the denominator for the percentage.

Table 14.1.1.2.2
Summary of Analysis Set - Dose Expansion by Indication
Screened Subjects

	Arm A				Arm B			
	RCC (N=XX)	NSCLC (N=XX)	HNSCC (N=XX)	XXXXX (N=XX)	CC (N=XX)	FL (N=XX)	DLBCL (N=XX)	YYYYY (N=XX)
Screened subjects	xx	xx	xx	xx	xx	xx	xx	xx
Screen failure	xx	xx	xx	xx	xx	xx	xx	xx
Enrolled subjects, n	x	x	x	x	x	x	x	x
Safety analysis set, n	x	x	x	x	x	x	x	x
Efficacy evaluable analysis set, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
[redacted]								
Anti-drug antibody analysis set, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)

Note: Arm A = Patients with indications for which a CPI is indicated/approved; Arm B = Patients with tumor types for which CPI therapy is not indicated/approved.
Note: RCC = Renal Cell Carcinoma; NSCLC = Non-small Cell Lung Cancer; HNSCC = Head and Neck Squamous Cell Carcinoma; XXXXX = __; CC = Colorectal Carcinoma; FL = Follicular Lymphoma; DLBCL = Diffuse Large B-cell Lymphoma; YYYYY = __.
Note: See SAP section 5 for the definition of each analysis set.
Note: N is the number of subjects in Safety Analysis Set. It is the denominator for the percentage.

Table 14.1.2.1
Summary of Subject Disposition - Dose Escalation
Safety Analysis Set

Disposition Description	WTX-330 0.016 mg/kg (N=x)	WTX-330 0.032 mg/kg (N=x)	WTX-330 0.056 mg/kg (N=x)	WTX-330 0.084 mg/kg (N=x)	WTX-330 0.126 mg/kg (N=x)	WTX-330 0.190 mg/kg (N=x)	WTX-330 0.290 mg/kg (N=x)	WTX-330 0.XXX mg/kg (N=x)	Total (N=XX)
Ongoing WTX-330 treatment, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Discontinued WTX-330 treatment, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Reason for WTX-330 treatment discontinuation, n(%)									
Adverse event	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Death	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Physician decision	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Pregnancy	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Progressive disease	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Radiological	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Clinical	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Study terminated by sponsor	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Withdrawal of ICF	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Other	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Ongoing study, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Discontinued study, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Reason for study discontinuation, n(%)									
Completed study	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Withdrawal of consent by patient	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Lost to follow-up	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Death	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Sponsor terminated the study	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
COVID-19 related	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Other	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)

Table 14.1.2.2
Summary of Subject Disposition - Dose Expansion
Safety Analysis Set

Disposition Description	Arm A (N=XX)	Arm B (N=XX)	Total (N=XX)
Ongoing WTX-330 treatment, n(%)	XX(XX.X)	XX(XX.X)	XX(XX.X)
Discontinued WTX-330 treatment, n(%)	XX(XX.X)	XX(XX.X)	XX(XX.X)
Reason for WTX-330 treatment discontinuation, n(%)			
Adverse event	XX(XX.X)	XX(XX.X)	XX(XX.X)
Death	XX(XX.X)	XX(XX.X)	XX(XX.X)
Physician decision	XX(XX.X)	XX(XX.X)	XX(XX.X)
Pregnancy	XX(XX.X)	XX(XX.X)	XX(XX.X)
Progressive disease	XX(XX.X)	XX(XX.X)	XX(XX.X)
Radiological	XX(XX.X)	XX(XX.X)	XX(XX.X)
Clinical	XX(XX.X)	XX(XX.X)	XX(XX.X)
Study terminated by sponsor	XX(XX.X)	XX(XX.X)	XX(XX.X)
Withdrawal of ICF	XX(XX.X)	XX(XX.X)	XX(XX.X)
Other	XX(XX.X)	XX(XX.X)	XX(XX.X)
Ongoing study, n(%)	XX(XX.X)	XX(XX.X)	XX(XX.X)
Discontinued study, n(%)	XX(XX.X)	XX(XX.X)	XX(XX.X)
Reason for study discontinuation, n(%)			
Completed study	XX(XX.X)	XX(XX.X)	XX(XX.X)
Withdrawal of consent by patient	XX(XX.X)	XX(XX.X)	XX(XX.X)
Lost to follow-up	XX(XX.X)	XX(XX.X)	XX(XX.X)
Death	XX(XX.X)	XX(XX.X)	XX(XX.X)
Sponsor terminated the study	XX(XX.X)	XX(XX.X)	XX(XX.X)
COVID-19 related	XX(XX.X)	XX(XX.X)	XX(XX.X)
Other	XX(XX.X)	XX(XX.X)	XX(XX.X)

Note: Arm A = Patients with indications for which a CPI is indicated/approved; Arm B = Patients with tumor types for which CPI therapy is not indicated/approved.

Table 14.1.3.1
Summary of Deviations from the Clinical Protocol - Dose Escalation
Safety Analysis Set

	WTX-330 0.016 mg/kg (N=x)	WTX-330 0.032 mg/kg (N=x)	WTX-330 0.056 mg/kg (N=x)	WTX-330 0.084 mg/kg (N=x)	WTX-330 0.126 mg/kg (N=x)	WTX-330 0.190 mg/kg (N=x)	WTX-330 0.290 mg/kg (N=x)	WTX-330 0.XXX mg/kg (N=x)	Total (N=XX)
Subjects with any deviation, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Deviation category									
ICF/Subject information	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Ineligible subject enrolled	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
IMP dose error	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
IMP other error	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Prohibited medication	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
<insert all non “0” Categories in EDC>	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
SAE or AESI reporting failure	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Other	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Subjects with any major deviation, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Deviation category									
ICF/Subject information	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Ineligible subject enrolled	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
IMP dose error	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
<insert all non “0” Categories in EDC>	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
SAE or AESI reporting failure	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Other	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Subjects with any minor deviation, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Deviation category									
ICF/Subject information	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Ineligible subject enrolled	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
IMP dose error	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
<insert all non “0” Categories in EDC>	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
SAE or AESI reporting failure	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Other	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)

Table 14.1.3.2
Summary of Deviations from the Clinical Protocol - Dose Expansion
Safety Analysis Set

	Arm A (N=XX)	Arm B (N=XX)	Total (N=XX)
Subjects with any deviation, n(%)	X(XX.X)	X(XX.X)	XX(XX.X)
Deviation category			
ICF/Subject information	X(XX.X)	X(XX.X)	XX(XX.X)
Ineligible subject enrolled	X(XX.X)	X(XX.X)	XX(XX.X)
IMP dose error	X(XX.X)	X(XX.X)	XX(XX.X)
IMP other error	X(XX.X)	X(XX.X)	XX(XX.X)
Prohibited medication	X(XX.X)	X(XX.X)	XX(XX.X)
<insert all non "0" Categories in EDC>	X(XX.X)	X(XX.X)	XX(XX.X)
SAE or AESI reporting failure	X(XX.X)	X(XX.X)	XX(XX.X)
Other	X(XX.X)	X(XX.X)	XX(XX.X)
Subjects with any major deviation, n(%)	X(XX.X)	X(XX.X)	XX(XX.X)
Deviation category			
ICF/Subject information	X(XX.X)	X(XX.X)	XX(XX.X)
Ineligible subject enrolled	X(XX.X)	X(XX.X)	XX(XX.X)
IMP dose error	X(XX.X)	X(XX.X)	XX(XX.X)
<insert all non "0" Categories in EDC>	X(XX.X)	X(XX.X)	XX(XX.X)
SAE or AESI reporting failure	X(XX.X)	X(XX.X)	XX(XX.X)
Other	X(XX.X)	X(XX.X)	XX(XX.X)
Subjects with any minor deviation, n(%)	X(XX.X)	X(XX.X)	XX(XX.X)
Deviation category			
ICF/Subject information	X(XX.X)	X(XX.X)	XX(XX.X)
Ineligible subject enrolled	X(XX.X)	X(XX.X)	XX(XX.X)
IMP dose error	X(XX.X)	X(XX.X)	XX(XX.X)
<insert all non "0" Categories in EDC>	X(XX.X)	X(XX.X)	XX(XX.X)
SAE or AESI reporting failure	X(XX.X)	X(XX.X)	XX(XX.X)
Other	X(XX.X)	X(XX.X)	XX(XX.X)

Note: Arm A = Patients with indications for which a CPI is indicated/approved; Arm B = Patients with tumor types for which CPI therapy is not indicated/approved.

Table 14.1.4.1
Summary of Demographic Characteristics - Dose Escalation
Safety Analysis Set

	WTX-330 0.016 mg/kg (N=x)	WTX-330 0.032 mg/kg (N=x)	WTX-330 0.056 mg/kg (N=x)	WTX-330 0.084 mg/kg (N=x)	WTX-330 0.126 mg/kg (N=x)	WTX-330 0.190 mg/kg (N=x)	WTX-330 0.290 mg/kg (N=x)	WTX-330 0.XXX mg/kg (N=x)	Total (N=xX)
Age (years)									
n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Age group, n(%)									
<45	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
≥45 - <65	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
≥65	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Sex, n(%)									
Male	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Female	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
With childbearing potential	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Without childbearing potential	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Ethnicity, n(%)									
Hispanic or Latino	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Not Hispanic or Latino	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Not Reported	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Race [1], n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
American Indian or Alaskan Native	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Asian	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Black or African American	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Native Hawaiian or Other Pacific Islander	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
White	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Other	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Not Reported	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)

Weight (kg) at baseline									
n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Height (cm) at baseline									
n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
ECOG performance status at baseline, n(%)									
0	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
1	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)

[1] Subjects might report multiple races.

Table 14.1.4.2
Summary of Demographic Characteristics - Dose Expansion
Safety Analysis Set

	Arm A (N=XX)	Arm B (N=XX)	Total (N=XX)
Age (years)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Standard Deviation	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Age group, n(%)			
<45	XX(XX.X)	XX(XX.X)	XX(XX.X)
≥45 - <65	XX(XX.X)	XX(XX.X)	XX(XX.X)
≥65	XX(XX.X)	XX(XX.X)	XX(XX.X)
Sex, n(%)			
Male	XX(XX.X)	XX(XX.X)	XX(XX.X)
Female	XX(XX.X)	XX(XX.X)	XX(XX.X)
With childbearing potential	XX(XX.X)	XX(XX.X)	XX(XX.X)
Without childbearing potential	XX(XX.X)	XX(XX.X)	XX(XX.X)
Ethnicity, n(%)			
Hispanic or Latino	XX(XX.X)	XX(XX.X)	XX(XX.X)
Not Hispanic or Latino	XX(XX.X)	XX(XX.X)	XX(XX.X)
Not Reported	XX(XX.X)	XX(XX.X)	XX(XX.X)
Race [1], n(%)	XX(XX.X)	XX(XX.X)	XX(XX.X)
American Indian or Alaskan Native	XX(XX.X)	XX(XX.X)	XX(XX.X)
Asian	XX(XX.X)	XX(XX.X)	XX(XX.X)
Black or African American	XX(XX.X)	XX(XX.X)	XX(XX.X)
Native Hawaiian or Other Pacific Islander	XX(XX.X)	XX(XX.X)	XX(XX.X)
White	XX(XX.X)	XX(XX.X)	XX(XX.X)
Other	XX(XX.X)	XX(XX.X)	XX(XX.X)
Not Reported	XX(XX.X)	XX(XX.X)	XX(XX.X)

Weight (kg) at baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Standard Deviation	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Height (cm) at baseline			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Standard Deviation	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
ECOG performance status at baseline, n(%)			
0	XX(XX.X)	XX(XX.X)	XX(XX.X)
1	XX(XX.X)	XX(XX.X)	XX(XX.X)

Note: Arm A = Patients with indications for which a CPI is indicated/approved; Arm B = Patients with tumor types for which CPI therapy is not indicated/approved.
[1] Subjects might report multiple races.

Table 14.1.5.1.1
Summary of Solid Tumor Disease Characteristics - Dose Escalation
Safety Analysis Set

	WTX-330 0.016 mg/kg (N=x)	WTX-330 0.032 mg/kg (N=x)	WTX-330 0.056 mg/kg (N=x)	WTX-330 0.084 mg/kg (N=x)	WTX-330 0.126 mg/kg (N=x)	WTX-330 0.190 mg/kg (N=x)	WTX-330 0.290 mg/kg (N=x)	WTX-330 0.XXX mg/kg (N=x)	Total (N=xX)
Time since date of initial histopathological diagnosis (months)									
n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
<12 months, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
>=12 months - < 24 months, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
>=24 months - < 36 months, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
>=36 months, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Time since date of most recent disease recurrence/progression (months)									
n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Cancer type, n(%)									
Adrenal cancer	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Basal cell skin cancer	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Bile duct cancer	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Bladder cancer	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Bone cancer	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Breast cancer	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
<insert EDC Cancer Type>	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Primary site of solid tumor, n(%)									
Bone	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Breast	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Bronchus	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Cervix	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Colon	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Duodenum	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)

<insert EDC non "0" records>	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Any pathologic sub-type, n(%)									
Yes	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
No	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Stage of solid tumor at initial diagnosis, n(%)									
0	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
I	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
II	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
III	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
IV	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Stage of solid tumor at baseline, n(%)									
0	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
I	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
II	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
III	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
IV	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Characterization of disease at study entry, n(%)									
Locally advanced	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Metastatic	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Metastatic site if metastatic									
Abdomen/Abdominal Wall	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Adrenal Glands	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
<insert EDC non "0" records>	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Other	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Any known genetic mutations, n(%)									
No	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Yes	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
BRAF	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
EGFR	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
HER2	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
KRAS	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
KIT	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
BRAF	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
EGFR	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
<insert EDC non "0" records>	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
MSI status, n(%)									
Not applicable	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Unknown	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Known	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)

MSI-H (microsatellite instability-high)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
MSI-L (microsatellite instability-low)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
MSS (microsatellite stable)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
dMMR (mismatch repair deficient)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
pMMR (mismatch repair proficient)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Other	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
TMB status known?, n(%)									
Not Applicable	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
No	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Yes	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
High	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Intermediate	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Other	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Tumoral genetic characterization, n(%)									
Yes	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
No	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Not Applicable	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)

Note: Time since date of initial histopathological diagnosis (months) = (date of first dose - date of initial histopathological diagnosis)/30.4375. Time since date of most recent disease recurrence/progression (months) = (date of first dose - date of most recent disease recurrence/progression)/30.4375.

Table 14.1.5.1.2
Summary of Solid Tumor Disease Characteristics - Dose Expansion
Safety Analysis Set

	Arm A (N=XX)	Arm B (N=XX)	Total (N=XX)
Time since date of initial histopathological diagnosis (months)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Standard Deviation	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
<12 months, n(%)	XX(XX.X)	XX(XX.X)	XX(XX.X)
>=12 months - < 24 months, n(%)	XX(XX.X)	XX(XX.X)	XX(XX.X)
>=24 months - < 36 months, n(%)	XX(XX.X)	XX(XX.X)	XX(XX.X)
>=36 months, n(%)	XX(XX.X)	XX(XX.X)	XX(XX.X)
Time since date of most recent disease recurrence/progression (months)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Standard Deviation	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Cancer type, n(%)			
Adrenal cancer	XX(XX.X)	XX(XX.X)	XX(XX.X)
Basal cell skin cancer	XX(XX.X)	XX(XX.X)	XX(XX.X)
Bile duct cancer	XX(XX.X)	XX(XX.X)	XX(XX.X)
Bladder cancer	XX(XX.X)	XX(XX.X)	XX(XX.X)
Bone cancer	XX(XX.X)	XX(XX.X)	XX(XX.X)
Breast cancer	XX(XX.X)	XX(XX.X)	XX(XX.X)
<insert EDC non “0” records>	XX(XX.X)	XX(XX.X)	XX(XX.X)
Primary site of solid tumor, n(%)			
Bone	XX(XX.X)	XX(XX.X)	XX(XX.X)
Breast	XX(XX.X)	XX(XX.X)	XX(XX.X)
Bronchus	XX(XX.X)	XX(XX.X)	XX(XX.X)
Cervix	XX(XX.X)	XX(XX.X)	XX(XX.X)
Colon	XX(XX.X)	XX(XX.X)	XX(XX.X)
Duodenum	XX(XX.X)	XX(XX.X)	XX(XX.X)
<insert EDC non “0” records >	XX(XX.X)	XX(XX.X)	XX(XX.X)

Any pathologic sub-type, n(%)			
Yes	XX(XX.X)	XX(XX.X)	XX(XX.X)
No	XX(XX.X)	XX(XX.X)	XX(XX.X)
Stage of solid tumor at initial diagnosis, n(%)			
0	XX(XX.X)	XX(XX.X)	XX(XX.X)
I	XX(XX.X)	XX(XX.X)	XX(XX.X)
II	XX(XX.X)	XX(XX.X)	XX(XX.X)
III	XX(XX.X)	XX(XX.X)	XX(XX.X)
IV	XX(XX.X)	XX(XX.X)	XX(XX.X)
Stage of solid tumor at baseline, n(%)			
0	XX(XX.X)	XX(XX.X)	XX(XX.X)
I	XX(XX.X)	XX(XX.X)	XX(XX.X)
II	XX(XX.X)	XX(XX.X)	XX(XX.X)
III	XX(XX.X)	XX(XX.X)	XX(XX.X)
IV	XX(XX.X)	XX(XX.X)	XX(XX.X)
Characterization of disease at study entry, n(%)			
Locally advanced	XX(XX.X)	XX(XX.X)	XX(XX.X)
Metastatic	XX(XX.X)	XX(XX.X)	XX(XX.X)
Metastatic site if metastatic			
Abdomen/Abdominal Wall	XX(XX.X)	XX(XX.X)	XX(XX.X)
Adrenal Glands	XX(XX.X)	XX(XX.X)	XX(XX.X)
<insert EDC non “0” records>	XX(XX.X)	XX(XX.X)	XX(XX.X)
Other	XX(XX.X)	XX(XX.X)	XX(XX.X)
Any known genetic mutations, n(%)			
No	XX(XX.X)	XX(XX.X)	XX(XX.X)
Yes	XX(XX.X)	XX(XX.X)	XX(XX.X)
BRAF	XX(XX.X)	XX(XX.X)	XX(XX.X)
EGFR	XX(XX.X)	XX(XX.X)	XX(XX.X)
HER2	XX(XX.X)	XX(XX.X)	XX(XX.X)
KRAS	XX(XX.X)	XX(XX.X)	XX(XX.X)
KIT	XX(XX.X)	XX(XX.X)	XX(XX.X)
BRAF	XX(XX.X)	XX(XX.X)	XX(XX.X)
EGFR	XX(XX.X)	XX(XX.X)	XX(XX.X)
<insert EDC non “0” records >	XX(XX.X)	XX(XX.X)	XX(XX.X)
MSI status, n(%)			
Not applicable	XX(XX.X)	XX(XX.X)	XX(XX.X)
Unknown	XX(XX.X)	XX(XX.X)	XX(XX.X)
Known	XX(XX.X)	XX(XX.X)	XX(XX.X)
MSI-H (microsatellite instability-high)	XX(XX.X)	XX(XX.X)	XX(XX.X)
MSI-L (microsatellite instability-low)	XX(XX.X)	XX(XX.X)	XX(XX.X)

MSS (microsatellite stable)	XX(XX.X)	XX(XX.X)	XX(XX.X)
dMMR (mismatch repair deficient)	XX(XX.X)	XX(XX.X)	XX(XX.X)
pMMR (mismatch repair proficient)	XX(XX.X)	XX(XX.X)	XX(XX.X)
Other	XX(XX.X)	XX(XX.X)	XX(XX.X)
TMB status known?, n(%)			
Not Applicable	XX(XX.X)	XX(XX.X)	XX(XX.X)
No	XX(XX.X)	XX(XX.X)	XX(XX.X)
Yes	XX(XX.X)	XX(XX.X)	XX(XX.X)
High	XX(XX.X)	XX(XX.X)	XX(XX.X)
Intermediate	XX(XX.X)	XX(XX.X)	XX(XX.X)
Other	XX(XX.X)	XX(XX.X)	XX(XX.X)
Tumoral genetic characterization, n(%)			
Yes	XX(XX.X)	XX(XX.X)	XX(XX.X)
No	XX(XX.X)	XX(XX.X)	XX(XX.X)
Not Applicable	XX(XX.X)	XX(XX.X)	XX(XX.X)

Note: Arm A = Patients with indications for which a CPI is indicated/approved; Arm B = Patients with tumor types for which CPI therapy is not indicated/approved.
Note: Time since date of initial histopathological diagnosis (months) = (date of first dose - date of initial histopathological diagnosis)/30.4375. Time since date of most recent disease recurrence/progression (months) = (date of first dose - date of most recent disease recurrence/progression)/30.4375.

Table 14.1.8.2.1
Summary of Concomitant Medications by WHO Drug ATC Category II and Preferred Term - Dose Escalation
Safety Analysis Set

ATC Category II Preferred Term	WTX-330 0.016 mg/kg (N=x)	WTX-330 0.032 mg/kg (N=x)	WTX-330 0.056 mg/kg (N=x)	WTX-330 0.084 mg/kg (N=x)	WTX-330 0.126 mg/kg (N=x)	WTX-330 0.190 mg/kg (N=x)	WTX-330 0.290 mg/kg (N=x)	WTX-330 0.XXX mg/kg (N=x)	Total (N=xX)
Subjects with concomitant medications, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
ATC category II #1	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Preferred name #1	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Preferred name #2	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
<insert>	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
ATC category II #2	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Preferred name #1	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Preferred name #2	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
<insert>	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
<insert>									

Note: Prior Medications are coded with WHODRUG Global B3 March 2023.
Note: Concomitant medication is the medication that is used on/after the first dose of WTX-330.

Table 14.1.8.2.2
Summary of Concomitant Medications by WHO Drug ATC Category II and Preferred Term - Dose Expansion
Safety Analysis Set

ATC Category II Preferred Term	Arm A (N=XX)	Arm B (N=XX)	Total (N=XX)
Subjects with concomitant medications, n(%)	X(XX.X)	X(XX.X)	XX(XX.X)
ATC category II #1	X(XX.X)	X(XX.X)	XX(XX.X)
Preferred name #1	X(XX.X)	X(XX.X)	XX(XX.X)
Preferred name #2	X(XX.X)	X(XX.X)	XX(XX.X)
<insert>	X(XX.X)	X(XX.X)	XX(XX.X)
ATC category II #2	X(XX.X)	X(XX.X)	XX(XX.X)
Preferred name #1	X(XX.X)	X(XX.X)	XX(XX.X)
Preferred name #2	X(XX.X)	X(XX.X)	XX(XX.X)
<insert>	X(XX.X)	X(XX.X)	XX(XX.X)
<insert>			

Note: Arm A = Patients with indications for which a CPI is indicated/approved; Arm B = Patients with tumor types for which CPI therapy is not indicated/approved.
Note: Prior Medications are coded with WHODRUG Global B3 March 2023.
Note: Concomitant medication is the medication that is used on/after the first dose of WTX-330.

Table 14.1.9.1
Summary of WTX-330 Exposure, Compliance and Dose Modification - Dose Escalation
Safety Analysis Set

	WTX-330 0.016 mg/kg (N=x)	WTX-330 0.032 mg/kg (N=x)	WTX-330 0.056 mg/kg (N=x)	WTX-330 0.084 mg/kg (N=x)	WTX-330 0.126 mg/kg (N=x)	WTX-330 0.190 mg/kg (N=x)	WTX-330 0.290 mg/kg (N=x)	WTX-330 0.XXX mg/kg (N=x)	Total (N=xX)
Duration of exposure [a], weeks									
n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Duration of exposure categories, n(%)									
<4 weeks	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
>=4 weeks - < 12 weeks	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
>=12 weeks	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Number of treatment cycle started									
n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Cumulative dose [b], mg/kg									
n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Average dose intensity [c],(mg/kg)/cycle									
n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Treatment compliance [d], %									
n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Treatment compliance categories, n(%)									
<80%	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
>=80% -<120%	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
>=120%	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Subjects with infusion interrupted, n(%)									
0	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
1	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
2	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
>=3	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Reason for infusion interruption [e] n(%)									
Infusion reaction	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Adverse event other than infusion reaction	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Other	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Subjects with Dose Adjusted [e], n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Dose missed	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Dose reduced	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Dose discontinued	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Dose interrupted	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Reason for dose missed [e] n(%)									
Adverse event	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
PI/Sponsor decision	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Other	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Reason for dose reduced [e] n(%)									
Adverse event	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
PI/Sponsor decision	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Other	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Reason for dose discontinued [e] n(%)									
Adverse event	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
PI/Sponsor decision	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Other	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)

Reason for dose interrupted [e] n(%)									
Adverse event	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
PI/Sponsor decision	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Other	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)

[a] Duration of exposure = (the date of last WTX-330 does - the date of first WTX-330 dose + 14)/7.
[b] Cumulative Dose of WTX-330 (mg/kg) = sum of the individual Total Dose Administered being reported in CRFs.
[c] Average Dose Intensity ((mg/kg)/cycle) is calculated by Cumulative Dose /Number of treatment cycles started.
[d] Treatment compliance (%) = 100*(Cumulative Dose/Total Planned Dose).
[e] Categories are not mutually exclusive.

Table 14.1.9.2
Summary of WTX-330 Exposure, Compliance and Dose Modification - Dose Expansion
Safety Analysis Set

	Arm A (N=XX)	Arm B (N=XX)	Total (N=XX)
Duration of exposure [a], weeks			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Standard Deviation	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Duration of exposure categories, n(%)			
<4 weeks	X(XX.X)	X(XX.X)	XX(XX.X)
>=4 weeks - < 12 weeks	X(XX.X)	X(XX.X)	XX(XX.X)
>=12 weeks	X(XX.X)	X(XX.X)	XX(XX.X)
Number of treatment cycle started			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Standard Deviation	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Cumulative dose [b], mg/kg			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Standard Deviation	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Average dose intensity [c],(mg/kg)/cycle			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Standard Deviation	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx

Treatment compliance [d], %			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Standard Deviation	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Treatment compliance categories, n(%)			
<80%	X(XX.X)	X(XX.X)	XX(XX.X)
>=80% -<120%	X(XX.X)	X(XX.X)	XX(XX.X)
>=120%	X(XX.X)	X(XX.X)	XX(XX.X)
Subjects with infusion interrupted, n(%)			
0	X(XX.X)	X(XX.X)	XX(XX.X)
1	X(XX.X)	X(XX.X)	XX(XX.X)
2	X(XX.X)	X(XX.X)	XX(XX.X)
>=3	X(XX.X)	X(XX.X)	XX(XX.X)
Reason for infusion interruption [e] n(%)			
Infusion reaction	X(XX.X)	X(XX.X)	XX(XX.X)
Adverse event other than infusion reaction	X(XX.X)	X(XX.X)	XX(XX.X)
Other	X(XX.X)	X(XX.X)	XX(XX.X)
Subjects with Dose Adjusted [e], n(%)	X(XX.X)	X(XX.X)	XX(XX.X)
Dose missed	X(XX.X)	X(XX.X)	XX(XX.X)
Dose reduced	X(XX.X)	X(XX.X)	XX(XX.X)
Dose discontinued	X(XX.X)	X(XX.X)	XX(XX.X)
Dose interrupted	X(XX.X)	X(XX.X)	XX(XX.X)
Reason for dose missed [e] n(%)			
Adverse event	X(XX.X)	X(XX.X)	XX(XX.X)
PI/Sponsor decision	X(XX.X)	X(XX.X)	XX(XX.X)
Other	X(XX.X)	X(XX.X)	XX(XX.X)
Reason for dose reduced [e] n(%)			
Adverse event	X(XX.X)	X(XX.X)	XX(XX.X)
PI/Sponsor decision	X(XX.X)	X(XX.X)	XX(XX.X)
Other	X(XX.X)	X(XX.X)	XX(XX.X)
Reason for dose discontinued [e] n(%)			
Adverse event	X(XX.X)	X(XX.X)	XX(XX.X)
PI/Sponsor decision	X(XX.X)	X(XX.X)	XX(XX.X)
Other	X(XX.X)	X(XX.X)	XX(XX.X)

Reason for dose interrupted [e] n(%)			
Adverse event	X(XX.X)	X(XX.X)	XX(XX.X)
PI/Sponsor decision	X(XX.X)	X(XX.X)	XX(XX.X)
Other	X(XX.X)	X(XX.X)	XX(XX.X)

Note: Arm A = Patients with indications for which a CPI is indicated/approved; Arm B = Patients with tumor types for which CPI therapy is not indicated/approved.
[a] Duration of exposure = (the date of last WTX-330 does - the date of first WTX-330 dose + 14)/7.
[b] Cumulative Dose of WTX-330 (mg/kg) = sum of the individual Total Dose Administered being reported in CRFs.
[c] Average Dose Intensity ((mg/kg)/cycle) is calculated by Cumulative Dose /Number of treatment cycles started.
[d] Treatment compliance (%) = 100*(Cumulative Dose/Total Planned Dose).
[e] Categories are not mutually exclusive.

14.2 Analyses of Efficacy

Table 14.2.1.1
Summary of Best Overall Response, Objective Response Rate, and Clinical Benefit Rate - Dose Escalation
Efficacy Evaluable Analysis Set

	WTX-330 0.016 mg/kg (N=x)	WTX-330 0.032 mg/kg (N=x)	WTX-330 0.056 mg/kg (N=x)	WTX-330 0.084 mg/kg (N=x)	WTX-330 0.126 mg/kg (N=x)	WTX-330 0.190 mg/kg (N=x)	WTX-330 0.290 mg/kg (N=x)	WTX-330 0.XXX mg/kg (N=x)	Total (N=xX)
RECIST 1.1									
BOR, n(%)									
Complete Response (CR)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Partial Response (PR)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Stable Disease (SD)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Progressive Disease (PD)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Not Evaluable	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
ORR n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
95% exact CI, %	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
CBR at 3 month, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
95% exact CI, %	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
CBR at 6 month, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
95% exact CI, %	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
CBR at 9 month, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
95% exact CI, %	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
iRECIST									
iBOR, n(%)									
iCR	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
iPR	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
iSD	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
iUPD	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
iCPD	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Not Evaluable	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
iORR, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
95% CI, %	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
iCBR at 3 month, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
95% CI, %	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
iCBR at 6 month, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
95% exact CI, %	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
iCBR at 9 month, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
95% exact CI, %	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X

Note: Best overall response (BOR) of CR and PR per RECIST 1.1 needs to be confirmed in a subsequent assessment (≥ 4 weeks). Immune Best overall response (iBOR) per iRECIST 1.1 is the best response among all visits according to the following sequence: Immune Complete Response (iCR), Immune Partial Response (iPR), Immune Stable Disease (iSD), Immune Confirmed Progressive Disease (iCPD), Immune Unconfirmed Progressive Disease (iUPD), Not Evaluable.

Note: Overall response rate (ORR or iORR) is defined as the proportion of patients achieving CR and/or PR in RECIST 1.1 or iCR and/or iPR in iRECIST.
Note: Clinical Benefit Rate (CBR or iCBR) is defined as the proportion of subjects achieving clinical benefit, which is defined as the time from the date of last CR/PR/SD per RECIST or iCR/iPR/iSD per iRECIST to the date of first dose is at least 3, 6, or 9 months.

Table 14.2.1.2.1
Summary of Best Overall Response, Objective Response Rate, and Clinical Benefit Rate - Dose Expansion
Efficacy Evaluable Analysis Set

	Arm A (N=XX)	Arm B [1] (N=XX)	Total (N=XX)
RECIST 1.1			
BOR, n(%)			
Complete Response (CR)	X(XX.X)	X(XX.X)	XX(XX.X)
Partial Response (PR)	X(XX.X)	X(XX.X)	XX(XX.X)
Stable Disease (SD)	X(XX.X)	X(XX.X)	XX(XX.X)
Progressive Disease (PD)	X(XX.X)	X(XX.X)	XX(XX.X)
Not Evaluable	X(XX.X)	X(XX.X)	XX(XX.X)
ORR n(%)	X(XX.X)	X(XX.X)	XX(XX.X)
95% exact CI, %	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
CBR at 3 month, n(%)	X(XX.X)	X(XX.X)	XX(XX.X)
95% exact CI, %	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
CBR at 6 month, n(%)	X(XX.X)	X(XX.X)	XX(XX.X)
95% exact CI, %	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
CBR at 9 month, n(%)	X(XX.X)	X(XX.X)	XX(XX.X)
95% exact CI, %	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
iRECIST			
iBOR, n(%)			
iCR	X(XX.X)	X(XX.X)	XX(XX.X)
iPR	X(XX.X)	X(XX.X)	XX(XX.X)
iSD	X(XX.X)	X(XX.X)	XX(XX.X)
iUPD	X(XX.X)	X(XX.X)	XX(XX.X)
iCPD	X(XX.X)	X(XX.X)	XX(XX.X)
Not Evaluable	X(XX.X)	X(XX.X)	XX(XX.X)
iORR, n(%)	X(XX.X)	X(XX.X)	XX(XX.X)
95% CI, %	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
iCBR at 3 month, n(%)	X(XX.X)	X(XX.X)	XX(XX.X)
95% CI, %	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
iCBR at 6 month, n(%)	X(XX.X)	X(XX.X)	XX(XX.X)
95% exact CI, %	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
iCBR at 9 month, n(%)	X(XX.X)	X(XX.X)	XX(XX.X)
95% exact CI, %	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X

Note: Arm A = Patients with indications for which a CPI is indicated/approved; Arm B = Patients with tumor types for which CPI therapy is not indicated/approved.
Note: Best overall response (BOR) of CR and PR per RECIST 1.1 needs to be confirmed in a subsequent assessment (≥ 4 weeks). Immune Best overall response (iBOR) per iRECIST 1.1 is the best response among all visits according to the following sequence: Immune

Complete Response (iCR), Immune Partial Response (iPR), Immune Stable Disease (iSD), Immune Confirmed Progressive Disease (iCPD), Immune Unconfirmed Progressive Disease (iUPD), Not Evaluable.
Note: Overall response rate (ORR or iORR) is defined as the proportion of patients achieving CR and/or PR in RECIST 1.1 or iCR and/or iPR in iRECIST.
Note: Clinical Benefit Rate (CBR or iCBR) is defined as the proportion of subjects achieving clinical benefit, which is defined as the time from the date of last CR/PR/SD per RECIST or iCR/iPR/iSD per iRECIST to the date of first dose is at least 3, 6, or 9 months.
[1] Include solid tumor only.

Table 14.2.1.2.2
Summary of Best Overall Response, Objective Response Rate, and Clinical Benefit Rate
- Dose Expansion by Type of Disease (Solid Tumor)
Efficacy Evaluable Analysis Set

	Arm A				Arm B	
	RCC (N=x)	NSCLC (N=x)	HNSCC (N=x)	XXXXX (N=x)	CC (N=x)	YYYYY (N=x)
RECIST 1.1						
BOR, n(%)						
Complete Response (CR)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
Partial Response (PR)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
Stable Disease (SD)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
Progressive Disease (PD)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
Not Evaluable	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
ORR n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
95% exact CI, %	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
CBR at 3 month, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
95% exact CI, %	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
CBR at 6 month, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
95% exact CI, %	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
CBR at 9 month, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
95% exact CI, %	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
iRECIST						
iBOR, n(%)						
iCR	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
iPR	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
iSD	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
iUPD	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
iCPD	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
Not Evaluable	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
iORR, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
95% CI, %	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
iCBR at 3 month, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
95% CI, %	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
iCBR at 6 month, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
95% exact CI, %	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X
iCBR at 9 month, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
95% exact CI, %	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X	XX.X,XX.X

Note: Arm A = Patients with indications for which a CPI is indicated/approved; Arm B = Patients with tumor types for which CPI therapy is not indicated/approved; RCC = Renal Cell Carcinoma; NSCLC = Non-small Cell Lung Cancer; HNSCC = Head and Neck Squamous Cell Carcinoma; XXXXX = __; CC = Colorectal Carcinoma; YYYYY = __.

Note: Best overall response (BOR) of CR and PR per RECIST 1.1 needs to be confirmed in a subsequent assessment (≥ 4 weeks). Immune Best overall response (iBOR) per iRECIST 1.1 is the best response among all visits according to the following sequence: Immune Complete Response (iCR), Immune Partial Response (iPR), Immune Stable Disease (iSD), Immune Confirmed Progressive Disease (iCPD), Immune Unconfirmed Progressive Disease (iUPD), Not Evaluable.
Note: Overall response rate (ORR or iORR) is defined as the proportion of patients achieving CR and/or PR in RECIST 1.1 or iCR and/or iPR in iRECIST.
Note: Clinical Benefit Rate (CBR or iCBR) is defined as the proportion of subjects achieving clinical benefit, which is defined as the time from the date of last CR/PR/SD per RECIST or iCR/iPR/iSD per iRECIST to the date of first dose is at least 3, 6, or 9 months.

14.3 Summaries and Analyses of Safety

Table 14.3.1.1.1
Overall Summary of Treatment-Emergent Adverse Events - Dose Escalation
Safety Analysis Set

Subjects Who Had Any, n(%)	WTX-330 0.016 mg/kg (N=x)	WTX-330 0.032 mg/kg (N=x)	WTX-330 0.056 mg/kg (N=x)	WTX-330 0.084 mg/kg (N=x)	WTX-330 0.126 mg/kg (N=x)	WTX-330 0.190 mg/kg (N=x)	WTX-330 0.290 mg/kg (N=x)	WTX-330 0.XXX mg/kg (N=x)	Total (N=xX)
TEAEs	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
TEAEs Related to WTX-330	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Grade 3 or Higher TEAEs	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Grade 3 or Higher TEAEs Related to WTX-330	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Serious TEAEs	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Serious TEAEs Related to WTX-330	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
TEAEs Leading to WTX-330 Withdrawal	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
WTX-330-Related TEAEs Leading to WTX-330 Withdrawal	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
TEAEs Leading to WTX-330 Modification	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Dose Delayed	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Dose Interrupted	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Dose Reduced	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Infusion Rate Reduced	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
WTX-330-Related TEAEs Leading to WTX-330 Modification	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
TEAEs of Special Interest	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Immune Related TEAEs	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Infusion Related Reaction	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Cytokine Release Syndrome	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
DLT	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
TEAE Leading to Death	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)

Note: A TEAE is defined as an AEs that emerges or worsens (ie increase in CTCAE grade) on/after the first WTX-330 dose and within 30 days of the last WTX-330 dose or the start of a new cancer regimen, whichever occurs earlier.
Note: Adverse Events are graded with CTCAE Grade 5.0, except for Cytokine Release Syndrome which is graded with ASTCT Grade.
Note: Each subject is counted only once in each category. TEAEs related to study drug are events reported with 'Definitely Related', 'Probably', 'Possibly' or missing in the relationship.

Table 14.3.1.1.2
Overall Summary of Treatment-Emergent Adverse Events - Dose Expansion
Safety Analysis Set

Subjects Who Had Any, n(%)	Arm A (N=XX)	Arm B (N=XX)	Total (N=XX)
TEAEs	X(XX.X)	X(XX.X)	XX(XX.X)
TEAEs Related to WTX-330	X(XX.X)	X(XX.X)	XX(XX.X)
Grade 3 or Higher TEAEs	X(XX.X)	X(XX.X)	XX(XX.X)
Grade 3 or Higher TEAEs Related to WTX-330	X(XX.X)	X(XX.X)	XX(XX.X)
Serious TEAEs	X(XX.X)	X(XX.X)	XX(XX.X)
Serious TEAEs Related to WTX-330	X(XX.X)	X(XX.X)	XX(XX.X)
TEAEs Leading to WTX-330 Withdrawal	X(XX.X)	X(XX.X)	XX(XX.X)
WTX-330-Related TEAEs Leading to WTX-330 Withdrawal	X(XX.X)	X(XX.X)	XX(XX.X)
TEAEs Leading to WTX-330 Modification	X(XX.X)	X(XX.X)	XX(XX.X)
Dose Delayed	X(XX.X)	X(XX.X)	XX(XX.X)
Dose Interrupted	X(XX.X)	X(XX.X)	XX(XX.X)
Dose Reduced	X(XX.X)	X(XX.X)	XX(XX.X)
Infusion Rate Reduced	X(XX.X)	X(XX.X)	XX(XX.X)
WTX-330-Related TEAEs Leading to WTX-330 Modification	X(XX.X)	X(XX.X)	XX(XX.X)
TEAEs of Special Interest	X(XX.X)	X(XX.X)	XX(XX.X)
Immune Related TEAEs	X(XX.X)	X(XX.X)	XX(XX.X)
Infusion Related Reaction	X(XX.X)	X(XX.X)	XX(XX.X)
Cytokine Release Syndrome	X(XX.X)	X(XX.X)	XX(XX.X)
TEAE Leading to Death	X(XX.X)	X(XX.X)	XX(XX.X)

Note: Arm A = Patients with indications for which a CPI is indicated/approved; Arm B = Patients with tumor types for which CPI therapy is not indicated/approved.
Note: A TEAE is defined as an AEs that emerges or worsens (ie increase in CTCAE grade) on/after the first WTX-330 dose and within 30 days of the last WTX-330 dose or the start of a new cancer regimen, whichever occurs earlier.
Note: Adverse Events are graded with CTCAE Grade 5.0, except for Cytokine Release Syndrome which is graded with ASTCT Grade.
Note: Each subject is counted only once in each category. TEAEs related to study drug are events reported with 'Definitely Related', 'Probably', 'Possibly' or missing in the relationship.

Table 14.3.2.1.1
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Dose Escalation
Safety Analysis Set

System Organ Class/ Preferred Term	WTX-330 0.016 mg/kg (N=x)	WTX-330 0.032 mg/kg (N=x)	WTX-330 0.056 mg/kg (N=x)	WTX-330 0.084 mg/kg (N=x)	WTX-330 0.126 mg/kg (N=x)	WTX-330 0.190 mg/kg (N=x)	WTX-330 0.290 mg/kg (N=x)	WTX-330 0.XXX mg/kg (N=x)	Total (N=xX)
Patients with Any Event, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
System Organ Class #1	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Preferred Term #1	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Preferred Term #2	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
<insert>	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
System Organ Class #2	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Preferred Term #1	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Preferred Term #2	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
<insert>	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
<insert>									

Note: Adverse Events are coded with MedDRA version 26.0.
Note: A TEAE is defined as an AEs that emerges or worsens (i.e. increase in CTCAE grade/ASTCT Grade) on/after the first WTX-330 dose and within 30 days of the last WTX-330 dose or the start of a new cancer regimen, whichever occurs earlier.
Note: Each subject is counted only once in each category. Table is sorted by System Organ Class count in total, and Preferred Term count in total within each System Organ Class.

Programming Note:
Sort by SOC count in total, and PT count in total within each SOC

Repeat table 14.3.2.1.1 for the following tables, except for the column header and footnote for Dose Expansion.

Table 14.3.2.1.2
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Dose Expansion
Safety Analysis Set

Table 14.3.2.2.1
Summary of WTX-330-related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Dose Escalation
Safety Analysis Set

Programming Note: Add "Note: TEAEs related to study drug are events reported with 'Definitely Related', 'Probably', 'Possibly' or missing in the relationship."

Table 14.3.2.2.2
Summary of WTX-330-related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Dose Expansion
Safety Analysis Set

Programming Note: Add "Note: TEAEs related to study drug are events reported with 'Definitely Related', 'Probably', 'Possibly' or missing in the relationship."

Table 14.3.2.3.1
Summary of Treatment-Emergent Adverse Events with Grade 3 or Higher by System Organ Class and Preferred Term - Dose Escalation
Safety Analysis Set

Table 14.3.2.3.2
Summary of Treatment-Emergent Adverse Events with Grade 3 or Higher by System Organ Class and Preferred Term - Dose Expansion
Safety Analysis Set

Table 14.3.2.4.1
Summary of WTX-330-related Treatment-Emergent Adverse Events with Grade 3 or Higher by System Organ Class and Preferred Term - Dose Escalation
Safety Analysis Set

Programming Note: Add "Note: TEAEs related to study drug are events reported with 'Definitely Related', 'Probably', 'Possibly' or missing in the relationship."

Table 14.3.2.4.2
Summary of WTX-330-related Treatment-Emergent Adverse Events with Grade 3 or Higher by System Organ Class and Preferred Term - Dose Expansion
Safety Analysis Set

Programming Note: Add “Note: TEAEs related to study drug are events reported with ‘Definitely Related’, ‘Probably’, ‘Possibly’ or missing in the relationship.”

Table 14.3.2.5.1
Summary of Treatment-Emergent Adverse Events Leading to WTX-330 Withdrawal by System Organ Class and Preferred Term - Dose Escalation
Safety Analysis Set

Table 14.3.2.5.2
Summary of Treatment-Emergent Adverse Events Leading to WTX-330 Withdrawal by System Organ Class and Preferred Term - Dose Expansion
Safety Analysis Set

Table 14.3.2.6.1
Summary of WTX-330-related Treatment-Emergent Adverse Events Leading to WTX-330 Withdrawal by System Organ Class and Preferred Term - Dose Escalation
Safety Analysis Set

Programming Note: Add “Note: TEAEs related to study drug are events reported with ‘Definitely Related’, ‘Probably’, ‘Possibly’ or missing in the relationship.”

Table 14.3.2.6.2
Summary of WTX-330-related Treatment-Emergent Adverse Events Leading to WTX-330 Withdrawal by System Organ Class and Preferred Term - Dose Expansion
Safety Analysis Set

Programming Note: Add “Note: TEAEs related to study drug are events reported with ‘Definitely Related’, ‘Probably’, ‘Possibly’ or missing in the relationship.”

Table 14.3.2.7.1
Summary of Treatment-Emergent Adverse Events Leading to WTX-330 Modification by System Organ Class and Preferred Term - Dose Escalation
Safety Analysis Set

Table 14.3.2.7.2
Summary of Treatment-Emergent Adverse Events Leading to WTX-330 Modification by System Organ Class and Preferred Term - Dose Expansion
Safety Analysis Set

Table 14.3.2.8.1
Summary of WTX-330-related Treatment-Emergent Adverse Events Leading to WTX-330 Modification by System Organ Class and Preferred Term - Dose Escalation
Safety Analysis Set

Programming Note: Add “Note: TEAEs related to study drug are events reported with ‘Definitely Related’, ‘Probably’, ‘Possibly’ or missing in the relationship.”

Table 14.3.2.8.2
Summary of WTX-330-related Treatment-Emergent Adverse Events Leading to WTX-330 Modification by System Organ Class and Preferred Term - Dose Expansion
Safety Analysis Set

Programming Note: Add “Note: TEAEs related to study drug are events reported with ‘Definitely Related’, ‘Probably’, ‘Possibly’ or missing in the relationship.”

Table 14.3.2.9.1
Summary of Immune Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Dose Escalation
Safety Analysis Set

Table 14.3.2.9.2
Summary of Immune Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Dose Expansion
Safety Analysis Set

Table 14.3.2.10.1
Summary of Treatment-Emergent Adverse Events of Infusion Related Reaction by System Organ Class and Preferred Term - Dose Escalation Safety Analysis Set

Table 14.3.2.10.2
Summary of Treatment-Emergent Adverse Events of Infusion Related Reaction by System Organ Class and Preferred Term - Dose Expansion Safety Analysis Set

Table 14.3.2.11.1
Summary of Treatment-Emergent Adverse Events of Cytokine Release Syndrome by System Organ Class and Preferred Term - Dose Escalation Safety Analysis Set

Table 14.3.2.11.2
Summary of Treatment-Emergent Adverse Events of Cytokine Release Syndrome by System Organ Class and Preferred Term - Dose Expansion Safety Analysis Set

Table 14.3.2.12.1
Summary of Treatment-Emergent Adverse Events of Special Interest by Special Interest Category and Preferred Term - Dose Escalation
Safety Analysis Set

Special Interest Category/ Preferred Term	WTX-330 0.016 mg/kg (N=x)	WTX-330 0.032 mg/kg (N=x)	WTX-330 0.056 mg/kg (N=x)	WTX-330 0.084 mg/kg (N=x)	WTX-330 0.126 mg/kg (N=x)	WTX-330 0.190 mg/kg (N=x)	WTX-330 0.290 mg/kg (N=x)	WTX-330 0.XXX mg/kg (N=x)	Total (N=xX)
Patients with Any Event, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Special Interest Category#1	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Preferred Term #1	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Preferred Term #2	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
<insert>	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Special Interest Category#2	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Preferred Term #1	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Preferred Term #2	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
<insert>	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
<insert>									

Note: Adverse Events are coded with MedDRA version 26.0.
Note: A TEAE is defined as an AEs that emerges or worsens (i.e. increase in CTCAE grade/ASTCT Grade) on/after the first WTX-330 dose and within 30 days of the last WTX-330 dose or the start of a new cancer regimen, whichever occurs earlier.
Note: Each subject is counted only once in each category. The table is sorted by Special Interest Category count in total, and Preferred Term count in total within each Special Interest Category.

Programming Note:
Sort by Special Interest Category count in total, and PT count in total within each Special Interest Category
Special Interest Category include >=Grade 2 CRS, >= Grade 3 Oral Mucositis, Hy's Law or >= Grade 3 increased ALT or AST

Table 14.3.2.12.2
Summary of Treatment-Emergent Adverse Events of Special Interest by Special Interest Category and Preferred Term - Dose Expansion
Safety Analysis Set

Special Interest Category/ Preferred Term	Arm A (N=XX)	Arm B (N=XX)	Total (N=XX)
Patients with Any Event, n(%)	XX(XX.X)	XX(XX.X)	XX(XX.X)
Special Interest Category#1	XX(XX.X)	XX(XX.X)	XX(XX.X)
Preferred Term #1	XX(XX.X)	XX(XX.X)	XX(XX.X)
Preferred Term #2	XX(XX.X)	XX(XX.X)	XX(XX.X)
<insert>	XX(XX.X)	XX(XX.X)	XX(XX.X)
Special Interest Category#2	XX(XX.X)	XX(XX.X)	XX(XX.X)
Preferred Term #1	XX(XX.X)	XX(XX.X)	XX(XX.X)
Preferred Term #2	XX(XX.X)	XX(XX.X)	XX(XX.X)
<insert>	XX(XX.X)	XX(XX.X)	XX(XX.X)
<insert>			

Note: Arm A = Patients with indications for which a CPI is indicated/approved; Arm B = Patients with tumor types for which CPI therapy is not indicated/approved.
Note: Adverse Events are coded with MedDRA version 26.0.
Note: A TEAE is defined as an AEs that emerges or worsens (i.e. increase in CTCAE grade/ASTCT Grade) on/after the first WTX-330 dose and within 30 days of the last WTX-330 dose or the start of a new cancer regimen, whichever occurs earlier.
Note: Each subject is counted only once in each category. The table is sorted by Special Interest Category count in total, and Preferred Term count in total within each Special Interest Category.

Programming Note:
Sort by Special Interest Category count in total, and PT count in total within each Special Interest Category
Special Interest Category include >=Grade 2 CRS, >= Grade 3 Oral Mucositis, Hy's Law or >= Grade 3 increased ALT or AST

Table 14.3.2.13.1
Summary of Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Maximum CTCAE/ASTCT Grade - Dose Escalation
Safety Analysis Set

Dose Escalation – WTX-330 0.016 mg/kg (N=xx)

System Organ Class/ Preferred Term/	Maximum CTCAE/ASTCT Grade						
	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Grade 3+	Total
Patients with Any Event, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
System Organ Class #1	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Preferred Term #1	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Preferred Term #2	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
<insert>	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
System Organ Class #2	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Preferred Term #1	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Preferred Term #2	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
<insert>	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)

Note: Adverse Events are coded with MedDRA version 26.0 and graded with CTCAE Grade 5.0, except for Cytokine Release Syndrome which is graded with ASTCT Grade.
Note: A TEAE is defined as an AEs that emerges or worsens (i.e. increase in CTCAE grade/ASTCT Grade) on/after the first WTX-330 dose and within 30 days of the last WTX-330 dose or the start of a new cancer regimen, whichever occurs earlier.
Note: Each subject is counted only once at maximum CTCAE Grade in each category. Table is sorted by System Organ Class count in total, and Preferred Term count in total within each System Organ Class.

Programming note:

- Repeat all dose levels and total on a new page.

Repeat table 14.3.2.13.1 for the following tables, except for the column header and footnote for Dose Expansion.

Table 14.3.2.13.2
Summary of Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Maximum CTCAE/ASTCT Grade - Dose Expansion
Safety Analysis Set

Table 14.3.2.14.1
Summary of WTX-330-related Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Maximum CTCAE/ASTCT Grade - Dose Escalation
Safety Analysis Set

Programming Note: Add “Note: TEAEs related to study drug are events reported with ‘Definitely Related’, ‘Probably’, ‘Possibly’ or missing in the relationship.”

Table 14.3.2.14.2
Summary of WTX-330-related Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Maximum CTCAE/ASTCT Grade - Dose Expansion
Safety Analysis Set

Programming Note: Add “Note: TEAEs related to study drug are events reported with ‘Definitely Related’, ‘Probably’, ‘Possibly’ or missing in the relationship.”

Table 14.3.2.15.1
Summary of Treatment-Emergent Adverse Events by Preferred Term - Dose Escalation
Safety Analysis Set

Preferred Term	WTX-330 0.016 mg/kg (N=x)	WTX-330 0.032 mg/kg (N=x)	WTX-330 0.056 mg/kg (N=x)	WTX-330 0.084 mg/kg (N=x)	WTX-330 0.126 mg/kg (N=x)	WTX-330 0.190 mg/kg (N=x)	WTX-330 0.290 mg/kg (N=x)	WTX-330 0.XXX mg/kg (N=x)	Total (N=xX)
Patients with Any Event, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Preferred Term #1	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Preferred Term #2	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Preferred Term #3	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Preferred Term #4	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
<insert>	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)

Note: Adverse Events are coded with MedDRA version 26.0.
Note: A TEAE is defined as an AEs that emerges or worsens (i.e. increase in CTCAE grade/ASTCT grade) on/after the first WTX-330 dose and within 30 days of the last WTX-330 dose or the start of a new cancer regimen, whichever occurs earlier.
Note: Each subject is counted only once in each category. The table is sorted by Preferred Term count in total.

Repeat table 14.3.2.15.1 for the following tables, except for the column header and footnote for Dose Expansion.

Table 14.3.2.15.2
Summary of Treatment-Emergent Adverse Events by Preferred Term - Dose Expansion
Safety Analysis Set

Repeat table 14.3.2.1a for the following tables, except for the column header and footnote for Dose expansion.

Table 14.3.3.1.1
Summary of Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term - Dose Escalation
Safety Analysis Set

Table 14.3.3.1.2
Summary of Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term - Dose Expansion
Safety Analysis Set

Table 14.3.3.2.1Summary of WTX-330-related Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term - Dose Escalation
Safety Analysis Set

Programming Note: Add “Note: TEAEs related to study drug are events reported with ‘Definitely Related’, ‘Probably’, ‘Possibly’ or missing in the relationship.”

Table 14.3.3.2.2
Summary of WTX-330-related Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term - Dose Expansion
Safety Analysis Set

Programming Note: Add “Note: TEAEs related to study drug are events reported with ‘Definitely Related’, ‘Probably’, ‘Possibly’ or missing in the relationship.”

Repeat table 14.3.2.13.1 for the following tables, except for the column header and footnote for Dose Expansion.

Table 14.3.3.3.1
Summary of Treatment-Emergent Serious Adverse Events by System Organ Class, Preferred Term and Maximum CTCAE /ASTCT Grade - Dose Escalation
Safety Analysis Set

Table 14.3.3.3.2
Summary of Treatment-Emergent Serious Adverse Events by System Organ Class, Preferred Term and Maximum CTCAE /ASTCT Grade - Dose Expansion
Safety Analysis Set

Table 14.3.3.4.1
Summary of WTX-330-related Treatment-Emergent Serious Adverse Events by System Organ Class, Preferred Term and Maximum CTCAE /ASTCT Grade - Dose Escalation
Safety Analysis Set

Programming Note: Add “Note: TEAEs related to study drug are events reported with ‘Definitely Related’, ‘Probably’, ‘Possibly’ or missing in the relationship.”

Table 14.3.3.4.2
Summary of WTX-330-related Treatment-Emergent Serious Adverse Events by System Organ Class, Preferred Term and Maximum CTCAE /ASTCT Grade - Dose Expansion
Safety Analysis Set

Programming Note: Add “Note: TEAEs related to study drug are events reported with ‘Definitely Related’, ‘Probably’, ‘Possibly’ or missing in the relationship.”

Repeat table 14.3.2.15.1 for the following tables, except for the column header and footnote for Dose Expansion.

Table 14.3.3.5.1
Summary of Treatment-Emergent Serious Adverse Events by Preferred Term - Dose Escalation
Safety Analysis Set

Table 14.3.3.5.2
Summary of Treatment-Emergent Serious Adverse Events by Preferred Term - Dose Expansion
Safety Analysis Set

Table 14.3.3.6.1
Summary of WTX-330-related Treatment-Emergent Serious Adverse Events by Preferred Term - Dose Escalation
Safety Analysis Set

Programming Note: Add “Note: TEAEs related to study drug are events reported with ‘Definitely Related’, ‘Probably’, ‘Possibly’ or missing in the relationship.”

Table 14.3.3.6.2
Summary of WTX-330-related Treatment-Emergent Serious Adverse Events by Preferred Term - Dose Expansion
Safety Analysis Set

Programming Note: Add “Note: TEAEs related to study drug are events reported with ‘Definitely Related’, ‘Probably’, ‘Possibly’ or missing in the relationship.”

Repeat table 14.3.2.1.1 for the following tables, except for the column header and footnote for Dose Expansion.

Table 14.3.3.7.1
Summary of Treatment-Emergent Adverse Events Leading Death by System Organ Class and Preferred Term - Dose Escalation
Safety Analysis Set

Table 14.3.3.7.2
Summary of Treatment-Emergent Adverse Events Leading Death by System Organ Class and Preferred Term - Dose Expansion
Safety Analysis Set

Table 14.3.3.8.1
Summary of Death - Dose Escalation
Safety Analysis Set

	WTX-330 0.016 mg/kg (N=x)	WTX-330 0.032 mg/kg (N=x)	WTX-330 0.056 mg/kg (N=x)	WTX-330 0.084 mg/kg (N=x)	WTX-330 0.126 mg/kg (N=x)	WTX-330 0.190 mg/kg (N=x)	WTX-330 0.290 mg/kg (N=x)	WTX-330 0.XXX mg/kg (N=x)	Total (N=xX)
Death on Study, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Primary Cause of Death									
Disease Progression	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Adverse Event	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Unknown	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Other	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Death within 30 Days of last study drug, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Primary Cause of Death									
Disease Progression	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Adverse Event	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Unknown	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Other	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Death after 30 Days of last study drug, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Primary Cause of Death									
Disease Progression	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Adverse Event	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Unknown	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Other	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)

Repeat table 14.3.3.8.1 for the following tables, except for the column header and footnote for Dose Expansion.

Table 14.3.3.8.2
Summary of Death - Dose Expansion
Safety Analysis Set

Table 14.3.7.1.1
Summary of Hematology Laboratory by Visit - Dose Escalation
Safety Analysis Set

Test (SI unit): Hemoglobin (g/L)

	WTX-330 0.016 mg/kg (N=x)	WTX-330 0.032 mg/kg (N=x)	WTX-330 0.056 mg/kg (N=x)	WTX-330 0.084 mg/kg (N=x)	WTX-330 0.126 mg/kg (N=x)	WTX-330 0.190 mg/kg (N=x)	WTX-330 0.290 mg/kg (N=x)	WTX-330 0.XXX mg/kg (N=x)	Total (N=xX)
Baseline									
n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Cycle 1 Day X									
Absolute Value									
n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Change from Baseline									
n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
<insert Visit>									

Note: Baseline is defined as the last non-missing value prior to the first WTX-330 dose.

Programming instruction:
Each parameter starts from a new page, including Red blood cell (RBC) count, hemoglobin (Hb), hematocrit, mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH); white blood cell (WBC) count and differentials, absolute lymphocyte count (ALC), and absolute neutrophil count (ANC), platelet count.

Repeat table 14.3.7.1.1 for the following tables, except for the column header and footnote.

Table 14.3.7.1.2
Summary of Hematology Laboratory by Visit - Dose Expansion
Safety Analysis Set

Table 14.3.7.1.3
Shift of Hematology CTCAE Grade from Baseline to Worst Post-baseline - Dose Escalation
Safety Analysis Set

Test: Anemia (Hypo-Hemoglobin)

		Worst Post-baseline CTCAE Grade, n(%)						
	Baseline CTCAE Grade	Missing	0	1	2	3	4	Total
WTX-330 0.016 mg/kg (N=xx)	Missing	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	0	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	1	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	2	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	3	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	4	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	Total	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
WTX-330 0.032 mg/kg (N=xx)	Missing	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	0	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	1	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	2	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	3	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	4	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	Total	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
<Insert Dose Levels>								
Total (N=xx)	Missing	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	0	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	1	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	2	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	3	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	4	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	Total	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)

Note: Baseline is defined to be the last non-missing value prior to the first WTX-330 dose.

Programming instruction:
Each parameter starts from a new page.

Repeat table 14.3.7.1.3 for the following tables, except for the column header.

Table 14.3.7.1.4
Shift of Hematology CTCAE Grade from Baseline to Worst Post-baseline - Dose Expansion
Safety Analysis Set

Programming instruction:
Replace dose levels with Arm A and Arm B
Add footnote for Dose expansion.

Table 14.3.7.1.5
Shift of Hematology Tests without CTCAE Grade from Baseline to Lowest/Highest Post-baseline - Dose Escalation
Safety Analysis Set

Test: Red blood cells (RBC) count

		Baseline n(%)				
	Lowest/Highest Post-baseline	Missing	Low	Normal	High	Total
WTX-330 0.016 mg/kg (N=xx)	Lowest Post-baseline Value					
	Missing	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	Low	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	Normal	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	High	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	Total	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	Highest Post-baseline Value					
	Missing	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	Low	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	Normal	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	High	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	Total	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
<Insert Dose Levels>						
Total (N=xx)	Lowest Post-baseline Value					
	Missing	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	Low	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	Normal	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	High	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	Total	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	Highest Post-baseline Value					
	Missing	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	Low	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	Normal	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	High	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)
	Total	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)

Note: Baseline is defined to be the last non-missing value prior to the first WTX-330 dose.

Programming instruction:
Each parameter starts from a new page.

Repeat table 14.3.7.1.5 for the following tables, except for the column header and footnote for Dose Expansion.

Table 14.3.7.1.6
Shift of Hematology Tests without CTCAE Grade from Baseline to Lowest/Highest Post-baseline - Dose Expansion
Safety Analysis Set

Programming instruction:
Replace dose levels with Arm A and Arm B
Add footnote for Dose expansion.

Repeat table 14.3.7.1.1 for the following tables, except for the column header and footnote for Dose Expansion.

Table 14.3.7.2.1
Summary of Chemistry Laboratory by Visit - Dose Escalation
Safety Analysis Set

Programming instruction:
Each parameter starts from a new page, including Calcium, magnesium, potassium, sodium, bicarbonate, chloride phosphate, albumin, total blood urea nitrogen (BUN), C-reactive protein (CRP), creatinine, urate, estimated glomerular filtration rate, glucose, Alanine transaminase (ALT), aspartate transaminase (AST), bilirubin, alkaline phosphatase (ALP), lactic acid dehydrogenase (LDH), gamma-glutamyl transferase (GGT)

Table 14.3.7.2.2
Summary of Chemistry Laboratory by Visit - Dose Expansion
Safety Analysis Set

Programming instruction:
Each parameter starts from a new page, including Calcium, magnesium, potassium, sodium, bicarbonate, chloride phosphate, albumin, total blood urea nitrogen (BUN), C-reactive protein (CRP), creatinine, urate, estimated glomerular filtration rate, glucose, Alanine transaminase (ALT), aspartate transaminase (AST), bilirubin, alkaline phosphatase (ALP), lactic acid dehydrogenase (LDH), gamma-glutamyl transferase (GGT)

Repeat table 14.3.7.1.3 for the following tables, except for the column header and footnote for Dose Expansion.

Table 14.3.7.2.3
Shift of Chemistry CTCAE Grade from Baseline to Worst Post-baseline - Dose Escalation
Safety Analysis Set

Table 14.3.7.2.4
Shift of Chemistry CTCAE Grade from Baseline to Worst Post-baseline - Dose Expansion
Safety Analysis Set

Repeat table 14.3.7.1.5 for the following tables, except for the column header and footnote for Dose Expansion.

Table 14.3.7.2.5
Shift of Chemistry Tests without CTCAE Grade from Baseline to Lowest/Highest Post-baseline - Dose Escalation
Safety Analysis Set

Table 14.3.7.2.6
Shift of Chemistry Tests without CTCAE Grade from Baseline to Lowest/Highest Post-baseline - Dose Expansion
Safety Analysis Set

Table 14.3.7.2.7
Summary of Clinically Significant Liver Function Tests - Dose Escalation
Safety Analysis Set

	WTX-330 0.016 mg/kg (N=x)	WTX-330 0.032 mg/kg (N=x)	WTX-330 0.056 mg/kg (N=x)	WTX-330 0.084 mg/kg (N=x)	WTX-330 0.126 mg/kg (N=x)	WTX-330 0.190 mg/kg (N=x)	WTX-330 0.290 mg/kg (N=x)	WTX-330 0.XXX mg/kg (N=x)	Total (N=xX)
Aspartate Aminotransferase (AST),n (%)									
> 3 x ULN	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
> 5 x ULN	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
> 10 x ULN	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
> 20 x ULN	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Alanine Aminotransferase (ALT),n (%)									
> 3 x ULN	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
> 5 x ULN	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
> 10 x ULN	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
> 20 x ULN	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
AST or ALT,n (%)									
> 3 x ULN	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
> 5 x ULN	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
> 10 x ULN	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
> 20 x ULN	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Total Bilirubin (TBL),n (%)									
> 1.5 x ULN	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
> 2 x ULN	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Alkaline Phosphatase (ALP),n (%)									
> 1.5 x ULN	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
(AST or ALT) and TBL,n (%)									
AST or ALT>3xULN and TBL>1.5xULN	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
AST or ALT>3xULN and TBL>2xULN	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)

Repeat table 14.3.7.2.7 for the following tables, except for the column header and footnote for Dose Expansion.

Table 14.3.7.2.8
Summary of Clinically Significant Liver Function Tests - Dose Expansion
Safety Analysis Set

Repeat table 14.3.7.1.1 for the following tables, except for the column header and footnote for Dose Expansion.

Table 14.3.7.3.1
Summary of Coagulation Laboratory by Visit - Dose Escalation
Safety Analysis Set

Programming instruction:
Each parameter starts from a new page, including Prothrombin time (PT) or International normalized ratio (INR), and Partial thromboplastin time (PTT) or Activated partial thromboplastin time (APTT).

Table 14.3.7.3.2
Summary of Coagulation Laboratory by Visit - Dose Expansion
Safety Analysis Set

Programming instruction:
Each parameter starts from a new page, including Prothrombin time (PT) or International normalized ratio (INR), and Partial thromboplastin time (PTT) or Activated partial thromboplastin time (APTT).

Repeat table 14.3.7.1.3 for the following tables, except for the column header and footnote for Dose Expansion.

Table 14.3.7.3.3
Shift of Coagulation CTCAE Grade from Baseline to Worst Post-baseline - Dose Escalation
Safety Analysis Set

Table 14.3.7.3.4
Shift of Coagulation CTCAE Grade from Baseline to Worst Post-baseline - Dose Expansion
Safety Analysis Set

Repeat table 14.3.7.1.5 for the following tables, except for the column header and footnote for Dose Expansion.

Table 14.3.7.3.5
Shift of Coagulation Tests without CTCAE Grade from Baseline to Lowest/Highest Post-baseline - Dose Escalation
Safety Analysis Set

Table 14.3.7.3.6
Shift of Coagulation Tests without CTCAE Grade from Baseline to Lowest/Highest Post-baseline - Dose Expansion
Safety Analysis Set

Repeat table 14.3.7.1.1 for the following table, except for the column header and footnote for Dose Expansion.

Table 14.3.8.1
Summary of Vital Signs by Visit - Dose Escalation
Safety Analysis Set

Table 14.3.8.2
Summary of Vital Signs by Visit - Dose Expansion
Safety Analysis Set

Table 14.3.8.3
Summary of Vital Signs Clinically Significant on Treatment - Dose Escalation
Safety Analysis Set

Abnormal Categories, n(%)	WTX-330 0.016 mg/kg (N=x)	WTX-330 0.032 mg/kg (N=x)	WTX-330 0.056 mg/kg (N=x)	WTX-330 0.084 mg/kg (N=x)	WTX-330 0.126 mg/kg (N=x)	WTX-330 0.190 mg/kg (N=x)	WTX-330 0.290 mg/kg (N=x)	WTX-330 0.XXX mg/kg (N=x)	Total (N=xX)
Systolic BP									
≥180mmHg and an increase ≥20mmHg from baseline	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
≤90mmHg and a decrease ≥20mmHg from baseline	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Diastolic BP									
≥105mmHg and an increase ≥15mmHg from baseline	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
≤50mmHg and a decrease ≥15mmHg from baseline	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Weight									
Increase of ≥10% from baseline	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Decrease of ≥10% from baseline	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Heart rate									
≥120bpm with an increase ≥15bpm from baseline	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
≤50bpm and a decrease ≥15bpm from baseline	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Temperature									
>38° C	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
<35° C	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)

Programming Note:

Repeat table 14.3.8.3 for the following table, except for the column header and footnote for Dose Expansion.

Table 14.3.8.4
Summary of Vital Signs Clinically Significant on Treatment - Dose Expansion
Safety Analysis Set

Repeat table 14.3.7.1.1 for the following table, except for the column header and footnote for Dose Expansion.

Table 14.3.9.1
Summary of Electrocardiograms by Visit - Dose Escalation
Safety Analysis Set

Table 14.3.9.2
Summary of Electrocardiograms by Visit - Dose Expansion
Safety Analysis Set

Table 14.3.9.3
Summary of QTcF Categories - Dose Escalation
Safety Analysis Set

QTcF Categories, n(%)	WTX-330 0.016 mg/kg (N=x)	WTX-330 0.032 mg/kg (N=x)	WTX-330 0.056 mg/kg (N=x)	WTX-330 0.084 mg/kg (N=x)	WTX-330 0.126 mg/kg (N=x)	WTX-330 0.190 mg/kg (N=x)	WTX-330 0.290 mg/kg (N=x)	WTX-330 0.XXX mg/kg (N=x)	Total (N=xX)
Baseline									
QTcF >450 msec	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
QTcF >480 msec	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
QTcF >500 msec	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Highest Post-Baseline	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
QTcF >450 msec									
QTcF >480 msec									
QTcF >500 msec	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Highest Change from Baseline	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
>30 msec	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
>60 msec	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
Cycle x Day y, Timepoint									
QTcF >450 msec	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
QTcF >480 msec	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
QTcF >500 msec	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)
<insert visits and timepoints>									

Programming notes:
The categories (“QTc > 450m msec”, “QTc > 480m msec”, “QTc > 500m msec”, “>30 msec”, “>60 msec”) are non-mutually exclusive categories.

Repeat table 14.3.9.3 for the following table, except for the column header and footnote for Dose Expansion.

Table 14.3.9.4
Summary of QTcF Categories - Dose Expansion
Safety Analysis Set

Table 14.4.1.1
Summary of WTX-330 Plasma Concentration (ug/mL) by Timepoint
Pharmacokinetic Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (N=x)

Timepoints	n	Mean (Standard Deviation)	Median	Min, Max	Geometric Mean	Coefficient of variation for Geometric Mean
Cycle 1 Day 1						
Pre-dose	xx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
Immediately after (±5 minutes) WTX-330 infusion	xx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
4 hours (±30 minutes) post start of WTX-330 infusion	xx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
8 hours (±30 minutes) post start of WTX-330 infusion	xx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
24 hours (±2 hours) post start of WTX-330 infusion	xx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
48 hours (±2 hours) post start of WTX-330 infusion	xx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
168 hours (±4 hours) post start of WTX-330 Infusion	xx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
Cycle 1 Day 15						
Pre-dose	xx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
Immediately after (±5 minutes) WTX-330 infusion	xx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
Cycle 1 Day 21						
Pre-dose	xx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
Immediately after (±5 minutes) WTX-330 infusion	xx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
4 hours (±30 minutes) post start of WTX-330 infusion	xx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
8 hours (±30 minutes) post start of WTX-330 infusion	xx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
24 hours (±2 hours) post start of WTX-330 infusion	xx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
48 hours (±2 hours) post start of WTX-330 infusion	xx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
168 hours (±4 hours) post start of WTX-330 Infusion	xx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx
Cycle X Day Y						
Pre-dose	xx	xx.x(xx.xx)	xx.x	xx,xx	xx.x	xx.xx

Programming Note:
Each Dose Escalation dose level will start from a new page.
Vendor data will need to be divided by 1000 to report in CSR as ug/mL.

The following table will be displayed as Table 14.4.1.1

Table 14.4.1.2
Summary of Free IL-12 Plasma Concentration (pg/mL) by Timepoint
Pharmacokinetic Analysis Set

Programming Note:
Units for Free IL-12, use pg/ml - multiply vendor conc by 1000

Table 14.4.2.1
Summary of WTX-330 Pharmacokinetic Parameters
Pharmacokinetic Analysis Set

Visit: Cycle 1 Day 1

Parameter (unit)	WTX-330 0.016 mg/kg (N=x)	WTX-330 0.032 mg/kg (N=x)	WTX-330 0.056 mg/kg (N=x)	WTX-330 0.084 mg/kg (N=x)	WTX-330 0.126 mg/kg (N=x)	WTX-330 0.190 mg/kg (N=x)	WTX-330 0.290 mg/kg (N=x)	WTX-330 0.XXX mg/kg (N=x)	Total (N=xX)
C_{max} (ug/mL)									
n	x	x	x	x	x	x	x	x	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Geometric Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
CV for Geometric Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
T_{max} (hours)									
n	x	x	x	x	x	x	x	x	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
<insert Parameter>									

Nore: CV = Coefficient of variation.

Programming Note:
Includes all PK parameters
Repeat table for Cycle 2 Day 1
T_{max} and T_{last} summary will no include Geometric Mean, Coefficient of variation

The following table will be displayed as Table 14.4.2.**1**,

Table 14.4.2.**2**
Summary of Free IL-12 Pharmacokinetic Parameters
Pharmacokinetic Analysis Set

Programming Note:
Units for Free IL-12, use pg/ml - multiply vendor conc by 1000

Table 14.4.3.1
Summary of Anti-drug Antibody for WTX-330 - Dose Escalation and **Dose Expansion**
Anti-Drug Antibody Analysis Set

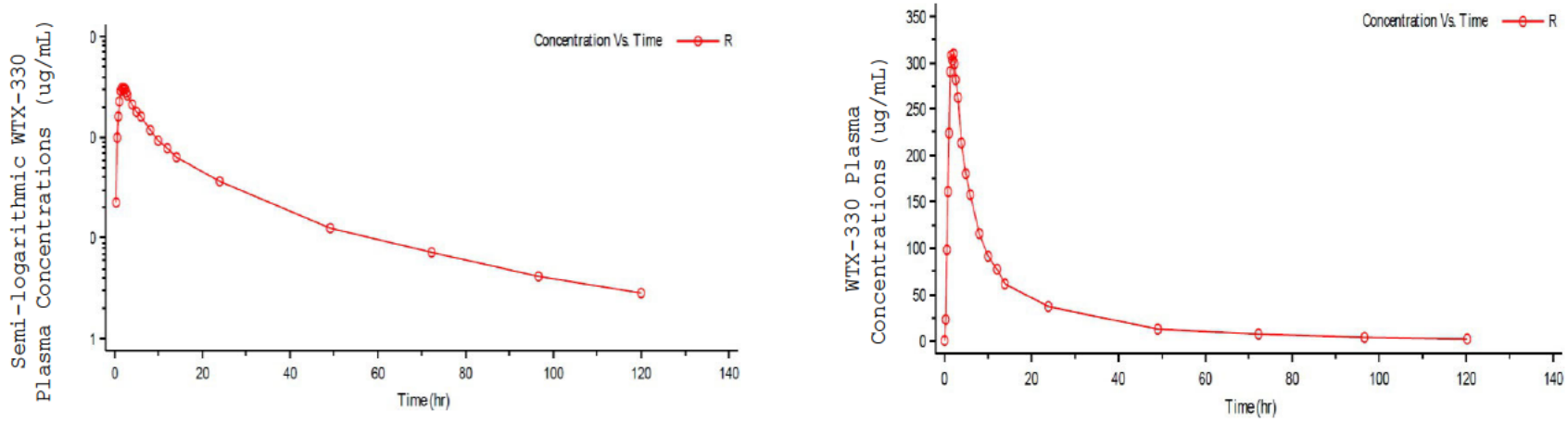
	WTX-330 0.016 mg/kg (N=x)	WTX-330 0.032 mg/kg (N=x)	WTX-330 0.056 mg/kg (N=x)	WTX-330 0.084 mg/kg (N=x)	WTX-330 0.126 mg/kg (N=x)	WTX-330 0.190 mg/kg (N=x)	WTX-330 0.290 mg/kg (N=x)	WTX-330 0.XXX mg/kg (N=x)	Total (N=xX)
ADA at Baseline, n(%)									
Positive	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
Negative	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
Unknown	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
ADA at Post-Baseline, n(%)									
At least one positive	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
All negative	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
Unknown	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
Treatment-induced ADA, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
Treatment-boosted ADA, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
Treatment-unaffected ADA, n(%)	X(XX.X)	X(XX.X)	X(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)

Note: Treatment-induced ADA is defined as those patients with no ADA at baseline and one or more post-treatment (Cycle 1 Day 15 and later) ADA-positive sample. Treatment-boosted ADA is defined as patients with a positive baseline ADA result who had one or more post-treatment (Cycle 1 Day 15 and later) ADA result with a higher titer than that of the baseline ADA sample. Treatment-unaffected ADA, defined as patients with a positive baseline ADA result who had post-treatment (Cycle 1 Day 15 and later) ADA result with a lower titer than that of the baseline ADA sample in all visits.
Note: Dose escalation and dose expansion are summarized together by dose level.

Programming Note:
Combine Dose Escalation and Dose Expansion and summary the results by dose level

Figure Shells

Figure 14.4.1.1.1
Semi-logarithmic Plot and Linear Plot for Individual WTX-330 Plasma Concentrations versus Time at Cycle 1 - Dose Escalation Pharmacokinetic Analysis Set



Programming Note:

- Different WTX-330 dose levels used different colors. Add legend to indicate dose level by color
- Each subject will be plotted in one line

Repeat Figure 14.4.1.1.1 for the following figures, except for the Treatment.

Figure 14.4.1.1.2
Semi-logarithmic Plot and Linear Plot for Individual WTX-330 Plasma Concentrations versus Time at Cycle 2 - Dose Escalation
Pharmacokinetic Analysis Set

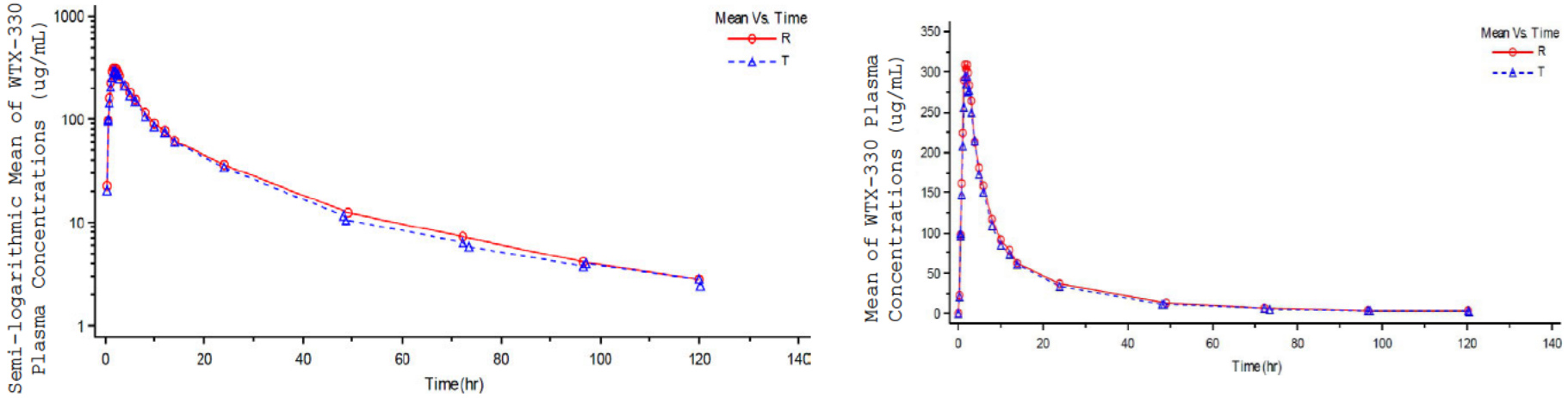
Figure 14.4.1.1.3
Semi-logarithmic Plot and Linear Plot for Individual Free IL-12 Plasma Concentrations versus Time at Cycle 1 - Dose Escalation
Pharmacokinetic Analysis Set

Programming Note:
Units for Free IL-12, use pg/ml - multiply vendor conc by 1000

Figure 14.4.1.1.4
Semi-logarithmic Plot and Linear Plot for Individual Free IL-12 Plasma Concentrations versus Time at Cycle 2 - Dose Escalation
Pharmacokinetic Analysis Set

Programming Note:
Units for Free IL-12, use pg/ml - multiply vendor conc by 1000

Figure 14.4.1.2.1
Semi-logarithmic Plot and Linear Plot for Mean WTX-330 Plasma Concentrations versus Time at Cycle 1 - Dose Escalation
Pharmacokinetic Analysis Set



Note: The error bars indicate the standard error (SE).

Programming Note:

- Different WTX-330 dose levels used different colors in Dose Escalation. Add legend to indicate dose level by color
- Add ± SE in the plot (not SD)

Repeat Figure 14.4.1.2.1 for the following figures, except for the Treatment.

Figure 14.4.1.2.2
Semi-logarithmic Plot and Linear Plot for Mean WTX-330 Plasma Concentrations versus Time at Cycle 2 - Dose Escalation
Pharmacokinetic Analysis Set

Figure 14.4.1.2.3
Semi-logarithmic Plot and Linear Plot for Mean Free IL-12 Plasma Concentrations versus Time at Cycle 1 - Dose Escalation
Pharmacokinetic Analysis Set

Programming Note:
Units for Free IL-12, use pg/ml - multiply vendor conc by 1000

Figure 14.4.1.2.4
Semi-logarithmic Plot and Linear Plot for Mean Free IL-12 Plasma Concentrations versus Time at Cycle 2 - Dose Escalation
Pharmacokinetic Analysis Set

Programming Note:
Units for Free IL-12, use pg/ml - multiply vendor conc by 1000

Listing Shells

Programming Note:

The data will be listed in each listing based on the following sequence if the cohort is available (new dose levels might be added upon protocol amendment):

Dose Escalation: WTX-330 0.016 mg/kg
Dose Escalation: WTX-330 0.032 mg/kg
Dose Escalation: WTX-330 0.056 mg/kg
Dose Escalation: WTX-330 0.084 mg/kg
Dose Escalation: WTX-330 0.126 mg/kg
Dose Escalation: WTX-330 0.190 mg/kg
Dose Escalation: WTX-330 0.290 mg/kg
Dose Escalation: WTX-330 0.XXX mg/kg

Dose Expansion (Arm A): Head and Neck Squamous Cell Carcinoma
Dose Expansion (Arm A): Non-small Cell Lung Cancer
Dose Expansion (Arm A): Renal Cell Carcinoma
Dose Expansion (Arm A): XXXXXXXXXXXXXXXXX
Dose Expansion (Arm B): Colorectal Carcinoma
Dose Expansion (Arm B): Diffuse Large B-cell Lymphoma
Dose Expansion (Arm B): Follicular Lymphoma
Dose Expansion (Arm B): YYYYYYYYYYYYY

Listing 16.2.2.1
Subject Disposition
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level and/or Arm/Disease)

Subject ID/Age/Sex	Date of Last Dose (Study Day)	Date of Treatment Discontinuation (Study Day)	Reason for Treatment Discontinuation	Date of Study Discontinuation (Study Day)	Reason for Study Discontinuation
XXXX-XXX/xx/M	DDMMMYYYY (xx)	DDMMMYYYY (xx)	PD: Radiographic	DDMMMYYY (XX)	Withdrawal of consent by the patient
XXXX-XXX/xx/F	DDMMMYYYY (xx)	DDMMMYYYY (xx)	PD: Clinical- DDMMMYYYY(xx)	DDMMMYYY (XX)	Loss to follow-up
XXXX-XXX/xx/F	DDMMMYYYY (xx)	DDMMMYYYY (xx)	Physician Decision	DDMMMYYY (XX)	Complete the Study
XXXX-XXX/xx/F	DDMMMYYYY (xx)	DDMMMYYYY (xx)	Withdrawal of ICF	DDMMMYYY (XX)	Study termination by Sponsor
XXXX-XXX/xx/F	DDMMMYYYY (xx)	DDMMMYYYY (xx)	Adverse Event: XX	DDMMMYYY (XX)	COVID-19 Related: MH #2
XXXX-XXX/xx/M	DDMMMYYYY (xx)	DDMMMYYYY (xx)	Study Terminated by Sponsor	DDMMMYYY (XX)	Other: XXXXXX
XXXX-XXX/xx/M	DDMMMYYYY (xx)	DDMMMYYYY (xx)	Death	DDMMMYYY (XX)	Death
XXXX-XXX/xx/M	DDMMMYYYY (xx)	DDMMMYYYY (xx)	Other: XXXXXXXX	DDMMMYYY (XX)	Complete the Study

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: PD = Progressive Disease.

Programming Note:
* Sorting order is by Subject ID
* Repeat each dose level and/or arm on a separate page.
* if ‘Did the Subject Complete the Study?’ = Yes, please assign ‘Complete the Study’ for reason for study Discontinuation

Listing 16.2.2.2
Safety and Survival Status Follow-Up
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level and/or Arm/Disease)

Subject ID/Age/Sex	Date of Contact (Study Day)	Subject Status	Date of Last Known to Be Alive (Study Day)	New Surgery or Therapy?: Radiotherapy/Antineoplastic Surgery/Anticancer Medications	Continuing in Survival Monitoring?
XXXX-XX/xx/M	DDMMMYYYY (xx)	Alive	DDMMMYYY (XX)	No	Yes
	DDMMMYYYY (xx)	Lost to follow up			
XXXX-XX/xx/F	DDMMMYYYY (xx)	Alive	DDMMMYYY (XX)	Yes: XXXXXXXXXX/ /XXXXXXXXXXXXXXXX	Yes
	DDMMMYYYY (xx)	Alive	DDMMMYYY (XX)	Yes: / / /XXXXXXXXXXXXXXX	Yes
	DDMMMYYYY (xx)	Dead			
XXXX-XX/xx/M	DDMMMYYYY (xx)	Alive	DDMMMYYY (XX)	No	Yes
	DDMMMYYYY (xx)	Alive	DDMMMYYY (XX)	Yes: XXXXXXXXXX/ /	Yes
	DDMMMYYYY (xx)	Lost to follow up			

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.

Programming Note:
* Sorting order is by Subject ID, and Date of Contact.

Listing 16.2.2.3
Death
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level and/or Arm/Disease)

Subject ID/Age/Sex	Date of Death (Study Day)	Primary Reason for Death	Death Period
XXXX-XXX/xx/M	DDMMMYYYY (xx)	Disease Progression	Death within 30 Days of last study drug
XXXX-XXX/xx/F	DDMMMYYYY (xx)	Adverse Event: #1, #4	Death within 30 Days of last study drug
XXXX-XXX/xx/F	DDMMMYYYY (xx)	Unknown	Death within 30 Days of last study drug
XXXX-XXX/xx/M	DDMMMYYYY (xx)	Other: XXXXXXXXXXXXXXXX	Death after 30 Days of last study drug

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.

Programming Note:
* Sorting order is by Subject ID.
* Repeat each dose level and/or arm on a separate page.

Listing 16.2.3
Deviations from the Clinical Protocol
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level and/or Arm/Disease)

Subject ID/Age/Sex	Date of Protocol Deviation (Study Day)	Protocol Deviation Term	Protocol Category	Major/Minor
XXXX-XXX/xx/M	DDMMMYYYY (xx)	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXX	Minor
XXXX-XXX/xx/F	DDMMMYYYY (xx)	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXX	Minor
XXXX-XXX/xx/F	DDMMMYYYY (xx)	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXX	Minor

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.

Programming Note:
* Sorting order is by Subject ID, Date of Protocol Deviation.

Listing 16.2.4.1
Demographic Data
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level and/or Arm/Disease)

Subject ID/Age/Sex	Date of Birth/ Age	Age Group	Sex	Childbearing Potential?	Ethnicity	Race
XXXX-XXX/xx/M	DDMMMYYYY/28	<45	Male		Hispanic or Latino	American Indian or Alaskan Native
XXXX-XXX/xx/F	DDMMMYYYY/37	<45	Male		Not Hispanic or Latino	Asian
XXXX-XXX/xx/F	DDMMMYYYY/40	<45	Female	Yes	Not Reported	Black or African American
XXXX-XXX/xx/M	DDMMMYYYY/56	≥45-<65	Male		Unknown	Native Hawaiian or Other Pacific Islander
XXXX-XXX/xx/F	DDMMMYYYY/70	≥65	Female	No	Not Hispanic or Latino	White
XXXX-XXX/xx/M	DDMMMYYYY/48	≥45-<65	Male		Not Hispanic or Latino	Not Reported
XXXX-XXX/xx/F	DDMMMYYYY/80	≥65	Female	No	Not Hispanic or Latino	White
XXXX-XXX/xx/M	DDMMMYYYY/66	≥65	Male		Not Reported	White

Programming Note:
* Sorting order is by Subject ID

Listing 16.2.4.2
Baseline Characteristics
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level and/or Arm/Disease)

Subject ID/Age/Sex	Weight (kg)	Height (cm)	Hepatitis B Virus	Hepatitis C Virus	ECOG Performance Status
XXXX-XXX/xx/M	XXX.X	XXX.X	Positive	Negative	0
XXXX-XXX/xx/F	XXX.X	XXX.X	Negative	Negative	0
XXXX-XXX/xx/F	XXX.X	XXX.X	Negative	Negative	1
XXXX-XXX/xx/M	XXX.X	XXX.X	Negative	Negative	1
XXXX-XXX/xx/F	XXX.X	XXX.X	Negative	Positive	1
XXXX-XXX/xx/M	XXX.X	XXX.X	Negative	Positive	1
XXXX-XXX/xx/M	XXX.X	XXX.X	Negative	Negative	0
XXXX-XXX/xx/F	XXX.X	XXX.X	Positive	Negative	0

Note: Baseline is defined to be the last non-missing value prior to the first WTX-330 dose.

Programming Note:
* Sorting order is by Subject ID

Listing 16.2.5
Study Drug Extent of Exposure and Compliance
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level and/or Arm/Disease)

Subject ID/Age/Sex	Duration of Exposure (week)	Number Of Treatment Cycle Started	Total Planned Dose (mg/kg)	Cumulative Dose (mg/kg)	Treatment Compliance (%)	Average Dose Intensity ((mg/kg)/cycle)	Infusion Interruption Events	Subject with Dose Adjustment
XXXX-XXX/xx/M	XXX	XX	XXX	XXX	XXX.X	XXX.X	0	No
XXXX-XXX/xx/F	XXX	XX	XXX	XXX	XXX.X	XXX.X	0	Yes/Missed
XXXX-XXX/xx/F	XXX	XX	XXX	XXX	XXX.X	XXX.X	1	Yes/Missed, Reduced
XXXX-XXX/xx/M	XXX	XX	XXX	XXX	XXX.X	XXX.X	2	Yes/Missed, Discontinued
XXXX-XXX/xx/F	XXX	XX	XXX	XXX	XXX.X	XXX.X	>=3	No
XXXX-XXX/xx/M	XXX	XX	XXX	XXX	XXX.X	XXX.X	2	Yes/Missed, Reduced, Interrupted, Discontinued
XXXX-XXX/xx/M	XXX	XX	XXX	XXX	XXX.X	XXX.X	>=3	No
XXXX-XXX/xx/F	XXX	XX	XXX	XXX	XXX.X	XXX.X	2	Yes/ Missed

Note: Duration of exposure (weeks) is (the date of last administration of WTX-330 – the date of first administration of WTX-330 + 14)/7.
Note: Total Planned Dose (mg/kg) is calculated by the sum of the individual Planned Dose Level being reported in eCRFs.
Note: Cumulative Dose (mg/kg) is calculated by sum of the individual Total Dose Administered being reported in eCRFs.
Note: Treatment compliance (%) is 100*(Cumulative Dose/Total Planned Dose).
Note: Average Dose Intensity((mg/kg)/cycle) is calculated by Cumulative Dose/number of treatment cycles started (any amount of the study drug was administered).

Programming Note:
* Sorting order is by Subject ID
* “Subject with Dose Adjustment” will be derived by concatenate all WTX-330 Administration records (remove duplicated dose adjustment)

Listing 16.2.6.1
Efficacy Parameters by RECIST 1.1 – Part 1 of 2
Evaluable Efficacy Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level and/or Arm/Disease)

Subject ID/Age/Sex	Best Overall Response	Objective Response	Clinical Benefit at Month 3/6/9	Duration of Response (month)	Progression-Free Survival (month)
XXXX-XXX/xx/M	CR	Yes	Yes/Yes/Yes	XXX.X*	XXX.X*
XXXX-XXX/xx/F	SD	No	Yes/Yes/Yes		XXX.X
XXXX-XXX/xx/F	SD	No	No/No/No		XXX.X
XXXX-XXX/xx/M	PR	Yes	Yes/Yes/Yes	XXX.X	XXX.X*
XXXX-XXX/xx/F	PD	No	No/No/No		XXX.X
XXXX-XXX/xx/M	SD	No	Yes/No/No		XXX.X
XXXX-XXX/xx/M	SD	No	Yes/Yes/No		XXX.X*
XXXX-XXX/xx/F	NE	No	No/No/No		XXX.X

Note: CR = Complete Response; PR = Partial Response; SD = Stable Disease; PD = Progressive Disease; NE = Not Evaluable.
Note: CR or PR of best overall response needs to be confirmed in a subsequent assessment at least 28 days apart. See the definition of each parameter in SAP section 8.2.
Note: * indicates the censor.

Programming Note:

* Sorting order is by Subject ID

Listing 16.2.6.2
Efficacy Parameters by iRECIST – Part 2 of 2
Evaluable Efficacy Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Best Percentage of TL from Baseline (%)	Best Overall Response (iBOR)	Objective Response (iOR)	Clinical Benefit at Month 3/6/9 (iCB)	Duration of Response (iDOR) (month)	Progression-Free Survival (iPFS) (month)	Overall Survival (month)
XXXX-XXX/xx/M	XX.X	iCR	Yes	Yes/Yes/Yes	XXX.X*	XXX.X*	XXX.X*
XXXX-XXX/xx/F	XX.X	iSD	No	Yes/Yes/Yes		XXX.X	XXX.X
XXXX-XXX/xx/F	XX.X	iSD	No	No/No/No		XXX.X	XXX.X
XXXX-XXX/xx/M	XX.X	iPR	Yes	Yes/Yes/Yes	XXX.X	XXX.X	XXX.X*
XXXX-XXX/xx/F	XX.X	iCPD	No	No/No/No		XXX.X	XXX.X
XXXX-XXX/xx/M	XX.X	iUPD	No	Yes/No/No		XXX.X	XXX.X
XXXX-XXX/xx/M	XX.X	iSD	No	Yes/No/No		XXX.X*	XXX.X*
XXXX-XXX/xx/F	XX.X	iSD	No	Yes/Yes/No		XXX.X*	XXX.X*
XXXX-XXX/xx/M		NE	No	No/No/No		XXX.X	XXX.X*

Note: TL = Target Lesion; iCR = Immune Complete Response; iPR = Immune Partial Response; iSD = Immune Stable Disease; iUPD = Immune Unconfirmed Progressive Disease; iCPD = Immune Confirmed Progressive Disease; NE = Not Evaluable.
Note: Best overall response of each subject is the best tumor response among all visits according to the following sequence: iCR, iPR, iSD, iCPD, iUPD, NE. See the definition of each parameter in SAP section 8.2.
Note: * indicates the censor.

Programming Note:

* Sorting order is by Subject ID

Listing 16.2.7.1
Treatment-Emergent Adverse Events
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	System Organ Class/ Preferred Term/ Verbatim	Start Date (Study Day)/ Stop Date (Study Day)	irAE?/ AESI?/ IRR?/ DLT?	CRS?/Serious?/ NCI-CTCAE Grade/ASTCT Grade	Relation to WTX-330/ Action Taken with WTX-330	Outcome/ Concomitant or Additional Treatment Given
XXXX-XXX/ xx/ M	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ Ongoing	No/No/ No/No	No/No/ 2/	Unlikely/ Dose Not Changed	Recovered/ Concurrent Procedure
	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY (xx)/	Yes/Yes/ No/No	No/No/ 1/	Unrelated/ Dose Interrupted	Recovered with Sequelae/ Concurrent Procedure
	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ Ongoing	No/Yes/ Yes/No	Yes/Yes/ 4/	Probable/ Dose Reduced	Not Recovered/ Concomitant Medication
XXXX-XXX/ XX/ F	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY(xx)	No/No/ Yes/Yes	Yes/No/ 1/	Definite/ Drug Withdrawn	Recovered with Sequelae/ Other:XXX
	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY (xx)	No/No/ No/No	No/Yes/ 5/	Possible/ Not Applicable	Fatal/ None

Note: Study day = Assessment date − Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date − Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: Adverse Events are coded with MedDRA version 26.0. Adverse Events are graded with CTCAE Grade 5.0, except for Cytokine Release Syndrome which is graded with ASTCT Grade.
Note: A TEAE is defined as an AEs that emerges or worsens (i.e. increase in CTCAE grade/ASTCT Grade) on/after the first WTX-330 dose and within 30 days of the last WTX-330 dose or the start of a new cancer regimen, whichever occurs earlier.
Note: irAE = Immune Related Adverse Event; AESI = Adverse Event of Special Interest; IRR = Infusion Related Reaction; CRS = Cytokine Release Syndrome; DLT = Dose Limiting Toxicity; ASTCT = American Society for Transplantation and Cellular Therapy; Recovered = Recovered/Resolved; Not Recovered = Not Recovered/Not Resolved; Recovered with Sequelae = Recovered/Resolved with Sequelae.

Programming Note:

* Sorting order is by Subject ID, Start Date, System Organ Class and Preferred Term.

Listing 16.2.7.2
Serious Adverse Events
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	System Organ Class/ Preferred Term/ Verbatim	Start Date (Study Day)/ Stop Date (Study Day)	irAE?/ AESI?/ IRR?/ DLT?	CRS?/Serious?/ NCI-CTCAE Grade/ASTCT Grade	Relation to WTX-330/ Action Taken with WTX-330	Serious Adverse Event Category
XXXX-XXX/ xx/ M	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ Ongoing	No/No/ No/No	No/Yes/ 2/	Unlikely/ Dose Not Changed	Required inpatient hospitalization or prolongation of existing hospitalization
	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY (xx)/	Yes/Yes/ No/No	No/Yes/ 4/	Unrelated/ Dose Interrupted	Life Threatening
XXXX-XXX/ xx/ M	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ Ongoing	No/Yes/ Yes/No	Yes/Yes/ 4/	Probable/ Dose Reduced	Life Threatening; Congenital Anomaly or Birth Defect
XXXX-XXX/ XX/ F	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY(xx)	No/No/ Yes/Yes	Yes/Yes/ 3/	Definite/ Drug Withdrawn	Other Medically Important Serious Event
	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY (xx)	No/No/ No/No	No/Yes/ 5/	Possible/ Not Applicable	Results in Death

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: Adverse Events are coded with MedDRA version 26.0. Adverse Events are graded with CTCAE Grade 5.0, except for Cytokine Release Syndrome which is graded with ASTCT Grade.
Note: A TEAE is defined as an AEs that emerges or worsens (i.e. increase in CTCAE grade/ASTCT Grade) on/after the first WTX-330 dose and within 30 days of the last WTX-330 dose or the start of a new cancer regimen, whichever occurs earlier.
Note: irAE = Immune Related Adverse Event; AESI = Adverse Event of Special Interest; IRR = Infusion Related Reaction; CRS = Cytokine Release Syndrome; DLT = Dose Limiting Toxicity; ASTCT = American Society for Transplantation and Cellular Therapy; Recovered = Recovered/Resolved; Not Recovered = Not Recovered/Not Resolved; Recovered with Sequelae = Recovered/Resolved with Sequelae.

Programming Note:

* Sorting order is by Subject ID, Start Date, System Organ Class and Preferred Term.

Listing 16.2.7.3
Treatment-Emergent Adverse Events Leading to Drug Withdrawal
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	System Organ Class/ Preferred Term/ Verbatim	Start Date (Study Day)/ Stop Date (Study Day)	irAE?/ AESI?/ IRR?/ DLT?	CRS?/Serious?/ NCI-CTCAE Grade/ASTCT Grade	Relation to WTX-330/ Action Taken with WTX-330	Outcome/ Concomitant or Additional Treatment Given
XXXX-XXX/ xx/ M	XXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ Ongoing	No/No/ No/No	No/No/ 2/	Unlikely/ Drug Withdrawn	Recovered/ Concurrent Procedure
XXXX-XXX/ xx/ M	XXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY (xx)/	Yes/Yes/ No/No	No/No/ 1/	Unrelated/ Drug Withdrawn	Recovered with Sequelae/ Concurrent Procedure
	XXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ Ongoing	No/Yes/ Yes/No	Yes/Yes/ 4/	Probable/ Drug Withdrawn	Not Recovered/ Concomitant Medication
XXXX-XXX/ XX/ F	XXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY(xx)	No/No/ Yes/Yes	Yes/No/ 1/	Definite/ Drug Withdrawn	Recovered with Sequelae/ Other:XXX

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: Adverse Events are coded with MedDRA version 26.0. Adverse Events are graded with CTCAE Grade 5.0, except for Cytokine Release Syndrome which is graded with ASTCT Grade.
Note: A TEAE is defined as an AEs that emerges or worsens (i.e. increase in CTCAE grade/ASTCT Grade) on/after the first WTX-330 dose and within 30 days of the last WTX-330 dose or the start of a new cancer regimen, whichever occurs earlier.
Note: irAE = Immune Related Adverse Event; AESI = Adverse Event of Special Interest; IRR = Infusion Related Reaction; CRS = Cytokine Release Syndrome; DLT = Dose Limiting Toxicity; ASTCT = American Society for Transplantation and Cellular Therapy; Recovered = Recovered/Resolved; Not Recovered = Not Recovered/Not Resolved; Recovered with Sequelae = Recovered/Resolved with Sequelae.

Programming Note:

* Sorting order is by Subject ID, Start Date, System Organ Class and Preferred Term.

Listing 16.2.7.4
Treatment-Emergent Adverse Events Leading to Drug Modification
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	System Organ Class/ Preferred Term/ Verbatim	Start Date (Study Day)/ Stop Date (Study Day)	irAE?/ AESI?/ IRR?/ DLT?	CRS?/Serious?/ NCI-CTCAE Grade/ASTCT Grade	Relation to WTX-330/ Action Taken with WTX-330	Outcome/ Concomitant or Additional Treatment Given
XXXX-XXX/ xx/ M	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ Ongoing	No/No/ No/No	No/No/ 2/	Unlikely/ Infusion Rate Reduced	Recovered/ Concurrent Procedure
	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY (xx)/	Yes/Yes/ No/No	No/No/ 1/	Unrelated/ Dose Interrupted	Recovered with Sequelae/ Concurrent Procedure
	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ Ongoing	No/Yes/ Yes/No	Yes/Yes/ 4/	Probable/ Dose Reduced	Not Recovered/ Concomitant Medication
XXXX-XXX/ XX/ F	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY(xx)	No/No/ Yes/Yes	Yes/No/ 1/	Definite/ Drug Withdrawn	Recovered with Sequelae/ Other:XXX
	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY (xx)	No/No/ No/No	No/Yes/ 3/	Possible/ Dose Delayed	Recovered with Sequelae/ None

Note: Study day = Assessment date − Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date − Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: Adverse Events are coded with MedDRA version 26.0. Adverse Events are graded with CTCAE Grade 5.0, except for Cytokine Release Syndrome which is graded with ASTCT Grade.
Note: A TEAE is defined as an AEs that emerges or worsens (i.e. increase in CTCAE grade/ASTCT Grade) on/after the first WTX-330 dose and within 30 days of the last WTX-330 dose or the start of a new cancer regimen, whichever occurs earlier.
Note: irAE = Immune Related Adverse Event; AESI = Adverse Event of Special Interest; IRR = Infusion Related Reaction; CRS = Cytokine Release Syndrome; DLT = Dose Limiting Toxicity; ASTCT = American Society for Transplantation and Cellular Therapy; Recovered = Recovered/Resolved; Not Recovered = Not Recovered/Not Resolved; Recovered with Sequelae = Recovered/Resolved with Sequelae.

Programming Note:

* Sorting order is by Subject ID, Start Date, System Organ Class and Preferred Term.
* WTX-330 Dose Delayed/ Dose Interrupted/Dose Reduced/Infusion Rate Reduced/Treatment Held

Listing 16.2.7.5
Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	System Organ Class/ Preferred Term/ Verbatim	Start Date (Study Day)/ Stop Date (Study Day)	irAE?/ AESI?/ IRR?/ DLT?	CRS?/Serious?/ NCI-CTCAE Grade/ASTCT Grade	Relation to WTX-330/ Action Taken with WTX-330	Outcome/ Concomitant or Additional Treatment Given/Special Interest Category
XXXX-XXX/ XX/ F	XXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ Ongoing	No/Yes/ No/No	No/No/ 2/	Unlikely/ Infusion Rate Reduced	Recovered/ Concurrent Procedure/ >=Grade 2 CRS
XXXX-XXX/ XX/ M	XXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY (xx)/	Yes/Yes/ No/No	Yes/No/ 1/	Unrelated/ Dose Interrupted	Recovered with Sequelae / Concurrent Procedure/ >=Grade 2 CLS
XXXX-XXX/ XX/ F	XXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY (xx)	No/Yes/ Yes/No	No/Yes/ 5/	Probable/ Dose Reduced	Fatal/ None/ Hy's Law

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: Adverse Events are coded with MedDRA version 26.0. Adverse Events are graded with CTCAE Grade 5.0, except for Cytokine Release Syndrome which is graded with ASTCT Grade.
Note: A TEAE is defined as an AEs that emerges or worsens (i.e. increase in CTCAE grade/ASTCT Grade) on/after the first WTX-330 dose and within 30 days of the last WTX-330 dose or the start of a new cancer regimen, whichever occurs earlier.
Note: irAE = Immune Related Adverse Event; AESI = Adverse Event of Special Interest; IRR = Infusion Related Reaction; CRS = Cytokine Release Syndrome; DLT = Dose Limiting Toxicity; ASTCT = American Society for Transplantation and Cellular Therapy; Recovered = Recovered/Resolved; Not Recovered = Not Recovered/Not Resolved; Recovered with Sequelae = Recovered/Resolved with Sequelae.

Programming Note:

* Sorting order is by Subject ID, Start Date, System Organ Class and Preferred Term.

Listing 16.2.7.6
Dose Limiting Toxicity
Dose Limiting Toxicity Evaluable Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	System Organ Class/ Preferred Term/ Verbatim	Start Date (Study Day)/ Stop Date (Study Day)	irAE?/ AESI?/ IRR?/ DLT?	CRS?/Serious?/ NCI-CTCAE Grade/ASTCT Grade	Relation to WTX-330/ Action Taken with WTX-330	Outcome/ Concomitant or Additional Treatment Given/Dose Limiting Toxicity Details
XXXX-XXX/ XX/ F	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ Ongoing	No/No/ No/Yes	No/No/ 2/	Unlikely/ Infusion Rate Reduced	Recovered/ Concurrent Procedure/ Any >= Grade 3 cytokine release syndrome (CRS) or capillary leak syndrome (CLS)
XXXX-XXX/ XX/ M	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY (xx)/	Yes/No/ No/ Yes	Yes/No/ 1/	Unrelated/ Dose Interrupted	Recovered with Sequelae / Concurrent Procedure/ Any Grade 2 non-hematological central nervous system (CNS)
XXXX-XXX/ XX/ F	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY (xx)	No/Yes/ Yes/ Yes	No/Yes/ 3/	Probable/ Dose Reduced	Fatal/ None/ Any >= Grade 4 hematological adverse event

Note: Study day = Assessment date − Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date − Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: Adverse Events are coded with MedDRA version 26.0. Adverse Events are graded with CTCAE Grade 5.0, except for Cytokine Release Syndrome which is graded with ASTCT Grade.
Note: irAE = Immune Related Adverse Event; AESI = Adverse Event of Special Interest; IRR = Infusion Related Reaction; CRS = Cytokine Release Syndrome; DLT = Dose Limiting Toxicity; ASTCT = American Society for Transplantation and Cellular Therapy; Recovered = Recovered/Resolved; Not Recovered = Not Recovered/Not Resolved; Recovered with Sequelae = Recovered/Resolved with Sequelae.

Programming Note:

* Sorting order is by Subject ID, Start Date, System Organ Class and Preferred Term.

Listing 16.2.7.7
Treatment Emergent Adverse Events Leading to Death
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	System Organ Class/ Preferred Term/ Verbatim	Start Date (Study Day)/ Stop Date (Study Day)	irAE?/ AESI?/ IRR?/ DLT?	CRS?/Serious?/ NCI-CTCAE Grade/ASTCT Grade	Relation to WTX-330/ Action Taken with WTX-330	Outcome/ Concomitant or Additional Treatment Given
XXXX-XXX/ XX/ F	XXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ Ongoing	No/No/ No/Yes	No/Yes/ 5/	Unlikely/ Infusion Rate Reduced	Fatal/ Concurrent Procedure
XXXX-XXX/ XX/ M	XXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY(xx)	Yes/No/ No/ Yes	Yes/Yes/ 5/	Unrelated/ Dose Interrupted	Fatal/ Other:XXX
	XXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY (xx)	No/Yes/ Yes/ Yes	No/Yes/ 5/	Probable/ Dose Reduced	Fatal/ None

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: Adverse Events are coded with MedDRA version 26.0. Adverse Events are graded with CTCAE Grade 5.0, except for Cytokine Release Syndrome which is graded with ASTCT Grade.
Note: A TEAE is defined as an AEs that emerges or worsens (i.e. increase in CTCAE grade/ASTCT Grade) on/after the first WTX-330 dose and within 30 days of the last WTX-330 dose or the start of a new cancer regimen, whichever occurs earlier.
Note: irAE = Immune Related Adverse Event; AESI = Adverse Event of Special Interest; IRR = Infusion Related Reaction; CRS = Cytokine Release Syndrome; DLT = Dose Limiting Toxicity; ASTCT = American Society for Transplantation and Cellular Therapy.

Programming Note:

* Sorting order is by Subject ID, Start Date, System Organ Class and Preferred Term.

Listing 16.2.8.1
Hematology Tests with CTCAE Grade ≥ 3
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Test	Visit	Collection Date Time (Study Day)	Result/ Change from Baseline	Units	Reference Range	Reference Range Indicator	CTCAE Grade
XXXX-XXX/XX/M	Hemoglobin	Screening	DDMMMYYYY HH:MM (XX)	XX.X	XX	XXX,XXX	Low	1
		C1D1*	DDMMMYYYY HH:MM (XX)	XX.X*	XX	XXX,XXX	Normal	0
		C1D8	DDMMMYYYY HH:MM (XX)	XX.X/XX.X	XX	XXX,XXX	High	2
		<insert>						
	<insert>							
XXXX-XXX/XX/F								

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: Lab data is graded with CTCAE version 5.0.
Note: * indicates baseline value.

Programming Note:
* Sorting order is by Subject ID, Test, Collection date.
* if a subject with a test with CTCAE grade>=3, all visits of the test will be listed.

Listing 16.2.8.2.1
Serum Chemistry Tests with CTCAE Grade ≥ 3
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Test	Visit	Collection Date Time (Study Day)/	Result/ Change from Baseline	Units	Reference Range	Reference Range Indicator	CTCAE Grade
XXXX-XXX/XX/M	ALT	Screening	DDMMMYYYY HH:MM (XX)	XX.X	XX	XXX,XXX	Low	1
		C1D1*	DDMMMYYYY HH:MM (XX)	XX.X*	XX	XXX,XXX	Normal	0
		C1D8	DDMMMYYYY HH:MM (XX)	XX.X/XX.X	XX	XXX,XXX	High	2
		<insert>						
	<insert>							
XXXX-XXX/XX/F								

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: Lab data is graded with CTCAE version 5.0.
Note: * indicates baseline value.

Programming Note:
* Sorting order is by Subject ID, Test, Collection date.
* if a subject with a test with CTCAE grade>=3, all visits of the test will be listed.

Listing 16.2.8.2.2
Liver Function Tests
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Visit	Collection Date Time (Study Day)/	Aspartate Aminotransferase (AST) (xULN)	Alanine Aminotransferase (ALT) (xULN)	Alkaline Phosphatase (ALP) (xULN)	Total Bilirubin (xULN)
XXXX-XXX/XX/M	Screening	DDMMMYYYY HH:MM (XX)	3	3	1.5	2
	C1D1*	DDMMMYYYY HH:MM (XX)	1.2	1.2	1.3	1.0
	C1D8	DDMMMYYYY HH:MM (XX)	5.1	4.2	1.2	3
	<insert>					
XXXX-XXX/XX/M						

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: * indicates baseline value.

Programming Note:
* Sorting order is by Subject ID, Collection date.
* if a subject with AST>=3, ALT>=3, or Total Bilirubin>=1.5, then all visits of these tests will be listed.

Listing 16.2.8.3
Coagulation Tests with CTCAE Grade ≥ 3
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Test	Visit	Collection Date Time (Study Day)/	Result/ Change from Baseline	Units	Reference Range	Reference Range Indicator	CTCAE Grade
XXXX-XXX/XX/M	Partial thromboplastin time	Screening	DDMMMYYYY HH:MM (XX)	XX.X	XX	XXX,XXX	Low	1
		C1D1*	DDMMMYYYY HH:MM (XX)	XX.X*	XX	XXX,XXX	Normal	0
		C1D8	DDMMMYYYY HH:MM (XX)	XX.X/XX.X	XX	XXX,XXX	High	2
		<insert>						
	<insert>							
XXXX-XXX/XX/F								

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: Lab data is graded with CTCAE version 5.0.
Note: * indicates baseline value.

Programming Note:
* Sorting order is by Subject ID, Test, Collection date.
* if a subject with a test with CTCAE grade>=3, all visits of the test will be listed.

Listing 16.2.9
Vital Signs Clinically Notable Increase and/or Decrease
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Test	Visit	Vital Signs Date Time (Study Day)/	Result/Change from Baseline	Units	Increase or Decrease [1]
XXXX-XXX/xx/F	Systolic blood pressure	Screening	DDMMMYYYY HH:MM (XX)	XX.X	XX	
		C1D1*	DDMMMYYYY HH:MM (XX)	XX.X*	XX	
		C1D2	DDMMMYYYY HH:MM (XX)	XX.X/XX.X	XX	
		C1D3	DDMMMYYYY HH:MM (XX)	XX.X/XX.X	XX	
		C1D8	DDMMMYYYY HH:MM (XX)	XX.X/XX.X	XX	Increase
		C1D15	DDMMMYYYY HH:MM (XX)	XX.X/XX.X	XX	
		C1D22	DDMMMYYYY HH:MM (XX)	XX.X/XX.X	XX	
		<insert>				
	<insert>					
XXXX-XXX/xx/M						

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: * indicates baseline value.
[1] See SAP section 9.7 for the category.

Programming Note:

* Sorting order is by Subject ID, Test, Collection date.
* if a subject with a test meeting the following category, all visits of the test will be listed.

- Clinically notable elevated values:
  - Systolic BP: ≥ 180 mmHg and an increase ≥ 20 mmHg from baseline
  - Diastolic BP: ≥ 105 mmHg and an increase ≥ 15 mmHg from baseline
  - Weight: Increase of ≥ 10% from baseline
  - Heart rate: ≥ 120 bpm with an increase of ≥ 15 bpm from baseline
  - Temperature: > 38° C
- Clinically notable decrease values:
  - Systolic BP: ≤90 mmHg and a decrease ≥ 20 mmHg from baseline
  - Diastolic BP: ≤ 50 mmHg and a decrease ≥ 15 mmHg from baseline
  - Weight: decrease of ≥ 10% from baseline
  - Heart rate: ≤ 50 bpm and a decrease ≥ 15 bpm from baseline
  - Temperature: < 35° C

Listing 16.4.2.1
Medical History
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Medical History Description	System Organ Class	Preferred Term	Date of Onset (Study Day)	End Date (Study Day)
XXXX-XXX/xx/M	XXXXXXXXXXXXXXX	XXXXXXXXXXXXXXX	XXXXXXXXXXXXXXX	DDMMMYYY (xx)	DDMMMYYY (xx)
	XXXXXXXXXXXXXXX	XXXXXXXXXXXXXXX	XXXXXXXXXXXXXXX	DDMMMYYY (xx)	Ongoing
	XXXXXXXXXXXXXXX	XXXXXXXXXXXXXXX	XXXXXXXXXXXXXXX	DDMMMYYY (xx)	YYYY
XXXX-XXX/xx/F	XXXXXXXXXXXXXXX	XXXXXXXXXXXXXXX	XXXXXXXXXXXXXXX	Unknown	Unknown
	XXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXX	DDMMMYYY (xx)	DDMMMYYY (xx)
	XXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXX	YYYY	Ongoing
	XXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXX	MMMYYY	YYYY
	XXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXX	DDMMMYYY (xx)	MMMYYY

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: Medical history was coded with MedDRA version 26.0.

Programming Note:
* Sorting order is by Subject ID, System Organ Class, Preferred Term.

Listing 16.4.2.2.1
Solid Tumor Cancer History – Part 1 of 2
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Date of Initial Histopathological Diagnosis (Study Day)	Stage of Solid Tumor at Initial Diagnosis/ Current	Date of most Recent Disease Recurrence/ Progression (Study Day)	Cancer Type	Pathologic Sub-type?	Primary Site of Tumor	Disease Measurable?
XXXX-XXX/xx/M	DDMMMYYY (xx)	0/II	DDMMMYYY (xx)	Adrenal Cancer	No	Bone	Yes
XXXX-XXX/xx/F	DDMMMYYY (xx)	II/III	DDMMMYYY (xx)	Basal Cell Skin Cancer	No	Brain	No
XXXX-XXX/xx/F	DDMMMYYY (xx)	II/IV	DDMMMYYY (xx)	Bile Duct Cancer	No	Breast	Yes
XXXX-XXX/xx/F	DDMMMYYY (xx)	I/III	DDMMMYYY (xx)	Bladder Cancer	Yes: XXXX	Bronchus	Yes
XXXX-XXX/xx/F	DDMMMYYY (xx)	0/IV	DDMMMYYY (xx)	Other: XXXXX	No	Cervix	No
XXXX-XXX/xx/M	DDMMMYYY (xx)	0/II	DDMMMYYY (xx)	Endometrial Cancer	Yes: XXXX	Colon	No
XXXX-XXX/xx/M	DDMMMYYY (xx)	II/II	DDMMMYYY (xx)	Esophageal Cancer	No	Other: XXXXX	Yes

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.

Programming Note:
* Sorting order is by Subject ID

Listing 16.4.2.2.2
Solid Tumor Cancer History – Part 2 of 2
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Genetic Analysis Performed?/ if Yes, Mutations	MSI status known?/ if Yes, Status	Characterization of Disease at Study Entry	TMB Status Known?/ Actual Mutation Burden	Unresectable	Tumoral Genetic Characterization?/if Yes, Specify Most Recent
XXXX-XXX/xx/M	No	Not Applicable	Locally Advanced	Not Applicable	Yes	No
XXXX-XXX/xx/F	Yes/BRAF	No	Metastatic: XXXXXX	No	No	Yes/XXXXXXXXXXXXXX
XXXX-XXX/xx/F	Yes/EGFR, HER2	Yes/MSI-H	Locally Advanced	Yes: High/xxx	Yes	No
XXXX-XXX/xx/F	Yes/KIT, PDGFRA,PIK3CA	Yes/MSI-L	Metastatic: XXXXXX	Yes: Other/xxx	Yes	Yes/XXXXXXXXXXXXXX
XXXX-XXX/xx/F	Yes/NRAS	Yes/MSS	Locally Advanced	No	No	No
XXXX-XXX/xx/M	Yes/VHL	Yes/pMMR	Metastatic: XXXXXX	Yes: Intermediate/xxx	No	No
XXXX-XXX/xx/M	Yes/Other: XXXX	No	Locally Advanced	Not Applicable	Yes	Yes/XXXXXXXXXXXXXX

Programming Note:
* Sorting order is by Subject ID

Listing 16.4.3.1
Prior Systemic Anti-Cancer Therapies
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Line of Therapy/ Therapy Number	Type of Therapy	ATC Category II/ Preferred Name Therapy Name/	Start Date/ End Date	Therapy setting/ Best Overall Response	Primary Reason for Stopping Treatment
XXXX-XXX/xx/F	1/1	Immunotherapy	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX	DDMMMYYYY/ MMYYYY	Advanced/Metastatic Partial Response	Treatment Completed
	1/2	Chemotherapy	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX	DDMMMYYYY/ DDMMMYYYY	Palliative/ Progression Of Disease	Progressive Disease
	2/1	Other: XXXXX	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX	YYYY/ YYYY	Other: XXXXXXXXXXXX/ Stable Disease	Toxicity
XXXX-XXX/xx/M	1/1	Hormonal Therapy	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX	Unknown/ Unknown	Palliative/ Complete Response	Adverse Event
			XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX	MMYYYY/ DDMMMYYYY	Other: XXXXXXXXXXXX/ Not Applicable	Other: XXXXX

Note: Medications are coded with WHODRUG Global B3 March 2023.

Programming Note:
* Sorting order is by Subject ID, Therapy Number, Therapy Name.

Listing 16.4.3.2
Prior Radiation Therapy
Safety Analysis Set

Cohort	Dose level or Arm/Disease	Subject ID/Age/Sex	Site of Radiation	Start Date	End Date
Dose Escalation	WTX-330 0.016 mg/kg	XXXX-XXX/xx/F	Adrenal Gland	DDMMMYYYY	DDMMMYYYY
			Bile duct	DDMMMYYYY	DDMMMYYYY
			Bronchus	YYYY	YYYY
		XXXX-XXX/xx/M	Gall bladder	Unknown	Unknown
			Large Intestine	DDMMMYYYY	DDMMMYYYY
		XXXX-XXX/xx/M	Other: XXXXXXXX	DDMMMYYYY	DDMMMYYYY

Programming Note:
* Sorting order is by Cohort, Dose level or Arm/Disease, Subject ID, Start Date, Site of Radiation.

Listing 16.4.3.3
Prior Cancer Surgery
Safety Analysis Set

Cohort	Dose level or Arm/Disease	Subject ID/Age/Sex	Surgical Procedure Name	Date of Surgery
Dose Escalation	WTX-330 0.016 mg/kg	XXXX-XXX/xx/F	XXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY
			XXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY
			XXXXXXXXXXXXXXXXXX	YYYY
		XXXX-XXX/xx/M	XXXXXXXXXXXXXXXXXXXXXXXXX	Unknown
			XXXXXXXXXXXXXXX	DDMMMYYYY
		XXXX-XXX/xx/M	XXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY

Programming Note:
* Sorting order is by Cohort, Dose level or Arm/Disease, Subject ID, Date of Surgery.

Listing 16.4.4.1
Prior and Concomitant Medications
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Prior or Concomitant	ATC Category II/ Preferred Name/ Medication Name	Start Date (Study Day)/ End Date (Study Day)	Dose/ Unit/ Route	Indication
XXXX-XXX/xx/F	Prior	XXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (XX)/ Ongoing	XX/ XXXXX/ XXXXXX	Adverse Event: #x,#y,
	Concomitant	XXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (XX)/ DDMMMYYY (XX)	XX/ XXXXX Other: XXXXXX	Medical History: #x,#y,#z
	Concomitant	XXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (XX)/ DDMMMYYY (XX)	XX/ XXXXX/ XXXXXXXXXX	Premedication
XXXX-XXX/xx/M	Concomitant	XXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (XX)/ DDMMMYYY (XX)	XX/ XXXXX/ XXXXXXXXX	Prophylactic Use
	Concomitant	XXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX	DDMMMYYY (XX)/ DDMMMYYY (XX)	XX/ XXXXX/ XXXXXXXXXXX	Other: XXXXXX
XXXX-XXX/xx/F	Prior	XXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (XX)/ DDMMMYYY (XX)	XX/ Other/ XXXXXXXXXXXXXX	Medical History: #x,#y,#z

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: Medications are coded with WHODRUG Global B3 March 2023.
Note: Prior medication is the medication that stopped before the first dose of WTX-330. Concomitant medication is the medication that is used on/after the first dose of WTX-330.

Programming Note:
* Sorting order is by Subject ID, Prior or Concomitant, ATC Category II.

Listing 16.4.4.2
Prior and Concomitant Procedures
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Prior or Concomitant	System Organ Class/ Preferred Term/ Name of Procedure	Start Date (Study Day)/ Stop Date (Study Day)	Indication
XXXX-XXX/xx/F	Prior	XXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY (xx)	Adverse Event: #x, #y
	Concomitant	XXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY (xx)	Medical History: #x, #y
	Concomitant	XXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY (xx)	Prophylaxis
XXXX-XXX/xx/M	Prior	XXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY (xx)	Diagnostic/Exploratory
	Concomitant	XXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY(xx)	Treatment Of Underlying Disease
XXXX-XXX/xx/F	Concomitant	XXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY (xx)	Other: XXXXXXXXXXX

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: Prior procedure was coded with MedDRA version 26.0.
Note: Prior procedure is the procedure that stopped before the first dose of WTX-330. Concomitant procedure is the procedure that is performed on/after the first dose of WTX-330.

Programming Note:
* Sorting order is by Subject ID, Start Date.

Listing 16.4.5.1.1
WTX-330 Administration - Part 1 of 2
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Visit	WTX-330 Administered/ Reason Not Done	Preinfusion Medication Taken?/ If Yes, Specify	Infusion Start Date Time (Study Day)	Infusion End Date Time (Study Day)	Planned Dose Level (mg/kg)	Planned Infusion Volume (mL)
XXXX-XXX/xx/F	C1D1	Yes	Yes/XXXXXXXXXXXXX	DDMMMYYY HH:MM (XX)	DDMMMYYY HH:MM(XX)	XX	XXX
	C1D15	No, COVID-19 Related	No			XX	XXX
	C2D1	Yes	No	DDMMMYYY HH:MM (XX)	DDMMMYYY HH:MM(XX)	XX	XXX
	C2D15	Yes	Yes/XXXXXXXXXXXXX	DDMMMYYY HH:MM (XX)	DDMMMYYY HH:MM(XX)	XX	XXX
	C3D1	Yes	Yes/XXXXXXXXXXXXX	DDMMMYYY HH:MM (XX)	DDMMMYYY HH:MM(XX)	XX	XXX
	C3D15	No, Other: XXX	No			XX	XXX
	<insert>			DDMMMYYY HH:MM (XX)	DDMMMYYY HH:MM(XX)	XX	XXX
XXXX-XXX/xx/M	C1D1	Yes	Yes/XXXXXXXXXXXXX	DDMMMYYY HH:MM (XX)	DDMMMYYY HH:MM(XX)	XX	XXX

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.

Programming Note:
* Sorting order is by Subject ID, Visit.

Listing 16.4.5.1.2
WTX-330 Administration - Part 2 of 2
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Visit	WTX-330 Administered/ Reason Not Done	Infusion Interrupted?/ Reason for Interruption	Time of Interruption/ Restart Time	Actual Dose (mg/kg)/Total Volume (mL)	Dose Adjustment?/ Adjustment Type	Reason for Adjustment
XXXX-XXX/xx/F	C1D1	Yes	No		XX/XXX	No	
	C1D15	No,COVID-19 Related					
	C2D1	Yes	No		XX/XXX	Yes/ Dose Missed	Adverse Event: #x
	C2D15	Yes	Yes/Infusion Reaction	HH:MM/HH:MM	XX/XXX	No	
	C3D1	Yes	No		XX/XXX	Yes/Dose Reduced	PI/Sponsor Decision
	C3D15	No,Other: XXX					
	<insert>						
XXXX-XXX/xx/M	C1D1	Yes	Yes/Other: XXXXXX	HH:MM/No	XX/XXX	Yes/Dose Discontinued	Other: XXXXXXXX

Programming Note:
* Sorting order is by Subject ID, Visit.

Listing 16.4.5.2.1
Antineoplastic Therapy since Discontinuation of Study Treatment - Medication
Safety Analysis Set

Cohort	Dose level or Arm/Disease	Subject ID/Age/Sex	Line of Therapy	**Agent**	Therapy Start Date	**Therapy Stop Date**
Dose Escalation	WTX-330 0.016 mg/kg	XXXX-XXX/xx/M	1	XXXXXXXXXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY
				XXXXXXXXXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY
			2	XXXXXXXXXXXXXXXXXXX	DDMMMYYYY	Ongoing
				XXXXXXXXXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY
			3	XXXXXXXXXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY
	XXXX-XXX	XXXX-XXX/xx/F	1	XXXXXXXXXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY

Programming Note:
* Sorting order is by Cohort, Dose level or Arm/Disease, Subject ID, Line of Therapy, Agent.

Listing 16.4.5.2.2
Antineoplastic Therapy since Discontinuation of Study Treatment - Radiation
Safety Analysis Set

Cohort	Dose level or Arm/Disease	Subject ID/Age/Sex	Site of Radiation	Start Date	End Date
Dose Escalation	WTX-330 0.016 mg/kg	XXXX-XXX/xx/M	Adrenal Gland	DDMMMYYYY	DDMMMYYYY
			Bile duct	DDMMMYYYY	DDMMMYYYY
			Bronchus	YYYY	YYYY
		XXXX-XXX/xx/M	Gall bladder	Unknown	Unknown
			Large Intestine	DDMMMYYYY	DDMMMYYYY
		XXXX-XXX/xx/F	Other: XXXXXXXX	DDMMMYYYY	DDMMMYYYY

Programming Note:
* Sorting order is by Cohort, Dose level or Arm/Disease, Subject ID, Start Date, Site of Radiation.

Listing 16.4.5.2.3
Antineoplastic Therapy since Discontinuation of Study Treatment - Surgery
Safety Analysis Set

Cohort	Dose level or Arm/Disease	Subject ID/Age/Sex	Surgical Procedure Name	Date of Surgery
Dose Escalation	WTX-330 0.016 mg/kg	XXXX-XXX/xx/F	XXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY
			XXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY
			XXXXXXXXXXXXXXXXXX	YYYY
		XXXX-XXX/xx/M	XXXXXXXXXXXXXXXXXXXXXXXXX	Unknown
			XXXXXXXXXXXXXXX	DDMMMYYYY
		XXXX-XXX/xx/M	XXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY

Programming Note:
* Sorting order is by Cohort, Dose level or Arm/Disease, Subject ID, Date of Surgery.

Listing 16.4.6.1.1
Target Lesion
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Visit	Date of Assessment (Study Day)	Lesion #	Site/organ	Location of the Lesion	Method	Short Axis and/or Longest diameter (mm)[1]	Target Lesion Status
XXXX-XXX/xx/F	Screening	DDMMMYYY (XX)	1	Adrenal Gland	XXXXXXXXXX	CTwC	XXX.X	
			2	Bronchus	XXXXXXXXXX	CTwC	XXX.X	
			3	Bone	XXXXXXXXXX	CTwC	XXX.X	
	Week 8	DDMMMYYY (XX)	1	Adrenal Gland	XXXXXXXXXX	CTwC	XXX.X	No change
			2	Bronchus	XXXXXXXXXX	CTwC	XXX.X	No change
			3	Bone	XXXXXXXXXX	CTwC	XXX.X	No change
XXXX-XXX/xx/M	Screening	DDMMMYYY (XX)	1	Kidney	XXXXXXXXXX	Other:XX	XXX.X	
			2	Other:XXX	XXXXXXXXXX	MRIwC	XXX.X	
	Week 8	DDMMMYYY (XX)	1	Kidney	XXXXXXXXXX	Other:XX	XXX.X	No change
			2	Other:XXX	XXXXXXXXXX	MRIwC	XXX.X	No change
	Week 16	DDMMMYYY (XX)	1	Kidney	XXXXXXXXXX	Other:XX	XXX.X	Merged
			2	Other:XXX	XXXXXXXXXX	MRIwC	NE	Absent

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: CTwC = CT scan with contrast; CTw/oC = CT scan without contrast; MRIwC = MRI scan with contrast; MRIw/oC = MRI scan without contrast; NE = Not evaluable.
[1] For the subjects with solid tumor, the results will be Lymph Node/Short Axis or Non-Lymph Node/Longest diameter; For the subjects with Lymphoma, the results will be Lymph Node/Short Axis and Lymph Node/Longest diameter. The results will be separated with "/".

Programming Note:

* Sorting order is by Subject ID, Visit, Lesion #

Listing 16.4.6.1.2
Non-Target Lesion
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Visit	Date of Assessment (Study Day)	Lesion #	Site/organ	Location of the Lesion	Method	Status of Non-Target Lesion
XXXX-XXX	Screening	DDMMMYYY (XX)	1	Adrenal Gland	XXXXXXXXXX	CTwC	
			2	Bronchus	XXXXXXXXXX	CTwC	
			3	Bone	XXXXXXXXXX	Bone Scan	
	Week 8	DDMMMYYY (XX)	1	Adrenal Gland	XXXXXXXXXX	CTwC	Absent
			2	Bronchus	XXXXXXXXXX	CTwC	UPD
			3	Bone	XXXXXXXXXX	Bone Scan	NE
XXXX-XXX	Screening	DDMMMYYY (XX)	1	Kidney	XXXXXXXXXX	Other:XX	
			2	Other:XXX	XXXXXXXXXX	MRIwC	
	Week 8	DDMMMYYY (XX)	1	Kidney	XXXXXXXXXX	Other:XX	No Increase
			2	Other:XXX	XXXXXXXXXX	MRIwC	No Increase
	Week 16	DDMMMYYY (XX)	1	Kidney	XXXXXXXXXX	Other:XX	Increase
			2	Other:XXX	XXXXXXXXXX	MRIwC	Increase

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: CTwC = CT scan with contrast; CTw/oC = CT scan without contrast; MRIwC = MRI scan with contrast; MRIw/oC = MRI scan without contrast; UPD=Unequivocal Progression; NE=Not Evaluable.

Programming Note:
* Sorting order is by Subject ID, Visit, Lesion #

Listing 16.4.6.1.3.1
New Target Lesion
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Visit	Date of Assessment (Study Day)	Lesion #	Site/organ	Location of the Lesion	Method	Short Axis or Longest Diameter (mm)	New Target Lesion Status
XXXX-XXX/xx/F	Week 8	DDMMMYYY (XX)	1	Bronchus	XXXXXXXXXX	CTwC	XXX.X	NA, New
	Week 16	DDMMMYYY (XX)	1	Bronchus	XXXXXXXXXX	CTwC	XXX.X	No Change
	Week 24	DDMMMYYY (XX)	1	Bronchus	XXXXXXXXXX	CTwC	XXX.X	Split
XXXX-XXX/xx/M	Week 8	DDMMMYYY (XX)	1	Kidney	XXXXXXXXXX	Other:XX	XXX.X	NA, New
			2	Other:XXX	XXXXXXXXXX	MRIwC	XXX.X	NA, New
	Week 16	DDMMMYYY (XX)	1	Kidney	XXXXXXXXXX	Other:XX	XXX.X	Merged
			2	Other:XXX	XXXXXXXXXX	MRIwC	NE	Absent

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: CTwC = CT scan with contrast; CTw/oC = CT scan without contrast; MRIwC = MRI scan with contrast; MRIw/oC = MRI scan without contrast; NE = Not evaluable.

Programming Note:

* Sorting order is by Subject ID, Visit, Lesion #

Listing 16.4.6.1.3.2
New Non-Target Lesion
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Visit	Date of Assessment (Study Day)	Lesion #	Site/organ	Location of the Lesion	Method	New Status of Non-Target Lesion
XXXX-XXX/xx/F	Week 8	DDMMMYYY (XX)	1	Adrenal Gland	XXXXXXXXXX	CTwC	NA, New
	Week 16	DDMMMYYY (XX)	1	Bronchus	XXXXXXXXXX	CTwC	UPD
	Week 24	DDMMMYYY (XX)	1	Bone	XXXXXXXXXX	Bone Scan	NE
XXXX-XXX/xxM	Week 8	DDMMMYYY (XX)	1	Kidney	XXXXXXXXXX	Other:XX	NA, New
			2	Other:XXX	XXXXXXXXXX	MRIwC	NA, New
	Week 16	DDMMMYYY (XX)	1	Kidney	XXXXXXXXXX	Other:XX	No Increase
			2	Other:XXX	XXXXXXXXXX	MRIwC	No Increase
	Week 24	DDMMMYYY (XX)	1	Kidney	XXXXXXXXXX	Other:XX	Increase
			2	Other:XXX	XXXXXXXXXX	MRIwC	Increase

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: CTwC = CT scan with contrast; CTw/oC = CT scan without contrast; MRIwC = MRI scan with contrast; MRIw/oC = MRI scan without contrast; UPD = Unequivocal Progression; NE = Not Evaluable.

Programming Note:
* Sorting order is by Subject ID, Visit, Lesion #

Listing 16.4.6.2
Disease Response – Solid Tumor
Efficacy Evaluable Population

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Visit	Date of Assessment (Study Day)	Target Lesion Response	Sum of Target Lesion (mm)/ % Change from Baseline/ % Change from Nadir	Non-Target Lesion Response	Any New Lesions?	Number of New Lesions	Overall RECIST 1.1 Response	Overall iRECIST Response
XXXX-XXX/xx/F	Screening	DDMMMYYY (XX)		xxx.x					
	Week 8	DDMMMYYY (XX)	PR	xxx.x/xx.x/xx.x	NCRNPD	No		PR*	iPR*
	Week 16	DDMMMYYY (XX)	PR	xxx.x/xx.x/xx.x	NCRNPD	No		PR	iPR
	Uns.	DDMMMYYY (XX)	PR	xxx.x/xx.x/xx.x	NCRNPD	No		PR	iPR
	Week 24	DDMMMYYY (XX)	PR	xxx.x/xx.x/xx.x	NCRNPD	No		PR	iPR
	Week 32	DDMMMYYY (XX)	PD	xxx.x/xx.x/xx.x	NE	Yes	1	PD	iUPD
XXXX-XXX/xx/M	Screening	DDMMMYYY (XX)		xxx.x					
	Week 8	DDMMMYYY (XX)	SD	xxx.x/xx.x/xx.x	NCRNPD	No		SD*	iSD*
	Week 16	DDMMMYYY (XX)	SD	xxx.x/xx.x/xx.x	NCRNPD	Yes	1	PD	iUPD
	Week 24	DDMMMYYY (XX)	PD	xxx.x/xx.x/xx.x	CR	Yes	1	PD	iCPD
	Week 32	DDMMMYYY (XX)	PD	xxx.x/xx.x/xx.x	CR	Yes	3	PD	iCPD

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: CR = Complete Response; PR = Partial Response; SD = Stable Disease; PD = Progressive Disease; NE=Not Evaluable; NCRNPD=Non-CR/Non-PD; iCR = Immune Complete Response; iPR = Immune Partial Response; iSD = Immune Stable Disease; iUPD = Immune Unconfirmed Progressive Disease; iCPD = Immune Confirmed Progressive Disease.
Note: * indicates the first best overall response.

Programming Note:
* Sorting order is by Subject ID, Visit.
* Flag the first best overall response

Listing 16.4.6.4
Prostate-specific Antigen (PSA)
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Visit	Collection Date Time (Study Day)/	PSA Sample Collected?	Result (ng/mL)	PSA Tumor Marker Response
XXXX-XXX/xx/F	Screening	DDMMMYYYY HH:MM (XX)	Yes	xxx.x	
	Week 8	DDMMMYYYY HH:MM (XX)	Yes	xxx.x	Non-response/Non-Progression
	Week 16	DDMMMYYYY HH:MM (XX)	Yes	xxx.x	Non-response/Non-Progression
	Uns.		No, COVID-19 Related		
	Week 24	DDMMMYYYY HH:MM (XX)	Yes	xxx.x	Progression
	Week 32	DDMMMYYYY HH:MM (XX)	Yes	xxx.x	Progression
XXXX-XXX/xx/M	Screening	DDMMMYYYY HH:MM (XX)	Yes	xxx.x	
	Week 8		No, Other: XXXXXXX		
	Week 16	DDMMMYYYY HH:MM (XX)	Yes	xxx.x	50% decrease from baseline
	Week 24	DDMMMYYYY HH:MM (XX)	Yes	xxx.x	50% decrease from baseline
	Week 32	DDMMMYYYY HH:MM (XX)	Yes	xxx.x	Not Evaluable

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.
Nore: Progression is defined as >= 25% increase and >=2 ng/mL increase from nadir.

Programming Note:
* Sorting order is by Subject ID, Visit.

Listing 16.4.7
All Adverse Events
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	System Organ Class/ Preferred Term/ Verbatim	Start Date (Study Day)/ Stop Date (Study Day)/ TEAE?	irAE?/ AESI?/ IRR?/ DLT?	CRS?/Serious?/ NCI-CTCAE Grade/ASTCT Grade	Relation to WTX-330/ Action Taken with WTX-330	Outcome/ Concomitant or Additional Treatment Given
XXXX-XXX/xx/F	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ Ongoing/ No	No/No/ No/No	No/No/ 2/	Unlikely/ Dose Not Changed	Recovered/ Concurrent Procedure
	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY (xx)/ Yes	Yes/Yes/ No/No	No/No/ 1/	Unrelated/ Dose Interrupted	Recovered with Sequelae/ Concurrent Procedure
	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ Ongoing/ Yes	No/Yes/ Yes/No	Yes/Yes/ 4/	Probable/ Dose Reduced	Not Recovered/ Concomitant Medication
XXXX-XXX/xx/M	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY(xx)/ Yes	No/No/ Yes/Yes	Yes/No/ 1/	Definite/ Drug Withdrawn	Recovered with Sequelae/ Other:XXX
	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXX	DDMMMYYY (xx)/ DDMMMYYY (xx)/ Yes	No/No/ No/No	No/Yes/ 5/	Possible/ Not Applicable	Fatal/ None

Note: Study day = Assessment date − Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date − Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: Adverse Events are coded with MedDRA version 26.0. Adverse Events are graded with CTCAE Grade 5.0, except for Cytokine Release Syndrome which is graded with ASTCT Grade.
Note: A TEAE is defined as an AEs that emerges or worsens (i.e. increase in CTCAE grade/ASTCT Grade) on/after the first WTX-330 dose and within 30 days of the last WTX-330 dose or the start of a new cancer regimen, whichever occurs earlier.
Note: irAE = Immune Related Adverse Event; AESI = Adverse Event of Special Interest; IRR = Infusion Related Reaction; CRS = Cytokine Release Syndrome; DLT = Dose Limiting Toxicity; ASTCT = American Society for Transplantation and Cellular Therapy; Recovered = Recovered/Resolved; Not Recovered = Not Recovered/Not Resolved; Recovered with Sequelae = Recovered/Resolved with Sequelae.

Programming Note:

* Sorting order is by Subject ID, Start Date, System Organ Class and Preferred Term.

Listing 16.4.8.1
Hematology Tests
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Test	Visit	Collection Date (Study Day)	Time	Result/ Change from Baseline	Units	Reference Range	Reference Range Indicator	CTCAE Grade
XXXX-XXX/xx/F	Hemoglobin	Screening	DDMMMYYYY	HH:MM (XX)	XX.X	XX	XXX,XXX	Low	1
		C1D1	DDMMMYYYY	HH:MM (XX)	XX.X*	XX	XXX,XXX	Normal	0
		C1D8	DDMMMYYYY	HH:MM (XX)	XX.X/XX.X	XX	XXX,XXX	High	2
		<insert>							
	<insert>								
XXXX-XXX/xx/M									

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: Lab data is graded with CTCAE version 5.0.
Note: * indicates baseline value.

Programming Note:

* Sorting order is by Subject ID, Test, Collection date.

Listing 16.4.8.2
Serum Chemistry Tests
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Test	Visit	Collection Date Time (Study Day)/	Result/ Change from Baseline	Units	Reference Range	Reference Range Indicator	CTCAE Grade
XXXX-XXX/xx/F	ALT	Screening	DDMMMYYYY HH:MM (XX)	XX.X	XX	XXX,XXX	Low	1
		C1D1	DDMMMYYYY HH:MM (XX)	XX.X*	XX	XXX,XXX	Normal	0
		C1D8	DDMMMYYYY HH:MM (XX)	XX.X/XX.X	XX	XXX,XXX	High	2
		<insert>						
	<insert>							
XXXX-XXX/xx/M								

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: Lab data is graded with CTCAE version 5.0.
Note: * indicates baseline value.

Programming Note:

* Sorting order is by Subject ID, Test, Collection date.

Listing 16.2.8.3
Coagulation Tests
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Test	Visit	Collection Date Time (Study Day)/	Result/ Change from Baseline	Units	Reference Range	Reference Range Indicator	CTCAE Grade
XXXX-XXX/xx/F	Partial thromboplastin time	Screening	DDMMMYYYY HH:MM (XX)	XX.X	XX	XXX,XXX	Low	1
		C1D1	DDMMMYYYY HH:MM (XX)	XX.X*	XX	XXX,XXX	Normal	0
		C1D8	DDMMMYYYY HH:MM (XX)	XX.X/XX.X	XX	XXX,XXX	High	2
		<insert>						
	<insert>							
XXXX-XXX/xx/M								

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: Lab data is graded with CTCAE version 5.0.
Note: * indicates baseline value.

Programming Note:

* Sorting order is by Subject ID, Test, Collection date.

Listing 16.4.8.4
Urinalysis Tests
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Test	Visit	Collection Date Time (Study Day)	Result
XXXX-XXX/xx/F	Turbidity	Screening	DDMMMYYYY HH:MM (XX)	Clear
		C1D1*	DDMMMYYYY HH:MM (XX)	Slightly Cloudy
		C1D8	DDMMMYYYY HH:MM (XX)	Cloudy
		C1D15	DDMMMYYYY HH:MM (XX)	Cloudy
		<insert>	DDMMMYYYY HH:MM (XX)	Turbid
	<insert>			
XXXX-XXX/xx/M				

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: * indicates baseline value.

Programming Note:
* Sorting order is by Subject ID, Test, Collection date.

Listing 16.4.8.5
Thyroid Stimulating Hormone
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Test	Visit	Collection Date Time (Study Day)/	Result/ Change from Baseline	Unit
XXXX-XXX/xx/F	Thyroid stimulating hormone	Screening	DDMMMYYYY HH:MM (XX)	XX.X	XX
		C1D1	DDMMMYYYY HH:MM (XX)	XX.X*	XX
		C1D8	DDMMMYYYY HH:MM (XX)	XX.X/XX.X	XX
		<insert>			
	<insert>				
XXXX-XXX/xx/M					

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: * indicates baseline value.

Programming Note:
* Sorting order is by Subject ID, Test, Collection date.
* including Thyroid stimulating hormone (TSH), Free triiodothyronine (T3), Free thyroxine (T4), Total triiodothyronine (T3), Total thyroxine (T4)

Listing 16.4.8.6
Pregnancy Test
Safety Analysis Set

Cohort	Dose level or Arm/Disease	Subject ID/Age/Sex	Visit	Collection Date Time (Study Day)	Pregnancy Test Type	Pregnancy Test Result
Dose Escalation	WTX-330 0.016 mg/kg	XXXX-XXX/xx/F	Screening	DDMMMYYYY HH:MM (XX)	Serum	Negative
			C1D15	DDMMMYYYY HH:MM (XX)	Urine	Negative
			<insert>	DDMMMYYYY HH:MM (XX)	Urine	Negative
		XXXX-XXX/xx/F				

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.

Programming Note:
* Sorting order is by Cohort, Dose level or Arm/Disease, Subject ID, Collection Date.

Listing 16.4.9.1
12-Lead ECG
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Test (unit)	Visit	ECG Position of Subject	ECG Date Time (Study Day)	Time Point	ECG #	Result	Mean/Change from Baseline
XXXX-XXX/xx/F	PR (msec)	Screening		DDMMMYYYY HH:MM(XX)	Screening		xxx.x	
		C1D1	Sitting	DDMMMYYYY HH:MM(XX)	Pre-dose	1	xxx.x	XX.X*
				DDMMMYYYY HH:MM(XX)	Pre-dose	2	xxx.x	
				DDMMMYYYY HH:MM(XX)	Pre-dose	3	xxx.x	
		C1D1	Sitting	DDMMMYYYY HH:MM(XX)	Immediately after WTX-330 infusion	1	xxx.x	XX.X/XX.X
				DDMMMYYYY HH:MM(XX)	Immediately after WTX-330 infusion	2	xxx.x	
				DDMMMYYYY HH:MM(XX)	Immediately after WTX-330 infusion	3	xxx.x	
		C1D1	Sitting	DDMMMYYYY HH:MM(XX)	4 hours after WTX-330 infusion	1	xxx.x	XX.X/XX.X
				DDMMMYYYY HH:MM(XX)	4 hours after WTX-330 infusion	2	xxx.x	
				DDMMMYYYY HH:MM(XX)	4 hours after WTX-330 infusion	3	xxx.x	
		<insert>						

XXXX-XXX

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: * indicates baseline value.

Programming Note:
* Sorting order is by Subject ID, Test, ECG Date, Time Point, ECG#
* Mean/Change from Baseline is reported in the row of ECG# =1.

Listing 16.4.9.2
Vital Signs
Safety Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Test (unit)	Visit	Vital Signs Date Time (Study Day)	Result	Change from Baseline
XXXX-XXX/xx/F	Weight (kg)	Screening	DDMMMYYYY HH:MM(XX)	xxx.x	
		C1D1	DDMMMYYYY HH:MM(XX)	xxx.x*	
		C1D2	DDMMMYYYY HH:MM(XX)	xxx.x	XX.X
		C1D3	DDMMMYYYY HH:MM(XX)	xxx.x	XX.X
		C1D8	DDMMMYYYY HH:MM(XX)	xxx.x	XX.X
		C1D15	DDMMMYYYY HH:MM(XX)	xxx.x	XX.X
		<insert>			
XXXX-XXX/xx/M					

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: * indicates baseline value.

Programming Note:
* Sorting order is by Subject ID, Test, Vital Signs Date

Listing 16.4.9.3
ECOG Performance Status
Safety Analysis Set

Cohort	Dose level or Arm/Disease	Subject ID/Age/Sex	Performed?/ Reason Not Done	Visit	Date of Assessment (Study Day)	Result
Dose Escalation	WTX-330 0.016 mg/kg	XXXX-XXX/xx/F	Yes	Screening	DDMMMYYYY (XX)	0
				C1D1	DDMMMYYYY (XX)	1
			No, Other: XXXXXXXX	C1D8		
				<insert>		
		XXXX-XXX/xx/M	Yes	Screening	DDMMMYYYY (XX)	0
			Yes	C1D1	DDMMMYYYY (XX)	0
			Yes	C1D8	DDMMMYYYY (XX)	2
			No, COVID-19 Related	C1D15		

Note: Study day = Assessment date − Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date − Date of Day 1 if assessment date is before the first WTX-330 dose.
Note: 0 - Fully active, able to carry on all pre-disease performance without restriction; 1 - Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work;
2 - Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours;
3 - Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours; 4 - Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair

Programming Note:
* Sorting order is by Cohort, Dose level or Arm/Disease, Subject ID, Visit.

Listing 16.4.9.4
Physical Examination
Safety Analysis Set

Cohort	Dose level or Arm/Disease	Subject ID/Age/Sex	Performed?/ Reason Not Done	Visit	Date of Assessment (Study Day)	Physical Exam Result	Clinical Significance
Dose Escalation	WTX-330 0.016 mg/kg	XXXX-XXX/xx/F	Yes	Screening	DDMMMYYYY (XX)	Normal	
				C1D1	DDMMMYYYY (XX)	Abnormal	No
			No, Other: XXXXXXXX	C1D8		Not Done	
				<insert>			
		XXXX-XXX/xx/M	Yes	Screening	DDMMMYYYY (XX)	Normal	
			Yes	C1D1	DDMMMYYYY (XX)	Abnormal	Yes: XXXXXX
			Yes	C1D8	DDMMMYYYY (XX)	Normal	
			No, COVID-19 Related	C1D15		Not Done	

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.

Programming Note:
* Sorting order is by Cohort, Dose level or Arm/Disease, Subject ID, Visit.

Listing 16.4.10.1.1
WTX-330 Plasma Concentrations (μg/ml)
Pharmacokinetic Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Visit	Collection Date Time (Study Day)	Time Point	Result
XXXX-XXX/xx/F	C1D1	DDMMMYYYY HH:MM(XX)	Pre-dose	xxx.x
	C1D1	DDMMMYYYY HH:MM(XX)	Immediately after (±2 minutes) WTX-330 infusion	xxx.x
	C1D1	DDMMMYYYY HH:MM(XX)	4 hours (±30 minutes) post start of WTX-330 infusion	xxx.x
	C1D1	DDMMMYYYY HH:MM(XX)	8 hours (±30 minutes) post start of WTX-330 infusion	xxx.x
	C1D2	DDMMMYYYY HH:MM(XX)	24 hours (±2 hours) post start of WTX-330 infusion	xxx.x
	C1D3	DDMMMYYYY HH:MM(XX)	48 hours (±2 hours) post start of WTX-330 infusion	xxx.x
	C1D8	DDMMMYYYY HH:MM(XX)	168 hours (±4 hours) post start of WTX-330 Infusion	xxx.x
	<insert>			

XXXX-XXX

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.

Programming Note:

* Sorting order is by Subject ID, Visit, Time Point

Listing 16.4.10.1.2
Free IL-12 Plasma Concentrations (pg/ml)
Pharmacokinetic Analysis Set

Dose Escalation: WTX-330 0.016 mg/kg (Phase Therapy: Dose level or Arm/Disease)

Subject ID/Age/Sex	Visit	Collection Date Time (Study Day)	Time Point	Result
XXXX-XXX/xx/F	C1D1	DDMMMYYYY HH:MM(XX)	Pre-dose	xxx.x
	C1D1	DDMMMYYYY HH:MM(XX)	Immediately after (±2 minutes) WTX-330 infusion	xxx.x
	C1D1	DDMMMYYYY HH:MM(XX)	4 hours (±30 minutes) post start of WTX-330 infusion	xxx.x
	C1D1	DDMMMYYYY HH:MM(XX)	8 hours (±30 minutes) post start of WTX-330 infusion	xxx.x
	C1D2	DDMMMYYYY HH:MM(XX)	24 hours (±2 hours) post start of WTX-330 infusion	xxx.x
	C1D3	DDMMMYYYY HH:MM(XX)	48 hours (±2 hours) post start of WTX-330 infusion	xxx.x
	C1D8	DDMMMYYYY HH:MM(XX)	168 hours (±4 hours) post start of WTX-330 Infusion	xxx.x
	<insert>			

XXXX-XXX

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.

Programming Note:
* Sorting order is by Subject ID, Visit, Time Point

Listing 16.4.10.2.1
WTX-330 Pharmacokinetic Parameters
Pharmacokinetic Analysis Set

Cohort	Dose level or Arm/Disease	Subject ID/Age/Sex	Cycle	Parameter	Result	Unit
Dose Escalation	WTX-330 0.016 mg/kg	XXXX-XXX/xx/F	Cycle 1	AUC_{0-14d}	XX.X	XXXX
				C_{max}	XX.X	XXXX
				T_{max}	XX.X	XXXX
				<insert>	XX.X	XXXX
			Cycle 2	AUC_{0-14d}	XX.X	XXXX
				C_{max}	XX.X	XXXX
				T_{max}	XX.X	XXXX
				<insert>	XX.X	XXXX
		<insert>				

Programming Note:
* Sorting order is by Cohort, Dose level or Arm/Disease, Subject ID, Cycle.

Listing 16.4.10.2.1
Free IL-12 Pharmacokinetic Parameters
Pharmacokinetic Analysis Set

Cohort	Dose level or Arm/Disease	Subject ID/Age/Sex	Cycle	Parameter	Result	Unit
Dose Escalation	WTX-330 0.016 mg/kg	XXXX-XXX/xx/F	Cycle 1	AUC_{0-14d}	XX.X	XXXX
				C_{max}	XX.X	XXXX
				T_{max}	XX.X	XXXX
				<insert>	XX.X	XXXX
			Cycle 2	AUC_{0-14d}	XX.X	XXXX
				C_{max}	XX.X	XXXX
				T_{max}	XX.X	XXXX
				<insert>	XX.X	XXXX
		<insert>				

Programming Note:
* Sorting order is by Cohort, Dose level or Arm/Disease, Subject ID, Cycle.

Listing 16.4.10.3
Anti-Drug Antibody
Anti-Drug Antibody Analysis Set

Cohort	Dose level or Arm/Disease	Subject ID/Age/Sex	Visit	Collection Date Time (Study Day)/	Time Point	Numeric Result	Categoric Result
Dose Escalation	WTX-330 0.016 mg/kg	XXXX-XXX/xx/F	C1D1	DDMMMYYYY HH:MM (XX)	Pre-dose	XX.X	Negative
			C1D15	DDMMMYYYY HH:MM (XX)	Pre-dose	XX.X	Negative
			C2D1	DDMMMYYYY HH:MM (XX)	Pre-dose	XX.X	Positive
			C2D15	DDMMMYYYY HH:MM (XX)	Any time	XX.X	Positive
			C3D1	DDMMMYYYY HH:MM (XX)	Pre-dose	XX.X	Positive
			<insert>				
		<insert>					

Note: Study day = Assessment date – Date of Day 1 + 1 if assessment date is on/after the first WTX-330 dose; Study day = Assessment date – Date of Day 1 if assessment date is before the first WTX-330 dose.

Programming Note:
* Sorting order is by Cohort, Dose level or Arm/Disease, Subject ID, Visit.

Certificate Of Completion

Envelope Id: 2EC316E2-48C0-4ED4-8261-DCEF7D99307B
Status: Completed
Subject: Complete with Docusign: WTX-330x2101 (WWT21330) SAP text 2.pdf, WTX-330x2101 (WWT21330) TFL she...
Source Envelope:
Document Pages: 193
Signatures: 4
Certificate Pages: 5
Initials: 0
AutoNav: Enabled
EnvelopeId Stamping: Disabled
Time Zone: (UTC) Monrovia, Reykjavik

Envelope Originator:
Shuangli Guo
Inc 2700 Wycliff Road, Suite 340
Raleigh, NC 27607
Shuangli.Guo@caidya.com
IP Address: 71.206.118.21

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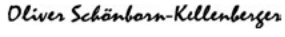
Oliver Schönborn-Kellenberger oliver.schoenborn-kellenberger@cogitars.com Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 988B94B1-FDA2-4A35-AEB8-361DCA46EBF3 Using IP Address: 176.199.208.46 Signed using mobile With Signing Authentication via Docusign password With Signing Reasons (on each tab): Ich genehmige dieses Dokument Ich habe dieses Dokument geprüft	Sent: 26-Feb-2025 | 19:27 Viewed: 26-Feb-2025 | 19:55 Signed: 26-Feb-2025 | 20:00
Electronic Record and Signature Disclosure: Accepted: 26-Feb-2025 | 19:55 ID: f4e5de15-c617-41b7-9f36-373027ccec1e		
Shuangli Guo shuangli.guo@caidya.com Senior Manager, Biostatistics Caidya Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 3F1277AD-321D-4048-BF56-4AE5BED08E47 Using IP Address: 71.206.118.21 With Signing Authentication via Docusign password With Signing Reasons (on each tab): I am the author of this document I am the author of this document	Sent: 26-Feb-2025 | 19:27 Viewed: 26-Feb-2025 | 19:28 Signed: 26-Feb-2025 | 19:29
Electronic Record and Signature Disclosure: Not Offered via Docusign		

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp
Carbon Copy Events	**Status**	**Timestamp**
Witness Events	**Signature**	**Timestamp**
Notary Events	**Signature**	**Timestamp**
Envelope Summary Events	**Status**	**Timestamps**
Envelope Sent	Hashed/Encrypted	26-Feb-2025 | 19:27
Certified Delivered	Security Checked	26-Feb-2025 | 19:28
Signing Complete	Security Checked	26-Feb-2025 | 19:29
Completed	Security Checked	26-Feb-2025 | 20:00
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