Nitto BioPharma Inc.

Statistical Analysis Plan

NBF-006-001: A Phase I/Ib Open-Label, Multi-Center, Dose-Escalation Study to Investigate the Safety, Pharmacokinetics and Preliminary Efficacy of Intravenous NBF-006 in Patients with Non-Small Cell Lung, Pancreatic, or Colorectal Cancer Followed by a Dose Expansion Study in Patients with KRAS-Mutated Non-Small Cell Lung Cancer

Investigational Product: NBF-006

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Statistical Analysis Plan

Final Version 2.0; March 14, 2023

Protocol No. NBF-006-001

IND Number: 139860

A Phase I/Ib Open-Label, Multi-Center, Dose-Escalation Study to Investigate the Safety, Pharmacokinetics and Preliminary Efficacy of Intravenous NBF-006 in Patients with Non-Small Cell Lung, Pancreatic, or Colorectal Cancer Followed by a Dose Expansion Study in Patients with KRAS-Mutated Non-Small Cell Lung Cancer

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Abbreviations

AE(s)	Adverse Event(s)
ALP	Alkaline Phosphatase
ALT	Alanine Transaminase
API	Active Pharmaceutical Ingredient
AST	Aspartate Transaminase
BOR	Best Overall (Tumor) Response
CIs	Confidence Intervals
CR	Complete Response
CRO	Contract Research Organization
CT	Computerized Tomography
CTCAE	Common Terminology Criteria for Adverse Events
DLT	Dose-Limiting Toxicity
DOR	Duration of Overall Response
ECG	Electrocardiogram
ECOG	Eastern Cooperative Oncology Group Performance Status
eCRF	Electronic Case Report Form
EOI	End of Infusion
GCP	Good Clinical Practice
GGT	Gamma Glutamyl Transferase
GSTT1	Glutathione S-Transferase theta class
ICF	Informed Consent Form
IMP	Investigational Medicinal Products
ITT	Intent to Treat
KRAS	Gene in the Ras Family of Oncogenes (Kirsten Ras Oncogene Homolog)
MedDRA	Medical Dictionary for Regulatory Activities
ms	Millisecond
MTD	Maximum Tolerated Dose
N	Number
NCI	National Cancer Institute
NSCLC	Non-Small Cell Lung Cancer
ORR	Overall Response Rate
OS	Overall Survival
PD	Progressive Disease
PK	Pharmacokinetic
PR	Partial Response
PR	PR Segment Duration in ECG
PT	Preferred Term
QT	QT Interval in ECG
QTcF	Fridericia Corrected QT Interval in ECG
RECIST	Response Evaluation Criteria in Solid Tumors
SAE	Serious Adverse Event(s)
SAP	Statistical Analysis Plan
SD	Stable Disease
siRNA	Small Interfering Ribonucleic Acid
SOC	MedDRA System Organ Class
SOI	Start of Infusion
TEAEs	Treatment-Emergent Adverse Events(s)
uCR	Unconfirmed Complete Response
uPR	Unconfirmed Partial Response
ULN	Upper Limit of Normal
WBC	White Blood Cell Count
WHO-DD	World Health Organization Drug Dictionary

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1.0 Introduction

This Statistical Analysis Plan (SAP) describes analyses and data presentations for Nitto BioPharma, Inc. Protocol NBF-006-001. It provides details of the analysis populations, derived variables, and statistical methods to be used in the analyses and reporting of safety and efficacy data.

The purpose of the SAP is to ensure the credibility of the study findings by specifying the statistical approaches to study data analyses prospectively. The SAP final 1.0 was used for the interim analysis of Part A of the study. Based on this interim analysis, specification of potential additional analyses to be included in the final analysis of data derived from Part B of the study may be incorporated in an amended version of the protocol and SAP, which is finalized prior to database lock for Part B of the study. Such additional analyses may, for example, entail assessments of efficacy in specific biomarker-defined subsets of study subjects of potential relevance based on exploratory analysis of the interim (Part A) biomarker data. All statistical analyses detailed in this SAP are conducted using SAS statistical software (version 9.4 or higher).

The Theradex Medical Monitor, supported by the Nitto BioPharma, Inc. GCP Clinical Lead as required in the setting of serious adverse events (SAEs), will be responsible for the assessment of ongoing safety data for the study. This will include a review of all adverse events (AEs) (serious and non-serious AEs) as they are reported, and laboratory and ECG results. Safety data will be reviewed periodically by a safety review committee consisting of Theradex Oncology Medical Monitor, Nitto BioPharma, Inc., and Investigators. Details are provided in the Safety Management Plan and/or the Communication Plan. Nitto BioPharma, Inc. will make decisions on dose modifications, cohort dose escalation, and transition to dose expansion phase (Part B) based on recommendations by the core safety committee comprised of the Theradex Medical Monitor, Investigators, and the Nitto BioPharma, Inc. GCP Clinical Lead.

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1.1 Study Documents Used in the Preparation of this Document

The following documents were used in preparation of this SAP:

List of Study Documents

Study Document	Approval Date
Protocol Amendment 4.0	06 June 2022
1165 Annotated CRF	18 May 2021

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2.0 Objectives and Endpoints

Table 1 Objectives and Related Endpoints

Objective	Endpoint
Primary (Part A Dose Escalation)	
To determine the safety profile, maximum tolerated dose (MTD), and recommended doses for Part B of NBF-006 in patients with advanced (NSCLC), pancreatic, or colorectal cancer for dose levels 1-4 (0.15, 0.3, 0.6, and 1.2 mg/kg) and in patients with KRAS-mutated NSCLC for dose level 5 (1.6 mg/kg).	Number of patients with DLTs and AEs.
Secondary (Part A Dose Escalation)	
To evaluate preliminary efficacy of NBF-006 in patients with advanced NSCLC, pancreatic, or colorectal cancer for dose levels 1-4 (0.15, 0.3, 0.6, and 1.2 mg/kg) and in patients with KRAS-mutated NSCLC for dose level 5 (1.6 mg/kg). To investigate the pharmacokinetics (PK) of NBF-006.	Best overall response (CR, PR, SD) per RECIST 1.1 and PK parameters (C_{max}, clearance [CL], volume of distribution [V_{ss}], terminal elimination half-life [$T_{1/2}$], area under the curve $[AUC]_{0-t}$) of siRNA, duration of overall response, duration of stable disease.
Exploratory (Part A Dose Escalation)	
To evaluate correlation between biomarkers and clinical outcome. To evaluate correlation between KRAS mutations and clinical outcome.	Biomarkers may include, but are not necessarily limited to, GSTP or related proteins of the GST family.
Primary (Part B Dose Expansion)	
To evaluate preliminary efficacy and safety profile of NBF-006 in patients with KRAS-mutated NSCLC.	Best overall response (CR, PR, SD) per RECIST 1.1 and safety (DLT, AEs), duration of overall response, duration of stable disease.
Secondary (Part B Dose Expansion)	
To investigate the PK of NBF-006	PK parameters (C_{max}, CL, V_{ss}, $T_{1/2}$, AUC_{0-t}, $AUC_{0-\infty}$) of siRNA.
Exploratory (Part B Dose Expansion)	
To evaluate correlation between glutathione S-transferase pi (GSTP) messenger ribonucleic acid (mRNA) knockdown (KD) in surrogate tissue (peripheral blood mononuclear cells [PBMCs]), biomarkers, and clinical outcome.	Biomarkers may include, but are not necessarily limited to, GSTP or related proteins of the GST family

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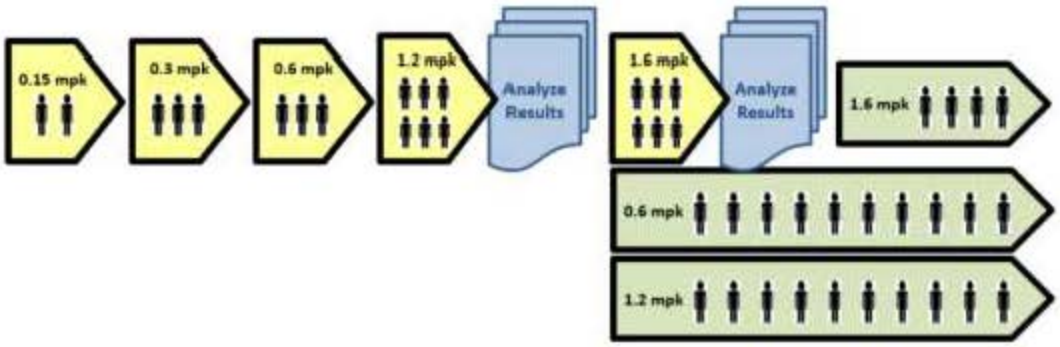
3.0 Study Design

3.1 Overall Study Design

This is an open-label, non-placebo-controlled study conducted in two parts - Part A (dose escalation) followed by Part B (dose expansion).

Figure 1 Part A and B Study Design Schematic



The end of study is defined as the last patient last visit date in the trial.

Part A Dose Escalation Phase

Patients in Part A will have previously treated progressive or metastatic NSCLC, pancreatic, or colorectal cancer, with or without KRAS mutation status.

In both parts, NBF-006 will be administered via intravenous (IV) infusion over 70 minutes once a week for 4 weeks followed by a 2-week rest period. The length of each cycle is 6 weeks.

The first dose level (0.15 mg/kg) will be a single patient cohort. If any grade 2 or greater drug-related event occurs during the first cycle of treatment, the cohort will be expanded up to 3 patients. If a dose-limiting toxicity (DLT) occurs during the first cycle, the cohort will be expanded up to 6 patients before proceeding with dose escalation.

Subsequent cohorts in the dose escalation phase will enroll patients following the standard 3+3 design. If 1 out of 3 patients experience a DLT during the first cycle of treatment, the dose cohort will be expanded up to 6 patients. If no DLT is observed in the first three patients enrolled at the

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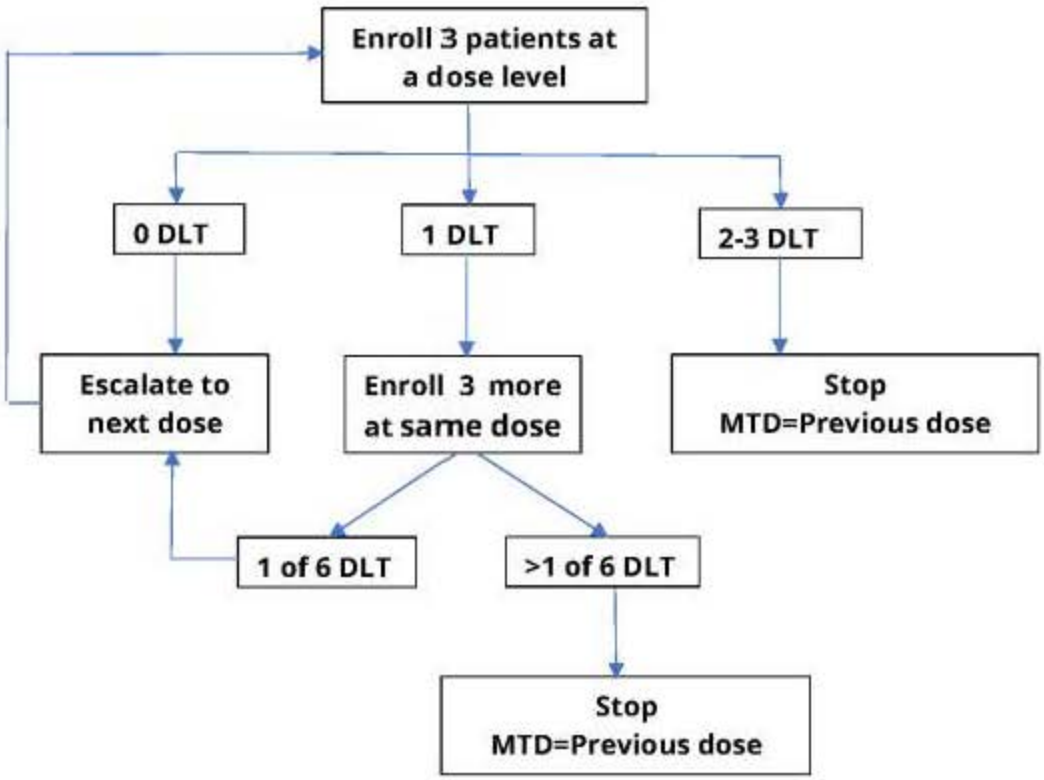
highest dose, this cohort will be expanded to 6 patients. If 2 or more out of 6 patients experience DLTs, the MTD has been exceeded, and dose escalation will cease. Up to 3 additional patients will be enrolled at a lower dose if only 3 patients were treated at that dose level, to confirm safety of that dose. To collect clinically important information in the target population, and prepare for Part B, the 6-patient cohort(s) must each include at least 3 patients with histologically or cytologically confirmed progressive or metastatic NSCLC, up to dose level 4 (1.2 mg/kg) in Part A. In dose level 5 (1.6 mg/kg) in Part A and all patients in Part B, only patients with previously treated NSCLC with KRAS mutation will be included. Once safety has been confirmed in Part A at 1.6 mg/kg (i.e., 0-1 DLT in 6 patients), an additional 4 patients with KRAS-mutated NSCLC will be enrolled in Part B of the study at this dose level. Stratification for GSTT1-null genotype patients will not occur in Part A.

One dose de-escalation is permitted.

Figure 2 Dose Escalation Study Design (3+ 3 Schema)



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Note that if a dose level is not tolerated, the protocol implies that three additional subjects should be enrolled at the next lowest dose level to confirm that it is the MTD (defined as dose at which 0-1 subjects experience DLTs).

Table 2 Part A NBF-006 Dose Levels

Dose Level	NBF-006 Dose	Number of Patients[#]
1	0.15 mg/kg	1-6*
2	0.3 mg/kg	3-6
3	0.6 mg/kg	3-6
4	1.2 mg/kg	3-6
5	1.6 mg/kg	3-6

*Two patients were dosed at 0.15 mg/kg; however, the first patient did not complete Cycle 1 due to disease progression and was replaced with another patient.
#The 6-patient cohort(s) must each include at least 3 patients with histologically or cytologically confirmed progressive or metastatic NSCLC.

The definition of MTD will be based on review of safety data and DLTs corresponding to the first cycle of therapy in at least 6 evaluable patients. MTD will be defined as the highest dose where 0 or 1 out of 6 patients have DLTs.

Part B Dose Expansion Phase

After MTD is confirmed in Part A for up to dose level 4 or 5 (1.2 or 1.6 mg/kg), enrollment in Part B may commence. Part B will enroll patients with previously treated progressive or metastatic NSCLC with confirmed KRAS mutation.

Two doses levels that will be explored further in Part B are 0.6 mg/kg and 1.2 mg/kg. Approximately twenty patients will be enrolled in Part B, with 10 patients enrolled in each of the two cohorts. Both cohorts will be stratified for GSTT1-null genotype patients. Once dose level 5 (1.6 mg/kg) has been confirmed to be safe in Part A, an additional 4 patients will then be enrolled at 1.6 mg/kg, for a planned total of 24 patients in Part B. The proportion of GSTT1-null patients treated at the highest dose level (1.6 mg/kg) will be balanced with the previous two expansion cohorts as much as possible by applying stratification rules in Part B (depending on the distribution of patients enrolled in Part A, unstratified).

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Table 3 Part B NBF-006 Dose Levels

Dose Level	NBF-006 Dose	Number of Patients
3	0.6 mg/kg	10
4	1.2 mg/kg	10
5	1.6 mg/kg	4*

*Dose level 5 pending confirmation of safety in Part A

For both phases, NBF-006 will be administered via intravenous (IV) infusion over 70 minutes once a week for 4 weeks followed by a 2-week rest period. The length of each cycle is 6 weeks.

Duration of Therapy

Upon completion of Cycle 1, in the absence of disease progression or unacceptable toxicity, patients may continue to be treated with NBF-006 at the same dose and schedule until disease progression, death, withdrawal of consent, investigator decision to remove patient, or intolerable toxicity, whichever occurs first. A patient may continue on study (even if one or more criterion meets Disease Progression per RECIST 1.1) at the Investigator's discretion if deemed that the drug is well-tolerated and that the patient may continue to receive benefit from continuing treatment.

3.2 Blinding and Unblinding

This is an open-label study; blinding techniques are not required.

3.3 Randomization and Stratification

This is an open-label, non-placebo-controlled study. Randomization is only implemented in IWRS for Part B at 0.6 and 1.2 mg/kg. Patients enrolled in Part B will be stratified for GSTT1-null genotype to ensure equal allocation to the cohorts with different doses. Patients treated at the highest dose level in Part B will be balanced for GSTT1-null genotype to match the distribution of patients at the other (stratified) dose levels as much as possible but may depend on the first 6 patients treated at this dose in Part A (not stratified). Stratification for GSTT1-null genotype patients will not occur in Part A.

3.4 Sample Size

This is an exploratory trial and therefore no sample size calculations have been performed. The number of patients in Part A (up to 20) is based on

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the planned number of dose escalation cohorts required to identify the MTD. The planned number of patients in Part B is approximately 20-24. Unless the reason was toxicity (i.e., a DLT), any patient who discontinues after receiving less than 4 doses during Cycle 1 will be replaced.

4.0 Management of Analysis Data

The data from all study centers will be pooled together for analyses.

4.1 Data Handling

Unscheduled laboratory results will not be analyzed for the visit summary of continuous values but will be included in the laboratory shift tables.

4.2 Missing Data

All partial date value(s) will be presented in the patient listing, as they are recorded on the eCRF. Unless otherwise specified, no imputation of values for missing data will be performed. The missing values will not be reported as a "0" numerical value in the database, and the missing values will not be included in the overall dataset.

If the start date/time of an AE is partially or completely missing, the AE will be assumed as Treatment-Emergent AE (TEAE). If the timing of a given concomitant medication cannot be determined, it will be included in the listings/summaries as concomitant.

4.3 Coding Conventions for Events and Medications

Event/Medication	Coding/Mapping Convention
AE, Medical History Coding	MedDRA version 21.1
Lab Test Grade	NCI CTCAE version 5.0
Prior and Concomitant Medications	WHO-DDE version 2018

5.0 Statistical Methods

5.1 General

Demographic and baseline characteristics, efficacy assessments, and safety data will be summarized by Dose Cohort and Overall for Part A; by dose level 0.6 mg/kg, 1.2 mg/kg, and 1.6 mg/kg (if dose level deemed safe), and Overall for Part B. Results from Part A and Part B will be presented separately for safety and baseline data, but for efficacy data, include all the 10 patients at 1.6 mg/kg, so can be compared to other expansion cohorts.

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Continuous data will be presented as n, mean, standard deviation, median, minimum, and maximum. Categorical data will be presented as frequency counts and percentages. All raw data collected will be listed.

5.1.1 Definitions

Baseline: The last measurements taken prior to first exposure to study drug, including Day 1 measurements taken pre-dosing. If patients have no value as defined above for a particular parameter, the baseline value will be missing.

5.1.2 Visit Window

In order to summarize longitudinal data per timepoint, assessment will be allocated to visits using pre-defined time windows. Unless otherwise specified, the schedule of event and windowing in protocol will be used. The deviations from visit windows will be captured by protocol deviations.

5.2 Statistical Analysis Populations

5.2.1 Intent-to-Treat (ITT)

All participants who were enrolled (signed consent) into the study, irrespective of whether study medication was administered or not. Demographic and baseline data are based on ITT population.

5.2.2 Safety Evaluable

All patients who received any component of study treatment. Safety data and study drug exposure are based on Safety Evaluable population.

5.2.3 Efficacy Evaluable

Patients with measurable disease by RECIST 1.1 who had a baseline assessment and at least one post-baseline assessment. Efficacy Evaluable is the population for efficacy analyses.

5.2.4 Pharmacokinetic Evaluable

Patients who receive at least 1 dose of study treatment and have blood samples collected for at least 6 hours after the end of infusion. Patients who do not complete the study treatment infusion will be excluded from the pharmacokinetic analysis.

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5.3 Study Population Characteristics

5.3.1 Study Enrollment

Patient enrollment, eligibility, and study populations are summarized by frequency and percentage of patients.

5.3.2 Patient Disposition

The disposition of patients, based on the reasons reported for study withdrawal, is summarized by frequency and percentage of patients.

5.3.3 Protocol Deviations

A classified list of protocol deviations can be found in the Project Management Plan, Appendix E. Protocol deviations are categorized by Theradex Oncology and Nitto BioPharma, Inc. as:

Minor:
Where evidence exists that departure(s) from the protocol requirements, ICH-GCP or local requirements has occurred with evidence that:

- Does not have a significant impact on the research participant's rights, safety or welfare; the integrity of the data; nor substantially alter risks to subjects.
- Isolated/infrequent procedure-related deviations (e.g., ECOG not performed, missed lab tests, PK time point deviations).
- Failure to follow ICH-GCP procedures for significant study processes (example: IMP accountability logs, patient identification code list) that can be retrospectively or prospectively corrected.

Major:
Where evidence exists that significant and unjustified departure(s) from the protocol requirements, ICH-GCP or local requirements has occurred with evidence that:

- The safety or well-being of trial subjects have the significant potential to be jeopardized.
- There are a significant number of Minor non-compliances within a single area of responsibility, indicating a systemic quality assurance failure.
- Impact significantly upon secondary study endpoints
- Variance from a protocol specified procedure results in questionable data.

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Critical:
Where evidence exists that significant and unjustified departure(s) from the protocol requirements, ICH-GCP or local requirements has occurred with evidence that:

- The safety or well-being of trial subjects have been jeopardized.
- The scientific value of the trial has been jeopardized.
- The clinical trial data are unreliable.
- There are a number of Major non-compliances across areas of responsibility, indicating a systemic quality assurance failure.
- Impacts significantly upon primary study endpoints.
- There has been clinical research misconduct or fraudulent activity.

5.3.4 Demographics

Demographics, including age categories (18 to 64, 65+), sex, race, ethnicity, and ECOG performance status, are summarized by frequency and percentage of patients within each category.

Age is summarized using descriptive statistics (n, mean, standard deviation, median, minimum, and maximum). The exact age is calculated in years without decimal places as follows:

Age (years) = (Year of First Dose – Year of Birth) – Correction,
Where: Correction = 1, if Birth Month > First Dose Month or Birth Month = First Dose Month and Birth Day > First Dose Day; Else: Correction = 0 (First Dose is first study drug administration).

5.3.5 Baseline Disease Characteristics

Primary site, disease stage, KRAS genotype mutation are summarized by frequency and percentage of patients. Duration of disease is calculated from the date of initial diagnosis to the date of first study drug administration for NSCLC (with or without KRAS mutation), pancreatic cancer, and colorectal cancer tumor types for each dose levels in Part A and B, respectively. EGFR Mutation, ALK/ROSI gene fusion will be summarized for the 14 early enrolled patients in Part A. Smoking history will be summarized for NSCLC patients in Part A and NSCLC patients in Part B in the category of never, former, current for NSCLC patients and the duration

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of tobacco consumption. GSTT1 genotype will be summarized in the category of null and wild type.

5.3.6 Prior Cancer Therapy

Prior cancer therapies, including chemotherapy, hormone therapy, immunotherapy, and other prior therapies for NSCLC (with or without KRAS mutation), pancreatic cancer, and colorectal cancer tumor types for each dose levels in Part A and Part B, respectively, prior cancer radiation, and prior surgeries are summarized by frequency and percentage of patients within each category. Number of patients with prior cancer therapies of 1 regimen, 2, 3, 4, 5, >=6 regimens and best response will be summarized by frequency and percentage of patients by dose level. Prior medications will be listed.

5.3.7 Prior Medical History

Medical History will be coded using MedDRA version 21.1 and summarized by system organ class (SOC) and preferred term (PT) by dose level.

5.4 Efficacy Analyses

Patients with measurable disease will be assessed at baseline and re-evaluated at the end of even numbered cycles for dose levels 1-4 in Part A and at baseline and at the end of every cycle for dose level 5 in Part A and all patients in Part B of the study. The patients could be assessed outside these protocol-specified windows at the investigator's discretion. Efficacy Evaluable population is used for efficacy analyses. Statistical comparisons will not be made among the dose levels.

The primary measure of tumor response is the overall response (CR+PR) reported and confirmed. An initial response of complete response (CR) or partial response (PR) based on RECIST 1.1 should be confirmed by a second imaging evaluation. The efficacy endpoints include best overall response (BOR), overall response rate (ORR = rate of PR + CR), disease control rate (DCR= rate of SD+PR+CR), duration of overall response (DOR), duration of CR, and duration of stable disease (SD).

BOR summary table in number (%) is provided. Duration of overall response, complete response, and stable disease life table estimates will be summarized. All efficacy tables and figures will be presented by dose

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level at 0.15, 0.3, 0.6, 1.2 mg/kg and overall for Part A; by dose level 0.6, 1.2, 1.6 mg/kg (including the 1.6 mg/kg from Part A) and overall for Part B.

5.4.1 Best Overall Tumor Response per RECIST 1.1

Tumor responses and progression will be evaluated using Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1. All measurable lesions up to a maximum of two lesions per organ and five lesions in total, representative of all involved organs, should be identified as target lesions and measured at baseline. Target lesions should be selected based on their size (lesions with the longest diameter) and their suitability for accurate repeated measurements (either by imaging techniques or clinically). A sum of the diameters (longest for non-nodal lesions, short axis for nodal lesions) for all target lesions will be calculated and reported as the baseline sum diameters, which will be used as reference by which to characterize the objective tumor response.

All other lesions (or sites of disease) including pathological lymph nodes should be identified as non-target lesions and should be also recorded at baseline. Measurements of these lesions are not required, and these lesions should be followed as "present," "absent," or in rare cases "unequivocal progression".

BOR is defined as the best response assessment depending on the findings of target, non-target lesion and new lesions from the start of study treatment until disease progression or recurrence. Valid response assessments (ranked from best to worst) are CR, PR, SD, and PD. CR or PR with only one evaluation will also be presented as unconfirmed PR (uPR) or unconfirmed CR (uCR). BOR for a patient without any valid assessments is not evaluable (NE). Symptomatic deterioration is not considered PD. The primary evaluation of efficacy will focus on PR and CR but analyses incorporating uPR and uCR will also be performed.

BOR is based on the overall response captured on the eCRF off-study summary. All available valid tumor assessments will be used, invalid assessments (not evaluable due to incomplete assessment, not assessed, or missing) will be ignored.

<u>Response Assessment after Palliative Radiotherapy</u>

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Palliative radiotherapy, which was implemented in Protocol Amendment 4 (dated 06-Jun-2022), is allowed as medically indicated after completion of the first treatment cycle, and after discussion with medical monitor. Lesions assigned as targets at baseline should preferably not be included in the radiotherapy field, as it would preclude further response assessment per RECIST. Following palliative radiotherapy of RECIST target lesions, the irradiated lesion(s) and overall response assessment should be NA/Not evaluated, but remaining target and non-target lesions should continue to be monitored (an individualized schedule for radiology assessment is acceptable).

BOR is summarized as the number (%) of patients in each response category (CR, PR, SD, PD, and NE) for NSCLC (with or without KRAS mutation), pancreatic cancer, and colorectal cancer tumor types in Part A and Part B, respectively. Patients are counted once in each of the response categories based on their best response assessment.

- PR and CR must be confirmed by a repeat assessment.
- A confirmed CR is a CR which is followed by another CR without any intervening assessments of PD.
- A confirmed PR is a PR preceded or followed by a CR or another PR, allowing for one interim assessment of SD.
- All other assessments of CR or PR are considered unconfirmed responses uCR or uPR.
- For SD, follow-up measurements must meet the SD criteria at least 5 weeks (35 days) after study entry.
- If the first two scheduled assessments are not evaluable and followed by PD or death, BOR is NE.

ORR is defined as the proportion of patients with a BOR of confirmed CR or confirmed PR. ORR_2 will also be provided for all CR (including uCR) and all PR (including uPR). DCR is defined as the proportion of patients with a BOR of CR or PR or SD. DCR_2 will also be provided for all CR (including uCR), all PR (including uPR), and SD. The two-sided 95% Clopper-Pearson [1] CIs is calculated for ORR, ORR_2, DCR, DCR_2using the following SAS code:

LowerCL = 1-betainv (1-alpha/2, N-x+1, x)
UpperCL = betainv (1-alpha/2, x+1, N-x)

where: N=sample size, X=number of responders, alpha=0.05 for a 95% confidence interval.

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Best percent changes from baseline in target tumor size based on RECIST 1.1 (waterfall plots) and percent change from baseline in tumor response overtime (spider plot) will be provided for NSCLC, pancreatic cancer, and colorectal cancer patients respectively.

Table 4 provides a summary of the overall response status calculation at each time point for patients who have measurable disease at baseline. When patients have non-measurable disease, Table 5**Table 5Table 5Table 5** should be used.

CR and PR must be confirmed by a repeat assessment at least 4 weeks but no later than 5 weeks for patients in dose levels 1-4 (0.15, 0.3, 0.6, and 1.2 mg/kg) in Part A after the criteria for response are first met. Response will be confirmed at 4 weeks or at the next scheduled scan (at Week 6 of the following cycle) for patients in dose level 5 (1.6 mg/kg) in Part A and all patients in Part B. If a confirmative scan is done after 4 weeks, the next scheduled scan (at Week 6 of the following cycle) may be omitted.

Follow-up measurements for SD must meet the SD criteria at least 5 weeks after study entry. In this circumstance, the best overall response can be interpreted as in Table 6**Table 6Table 6Table 6Table 6Table 5Table 5Table 5.Table 5**

Table 4 Response: Patients with target (+/- non-target) disease

Target Lesions	Non-target Lesions	New Lesions	Overall Response
CR	CR	No	CR
CR	Non-CR / non-PD	No	PR
CR	Not evaluated	No	PR
PR	Non-PD or not all evaluated	No	PR
SD	Non-PD or not all evaluated	No	SD
Not all evaluated	Non-PD	No	NE
PD	Any	Yes or No	PD
Any	PD	Yes or No	PD
Any	Any	Yes	PD
CR=complete response, PR=partial response, SD=stable disease			

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PD=progressive disease, NE=not evaluable

Table 5 Response: Patients with non-target disease only

Non-target Lesions	New Lesions	Overall Response
CR	No	CR
Non-CR / non-PD	No	Non-CR / non-PD*
Not all evaluated	No	NE
Unequivocal PD	Yes or No	PD
Any	Yes	PD

CR=complete response; PD=progressive disease; NE=not evaluable
* Non-CR/non-PD is preferred over SD for non-target disease

Table 6 Best overall response when CR and PR confirmation required

Overall response First time point	Overall response Subsequent time point	BEST overall response
CR	CR	CR
CR	PR	SD, PD or PR*
CR	SD	SD provided minimum criteria for SD duration met, otherwise PD
CR	PD	SD provided minimum criteria for SD duration met, otherwise PD
CR	NE	SD provided minimum criteria for SD duration met, otherwise NE
PR	CR	PR
PR	PR	PR
PR	SD	SD
PR	PD	SD provided minimum criteria for SD duration met, otherwise PD
PR	NE	SD provided minimum criteria for SD duration met, otherwise NE
NE	NE	NE

CR=complete response; PR=partial response; SD=stable disease; PD=progressive disease; NE=nonevaluable

* If CR is truly met at first time point, then any disease seen at a subsequent time point, even disease meeting PR criteria relative to baseline, makes the disease PD at that point (since disease must have reappeared after CR). Best response would depend on whether minimum duration for SD was met. However, sometimes 'CR' may be claimed

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when subsequent scans suggest small lesions were likely still present and in fact the patient had PR, not CR, at the first time point. Under these circumstances, the original CR should be changed to PR and the best response is PR.

5.4.2 Duration of Overall Response

DOR is measured from the time measurement criteria are met for CR or PR (whichever is first recorded) until the first date that recurrent or progressive disease is objectively documented (taking as reference for PD the smallest measurements recorded since the treatment started). Only patients with a confirmed CR or PR are included in the analysis. For a patient without evidence of PD, DOR censoring details are listed in Table 7.

The duration of overall CR is measured from the time measurement criteria are first met for CR until the first date that recurrent disease is objectively documented.

CIs for the median duration times are calculated using Brookmeyer and Crowley method [2]. CIs for point estimates of the survival distribution are calculated using the method by Kalbfleisch and Prentice [3].

Duration of treatment per dose level with patient's response overtime (swimmer plot) will be presented for Part A and Part B, respectively.

Table 7 RECIST 1.1 Event /Censored Date used in DOR

Scenario		Outcome	Date
A	No baseline assessment	Censored*	Date of first dose
B	Progression at or before next scheduled assessment	Progressed	Date of progression
C1	Progression after one missing assessment	Progressed	Date of progression
C2	Progression after two or more missing assessments	Censored*	Date of last evaluable assessment
D	No progression	Censored*	Date of last evaluable assessment
E	Discontinued treatment due to toxicity, withdrew consent without progressive disease (PD)	Censored*	Date of last evaluable assessment
F	No evaluable tumor assessments or drop out before first follow-up period	Censored*	Date of enrollment
G	New anticancer therapy given (including localized therapy to target lesions such as radiotherapy or surgery, after which RECIST response will be NA).	Censored*	Date of last evaluable assessment

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*Censored = without progressive disease at that time

5.4.3 Duration of Stable Disease per RECIST 1.1

Stable Disease is measured from the start of the treatment until the criteria for progression are met, taking as reference the smallest measurements recorded since the treatment started. Duration of stable disease will be analyzed in a similar method as DOR.

5.5 Safety and Tolerability Analysis

Safety analyses are based on Safety Evaluable population. Descriptive statistics are used to summarize the safety parameters. Safety data include AEs, laboratory parameters, vital signs, electrocardiogram (ECG) parameters, and ECOG performance status. Protocol schedule of events and windowing will be used for the applicable safety table assessments.

5.5.1 Study Drug Exposure and Compliance

NBF-006 exposure and compliance are summarized for cycle 1 and all treatment cycles using descriptive statistics. Number of subjects to whom NBF-006 is administered will be summarized. Duration of Exposure is defined as the duration between the first and last dose of study drug (last dose date - first dose date+1) during the treatment period. Total Dose is defined as the sum of all study drug administered over the entire course of the study. Total intended dose is defined as the sum of intended doses during the duration of exposure, based on no modifications to the protocol-specified dose and schedule.

Percent Compliance is defined as the total dose divided by total intended dose multiplied by 100% for each patient. The frequency and percentage of patient receiving <100%, 100%, and >100% of their intended dose will be summarized.

The number of patients with dose delayed and interrupted will be each summarized using frequency counts and percentages, along with the reasons for patients receiving NBF-006.

5.5.2 Dose Limiting Toxicity

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DLT is defined as any treatment-related toxicity during the first cycle (42 days) that meets any of the following criteria based on CTCAE version 5.0 for all patients enrolled in the study, regardless of their replacement.

Table 8 Dose Limiting Toxicity

A DLT will be defined as

(1) Treatment-related hematological toxicities including Grade 4 neutropenia, any grade neutropenic fever, ≥ Grade 3 thrombocytopenia lasting longer than 3 consecutive days, ≥ Grade 3 thrombocytopenia with bleeding, any other confirmed hematological toxicity ≥ Grade 4
(2) Treatment-related non-hematological toxicity ≥ Grade 3 including Electrolyte abnormalities that do not resolve within 48 hours of intervention, ≥ Grade 3 infusion-related reactions, Grade 3 cytokine release syndrome, any hepatic toxicity meeting Hy's Law criteria, Grade 3 nausea/vomiting or diarrhea or other self-limited or medically controllable toxicities that last > 72 hours regardless of medical intervention
(3) Any other treatment-related toxicity, i.e., greater than at baseline, is clinically significant and/or unacceptable, does not respond to supportive care and results in a disruption of the dosing schedule of more than 14 days
(4) Any death not clearly due to the underlying disease or extraneous causes
DLT excludes: Alopecia of any grade

5.5.3 Adverse Events

TEAEs are defined as adverse events that occurred on or after the first dose date of study drug up to 30 days post the last dose date. If an AE occurs before the first dose of study drug, it will be considered as non-treatment emergent.

TEAEs are summarized by frequency and percentage of patients and tabulated by MedDRA system organ class (SOC) and preferred term (PT), by maximum NCI-CTCAE version 5.0 grade and by unrelated, unlikely, possible, probable and definite relationships to NBF-006. Serious adverse events (SAEs), TEAEs leading to treatment discontinuation and death are summarized. Drug-related TEAEs by CTCAE grade, and drug-related grade 3 or greater TEAEs are summarized. Patients with multiple instances of a specific TEAE or AE are counted once within a summary category-SOC, PT, maximum grade, or closest relationship to treatment. Infusion-related reactions (IRR) by severity grade will be summarized by dose. Number of

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IRR per patient per dose level will be summarized as well. All AEs, DLTs, and IRRs will be listed respectively.

5.5.4 Laboratory Data

Laboratory data will be summarized by laboratory tests for the treatment period, defined as the time from first dose up to 30 days post last dose of study drug. Laboratory data will be converted to SI units prior to summarization. All laboratory tests will be provided in patient listings. The listings indicate the normal ranges for each parameter. Each value, if appropriate, is classified as falling above (H), below (L), or within normal range and graded using the CTCAE criteria.

The observed data and change from baseline will be summarized at each of the laboratory timepoints, using descriptive statistics, for hematology, chemistry and urinalysis laboratory tests, as specified below in Table 9.

The changes from baseline to maximum CTCAE grade during treatment will be summarized by frequency and percentage of patients using shift tables for every gradable hematology and chemistry test. Maximum CTCAE Grade is defined as the highest CTCAE version 5.0 grade reported for a patient after first dose and up to 30 days post last dose.

Table 9 Clinical Laboratory Parameters Collection

Hematology	Serum Chemistry	Urinalysis
Hemoglobin Hematocrit WBC and differential Platelet	Sodium Potassium BUN Calcium SGOT/ALT SGPT/AST Alkaline phosphatase Total protein Total bilirubin Albumin Creatinine Glucose	Glucose Protein Ketones Nitrite Leukocyte esterase Specific gravity pH Microscopic analysis WBC, RBC, bacteria, epithelial cells, casts, mucous, crystals

A listing of patients with grade 3 or 4 laboratory values during treatment period from first dose up to 30 days post last dose study drug will also be provided.

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5.5.5 Electrocardiogram Data

ECG parameters including heart rate, PR, QT, and QTcF observed data and change from baseline will be summarized by visit. The average of the triplicate ECG measurements performed pre-infusion on or before Day 1 will serve as baseline. The number and percentage of QT and QTcF in categories of interval ≤440, >440, >480, >500 ms, and increase from baseline >30 ms or >60 ms will be summarized. Patient listings of QT/QTcF maximum change from baseline >50 ms or increase to 500 ms will be provided.

5.5.6 Other Safety Parameters

Vital signs including blood pressure, heart rate, respiration rate, and temperature, as well as weight will be summarized using descriptive statistics. Change from baseline to maximum ECOG scores will be summarized by frequency and percentage of patients using shift tables. Pain Assessment will be listed.

5.5.7 Concomitant Measures

Concomitant measures will be coded using the World Health Organization Drug Dictionary (WHO-DD version 2018), tabulated by drug class and term, and summarized by frequency and percentage of patients. Patients are counted only once in each summary category (e.g., drug class or term). All concomitant medications that were ongoing at Day 1 of treatment or taken on Day 1 of treatment or thereafter up to the last dose of study drug will be summarized within each category and listed. Palliative radiotherapy is allowed upon implementation of Protocol Amendment 4 (dated 06-Jun-2022) as medically indicated after completion of the first treatment cycle, and after discussion with medical monitor and will be listed separately.

5.5.8 Pharmacokinetic Analyses

5.5.8.1 Summary of PK Concentration Data

Mean and individual NDT-05-1040 plasma concentration-time curves on Day 1 and Day 22 of Cycle 1 will be expressed graphically using both linear and semi-logarithmic scale. PK concentration data will be summarized using descriptive statistics: number of patients, arithmetic mean (Mean), standard deviation (SD), %coefficient variance (CV%), minimum (Min), median (Med), and maximum (Max). Individual data will be reported using

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the actual collection time points whereas mean summary data will be reported using nominal time points.

5.5.8.2 Estimation of Individual Pharmacokinetic Parameters Using Non-Compartmental Analysis (NCA)

Individual PK parameters will be calculated from plasma concentration-time profiles of NDT-05-1040 using non-compartmental analysis (NCA) method on Day 1 and Day 22 of Cycle 1. NCA will be conducted) to obtain estimation of individual PK parameters in Phoenix WinNonlin 64, version 8.3.4.

Calculation of PK Parameters

For the calculation of PK parameters, actual times and dose will be used in PK parameter calculations. All plasma concentrations that are below limit of quantification (BLQ) will be set as zero. The following parameters will be calculated and reported:

Table 10 PK Parameters

PK parameter	Definition
C_{max}	maximum plasma concentration observed
T_{max}	time to maximum plasma concentration, or first maximum plasma concentration if this occurs at more than 1 time point
C_{min}	minimum plasma concentration observed
AUC_{0-t}	area under the plasma concentration-time curve from time 0 to the last quantifiable concentration, calculated by the linear up/log down trapezoidal rule
AUC_{0-72}	area under the plasma concentration-time curve from time 0 to 72 hours, calculated by the linear up/log down trapezoidal rule
$AUC_{0-\infty}$	area under the plasma concentration-time curve extrapolated to infinity, calculated as $AUC_{0-t} + C_{last}/\lambda_z$
V_z	volume of distribution during terminal elimination phase following intravenous administration $V_z = \left(\frac{Dose}{\lambda_z * AUC_{0-\infty}}\right)$
V_{ss}	Volume of distribution at equilibrium following intravenous administration, Vss = $(MRTINF * CL)$
CL	total body clearance following intravenous administration $CL = \left(\frac{Dose}{AUC_{0-\infty}}\right)$

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PK parameter	Definition
$T_{1/2}$	first-order terminal elimination half-life, calculated as $\ln(2)/\lambda_z$

The minimum requirement for CL, V_z, V_{ss} and $T_{1/2}$ calculation will be the inclusion of at least 3 consecutive plasma concentrations above the lower limit of quantification (LLOQ) with at least one of these concentrations following C_{max}. R^2 adjustment of the terminal elimination phase regression line must be greater than or equal to 0.80. To have a meaningful reportable $AUC_{0-\infty}$, CL, V_z, V_{ss}, $T_{1/2}$, $\%AUC_{0-\infty}$ (percent extrapolated) will not exceed 30%.

Descriptive Analysis and Presentation of PK Parameters

PK parameters will be summarized by dose level using descriptive statistics including number of patients, arithmetic mean (Mean), %coefficient of variation (CV%), standard deviation (SD), median (Median), minimum (Min) and maximum (Max) values.

Additional analysis will be performed on calculated PK parameters to assess dose proportionality for the C_{max}, AUC_{0-72} and $AUC_{0-\infty}$ at Cycle 1 Day1 and Day22 and to estimate accumulation ratio (R_{acc}) for the C_{max}, AUC_{0-72}, $AUC_{0-\infty}$ at Cycle 1.

5.5.9 Estimation of population pharmacokinetic parameters using population pharmacokinetic (PopPK) modeling approach

To quantify the typical disposition characteristics and sources of PK variability (such as between-subject, within-subject, and inter-occasion variability), population pharmacokinetic (PopPK) analyses will be performed by an outside vendor Ann Arbor Pharmacometrics Group, Inc. (A2PG) and will be included in the final Clinical Study Report. In addition, PopPK analysis will be used to quantitatively identify the impact of covariates (such as age, sex, race, body weight, concomitant medications, disease state) on systemic drug exposures and assess their potential implications on dosing regimen.

A population PK model will be developed using the nonlinear mixed-effects modeling approach. The data will be analyzed in NONMEM (version 7.3.0 whereas R (version 3.6.1 (2019-07-05) and RStudio (v1.3.959-1) will be used for pre- and post-processing of data. Detailed PopPK analysis will be

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described in a separate stand-alone modeling plan and a specific report will be produced to reflect the entire PopPK analysis work performed by Amador.
Final pharmacokinetics analyses will be performed by an outside vendor and will be included in the final Clinical Study Report.

5.5.10 Biomarker Related Analyses

The actual value, change from baseline for cytokines (TNF-α, IL-1β, IL-6, and IFN-γ) and complements (CH50, Bb, C3a, and C5a) will be listed. Spaghetti plots overtime will be provided for each patient for cytokines and complements. The actual value for complements assessment, ADA assay, and exploratory biomarkers will be listed. Other biomarkers related analyses will be provided in separate reports.

Listing to show mRNA level for GST family (GSTP1, GSTT1, MGST3 and GSTM3) will be provided. Spaghetti plots overtime will be provided for each patient for GSTP1 will be provided.

6.0 Changes to Planned Analyses

Not applicable.

7.0 References

[1] Clopper CJ, Pearson ES The use of confidence or fiducial limits illustrated in the case of the binomial. Biometrika 1934; 26(4):404-13.

[2] Brookmeyer R Crowley J. A confidence interval for the median survival time, Biometrics 1982;38:29-41.

[3] Kalbfleisch JD, Prentise RL. The Statistical Analysis of Failure Time Data. New York: John Wiley & Sons, Inc. 1980.

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Table 7-1 Study Calendar Part A (Protocol Amendment 4.0 Table 3)

Part A Evaluations	Pre-treatment[a]	Cycle 1						Cycle 2						Cycle 3 & beyond				EOT	30-day safety FU visit (±3)
		Wk 1 D1	Wk 2 D8 ±3	Wk 3 D15 ±3	Wk 4 D22 ±3	Wk 5 D29-35	Wk 6 D36-42	Wk 1 D1	Wk 2 D8 ±3	Wk 3 D15 ±3	Wk 4 D22 ±3	Wk 5 D29-35	Wk 6 D36-42	Wk 1 D1	Wk 2 Wk 3 Wk 4	Wk 5	Wk 6		
Informed consent (incl. optional biopsy consent)	X																		
Medical history	X																		
Physical exam	X	X[b]						X						X				X	X
Weight	X	X[b]						X						X				X	X
Vital signs[a]	X	X[b]	X	X	X			X	X	X	X			X				X	
ECG[f]	X	X[b]			X													X	
ECOG performance status	X	X[b]						X						X				X	X
Tumor measurement[g] (tumor markers, if applicable)	X						X						X				X	X	
Hematology[h]	X	X[b]	X	X	X			X	X	X	X			X				X	X
Blood chemistry[i]	X	X[b]	X	X	X			X	X	X	X			X				X	X
Urinalysis	X	X[b]						X						X				X	X
Blood sample for immune activation biomarkers[j]		X																	
Pregnancy test	X[k]							X						X				X	
Blood sample for ADA assay[c]		X		X				X						X				X	X
PK blood sampling[d]		X	X		X			X											
Blood sample for exploratory biomarkers	X																		
Blood sample for GSTP KD[n]		X	X																

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You	X																		
GSTT1 genotyping[a]	X																		
Optional biopsy[b]	X				X														
NBF-006 administration [c]		X	X	X	X			X	X	X	X			X	X				
Concomitant medications	X	<---------- **throughout study** ---------->																X	
Adverse events		<---------- **throughout study** ---------->																X	X

a: Screening assessments may be performed within 28 days of study to treatment initiation, unless specified.

b: For Cycle 1 Day 1, these tests may be performed within 3 days prior to Cycle 1 Day 1. Physical exam and pre-treatment tests done within 3 days of Cycle 1 Day 1 do not need to be repeated for Wk1D1 unless clinically indicated.

c: ADA assay timepoints:

- Cycle 1, Day 1: pre-dose
- Cycle 1, Day 15: pre-dose
- Cycle 2, Cycle 4, Cycle 6, Cycle 8, etc. (i.e., every even numbered cycle), up to one year: Day 1 pre-dose
- Year 2 and beyond: every 6 months
- EOT
- 30-day safety follow up visit

d: PK timepoints:

- Cycle 1, Day 1:
  - Before start of infusion (SOI),
  - During the infusion: 20 m (±5min) after the start of the last infusion step implemented at 6 mL/min rate
  - End of Infusion (EOI); after EOI: 0.5 hr (±5min), 2 hr (±10min), 6 hr (±15min), 24 hr (±1hr), 48 hr (±2hr), 72 hr (±3hr)
- Cycle 1, Day 8: pre-dose
- Cycle 1, Day 22:
  - Before SOI
  - During the infusion: 20 min (±5min) after the start of the last infusion step implemented at 6 mL/min rate
  - End of Infusion (EOI); after EOI: 0.5 hr (±5min), 2 hr (±10min), 6 hr (±15min), 24 hr (±1hr), 48 hr (±2hr), 72 hr (±3hr)
- Cycle 2, Day 1: pre-dose

e: Vital signs, including blood pressure, heart rate, respiration rate, and temperature. During Cycle 1: Before SOI, EOI; after EOI: 1hr (±5min), 2hr (±10min). Other days: only before SOI and EOI.

f: Standard 12-lead ECG (in triplicate) while patient is in semi-recumbent position. Perform at screening, Cycle 1 First and fourth doses: within 15 minutes prior to SOI, then 15 min (±5min), 30 min (±10min), 1 hr (±10min) (at EOI)

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g: Tumor measurement by RECIST version 1.1 and tumor markers will be collected at baseline and at the end of every even numbered cycle in Part A, dose levels 1-4 (0.15 mg/kg, 0.3 mg/kg, 0.6 mg/kg, 1.2 mg/kg) and at the end of every cycle for dose level 5 (1.6 mg/kg), if applicable; the same method used at baseline for a patient should be used consistently for all evaluations throughout the study. To be assigned a status of PR or CR, changes in tumor measurements must be confirmed by repeat assessments that should be performed at 4 weeks but no later than 5 weeks for patients in dose levels 1-4 (0.15 mg/kg, 0.3 mg/kg, 0.6 mg/kg, and 1.2 mg/kg) in Part A after the criteria for response are first met. Response will be confirmed at 4 weeks or at the next scheduled scan (at Week 6 of the following cycle) for patients in dose level 5 (1.6 mg/kg) in Part A. If a confirmative scan is done after 4 weeks, the next scheduled scan at Week 6 of the following cycle may be omitted. In the case of SD, follow-up measurements must have met the SD criteria at least once after study entry at a minimum interval of 5 weeks.

h: Hematology, including hemoglobin, white blood cell with differential, and platelet count.

i: Blood chemistry, including sodium, potassium, blood urea nitrogen, glucose, SGOT/SGPT (ALT/AST), alkaline phosphatase, total protein, total bilirubin, albumin, creatinine, and calcium.

j: Blood samples collected during Cycle 1 (Week 1) for all patients treated in Part A of the study for determination of complement (CH50, Bb, C3a, C5a) and cytokines (IFN-γ, IL-1β, IL-6, TNF-α):

- Pre-dose
- 10 ± 3 minutes after SOI
- 60 ± 10 minutes after EOI
- 6 hr ± 15 minutes after EOI
- 24 hr ± 1 hr after EOI

k: Pregnancy test; for women of childbearing potential, a negative pregnancy test (urine or serum) must be done within 7 days prior to study treatment initiation and documented.

l: Confirmation of KRAS mutation: optional for Part A dose levels 1-4 and mandatory for Part A dose level 5 (1.6 mg/kg). Obtain archive sample if available; otherwise, a fresh biopsy (low or minimal risk only) is required. If such type of biopsy is needed but cannot feasibly be collected, the Sponsor and Medical Monitor should be consulted. Genomic tumor profile report is acceptable in lieu of a biopsy. Note: if at any time during the trial a biopsy is performed as part of routine medical care, we may request a sample.

m: NBF-006 is administered IV QC (minimum 4 days apart) preferably on a Monday or Tuesday (to accommodate the PK schedule) during Cycle 1.

n: GSTP KD time points collected in the 6 patients from Part A at dose level 5 (1.6 mg/kg):

- Cycle 1, Day 1:
  - Before SOI
  - After EOI: 6 hr (±15min), 24 hr (±1hr)
- Cycle 1, Day 8: before SOI

o: Optional biopsy collected during screening and 24 (±3) hours after the 4th dose in cycle 1. Only for patients signing the optional biopsy consent, and when the biopsy can be safely obtained.

p: In Part A of the study, patients will not be stratified for the GSTT1- null genotype, but whole blood samples will still be collected during the screening visit and batch-analyzed at a central laboratory.

Note: Each patient must remain in clinic for a 6-hour safety observation period after each NBF-006 infusion, until the safety review committee has reviewed a 3-patient cohort and recommended a reduced observation time at that dose level. Please see Protocol Amendment Section 8.1.2.8 for details.

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Table 7-2 Study Calendar Part B (Protocol Amendment 4.0 Table 4)

Part B Evaluations	Pre-treatment[a]	Cycle 1						Cycle 2						Cycle 3 & beyond				EOT	30-day safety FU visit (±3)
		Wk 1 D1	Wk 2 D8 ±3	Wk 3 D15 ±3	Wk 4 D22 ±3	Wk 5 D29-35	Wk 6 D36-42	Wk 1 D1	Wk 2 D8 ±3	Wk 3 D15 ±3	Wk 4 D22 ±3	Wk 5 D29-35	Wk 6 D36-42	Wk 1 D1	Wk 2 Wk 3 Wk 4	Wk 5	Wk 6		
Informed consent (incl. optional biopsy consent)	X																		
Medical history	X																		
Physical exam	X	X[b]						X						X				X	X
Weight	X	X[b]						X						X				X	X
Vital signs[e]	X	X[b]	X	X	X			X	X	X	X			X				X	
ECG[f]	X	X[b]			X													X	
ECOG performance status	X	X[b]						X						X				X	X
Tumor measurement[g] (tumor markers, if applicable)	X						X						X				X	X	
Hematology[h]	X	X[b]	X	X	X			X	X	X	X			X				X	X
Blood chemistry[i]	X	X[b]	X	X	X			X	X	X	X			X				X	X
Urinalysis	X	X[b]						X						X				X	X
Blood sample for immune activation biomarkers[j]		X																	
Pregnancy test	X[k]							X						X				X	
Blood sample for ADA assay[c]		X		X				X						X				X	X
PK blood sampling[d]		X	X		X			X											
Blood sample for exploratory biomarkers	X																		
Blood sample for GSTP KD[n]		X	X																

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Confirmation of KRAS mutation[1] (Part B mandatory)	X																		
GSTT1 genotyping[2]	X																		
Optional biopsy[3]	X				X														
NBF-006 administration[4]		X	X	X	X			X	X	X	X			X	X				
Concomitant medications	X	<---------- **throughout study** ---------->																X	
Adverse events		<---------- **throughout study** ---------->																X	X

a: Screening assessments may be performed within 28 days of study to treatment initiation, unless specified.

b: For Cycle 1 Day 1, these tests may be performed within 3 days prior to Cycle 1 Day 1. Physical exam and pre-treatment tests done within 3 days of Cycle 1 Day 1 do not need to be repeated for Wk1D1 unless clinically indicated.

c: ADA assay timepoints:

- Cycle 1, Day 1: pre-dose
- Cycle 1, Day 15: pre-dose
- Cycle 2, Cycle 4, Cycle 6, Cycle 8, etc. (i.e., every even numbered cycle), up to one year: Day 1 pre-dose
- Year 2 and beyond: every 6 months
- EOTs
- 30-day safety follow up visit

d: PK timepoints:

- Cycle 1, Day 1:
  - Before start of infusion (SOI),
  - During the infusion: 20 m (±5min) after the start of the last infusion step implemented at 6 mL/min rate
  - End of Infusion (EOI); after EOI: 0.5 hr (±5min), 2 hr (±10min), 6 hr (±15min), 24 hr (±1hr)
- Cycle 1, Day 8: pre-dose
- Cycle 1, Day 22:
  - Before SOI
  - During the infusion: 20 m (±5min) after the start of the last infusion step implemented at 6 mL/min rate
  - End of Infusion (EOI); after EOI: 0.5 hr (±5min), 2 hr (±10min), 6 hr (±15min), 24 hr (±1hr)
- Cycle 2, Day 1: pre-dose

e: Vital signs, including blood pressure, heart rate, respiration rate, and temperature. During Cycle 1: Before SOI, EOI; after EOI: 1hr (±5min), 2hr (±10min). Other days: only before SOI and EOI.

f: Standard 12-lead ECG (in triplicate) while patient is in semi-recumbent position. Perform at screening. Cycle 1 First and fourth doses: within 15 minutes prior to SOI, then 15 min (±5min), 30 min (±10min), 1 hr (±10min) (at EOI)

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g: Tumor measurement by RECIST version 1.1 and tumor markers will be measured at baseline and at the end every cycle, if applicable; the same method used at baseline for a patient should be used consistently for all evaluations throughout the study. To be assigned a status of PR or CR, changes in tumor measurements must be confirmed at 4 weeks or at the next scheduled scan (at Week 6 of the following cycle). If a confirmative scan is done after 4 weeks, the next scheduled scan at Week 6 of the following cycle may be omitted. In the case of SD, follow-up measurements must have met the SD criteria at least once after study entry at a minimum interval of 5 weeks.

h: Hematology, including hemoglobin, white blood cell with differential, and platelet count.

i: Blood chemistry, including sodium, potassium, blood urea nitrogen, glucose, SGOT/SGPT (ALT/AST), alkaline phosphatase, total protein, total bilirubin, albumin, creatinine, and calcium.

j: Blood samples collected during Cycle 1 (Week 1) for all patients treated in Part B of the study for determination of complement (CH50, Bb, C3a, C5a):

- Pre-dose
- 10 ± 3 minutes after SOI
- 60 ± 10 minutes after EOI
- 6 hr ± 15 minutes after EOI
- 24 hr ± 1 hr after EOI

Dose levels 3 (0.6 mg/kg) and 4 (1.2 mg/kg) did not result in immune activation in Part A and therefore, cytokine activity will not be monitored at those two dose levels in Part B. However if a patient, during or after any infusion of NBF-006, develops IRR symptoms (e.g. backache, fever, nausea, headache, rash, rapid heartbeat, low blood pressure, or trouble breathing), best attempts should be made to collect cytokines as described for Part A with the exception of 10 ± 3 minutes after SOI, which should be collected as close as feasible to the IRR. If there is no meaningful cytokine induction in the 6-patient dose level 5 (1.6 mg/kg) during Part A, then cytokine testing will also not be needed in the remaining 4 patients at that same dose level (1.6 mg/kg), unless there are symptoms of IRR. However, complement samples will continue to be collected for all patients.

k: Pregnancy test: for women of childbearing potential, a negative pregnancy test (urine or serum) must be done within 7 days prior to study treatment initiation and documented.

l: Confirmation of KRAS mutation required for Part B. Obtain archive sample if available; otherwise, a fresh biopsy (low or minimal risk only) is required. If such type of biopsy is needed but cannot feasibly be collected, the sponsor and Medical Monitor should be consulted. Genomic tumor profile report is acceptable in lieu of a biopsy. Note: if at any time during the trial a biopsy is performed as part of routine medical care, we may request a sample.

m: NBF-006 is administered IV QC (minimum 4 days apart) preferably on a Monday or Tuesday (to accommodate the PK schedule) during Cycle 1.

n: GSTP mRNA KD time points:

- Cycle 1, Day 1:
  - Before SOI
  - After EOI: 6 hr (±15min), 24 hr (±1hr)
- Cycle 1, Day 8: before SOI

o: Optional biopsy collected during screening and 24 (±3) hours after the 4th dose in cycle 1. Only for patients signing the optional biopsy consent, and when the biopsy can be safely obtained.

p: In Part B of the study, patients will be stratified for the GSTT1- null genotype. Analysis will be done at a central lab from blood samples collected during the screening visit. Initial patients may be enrolled before the GSTT1 status is known.

Note: Each patient must remain in clinic for a 6-hour safety observation period after the first dose, 2 hours after EOI for remaining doses in Cycle 1. The observation period may be further reduced to 30 minutes starting Cycle 2, after Medical Monitor and Investigator safety review. Please see Protocol Amendment Section 8.1.2.8 for details.

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8.0 Index of Tables and Figures

8.1 Tables

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8.2 Figures

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9.0 Index of Appendix Listings

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Nitto NBF-006-001_SAP Part A & B Final 2.0_clean_14Mar2023

Final Audit Report 2023-03-20

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Protocol No. NBF-006-001
IND Number: 139860

A Phase I/Ib Open-Label, Multi-Center, Dose-Escalation Study to Investigate the Safety, Pharmacokinetics and Preliminary Efficacy of Intravenous NBF-006 in Patients with Non-Small Cell Lung, Pancreatic, or Colorectal Cancer Followed by a Dose Expansion Study in Patients with KRAS-Mutated Non-Small Cell Lung Cancer

Prepared by: Dailan Danforth — Electronically signed by: Dailan Danforth; Reason: author; Date: Mar 16, 2023 10:29 EDT — Date: 16-Mar-2023

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Reviewed by: Judy DeChamplain — Electronically signed by: Judy DeChamplain; Reason: approval; Date: Mar 16, 2023 11:03 EDT — Date: 16-Mar-2023

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Senior Clinical Project Manager
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Joachim Gullbo, MD PhD
Medical Monitor
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Approved by: Sonya Zabludoff — Electronically signed by: Sonya Zabludoff; Reason: approval; Date: Mar 20, 2023 12:13 PDT — Date: 20-Mar-2023

Sonya Zabludoff, PhD
Vice President, Clinical Operations (GCP Clinical Director & Project Lead)
Nitto BioPharma, Inc.

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Table Shells, Listings and Figures for Statistical Analysis Plan

Signature Page
Final Version 2.0; March 14, 2023

Protocol No. NBF-006-001
IND Number: 139860

A Phase I/Ib Open-Label, Multi-Center, Dose-Escalation Study to Investigate the Safety, Pharmacokinetics and Preliminary Efficacy of Intravenous NBF-006 in Patients with Non-Small Cell Lung, Pancreatic, or Colorectal Cancer Followed by a Dose Expansion Study in Patients with KRAS-Mutated Non-Small Cell Lung Cancer

Sponsor:	Nitto BioPharma, Inc. 10618 Science Center Drive, San Diego, California, 92121 USA
CRO:	Theradex Oncology, Inc. 4365 Route 1 South Suite 101 Princeton, New Jersey 08540 USA

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1.0 Table of Contents

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2.0 Programming Considerations

All tables, data listings, figures (TLFs), and statistical analyses will be generated using SAS® Version 9.4.

2.1 TLF Outputs

Unless otherwise noted, the estimated mean and median for a set of values are printed out to one more significant digit than the original values; Standard Deviations are printed out to 2 more significant digits than the original values. The minimum and maximum will be reported the same significant digits as the original values. For example, for age:

N	xx
Mean	xx.x
Standard Deviation	x.xx
Median	xx.x
Minimum	xx
Maximum	xx

Percentage values will be printed with one digit to the right of the decimal point in parentheses 1 space after the count (e.g., 7 (12.8%), 13 (5.4%).

2.2 Data Conventions and Rules

This section provided rules for calculations and definitions for naming conventions that are common to all applicable tables.

The baseline value of a variable is defined as the last value obtained on or before the administration date and time of the first study drug dose.

For any variable where percent change from baseline is evaluated at Visit X: Percent Change from Baseline value = [(Visit X value - Baseline value)/Baseline value] x100

For any variable where absolute change from Baseline is evaluated at Visit X: Absolute Change from Baseline value = Visit X value - Baseline value

Concomitant drugs missing both start and stop dates or having a start date prior to the last dose of study drug and missing the stop date or having a stop date after the start of study drug and missing the start date, are counted as concomitant.

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Relative Study Day: The first day of treatment is Day 1. A minus (-) sign indicated days prior to the start of treatment (e.g., Day -3 represented 3 days before start of therapy; there is no Day 0). The relative study day for a specific visit (day of study relative to start of treatment) is calculated as Visit Date - Date of First Dose +1 (for post-treatment visits) and Visit Date - Date of First Dose (for Screening visits).

2.3 NBF-006 Starting Dose and Dose Levels

The pre-planned doses of NBF-006 will be

Dose Level 1: 0.15 mg/kg

Dose Level 2: 0.3 mg/kg

Dose Level 3: 0.6 mg/kg

Dose Level 4: 1.2 mg/kg

Dose Level 5: 1.6 mg/kg

2.4 Output Presentation Rules

Tables and figures will be presented separately for Part A and Part B, adjust titles as below:

Title (Dose Escalation Part A)

Title (Dose Expansion Part B)

For Baseline and Safety tables and figures, present Part A dose escalation at dose levels 0.15, 0.3, 0.6, 1.2, 1.6 mg/kg (6 patients), and overall; present Part B expansion cohorts at 3 Dose Level 0.6, 1.2, 1.6 mg/kg (4 patients), and overall.

For Efficacy data, present Part A dose escalation at dose level 0.15, 0.3, 0.6, 1.2 mg/kg, and overall; present Part B expansion cohorts at 3 Dose Level 0.6 , 1.2, 1.6 mg/kg (4 patients, also include the 6 patients from Part A at 1.6 mg/kg), and overall.

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3.0 Index of Tables and Figures

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14.1 Demographic and Baseline Data Summary Tables

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Table 14.1.1.1
Study Populations (Dose Escalation Part A)
All Enrolled (N=n)

Study Population	NBF-006 Dose Level (mg/kg) for Escalation (Part A)				NBF-006 Dose Expansion (mg/kg) (Part B)			
	0.15	0.3	onwards	Overall	0.6	1.2	1.6	Overall
Number of Patients	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Patients Enrolled [1]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Met All Eligibility Criteria	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Did Not Meet All Eligibility Criteria	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Waiver	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Intent-to-Treat [1]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Safety Evaluable [2]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Efficacy Evaluable [3]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)

[1] Intent-to-Treat (ITT) includes all participants who were enrolled (signed consent) into the study, irrespective of whether study medication was administrated or not.
[2] Safety Evaluable include all patients who received any component of study treatment.
[3] Efficacy Evaluable include patients with measurable disease by RECIST 1.1 who had a baseline assessment and at least one post-baseline assessment.
Cross-References: Listing 16.2.1.1, 16.2.2.1

PROGRAMMER'S NOTES:
Present Part A and Part B output separately, adjust title for Part B accordingly.

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Table 14.1.1.2
Patient Disposition (Dose Escalation Part A)
Intent-to-Treat (N=n)

	NBF-006 Dose Level (mg/kg) for Escalation (Part A)				NBF-006 Dose Expansion (mg/kg) (Part B)			
Patient Disposition	0.15	0.3	onwards	Overall	0.6	1.2	1.6	Overall
Number of Patient	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Patients Off-Study [1]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Reasons for Off-Study [2]								
Off-Study Reason	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Off-Study Reason	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Off-Study Reason	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Off-Study Reason	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Off-Study Reason	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)

[1] Number of Patients used as denominator to calculate percentages.
[2] Patients Off-Study used as denominator to calculate percentages.
Cross-References: Listing 16.2.1.1

PROGRAMMER'S NOTES:
Only present Off-Study reason categories that are used in the database from the "Off-Study" CRF.
Sort "Reasons for Off-Study" in descending order of "Overall" frequency.
Present Part A and Part B output separately, adjust title for Part B accordingly.

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Table 14.1.2
Demographics (Dose Escalation Part A)
Intent-to-Treat (N=n)

	NBF-006 Dose Level (mg/kg) for Escalation (Part A)				NBF-006 Dose Expansion (mg/kg) (Part B)			
Demographics	0.15	0.3	onwards	Overall	0.6	1.2	1.6	Overall
Number of Patient	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Age (years)								
N	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx	xx	xx
Age Group (years) [1]								
18 to 64	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
65 +	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Sex [1]								
Male	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Female	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Race [1]								
White	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Asian	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Black or African American	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Native Hawaiian or Pacific Islander	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
American Indian or Alaska native	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Not Reported	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Other	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Ethnicity [1]								
Hispanic or Latino	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Not Hispanic or Latino	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)

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Weight (kg)								
N	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx	xx	xx
BMI								
N	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx	xx	xx

[1] Number of Patients used as denominator to calculate percentages.
Cross-References: Listing 16.2.4.1, 16.2.9.1

PROGRAMMER'S NOTES:
Sort Age categories as shown in table.
If age is missing, the exact age was calculated in years without decimal places as follows:

Age (years) = (Year of On-Study – Year of Birth) – Correction

Where: Correction = 1, if Birth Month > On-Study Month or Birth Month = On-Study Month and Birth Day > On-Study Day Else: Correction = 0
Sort Age categories as shown in table.
Sort Sex categories in descending order of "Overall" frequency.
Sort Ethnicity Origin categories in descending order of "Overall" frequency.
Present Part A and Part B output separately, adjust title for Part B accordingly.

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Table 14.1.3.1
Baseline Disease Characteristics for NSCLC (Dose Escalation Part A)
Intent-to-Treat (N=n)

	NBF-006 Dose Level (mg/kg) for Escalation (Part A)			
Baseline Disease Characteristics	0.15	0.3	onwards	Overall
Number of Patient	nnn	nnn	nnn	nnn
Primary Site [1]				
Primary Site	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Primary Site	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Primary Site	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Disease Stage [1]				
Stage	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Stage	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Stage	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
ECOG Performance Status [1]				
0	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
1	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
2	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
EGFR Mutation [1]				
Yes	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
No	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Unknown	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
ALK/ROSI Gene Fusion [1]				
Yes	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
No	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Unknown	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
KRAS Genotype Mutated [1]				
Yes	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
No	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Unknown	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Duration of Disease (month) [2]				

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N	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx
Maximum	xx	xx	xx	xx
Smoking History [3]				
Never	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Former	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Duration of Tobacco Use (month)				
N	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx
Maximum	xx	xx	xx	xx
Current	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Duration of Tobacco Use (month)				
N	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx
Maximum	xx	xx	xx	xx
GSTT1 Genotype [1][4]				
Null	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Wild Type	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Unknown	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)

NSCLC= Non-Small Cell Lung Cancer; GSTT1= Glutathione S-Transferase theta class
[1] Number of Patients used as denominator to calculate percentages.
[2] Duration of disease is calculated from the date of initial diagnosis to the date of first study drug administration.
[3] Number of NSCLC patients used as denominator to calculate percentages.
[4] This genotype only determined for the 1.6 mg/kg dose level.
Cross-References: Listing 16.2.4.2.1, 16.2.4.2.2

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PROGRAMMER'S NOTES:
Calculated in Months: (Date of Initial Diagnosis - Date of First Dose)/ (365.25/12).
Sort categories in descending order of "Overall" frequency.
Note: '01Jan' used when day and month missing from date of diagnosis. '01' used when only day missing from date of diagnosis.
Remove "Primary Site" if there is only one site input in data for NSCLC.
Sort ECOG Performance Status categories as shown in table.
Present Part A and Part B output separately, adjust title for Part B accordingly.
Present GSTT1 only if result data is available. GSTT1 data is also available for 1.6 mg/kg in Part A.

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Table 14.1.3.1
Baseline Disease Characteristics for NSCLC (Dose Expansion Part B)
Intent-to-Treat (N=n)

	NBF-006 Dose Expansion (mg/kg) (Part B)			
Baseline Disease Characteristics	0.6	1.2	1.6	Overall
Number of Patient	nnn	nnn	nnn	nnn
Primary Site [1]				
Primary Site	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Primary Site	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Primary Site	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Disease Stage [1]				
Stage	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Stage	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Stage	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
KRAS Genotype Mutated [1][2]				
Yes	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
No	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Unknown	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Duration of Disease (month) [3]				
N	nnn	nnn	nnn	Nnn
Mean	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx
Maximum	xx	xx	xx	xx
Smoking History [4]				
Never	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Former	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Duration of Tobacco Use (month)				
N	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx

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Median	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx
Maximum	xx	xx	xx	xx
Current	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Duration of Tobacco Use (month)				
N	nnn	nnn	nnn	Nnn
Mean	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx
Maximum	xx	xx	xx	xx
GSTT1 Genotype [1]				
Null	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Wild Type	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Unknown	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)

NSCLC= Non-Small Cell Lung Cancer; GSTT1= Glutathione S-Transferase theta class
[1] Number of Patients used as denominator to calculate percentages.
[2] In dose expansion for NSCLC, all patients must have KRAS Genotype Mutated but not have EGFR and ALK/ROS1 Gene mutation.
[3] Duration of disease is calculated from the date of initial diagnosis to the date of first study drug administration.
[4] Number of NSCLC patients used as denominator to calculate percentages.
Cross-References: Listing 16.2.4.2.1, 16.2.4.2.2

PROGRAMMERS NOTES:
Calculated in Months: (Date of Initial Diagnosis - Date of First Dose)/ (365.25/12).
Sort categories in descending order of "Overall" frequency.
Note: '01Jan' used when day and month missing from date of diagnosis. '01' used when only day missing from date of diagnosis.
Remove "Primary Site" if there is only one site input in data for NSCLC.
Present Part A and Part B output separately, adjust title for Part B accordingly.
Present GSTT1 only if result data is available.

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<Use the above table as template for tables as below>

Table 14.1.3.2
Baseline Disease Characteristics for Pancreatic Cancer (Dose Escalation Part A)
Intent-to-Treat (N=n)

For Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg
[1] Number of Patients used as denominator to calculate percentages.
[2] Duration of disease is calculated from the date of initial diagnosis to the date of first study drug administration.
Cross-References: Listing 16.2.4.2.1, 16.2.4.2.2

PROGRAMMERS NOTES:
Calculated in Months: (Date of Initial Diagnosis - Date of First Dose)/ (365.25/12).
Sort categories in descending order of "Overall" frequency.
Note: '01jan' used when day and month missing from date of diagnosis. '01' used when only day missing from date of diagnosis.
Remove "Primary Site" if there is only one site input in data for Pancreatic Cancer .
This table is only for Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg, not for Part A (1.6 mg/kg).
Remove Smoking History, EGFR Mutation, ALK/ROS1 Gene Fusion, which are only for NSCLC patients.

Table 14.1.3.3
Baseline Disease Characteristics for Colorectal Cancer (Dose Escalation Part A)
Intent-to-Treat (N=n)

For Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg.
[1] Number of Patients used as denominator to calculate percentages.
[2] Duration of disease is calculated from the date of initial diagnosis to the date of first study drug administration.
Cross-References: Listing 16.2.4.2.1, 16.2.4.2.2

PROGRAMMERS NOTES:
Calculated in Months: (Date of Initial Diagnosis - Date of First Dose)/ (365.25/12).
Sort categories in descending order of "Overall" frequency.
Note: '01jan' used when day and month missing from date of diagnosis. '01' used when only day missing from date of diagnosis.
Remove "Primary Site" if there is only one site input in data for Colorectal Cancer .
This table is only for Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg, not for Part A (1.6 mg/kg).
Remove Smoking History, EGFR Mutation, ALK/ROS1 Gene Fusion, which are only for NSCLC patients.

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Table 14.1.4
Summary of Medical History (Dose Escalation Part A)
Intent-to-Treat (N=n)

MedDRA System Organ Class	NBF-006 Dose Level (mg/kg) for Escalation (Part A)				NBF-006 Dose Expansion (mg/kg) (Part B)			
MedDRA Preferred Term [1][2]	0.15	0.3	onwards	Overall	0.6	1.2	1.6	Overall
Number of Patient	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Number of Patients with Any Medical History	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA System Organ Class	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA System Organ Class	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)

[1] MedDRA version 21.1
[2] Number of Patients is used as denominator to calculate percentages.
[3] Patients with multiple Medical History Events were only counted once within a summary category: system organ class and preferred term. Patients with events in more than one category were counted once within each category.
Cross-References: Listing 16.2.4.3

PROGRAMMER'S NOTES:
Include all "Therapeutic Class" categories found in the database.
Sort "Therapeutic Class" column in descending order based on "Overall" column frequency count.
Present Part A and Part B output separately, adjust title for Part B accordingly.

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Table 14.1.5.1
Prior Cancer Therapy for NSCLC (Dose Escalation Part A)
Intent-to-Treat (N=n)

	NBF-006 Dose Level (mg/kg) for Escalation (Part A)				NBF-006 Dose Expansion (mg/kg) (Part B)			
Prior Cancer Therapy [1][2]	0.15	0.3	onwards	Overall	0.6	1.2	1.6	Overall
Number of Patient	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Prior Chemotherapy								
No Regimen	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
1 Regimen	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
2 Regimens	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
.....								
>=6 Regimens	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Best Response								
Complete Response	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Partial Response	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Stable Disease	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Progressive Disease	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Not Applicable	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Unknown	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Prior Immunotherapy								
No Regimen	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
1 Regimen	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
2 Regimens	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
.....								
>=6 Regimens	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Best Response								
Complete Response	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Partial Response	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Stable Disease	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Progressive Disease	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Not Applicable	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Unknown	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)

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Prior Hormone Therapy								
No Regimen	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
1 Regimen	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
2 Regimens	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
.....								
>=6 Regimens	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Best Response								
Complete Response	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Partial Response	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Stable Disease	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Progressive Disease	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Not Applicable	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Unknown	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Other Prior Therapies								
No Regimen	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
1 Regimen	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
2 Regimens	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
.....								
>=6 Regimens	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Best Response								
Complete Response	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Partial Response	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Stable Disease	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Progressive Disease	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Not Applicable	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Unknown	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
All lines of Therapies								
No Regimen	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
1 Regimen	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
2 Regimens	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
.....								
>=6 Regimens	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Best Response								
Complete Response	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Partial Response	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Stable Disease	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)

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Progressive Disease	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Not Applicable	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Unknown	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Prior Cancer Radiation [2]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Prior Cancer Surgeries [2]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)

NSCLC= Non-Small Cell Lung Cancer
[1] Number of Patients used as denominator to calculate percentages.
[2] Patients may be counted in more than one prior therapy categories.
Cross-References: Listing 16.2.4.4, 16.2.4.5, 16.2.4.6, 16.2.4.7

PROGRAMMERS NOTES:
Present Part A and Part B output separately, adjust title for Part B accordingly.

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Table 14.1.5.2
Prior Cancer Therapy for Pancreatic Cancer (Dose Escalation Part A)
Intent-to-Treat (N=n)

For Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg.
[1] Number of Patients used as denominator to calculate percentages.
[2] Patients may be counted in more than one prior therapy categories.
Cross-References: Listing 16.2.4.4, 16.2.4.5, 16.2.4.6, 16.2.4.7

PROGRAMMERS NOTES:
This table is only for Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg, not for Part A (1.6 mg/kg)

Table 14.1.5.3
Prior Cancer Therapy for Colorectal Cancer (Dose Escalation Part A)
Intent-to-Treat (N=n)

For Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg.
[1] Number of Patients used as denominator to calculate percentages.
[2] Patients may be counted in more than one prior therapy categories.
Cross-References: Listing 16.2.4.4, 16.2.4.5, 16.2.4.6, 16.2.4.7

PROGRAMMERS NOTES:
This table is only for Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg, not for Part A (1.6 mg/kg).

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14.2 Efficacy Data Summary Tables and Figures

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Table 14.2.1.1
Best Overall Response Summary based for NSCLC (Dose Escalation Part A and Dose Expansion Part B)
Efficacy Evaluable (N=n)

	NBF-006 Dose Level (mg/kg) for Escalation (Part A)				NBF-006 Dose Expansion (mg/kg) (Part B)			
Best Overall Response	0.15	0.3	onwards	Overall	0.6	1.2	1.6	Overall
Number of Patient	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Best Overall Response [1]								
Complete Response (CR)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
CR Unconfirmed (uCR)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Partial Response (PR)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
PR Unconfirmed (uPR)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Stable Disease (SD)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Progressive Disease (PD)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Not Evaluable (NE)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Missing	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Overall Response (CR or PR) [2][3]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Lower 95% Confidence Limit	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Upper 95% Confidence Limit	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Overall Response 2 (CR or uCR or PR or uPR) [3][4]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Lower 95% Confidence Limit	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Upper 95% Confidence Limit	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Disease Control Rate (CR or PR or SD) [3][5]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Lower 95% Confidence Limit	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Upper 95% Confidence Limit	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Disease Control Rate 2 (CR or uCR or PR or uPR or SD) [3][6]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Lower 95% Confidence Limit	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Upper 95% Confidence Limit	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Complete Response (CR) [3]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Lower 95% Confidence Limit	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%

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Upper 95% Confidence Limit	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Complete Response 2 (CR or uCR) [3][7]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Lower 95% Confidence Limit	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%
Upper 95% Confidence Limit	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%	xx.x%

NSCLC= Non-Small Cell Lung Cancer
Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg except Part A 1.6 mg/kg. Part B at 0.6, 1.2 & 1.6 mg/kg including the 1.6 mg/kg from Part A.
[1] Number of Patients is used as denominator to calculate percentages.
[2] Overall Response is based on patients with either a Complete Response (CR) or Partial Response (PR).
[3] Clopper-Pearson method is used for the calculation of the 95% confidence interval.
[4] Overall Response 2 is based on patients with CR or uCR or PR or uPR.
[5] Disease Control Rate is based on patients with CR or PR or SD.
[6] Disease Control Rate 2 is based on patients with CR or uCR or PR or uPR or SD.
[7] Complete Response 2 is based on patients with CR or uCR.
Cross-References: Figure 14.2.1.1, Listing 16.2.6.2

PROGRAMMERS NOTES:
Assumptions: Assessments of SD before Study week 5 (35 days) were treated as missing. Confirmatory scans for CR and PR must have been at least 4 weeks following initial documentation of a valid overall response.
The two-sided 95% Clopper-Pearson confidence interval was calculated for the overall response rates using the following SAS® code:

LowerCL = 1-betainv (1-alpha/2, N-x+1, x)
UpperCL = betainv (1-alpha/2, x+1, N-x)

where: N=sample size, X=number of responders, alpha=0.05 for a 95% confidence interval.
Derive uCR and uPR per SAP, they are not collected on CRF.
Remove missing if no missing value.
Present Part A and Part B output in same table.
Present Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg except Part A 1.6 mg/kg. Present Part B at 0.6, 1.2 & 1.6 mg/kg including the 1.6 mg/kg from Part A.

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Table 14.2.1.2
Best Overall Response Summary based for Pancreatic Cancer (Dose Escalation Part A)
Efficacy Evaluable (N=n)

For Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg
Cross-References: Figure 14.2.1.2, Listing 16.2.6.2

PROGRAMMER'S NOTES:
This table is only for Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg, not for Part A 1.6 mg/kg.

Table 14.2.1.3
Best Overall Response Summary based for Colorectal Cancer (Dose Escalation Part A)
Efficacy Evaluable (N=n)

For Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg
Cross-References: Figure 14.2.1.3, Listing 16.2.6.2

PROGRAMMER'S NOTES:
This table is only for Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg, not for Part A 1.6 mg/kg.

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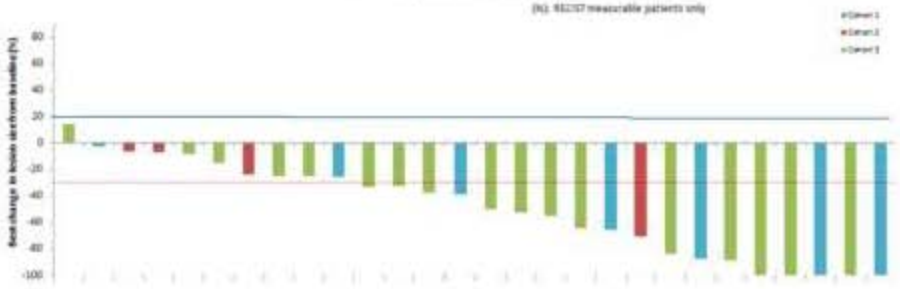
Figure 14.2.1.1: Best Change from Baseline in Tumor Measurements for NSCLC (Waterfall Plot) for Dose Escalation (Part A) and Dose Expansion (Part B) Efficacy Evaluable (N=n)



Horizontal reference ranges using definitions for progression (+20) and partial response (-30)
Y-axis scale should always be -100 to 100 to avoid presenting extreme values. Values that are capped as a result of this restriction to the scale are marked with *
Cross-References: Table 14.2.1.1, Listings 16.2.6.2

PROGRAMMER'S NOTES:
Horizontal reference ranges use (+20) for progression and (-30) for partial response.
Y-axis scale should always be -100 to 100 to avoid presenting extreme values.
Use colors and/or patterns, and legend to present different dose levels.
Add patient number with best response.
Present Part A and Part B output in same figure.

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Figure 24.2.1.2: Best Change from Baseline in Tumor Measurements for Pancreatic Cancer (Waterfall Plot) (Dose Escalation Part A)

For Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg
Cross-References: Table 14.2.1.2, Listings 16.2.6.2

PROGRAMMER'S NOTE: This is for Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg.

Figure 34.2.1.3: Best Change from Baseline in Tumor Measurements for Colorectal Cancer (Waterfall Plot) (Dose Escalation Part A)

For Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg
Cross-References: Table 14.2.1.3, Listings 16.2.6.2

PROGRAMMER'S NOTE: This is for Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg.

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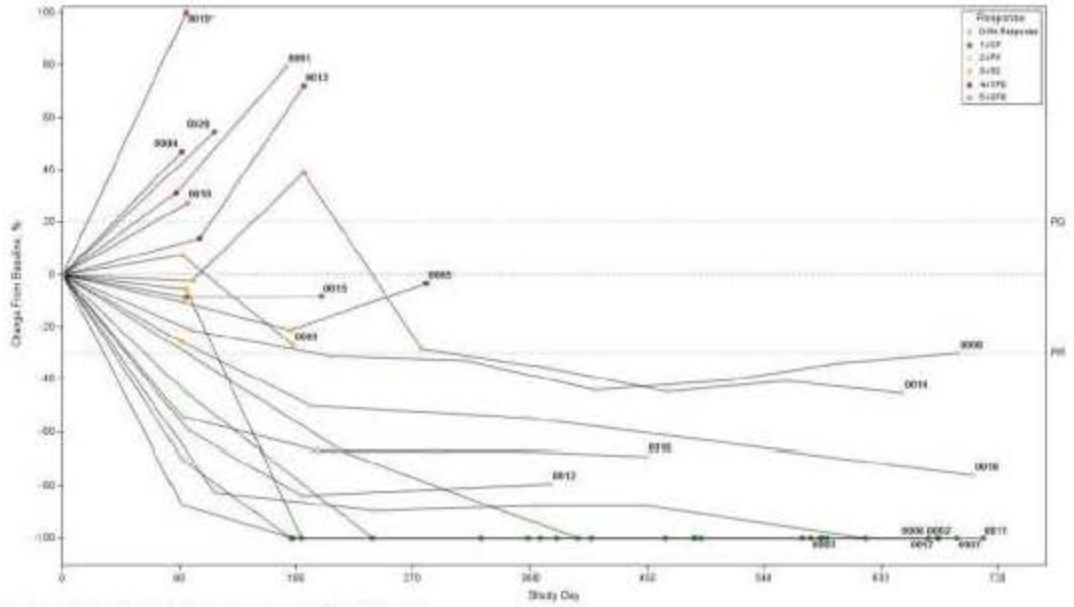
Figure 44.2.1.4.1: Percent Change from Baseline in Tumor Response for NSCLC (Spider Plot) (Dose Escalation Part A)
Efficacy Evaluable (N=n)



For Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg except Part A 1.6 mg/kg.
Y-axis scale should always be -100 to 100 to avoid presenting extreme values. Values that are capped as a result of this restriction to the scale are marked with *
Cross-References: Table 14.2.1.1, Listings 16.2.6.2

PROGRAMMER'S NOTES:
Y-axis scale should always be -100 to 100 to avoid presenting extreme values.
Add patient number and responses.
Use colors and/or patterns, and legend to present different dose levels.
For Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg except Part A 1.6 mg/kg.

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Figure 54.2.1.4.2: Percent Change from Baseline in Tumor Response for NSCLC (Spider Plot) (Dose Expansion Part B)
Efficacy Evaluable (N=n)

For Part B at 0.6, 1.2 & 1.6 mg/kg including the 1.6 mg/kg from Part A.
Y-axis scale should always be -100 to 100 to avoid presenting extreme values. Values that are capped as a result of this restriction to the scale are marked with *
Cross-References: Table 14.2.1.1, Listings 16.2.6.2

PROGRAMMER'S NOTES:
Y-axis scale should always be -100 to 100 to avoid presenting extreme values.
Add patient number and responses.
Use colors and/or patterns, and legend to present different dose levels.
Present Part B at 0.6, 1.2 & 1.6 mg/kg including the 1.6 mg/kg from Part A.

<Use the above as template repeat for>

Figure 64.2.1.5: Percent Change from Baseline in Tumor Response for Pancreatic Cancer (Spider Plot) (Dose Escalation Part A)
Efficacy Evaluable (N=n)

For Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg.
Cross-References: Table 14.2.1.2, Listings 16.2.6.2

PROGRAMMER'S NOTE:
This is for Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg.
Use colors and/or patterns, and legend to present different dose levels.

Figure 74.2.1.6: Percent Change from Baseline in Tumor Response for Colorectal Cancer (Spider Plot) (Dose Escalation Part A)
Efficacy Evaluable (N=n)

For Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg.
Cross-References: Table 14.2.1.3, Listings 16.2.6.2

PROGRAMMER'S NOTE:
This is for Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg.
Use colors and/or patterns, and legend to present different dose levels.

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Table 14.2.2.1
Life Table Summary of Duration of Overall Response (Dose Escalation Part A)
Efficacy Evaluable (N=n)

	NBF-006 Dose Level (mg/kg) for Escalation (Part A)				
Duration of Overall Response	0.15	0.3	0.6	1.2	Overall
Number of Patients	xx	xx	xx	xx	xx
Number of Events	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Censored [1]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Duration of Overall Response [1][3]					
75% Progression-free	xxx days	xxx days	xxx days	xxx days	xxx days
Median	xxx days	xxx days	xxx days	xxx days	xxx days
Lower 95% Confidence Limit	xxx days	xxx days	xxx days	xxx days	xxx days
Upper 95% Confidence Limit	xxx days	xxx days	xxx days	xxx days	xxx days
25% Progression-free	xxx days	xxx days	xxx days	xxx days	xxx days
Last Observation	xxx days	xxx days	xxx days	xxx days	xxx days
Duration of Overall CR [2][3]					
75% Progression-free	xxx days	xxx days	xxx days	xxx days	xxx days
Median	xxx days	xxx days	xxx days	xxx days	xxx days
Lower 95% Confidence Limit	xxx days	xxx days	xxx days	xxx days	xxx days
Upper 95% Confidence Limit	xxx days	xxx days	xxx days	xxx days	xxx days
25% Progression-free	xxx days	xxx days	xxx days	xxx days	xxx days
Last Observation	xxx days	xxx days	xxx days	xxx days	xxx days
Progression-Free Rate					
Baseline	100.0%	100.0%	100.0%	100.0%	100.0%
2 cycles (84 days)	xx.x %	xx.x %	xx.x %	xx.x %	xx.x %
4 cycles (168 days)	xx.x %	xx.x %	xx.x %	xx.x %	xx.x %
6 cycles (252 days)	xx.x %	xx.x %	xx.x %	xx.x %	xx.x %
8 cycles (336 days)	xx.x %	xx.x %	xx.x %	xx.x %	xx.x %
.....	.....	.....	.....	.....	.....
Last Event (xxx days)	xx.x %	xx.x %	xx.x %	xx.x %	xx.x %

For Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg except Part A 1.6 mg/kg.
[1] Duration of overall response is measured from the time measurement criteria are met for CR or PR (whichever is first recorded) until the first date that recurrent or progressive disease is objectively documented (taking as reference for progressive disease the smallest measurements recorded since the treatment started). Only

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patients with a confirmed CR or PR are included in the analysis. Symptomatic deterioration is not considered PD. For a patient without evidence of disease progression, duration of overall response will be censored at the date of last evaluable tumor assessment.

[2] Duration of overall complete response is measured from the time measurement criteria are first met for CR until the first date that recurrent disease is objectively documented. Only patients with a confirmed CR are included in the analysis. Symptomatic deterioration is not considered PD. For a patient without evidence of disease progression, duration of overall CR will be censored at the date of last evaluable tumor assessment.

[3] Life Table estimates are calculated using Kaplan-Meier methodology. Confidence interval for the median survival time was calculated using the method by Brookmeyer and Crowley.

Cross-References: Figure 14.2.2.1, Table 14.2.4, Listing 16.2.6.2

PROGRAMMERS NOTES:
Only include if CR or PR responses are found in the database.
Life Table estimates are calculated using Kaplan-Meier methodology. Confidence interval for the median duration time is calculated using the method by Brookmeyer and Crowley.
Update timepoint prior to last event per available data.
Present at every even numbered cycle for Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg except Part A 1.6 mg/kg

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Table 14.2.2.2
Life Table Summary of Duration of Overall Response (Dose Expansion Part B)
Efficacy Evaluable (N=n)

	NBF-006 Dose Expansion (mg/kg) (Part B)			
Duration of Overall Response	0.6	1.2	1.6	Overall
Number of Patients	xx	xx	xx	xx
Number of Events	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Censored [1]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Duration of Overall Response [1][3]				
75% Progression-free	xxx days	xxx days	xxx days	xxx days
Median	xxx days	xxx days	xxx days	xxx days
Lower 95% Confidence Limit	xxx days	xxx days	xxx days	xxx days
Upper 95% Confidence Limit	xxx days	xxx days	xxx days	xxx days
25% Progression-free	xxx days	xxx days	xxx days	xxx days
Last Observation	xxx days	xxx days	xxx days	xxx days
Duration of Overall CR [2][3]				
75% Progression-free	xxx days	xxx days	xxx days	xxx days
Median	xxx days	xxx days	xxx days	xxx days
Lower 95% Confidence Limit	xxx days	xxx days	xxx days	xxx days
Upper 95% Confidence Limit	xxx days	xxx days	xxx days	xxx days
25% Progression-free	xxx days	xxx days	xxx days	xxx days
Last Observation	xxx days	xxx days	xxx days	xxx days
Progression-Free Rate				
Baseline	100.0%	100.0%	100.0%	100.0%
1 cycle (42 days)	xx.x %	xx.x %	xx.x %	xx.x %
2 cycles (84 days)	xx.x %	xx.x %	xx.x %	xx.x %
3 cycles (126 days)	xx.x %	xx.x %	xx.x %	xx.x %
4 cycles (168 days)	xx.x %	xx.x %	xx.x %	xx.x %
5 cycles (210 days)	xx.x %	xx.x %	xx.x %	xx.x %
.....	.....	.....	.....	.....
Last Event (xxx days)	xx.x %	xx.x %	xx.x %	xx.x %

[1] Duration of overall response is measured from the time measurement criteria are met for CR or PR (whichever is first recorded) until the first date that recurrent or progressive disease is objectively documented (taking as reference for progressive disease the smallest measurements recorded since the treatment started). Only

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patients with a confirmed CR or PR are included in the analysis. Symptomatic deterioration is not considered PD. For a patient without evidence of disease progression, duration of overall response will be censored at the date of last evaluable tumor assessment.

[2] Duration of overall complete response is measured from the time measurement criteria are first met for CR until the first date that recurrent disease is objectively documented. Only patients with a confirmed CR are included in the analysis. Symptomatic deterioration is not considered PD. For a patient without evidence of disease progression, duration of overall CR will be censored at the date of last evaluable tumor assessment.

[3] Life Table estimates are calculated using Kaplan-Meier methodology. Confidence interval for the median survival time was calculated using the method by Brookmeyer and Crowley.

Cross-References: Figure 14.2.2.2, Table 14.2.4, Listing 16.2.6.2

PROGRAMMER'S NOTES:
Only include if CR or PR responses are found in the database.
Life Table estimates are calculated using Kaplan-Meier methodology. Confidence interval for the median duration time is calculated using the method by Brookmeyer and Crowley.
Update timepoint prior to last event per available data.
Present Part A and Part B output separately, adjust title for Part B accordingly.
Present at every cycle for Part B at 0.6, 1.2, 1.6 mg/kg including the 1.6 mg/kg from Part A.

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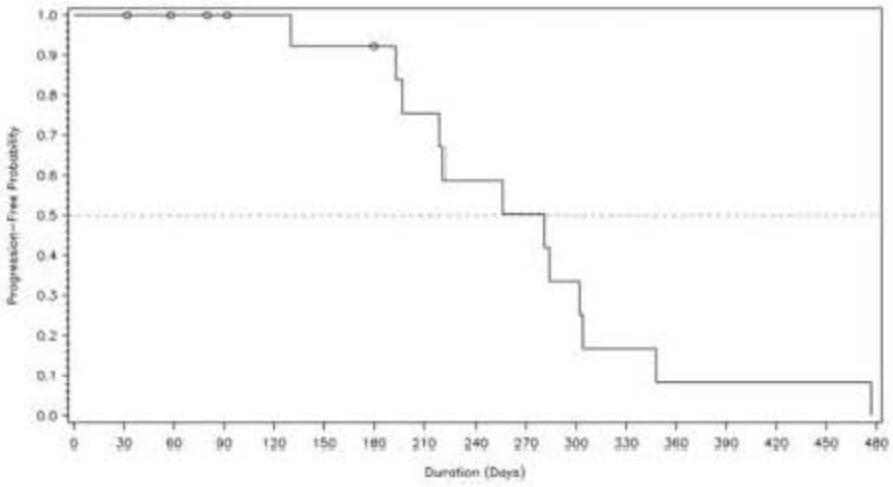
Figure 84.2.2.1: Duration of Overall Response (Kaplan-Meier) (Dose Escalation Part A)
Efficacy Evaluable (N=n)



○ ○ ○ Censored Patients

For Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg.
Duration of overall response is measured from the time measurement criteria are met for CR or PR (whichever is first recorded) until the first date that recurrent or progressive disease is objectively documented (taking as reference for progressive disease the smallest measurements recorded since the treatment started). Only patients with a confirmed CR or PR (SAP section 5.4.1) are included in the analysis. Symptomatic deterioration is not considered PD. For a patient without evidence of disease progression, duration of overall response will be censored at the date of last evaluable tumor assessment.
Cross-References: Table 14.2.2.1, Table 14.2.4, Listing 16.2.6.2

PROGRAMMER'S NOTES:
Kaplan-Meier curves are generated using log-rank test. Draw horizontal reference line representing 50% level (median).
Update timepoint prior to last event per available data.
Present for Part A at dose level at 0.15, 0.3, 0.6, 1.2 mg/kg except Part A 1.6 mg/kg, and overall.
Use different colors or patterns and legend to indicate 0.15, 0.3, 0.6, 1.2 mg/kg and Overall.

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Figure 94.2.2.2: Duration of Overall Response (Kaplan-Meier) (Dose Expansion Part B)
Efficacy Evaluable (N=n)

For Part B at 0.6, 1.2, 1.6 mg/kg including the 1.6 mg/kg from Part A.
Cross-References: Table 14.2.2.2, Table 14.2.4, Listing 16.2.6.2

PROGRAMMER'S NOTES:
Add 1.6 mg/kg for Dose Expansion (Part B). Present Part A and Part B output separately, adjust title for Part B accordingly.
Present for Part B at 0.6, 1.2, 1.6 mg/kg including the 1.6 mg/kg from Part A.
Use different colors or patterns and legend to indicate 0.6, 1.2, 1.6 mg/kg and Overall.

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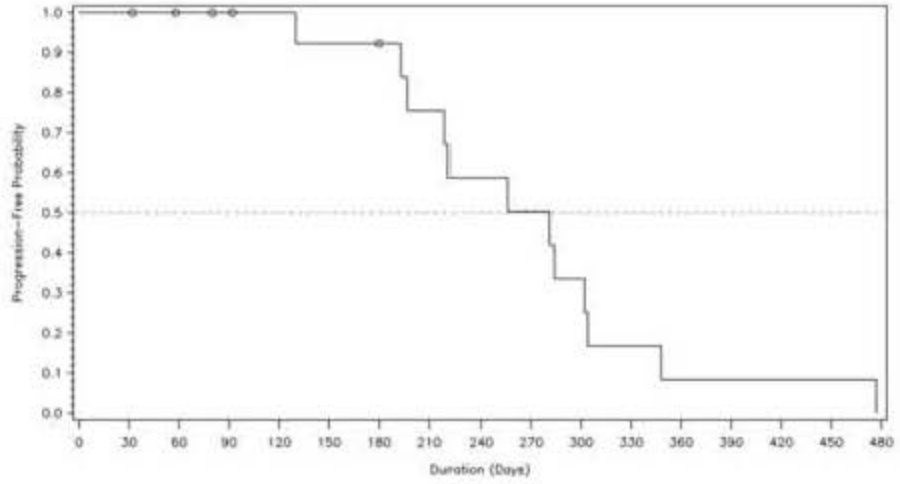
Figure 104.2.2.3: Duration of Overall Complete Response (Kaplan-Meier) (Dose Escalation Part A)
Efficacy Evaluable (N=n)



○ ○ ○ Censored Patients

For Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg.

Duration of overall complete response is measured from the time measurement criteria are first met for CR until the first date that recurrent or progressive disease is objectively documented. Only confirmed CR is included. Symptomatic deterioration is not considered PD. For a patient without evidence of disease progression, duration of overall complete response will be censored on the date of last evaluable tumor assessment.

Cross-References: Table 14.2.2.1, Table 14.2.4, Listing 16.2.6.2

PROGRAMMER'S NOTES:
Kaplan-Meier curves are generated using log-rank test. Draw horizontal reference line representing 50% level (median).
Update timepoint prior to last event per available data.
Present for Part A at dose level at 0.15, 0.3, 0.6, 1.2 mg/kg except Part A 1.6 mg/kg, and overall.
Use different colors or patterns and legend to indicate 0.15, 0.3, 0.6, 1.2 mg/kg and Overall.

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Figure 114.2.2.4: Duration of Overall Complete Response (Kaplan-Meier) (Dose Expansion Part B)
Efficacy Evaluable (N=n)

For Part B at 0.6, 1.2, 1.6 mg/kg including the 1.6 mg/kg from Part A.
Cross-References: Table 14.2.2.2, Table 14.2.4, Listing 16.2.6.2

PROGRAMMER'S NOTES:
Add 1.6 mg/kg for Dose Expansion (Part B). Present Part A and Part B output separately, adjust title for Part B accordingly.
Present for Part B at 0.6, 1.2, 1.6 mg/kg including the 1.6 mg/kg from Part A.
Use different colors or patterns and legend to indicate 0.6, 1.2, 1.6 mg/kg and Overall.

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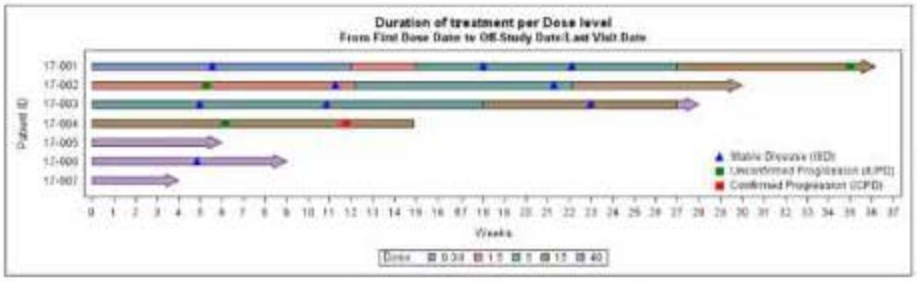
Figure 124.2.2.5: Duration of Treatment per Dose Level with Patient's Response Overtime (Swimmer Plot) (Dose Escalation Part A)
Efficacy Evaluable (N=n)



Cross-References: Appendix Listing 16.2.6.2

PROGRAMMER'S NOTES:
The X-axis displays individual patient's tumor response overtime.
The Y-axis displays the individual patients that received the study drug.
Present patient ID on the left.

Figure 134.2.2.6: Duration of Treatment per Expansion Cohort with Patient's Response Overtime (Swimmer Plot) (Dose Expansion Part B)
Efficacy Evaluable (N=n)

Cross-References: Appendix Listing 16.2.6.2

PROGRAMMER'S NOTES:
The X-axis displays individual patient's tumor response overtime.
The Y-axis displays the individual patients that received the study drug.
Present patient ID on the left.

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Table 14.2.3.1
Life Table Analysis of Duration of Overall Response: Confidence Intervals for Point Estimates (Dose Escalation Part A)
Efficacy Evaluable (N=n)

NBF-006 Dose Timepoint	Number at Risk	Cumulative Events [1]	Progression-Free Rate	95% Confidence Interval [2] Lower	Upper
0.15 mg/kg					
Baseline	nnn	nnn	100.0%	xx.x%	xx.x%
2 cycles (84 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
4 cycles (168 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
6 cycles (252 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
8 cycles (336 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
.....	.....	.....	.....	.....	.....
Last Event (xxx days)	nnn	nnn	xx.x%	xx.x%	xx.x%
0.3 mg/kg					
Baseline	nnn	nnn	100.0%	xx.x%	xx.x%
2 cycles (84 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
4 cycles (168 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
6 cycles (252 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
8 cycles (336 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
.....	.....	.....	.....	.....	.....
Last Event (xxx days)	nnn	nnn	xx.x%	xx.x%	xx.x%
0.6 mg/kg					
Baseline	nnn	nnn	100.0%	xx.x%	xx.x%
2 cycles (84 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
4 cycles (168 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
6 cycles (252 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
8 cycles (336 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
.....	.....	.....	.....	.....	.....
Last Event (xxx days)	nnn	nnn	xx.x%	xx.x%	xx.x%
Onward					
Baseline	nnn	nnn	100.0%	xx.x%	xx.x%
2 cycles (84 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
4 cycles (168 days)	nnn	nnn	xx.x%	xx.x%	xx.x%

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6 cycles (252 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
8 cycles (336 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
.....	.....	.....	.....	.....	.....
Last Event (xxx days)	nnn	nnn	xx.x%	xx.x%	xx.x%
Overall					
Baseline	nnn	nnn	100.0%	xx.x%	xx.x%
2 cycles (84 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
4 cycles (168 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
6 cycles (252 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
8 cycles (336 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
.....	.....	.....	.....	.....	.....
Last Event (xxx days)	nnn	nnn	xx.x%	xx.x%	xx.x%

[1] Duration of overall response is measured from the time measurement criteria are met for CR or PR (whichever is first recorded) until the first date that recurrent or progressive disease is objectively documented (taking as reference for progressive disease the smallest measurements recorded since the treatment started). Only patients with a confirmed CR or PR (SAP section 5.4.1) are included in the analysis. Symptomatic deterioration is not considered PD. For a patient without evidence of disease progression, duration of overall response will be censored at the date of last evaluable tumor assessment.

[2] Life Table estimates are calculated using Kaplan-Meier methodology. Confidence interval for a point estimate on the survival distribution is calculated using the method by Kalbfleisch and Prentice.

Cross-Reference: Table 14.2.4, Listing 16.2.6.2

PROGRAMMER'S NOTES:
Life Table estimates are calculated using Kaplan-Meier methodology. Confidence interval for a point estimate on the survival distribution is calculated using the method by Kalbfleisch and Prentice.
Present at every even numbered cycle for Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg except Part A 1.6 mg/kg.

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Table 14.2.3.2
Life Table Analysis of Duration of Overall Response: Confidence Intervals for Point Estimates (Dose Expansion Part B)
Efficacy Evaluable (N=n)

NBF-006 Dose Timepoint	Number at Risk	Cumulative Events [1]	Progression-Free Rate	95% Confidence Interval [2] Lower	Upper
0.6 mg/kg					
Baseline	nnn	nnn	100.0%	xx.x%	xx.x%
1 cycle (42 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
2 cycles (84 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
3 cycles (126 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
4 cycles (168 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
5 cycles (210 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
.....	.....	.....	.....	.....	.....
Last Event (xxx days)	nnn	nnn	xx.x%	xx.x%	xx.x%
1.2 mg/kg					
Baseline	nnn	nnn	100.0%	xx.x%	xx.x%
1 cycle (42 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
2 cycles (84 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
3 cycles (126 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
4 cycles (168 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
5 cycles (210 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
.....	.....	.....	.....	.....	.....
Last Event (xxx days)	nnn	nnn	xx.x%	xx.x%	xx.x%
1.6 mg/kg					
Baseline	nnn	nnn	100.0%	xx.x%	xx.x%
1 cycle (42 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
2 cycles (84 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
3 cycles (126 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
4 cycles (168 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
5 cycles (210 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
.....	.....	.....	.....	.....	.....
Last Event (xxx days)	nnn	nnn	xx.x%	xx.x%	xx.x%
Overall					
Baseline	nnn	nnn	100.0%	xx.x%	xx.x%
1 cycle (42 days)	nnn	nnn	xx.x%	xx.x%	xx.x%

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2 cycles (84 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
3 cycles (126 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
4 cycles (168 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
5 cycles (210 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
.....	.....	.....	.....	.....	.....
Last Event (xxx days)	nnn	nnn	xx.x%	xx.x%	xx.x%

[1] Duration of overall response is measured from the time measurement criteria are met for CR or PR (whichever is first recorded) until the first date that recurrent or progressive disease is objectively documented (taking as reference for progressive disease the smallest measurements recorded since the treatment started). Only patients with a confirmed CR or PR (SAP section 5.4.1) are included in the analysis. Symptomatic deterioration is not considered PD. For a patient without evidence of disease progression, duration of overall response will be censored at the date of last evaluable tumor assessment.

[2] Life Table estimates are calculated using Kaplan-Meier methodology. Confidence interval for a point estimate on the survival distribution is calculated using the method by Kalbfleisch and Prentice.

Cross-Reference: Table 14.2.4, Listing 16.2.6.2

PROGRAMMERS NOTES:
Life Table estimates are calculated using Kaplan-Meier methodology. Confidence interval for a point estimate on the survival distribution is calculated using the method by Kalbfleisch and Prentice.
Present Part A and Part B output separately, adjust title for Part B accordingly.
Present at every cycle for Part B at 0.6, 1.2, 1.6 mg/kg including the 1.6 mg/kg from Part A.

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Table 14.2.4
Patient Listing for Duration of Overall Response
Efficacy Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose(mg/kg)	Date of First Dose	Date of First CR [1]	Date of First uCR [1]	Date of First PR [1]	Date of First uPR [1]	Date of Progression	Date of Censoring	Duration of Overall Response (day) [2]	Duration of Overall CR [3]
ccc-pppp /xx/x	x	xxx	ddmmmyyyy	xxxx						xxx	xxx
ccc-pppp /xx/x	x	xxx	ddmmmyyyy			xxxx				xxx	xxx
ccc-pppp /xx/x	x	xxx	ddmmmyyyy		xxxx					xxx	xxx
ccc-pppp /xx/x	x	xxx	ddmmmyyyy				xxxx	xxxx		xxx	xxx
ccc-pppp /xx/x	x	xxx	ddmmmyyyy	xxxx						xxx	xxx
ccc-pppp /xx/x	x	xxx	ddmmmyyyy						xxxxxx	xxx	xxx

[1] CR = Complete Response, PR = Partial Response, uCR = Unconfirmed Complete Response, uPR = Unconfirmed Partial Response
[2] Duration of overall response is measured from the time measurement criteria are met for CR or PR (whichever is first recorded) until the first date that recurrent or progressive disease is objectively documented (taking as reference for progressive disease the smallest measurements recorded since the treatment started). Symptomatic deterioration is not considered PD. For a patient without evidence of disease progression, duration of overall response will be censored.
[3] Duration of overall CR is measured from the time measurement criteria are first met for CR until the first date that recurrent disease is objectively documented. Only patients with a confirmed CR are included in the analysis. For a patient without evidence of disease progression, duration of overall CR will be censored
Cross-Reference: Case Report Forms: Cycle Response Assessment (RS)

PROGRAMMER'S NOTES:
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Data used in the SAS Life Table procedure.

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Table 14.2.5.1
Life Table Summary of Duration of Stable Disease (Dose Escalation Part A)
Efficacy Evaluable (N=n)

	NBF-006 Dose Level (mg/kg) for Escalation (Part A)				
Duration of Stable Disease	0.15	0.3	0.6	1.2	Overall
Number of Patients	xx	xx	xx	xx	xx
Number of Events	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Censored [1]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Duration of Stable Disease [1][2]					
75% Progression-free	xxx days	xxx days	xxx days	xxx days	xxx days
Median	xxx days	xxx days	xxx days	xxx days	xxx days
Lower 95% Confidence Limit	xxx days	xxx days	xxx days	xxx days	xxx days
Upper 95% Confidence Limit	xxx days	xxx days	xxx days	xxx days	xxx days
25% Progression-free	xxx days	xxx days	xxx days	xxx days	xxx days
Last Observation	xxx days	xxx days	xxx days	xxx days	xxx days
Progression-Free Rate					
2 cycles (84 days)	xx.x %	xx.x %	xx.x %	xx.x %	xx.x %
4 cycles (168 days)	xx.x %	xx.x %	xx.x %	xx.x %	xx.x %
6 cycles (252 days)	xx.x %	xx.x %	xx.x %	xx.x %	xx.x %
8 cycles (336 days)	xx.x %	xx.x %	xx.x %	xx.x %	xx.x %
.....	.....	.....	.....	.....	.....
Last Event (xxx days)	xx.x %	xx.x %	xx.x %	xx.x %	xx.x %

[1] Stable Disease is measured from the start of the treatment until the criteria for progression are met, taking as reference the smallest measurements recorded since the treatment started. Only patients with a SD are included in the analysis. Follow-up measurements for SD must meet the SD criteria at least 5 weeks after study entry. Symptomatic deterioration is not considered PD. For a patient without evidence of disease progression, duration of stable disease will be censored at the date of last evaluable tumor assessment.

[2] Life Table estimates are calculated using Kaplan-Meier methodology. Confidence interval for the median survival time was calculated using the method by Brookmeyer and Crowley.

Cross-References: Figure 14.2.5.1, Listing 16.2.6.2

PROGRAMMER'S NOTES:
Life Table estimates are calculated using Kaplan-Meier methodology. Confidence interval for the median duration time is calculated using the method by Brookmeyer and Crowley.
Update timepoint prior to last event per available data.
Present at every even numbered cycle for Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg except Part A 1.6 mg/kg.

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Table 14.2.5.2
Life Table Summary of Duration of Stable Disease (Dose Expansion Part B)
Efficacy Evaluable (N=n)

	NBF-006 Dose Expansion (mg/kg) (Part B)			
Duration of Stable Disease	0.6	1.2	1.6	Overall
Number of Patients	xx	xx	xx	xx
Number of Events	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Censored [1]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Duration of Stable Disease [1][2]				
75% Progression-free	xxx days	xxx days	xxx days	xxx days
Median	xxx days	xxx days	xxx days	xxx days
Lower 95% Confidence Limit	xxx days	xxx days	xxx days	xxx days
Upper 95% Confidence Limit	xxx days	xxx days	xxx days	xxx days
25% Progression-free	xxx days	xxx days	xxx days	xxx days
Last Observation	xxx days	xxx days	xxx days	xxx days
Progression-Free Rate				
1 cycle (42 days)	xx.x %	xx.x %	xx.x %	xx.x %
2 cycles (84 days)	xx.x %	xx.x %	xx.x %	xx.x %
3 cycles (126 days)	xx.x %	xx.x %	xx.x %	xx.x %
4 cycles (168 days)	xx.x %	xx.x %	xx.x %	xx.x %
5 cycles (210 days)	xx.x %	xx.x %	xx.x %	xx.x %
.....	.....	.....	.....	.....
Last Event (xxx days)	xx.x %	xx.x %	xx.x %	xx.x %

[1] Stable Disease is measured from the start of the treatment until the criteria for progression are met, taking as reference the smallest measurements recorded since the treatment started. Only patients with a SD are included in the analysis. Follow-up measurements for SD must meet the SD criteria at least 5 weeks after study entry. Symptomatic deterioration is not considered PD. For a patient without evidence of disease progression, duration of stable disease will be censored at the date of last evaluable tumor assessment.

[2] Life Table estimates are calculated using Kaplan-Meier methodology. Confidence interval for the median survival time was calculated using the method by Brookmeyer and Crowley.

Cross-References: Figure 14.2.5.2, Listing 16.2.6.2

PROGRAMMER'S NOTES:
Life Table estimates are calculated using Kaplan-Meier methodology. Confidence interval for the median duration time is calculated using the method by Brookmeyer and Crowley.
Update timepoint prior to last event per available data.
Present at every cycle for Part B at 0.6, 1.2, 1.6 mg/kg including the 1.6 mg/kg from Part A.

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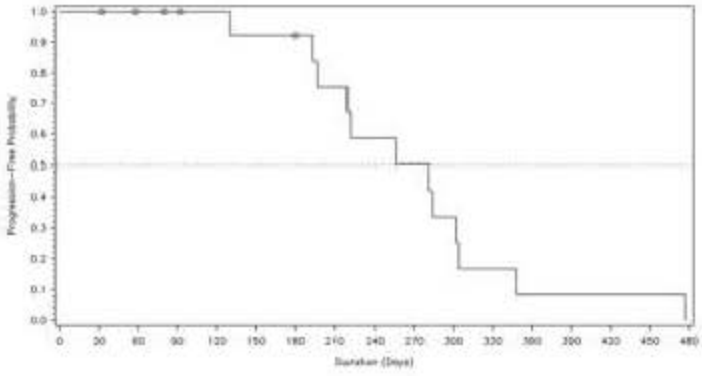
Figure 144.2.5.1: Duration of Stable Disease (Kaplan-Meier) (Dose Escalation Part A)
Efficacy Evaluable (N=n)
NBF-006-001 Phase 1/1b Phase I Study



○ ○ ○ Censored Patients

For Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg.
Stable Disease is measured from the start of the treatment until the criteria for progression are met, taking as reference the smallest measurements recorded since the treatment started. Only patients with a SD are included in the analysis. Follow-up measurements for SD must meet the SD criteria at least 5 weeks after study entry. For a patient without evidence of disease progression, duration of stable disease will be censored at the date of last evaluable tumor assessment.
Cross-References: Table 14.2.5.1, Listing 16.2.6.2

PROGRAMMER'S NOTES:
Kaplan-Meier curves are generated using log-rank test. Draw horizontal reference line representing 50% level (median).
Update timepoint prior to last event per available data.
Present Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg except Part A 1.6 mg/kg, and overall.

Figure 154.2.5.2: Duration of Stable Disease (Kaplan-Meier) (Dose Expansion Part B)
Efficacy Evaluable (N=n)

For Part B at 0.6, 1.2, 1.6 mg/kg including the 1.6 mg/kg from Part A.
Cross-References: Table 14.2.5.2, Listing 16.2.6.2

PROGRAMMER'S NOTES:
Present Part A and Part B output separately, adjust title for Part B accordingly.
Present for Part B at 0.6, 1.2, 1.6 mg/kg including the 1.6 mg/kg from Part A.
Use different colors or patterns and legend to indicate 0.6, 1.2, 1.6 mg/kg and Overall.

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Table 14.2.6.1
Life Table Analysis of Duration of Stable Disease: Confidence Intervals for Point Estimates (Dose Escalation Part A)
Efficacy Evaluable (N=n)

NBF-006 Dose Timepoint	Number at Risk	Cumulative Events [1]	Progression-Free Rate	95% Confidence Interval [2] Lower	Upper
0.15 mg/kg					
Baseline	nnn	nnn	100.0%	xx.x%	xx.x%
2 cycles (84 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
4 cycles (168 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
6 cycles (252 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
8 cycles (336 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
.....	.....	.....	.....	.....	.....
Last Event (xxx days)	nnn	nnn	xx.x%	xx.x%	xx.x%
0.3 mg/kg					
Baseline	nnn	nnn	100.0%	xx.x%	xx.x%
2 cycles (84 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
4 cycles (168 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
6 cycles (252 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
8 cycles (336 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
.....	.....	.....	.....	.....	.....
Last Event (xxx days)	nnn	nnn	xx.x%	xx.x%	xx.x%
0.6 mg/kg					
Baseline	nnn	nnn	100.0%	xx.x%	xx.x%
2 cycles (84 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
4 cycles (168 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
6 cycles (252 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
8 cycles (336 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
.....	.....	.....	.....	.....	.....
Last Event (xxx days)	nnn	nnn	xx.x%	xx.x%	xx.x%
1.2 mg/kg					
Baseline	nnn	nnn	100.0%	xx.x%	xx.x%
2 cycles (84 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
4 cycles (168 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
6 cycles (252 days)	nnn	nnn	xx.x%	xx.x%	xx.x%

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8 cycles (336 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
.....	.....	.....	.....	.....	.....
Last Event (xxx days)	nnn	nnn	xx.x%	xx.x%	xx.x%
Overall					
Baseline	nnn	nnn	100.0%	xx.x%	xx.x%
2 cycles (84 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
4 cycles (168 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
6 cycles (252 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
8 cycles (336 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
.....	.....	.....	.....	.....	.....
Last Event (xxx days)	nnn	nnn	xx.x%	xx.x%	xx.x%

[1] Stable Disease is measured from the start of the treatment until the criteria for progression are met, taking as reference the smallest measurements recorded since the treatment started. Only patients with a SD are included in the analysis. Follow-up measurements for SD must meet the SD criteria at least 5 weeks after study entry. For a patient without evidence of disease progression, duration of stable disease will be censored.

[2] Life Table estimates are calculated using Kaplan-Meier methodology. Confidence interval for a point estimate on the survival distribution is calculated using the method by Kalbfleisch and Prentice.

Cross-Reference: Table 14.2.7, Listing 16.2.6.2

PROGRAMMER'S NOTES:

Life Table estimates are calculated using Kaplan-Meier methodology. Confidence interval for a point estimate on the survival distribution is calculated using the method by Kalbfleisch and Prentice.

Present at every even numbered cycle for Part A dose level at 0.15, 0.3, 0.6, 1.2 mg/kg except Part A 1.6 mg/kg and overall.

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Table 14.2.6.2
Life Table Analysis of Duration of Stable Disease: Confidence Intervals for Point Estimates (Dose Expansion Part B)
Efficacy Evaluable (N=n)

NBF-006 Dose Timepoint	Number at Risk	Cumulative Events [1]	Progression-Free Rate	95% Confidence Interval [2] Lower	Upper
0.6 mg/kg					
Baseline	nnn	nnn	100.0%	xx.x%	xx.x%
1 cycle (42 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
2 cycles (84 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
3 cycles (126 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
4 cycles (168 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
5 cycles (210 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
.....	.....	.....	.....	.....	.....
Last Event (xxx days)	nnn	nnn	xx.x%	xx.x%	xx.x%
1.2 mg/kg					
Baseline	nnn	nnn	100.0%	xx.x%	xx.x%
1 cycle (42 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
2 cycles (84 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
3 cycles (126 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
4 cycles (168 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
5 cycles (210 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
.....	.....	.....	.....	.....	.....
Last Event (xxx days)	nnn	nnn	xx.x%	xx.x%	xx.x%
1.6mg/kg					
Baseline	nnn	nnn	100.0%	xx.x%	xx.x%
1 cycle (42 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
2 cycles (84 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
3 cycles (126 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
4 cycles (168 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
5 cycles (210 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
.....	.....	.....	.....	.....	.....
Last Event (xxx days)	nnn	nnn	xx.x%	xx.x%	xx.x%
Overall					
Baseline	nnn	nnn	100.0%	xx.x%	xx.x%

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1 cycle (42 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
2 cycles (84 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
3 cycles (126 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
4 cycles (168 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
5 cycles (210 days)	nnn	nnn	xx.x%	xx.x%	xx.x%
.....	.....	.....	.....	.....	.....
Last Event (xxx days)	nnn	nnn	xx.x%	xx.x%	xx.x%

[1] Stable Disease is measured from the start of the treatment until the criteria for progression are met, taking as reference the smallest measurements recorded since the treatment started. Only patients with a SD are included in the analysis. Follow-up measurements for SD must meet the SD criteria at least 5 weeks after study entry. For a patient without evidence of disease progression, duration of stable disease will be censored.

[2] Life Table estimates are calculated using Kaplan-Meier methodology. Confidence interval for a point estimate on the survival distribution is calculated using the method by Kalbfleisch and Prentice.

Cross-Reference: Table 14.2.7, Listing 16.2.6.2

PROGRAMMERS NOTES:

Life Table estimates are calculated using Kaplan-Meier methodology. Confidence interval for a point estimate on the survival distribution is calculated using the method by Kalbfleisch and Prentice.

Present Part A and Part B output separately. Present at every cycle for Part B at 0.6, 1.2, 1.6 mg/kg including the 1.6 mg/kg from Part A

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Table 14.2.7
Patient Listing of Duration of Stable Disease
Efficacy Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Date of First Dose	Date of First CR [1]	Date of First PR [1]	Date of Progression	Date of Censoring	Duration of SD (day)[1][2]
ccc-pppp /xx/x	x	xx	dd/mm/yyyy	dd/mm/yyyy		dd/mm/yyyy		xxx
ccc-pppp /xx/x	x	xx	dd/mm/yyyy		dd/mm/yyyy		dd/mm/yyyy	xxx
ccc-pppp /xx/x	x	xx	dd/mm/yyyy		dd/mm/yyyy	dd/mm/yyyy		xxx
ccc-pppp /xx/x	x	xx	dd/mm/yyyy		dd/mm/yyyy		dd/mm/yyyy	xxx

[1] CR= complete response, PR= partial response, SD= stable disease
[2] Stable Disease is measured from the start of the treatment until the criteria for progression are met, taking as reference the smallest measurements recorded since the treatment started. Only patients with a SD are included in the analysis. Follow-up measurements for SD must meet the SD criteria at least 5 weeks after study entry. For a patient without evidence of disease progression, duration of stable disease will be censored.
Cross-Reference: Case Report Forms: Cycle Response Assessment (RS)

PROGRAMMER'S NOTES:
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Data used in the SAS Life Table procedure.

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14.3 Safety Data Summary Tables

14.3.1 Display of Adverse Events

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Table 14.3.1.1
Overall Summary of Treatment-Emergent Adverse Events (Dose Escalation Part A)
Safety Evaluable (N=n)

	NBF-006 Dose Level (mg/kg) for Escalation (Part A)				NBF-006 Dose Expansion (mg/kg) (Part B)			
Treatment-Emergent Adverse Event [1][2]	0.15	0.3	onwards	Overall	0.6	1.2	1.6	Overall
Number of Patients	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Patients								
With Any TEAEs	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
With Drug Related TEAEs [3]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
With Severity Grade 3, 4, or 5	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
With Severity Grade 3, 4, or 5 Drug Related TEAEs [3]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
With Any Serious TEAEs	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
With Any Serious, Drug Related TEAEs [3]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Who Discontinued Treatment Due to TEAEs	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Who Died Due to Any TEAEs	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Who Experienced DLT [4]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)

[1] Number of Patients is used as denominator to calculate percentages.
[2] Treatment-Emergent Adverse Events (TEAEs) are defined as adverse events that occurred on and after the first dose date up to 30 days post last dose date. Patients with multiple TEAEs were counted once within a summary category: system organ class, preferred term, maximum grade, or relationship to treatment. Patients with events in more than one category were counted once within each category.
[2] Number of Patients is used as denominator to calculate percentages.
[3] Drug Related include relationship as Definite or Probable or Possible.
[4] DLT: Dose-limiting toxicity
Cross-References: Listing 16.2.7.1, 16.2.7.4

PROGRAMMERS NOTES:
Sort in descending order using "Overall" frequency column.
Excludes events with incomplete information for grade or drug relationship. Add footnote if required: See Listing 16.2.7.4 for excluded events.
Present Part A and Part B output separately, adjust title for Part B accordingly.

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Table 14.3.1.2
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Dose Escalation Part A)
Safety Evaluable (N=n)

MedDRA System Organ Class	NBF-006 Dose Level (mg/kg) for Escalation (Part A)				NBF-006 Dose Expansion (mg/kg) (Part B)			
MedDRA Preferred Term [1]	0.15	0.3	onwards	Overall	0.6	1.2	1.6	Overall
Number of Patients	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Patients with Any TEAE [2][3]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA System Organ Class	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA System Organ Class	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)

[1] MedDRA version 21.1
[2] Number of Patients used as denominator to calculate percentages.
[3] Treatment-Emergent Adverse Event (TEAEs) are defined as adverse events that occurred on and after the first dose date up to 30 days post last dose date. Patients with multiple TEAEs were only counted once within a summary category: system organ class, preferred term. Patients with events in more than one category were counted once within each category.
Cross-References: Listing 16.2.7.1, 16.2.7.4

PROGRAMMER'S NOTES:
Sort System Organ Class and then Preferred term in descending order using "Overall" frequency column.
Excludes events with incomplete information for grade or drug relationship. Add footnote if required: See Listing 16.2.7.4 for excluded events.
Medical writer will determine the appropriate percentage cut-off point e.g., 5% or 10 % in CSR.
Present Part A and Part B output separately, adjust title for Part B accordingly.

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Table 14.3.1.3
Summary of Treatment-Emergent Adverse Events by System Organ Class (Dose Escalation Part A)
Safety Evaluable (N=n)

<0.15 mg/kg>

MedDRA System Organ Class [1][2]	All TEAE	Drug-Related[4] Any Grade [5]	Grade>= 3 [5]	Drug-Related >=Grade 3 [4][5]
Number of Patients	nnn	nnn	nnn	nnn
Number of Patients with Any TEAE [3]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Blood and lymphatic system disorders	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Cardiac disorders	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Ear and labyrinth disorders	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Eye disorders	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Gastrointestinal disorders	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
General disorders and administration site conditions	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Infections and infestations	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Investigations	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Metabolism and nutrition disorders	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Musculoskeletal and connective tissue disorders	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Nervous system disorders	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Psychiatric disorders	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Renal and urinary disorders	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Reproductive system and breast disorders	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Respiratory, thoracic and mediastinal disorders	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Skin and subcutaneous tissue disorders	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Vascular disorders	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)

[1] MedDRA version 21.1
[2] Number of Patients used as denominator to calculate percentages.

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[3] Treatment-Emergent Adverse Events (TEAEs) are defined as adverse events that occurred on and after the first dose date up to 30 days post last dose date. Patients with multiple TEAEs were only counted once within a summary category: system organ class, preferred term, maximum grade, or relationship to treatment. Patients with events in more than one category were counted once within each category.
[4] Drug Related include relationship as Definite or Probable or Possible.
[5] Grade: 1=Mild, 2=Moderate, 3=Severe, 4=Life threatening, 5= Death
Cross-References: Listing 16.2.7.1, 16.2.7.4

PROGRAMMERS NOTES:
Sort System Organ Class in descending order using "All TEAE" frequency column.
Excludes events with incomplete information for grade or drug relationship. Add footnote if required: See Listing 16.2.7.4 for excluded events.
Repeat for
<0.3 mg/kg>
onwards
<Overall for Dose Escalation>
Present Part A and Part B output separately, adjust title for Part B accordingly.

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Table 14.3.1.4
Summary of Drug-Related, Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Dose Escalation Part A)
Safety Evaluable (N=n)

MedDRA System Organ Class	NBF-006 Dose Level (mg/kg) for Escalation (Part A)				NBF-006 Dose Expansion (mg/kg) (Part B)			
MedDRA Preferred Term [1][2]	0.15	0.3	onwards	Overall	0.6	1.2	1.6	Overall
Number of Patients	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Number of Patients with Any Drug-Related TEAE[3][4]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA System Organ Class	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA System Organ Class	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)

[1] MedDRA version 21.1
[2] Number of Patients used as denominator to calculate percentages.
[3] Treatment-Emergent Adverse Events (TEAEs) are defined as adverse events that occurred on and after the first dose date up to 30 days post last dose date. Patients with multiple TEAEs were counted once within a summary category: system organ class, preferred term, or relationship to therapy. Patients with events in more than one category were counted once within each category.
[4] Drug Related include relationship as Definite or Probable or Possible.
Cross-References: Listing 16.2.7.1, 16.2.7.4

PROGRAMMER'S NOTES:
Sort System Organ Class and then Preferred term in descending order using "Overall" frequency column.
Excludes events with incomplete information for grade or drug relationship. Add footnote if required: See Listing 16.2.7.4 for excluded events.
Present Part A and Part B output separately, adjust title for Part B accordingly.

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Table 14.3.1.5
Summary of Grade 3 or Greater, Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Dose Escalation Part A)
Safety Evaluable (N=n)

MedDRA System Organ Class	NBF-006 Dose Level (mg/kg) for Escalation (Part A)				NBF-006 Dose Expansion (mg/kg) (Part B)			
MedDRA Preferred Term [1][2]	0.15	0.3	onwards	Overall	0.6	1.2	1.6	Overall
Number of Patients	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Number of Patients with Any Grade 3 or Greater TEAE [3][4]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA System Organ Class	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA System Organ Class	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)

[1] MedDRA version 21.1
[2] Number of Patients used as denominator to calculate percentages.
[3] Treatment-Emergent Adverse Events (TEAEs) are defined as adverse events that occurred on and after the first dose date up to 30 days post last dose date. Patients with multiple TEAEs were counted once within a summary category: system organ class, preferred term, or maximum grade. Patients with events in more than one category were counted once within each category.
[4] Grade: 3=Severe, 4=Life threatening, 5=Fatal
Cross-References: Listing 16.2.7.1, 16.2.7.4

PROGRAMMER'S NOTES:
Sort System Organ Class and then Preferred term in descending order using "Overall" frequency column.
Excludes events with incomplete information for grade or drug relationship. Add footnote if required: See Listing 16.2.7.4 for excluded events.
Medical writer will determine the appropriate percentage cut-off point e.g., 5% or 10 % in CSR.
Present Part A and Part B output separately, adjust title for Part B accordingly.

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Table 14.3.1.6
Summary of Grade 3 or Greater, Drug-Related, TEAE by System Organ Class and Preferred Term (Dose Escalation Part A)
Safety Evaluable (N=n)

MedDRA System Organ Class	NBF-006 Dose Level (mg/kg) for Escalation (Part A)				NBF-006 Dose Expansion (mg/kg) (Part B)			
MedDRA Preferred Term [1][2]	0.15	0.3	onwards	Overall	0.6	1.2	1.6	Overall
Number of Patients	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Number of Patients with Any Drug-Related Grade >=3 TEAE [3][4][5]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA System Organ Class	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA System Organ Class	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)

[1] MedDRA version 21.1
[2] Number of Patients used as denominator to calculate percentages.
[3] Treatment-Emergent Adverse Events (TEAEs) are defined as adverse events that occurred on and after the first dose date up to 30 days post last dose date. Patients with multiple TEAEs were counted once within a summary category: system organ class, preferred term, maximum grade, or relationship to therapy. Patients with events in more than one category were counted once within each category.
[4] Grade: 3=Severe, 4=Life threatening, 5=Fatal.
[5] Drug Related include relationship as Definite or Probable or Possible.
Cross-References: Listing 16.2.7.1, 16.2.7.4

PROGRAMMER'S NOTES:
Sort System Organ Class and then Preferred term in descending order using "Overall" frequency column.
Excludes events with incomplete information for grade or drug relationship. Add footnote if required: See Listing 16.2.7.4 for excluded events.
Medical writer will determine the appropriate percentage cut-off point e.g., 5% or 10 % in CSR.
Present Part A and Part B output separately, adjust title for Part B accordingly.

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Table 14.3.1.7
Summary of TEAE by Maximum Severity Grade, System Organ Class and Preferred Term (Dose Escalation Part A)
Safety Evaluable (N=n)

MedDRA System Organ Class MedDRA Preferred Term	NBF-006 Dose Level (mg/kg) for Escalation (Part A)				NBF-006 Dose Expansion (mg/kg) (Part B)			
Maximum Severity Grade [1][2]	0.15	0.3	onwards	Overall	0.6	1.2	1.6	Overall
Number of Patients	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Patients with Any TEAE [3]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA System Organ Class	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
< Grade 3	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 1	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 2	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 3	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 4	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 5	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
>= Grade 3	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)

[1] MedDRA version 21.1
[2] Number of Patients used as denominator to calculate percentages.
[3] Treatment-Emergent Adverse Event (TEAEs) are defined as adverse events that occurred on and after the first dose date up to 30 days post last dose date. Patients with multiple TEAEs were only counted once within a summary category: system organ class, preferred term or maximum grade. Patients with events in more than one category were counted once within each category.
Cross-References: Listing 16.2.7.1, 16.2.7.4

PROGRAMMER'S NOTES:
Sort System Organ Class and then Preferred term in descending order using "Overall" frequency column.
Excludes events with incomplete information for grade or drug relationship. Add footnote if required: See Listing 16.2.7.4 for excluded events.
Present Part A and Part B output separately, adjust title for Part B accordingly.

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Table 14.3.1.8
Summary of Drug-Related, TEAE by Maximum Severity Grade, System Organ Class and Preferred Term (Dose Escalation Part A)
Safety Evaluable (N=n)

MedDRA System Organ Class MedDRA Preferred Term Maximum Severity Grade [1][2]	NBF-006 Dose Level (mg/kg) for Escalation (Part A)				NBF-006 Dose Expansion (mg/kg) (Part B)			
	0.15	0.3	onwards	Overall	0.6	1.2	1.6	Overall
Number of Patients	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Patients with Any Drug-Related TEAE[3][4]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA System Organ Class	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
< Grade 3	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 1	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 2	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 3	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 4	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 5	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
>= Grade 3	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)

[1] MedDRA version 21.1
[2] Number of Patients used as denominator to calculate percentages.
[3] Treatment-Emergent Adverse Event (TEAEs) are defined as adverse events that occurred on and after the first dose date up to 30 days post last dose date. Patients with multiple TEAEs were only counted once within a summary category: system organ class, preferred term, maximum grade or relationship to therapy. Patients with events in more than one category were counted once within each category.
[4] Drug Related include relationship as Definite or Probable or Possible.
Cross-References: Listing 16.2.7.1, 16.2.7.4

PROGRAMMER'S NOTES:
Sort System Organ Class and then Preferred term in descending order using "Overall" frequency column.
Excludes events with incomplete information for grade or drug relationship. Add footnote if required: See Listing 16.2.7.4 for excluded events.
Present Part A and Part B output separately, adjust title for Part B accordingly.

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Table 14.3.1.9
Summary of Serious Adverse Events by System Organ Class and Preferred Term (Dose Escalation Part A)
Safety Evaluable (N=n)

MedDRA System Organ Class	NBF-006 Dose Level (mg/kg) for Escalation (Part A)				NBF-006 Dose Expansion (mg/kg) (Part B)			
MedDRA Preferred Term [1][2]	0.15	0.3	onwards	Overall	0.6	1.2	1.6	Overall
Number of Patients	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Number of Patients with Any Serious Adverse Event	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA System Organ Class	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA System Organ Class	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)

[1] MedDRA version 21.1
[2] Number of Patients used as denominator to calculate percentages.
Cross-References: Listing 16.2.7.1, 16.2.7.4

PROGRAMMER'S NOTES:
Use Serious Code >1. Serious: 1=Not serious, 2=Results in Death, 3=Life threatening, 4=Requires or Prolongs Hospitalization, 5=Persist or Significant Disability/Incapacity, 6=Congenital Anomaly or Birth Defect, 7=Other Medically Important Serious Event.
Sort System Organ Class and then Preferred term in descending order based on "Overall" column frequency.
Present Part A and Part B output separately, adjust title for Part B accordingly.

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Table 14.3.1.10
Summary of Death On-Study or within 30 Days Post Last Dose (Dose Escalation Part A)
Safety Evaluable (N=n)

	NBF-006 Dose Level (mg/kg) for Escalation (Part A)				NBF-006 Dose Expansion (mg/kg) (Part B)			
Primary Cause of Death[1]	0.15	0.3	onwards	Overall	0.6	1.2	1.6	Overall
Number of Patients	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
All Death								
Primary Cause	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Primary Cause	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Primary Cause	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Death within 30 days of Last Dose								
Primary Cause	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Primary Cause	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Primary Cause	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)

[1] Number of Patients used as denominator to calculate percentages.
Cross-References: Listing 16.2.7.4

PROGRAMMER'S NOTES:
Present Part A and Part B output separately, adjust title for Part B accordingly.

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14.3.2 Listings of Death, Other Serious and Significant Adverse Events

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Table 14.3.2.1
Patient Listing of Treatment-Emergent Adverse Events Leading to Death
Safety Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	MedDRA Preferred Term	Day [1]	Grade [2]	Duration (day) [3]	Drug Related[4]	Outcome [5]
ccc-pppp/xx/x	x	xx	xxx	x	xx	xx	Possible	x
			xxx	x	xx	xx	Possible	x
			xxx	x	xx	xx	Related	x
ccc-pppp/xx/x	x	xx	xxx	x	xx	xx	Possible	x
			xxx	x	xx	xx	Possible	x
			xxx	x	xx	xx	Possible	x
ccc-pppp/xx/x	x	xx	xxx	x	xx	xx	Related	x
			xxx	x	xx	xx	Possible	x

MedDRA version 21.1
[1] Day is relative to the first dose date.
[2] Grade: 1=Mild, 2=Moderate, 3=Severe, 4=Life threatening, 5=Fatal.
[3] Duration of adverse event is calculated in days from Onset Date to Resolution Date.
[4] Drug Related include relationship as Definite or Probable or Possible.
[5] Outcome: 1=Recovered/Resolved, 2=Recovered/Resolved with sequelae, 3=Recovering/Resolving, 4=Not Recovered /Not Resolved, 5=Fatal, 6=Unknown
Cross-References: Listing 16.2.7.1, 16.2.7.4

PROGRAMMER'S NOTES:
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.

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Table 14.3.2.2
Patient Listing of Serious Adverse Events
Safety Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	MedDRA Preferred Term	Day [1]	Grade [2]	Duration (day) [3]	Drug Related[4]	Outcome [5]
ccc-pppp/xx/x	x	xx	xxx	x	xx	xx	Possible	x
			xxx	x	xx	xx	Possible	x
			xxx	x	xx	xx	Related	x
ccc-pppp/xx/x	x	xx	xxx	x	xx	xx	Possible	x
			xxx	x	xx	xx	Possible	x
			xxx	x	xx	xx	Possible	x
ccc-pppp/xx/x	x	xx	xxx	x	xx	xx	Related	x
			xxx	x	xx	xx	Possible	x

MedDRA version 21.1
[1] Day is relative to the first dose date.
[2] Grade: 1=Mild, 2=Moderate, 3=Severe, 4=Life threatening, 5=Fatal.
[3] Duration of adverse event is calculated in days from Onset Date to Resolution Date.
[4] Drug Related include relationship as Definite or Probable or Possible.
[5] Outcome: 1=Recovered/Resolved, 2=Recovered/Resolved with sequelae, 3=Recovering/Resolving, 4=Not Recovered /Not Resolved, 5=Fatal, 6=Unknown
Cross-References: Listing 16.2.7.1, 16.2.7.3, 16.2.7.4

PROGRAMMER'S NOTES:
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.

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Table 14.3.2.3
Patient Listing of Treatment-Emergent Adverse Events Leading to Drug Withdrawn
Safety Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	MedDRA Preferred Term	Day [1]	Grade [2]	Duration (Days) [3]	Drug Related[4]	Outcome [5]
ccc-pppp /xx/x	x	xx	MedDRA PT	x	xx	x	Possible	x
		xx	MedDRA PT	x	xx	xx	Related	x
ccc-pppp /xx/x	x	xx	MedDRA PT	x	xx	x	Unrelated	x
		xx	MedDRA PT	x	xx	xx	Possible	x
		xx	MedDRA PT	x	xx	xx	Related	x
ccc-pppp /xx/x	x	xx	MedDRA PT	x	xx	xx	Possible	x
		xx	MedDRA PT	x	xx	xx	Related	x

MedDRA version 21.1
[1] Day is relative to the first dose date.
[2] Grade: 1=Mild, 2=Moderate, 3=Severe, 4=Life threatening, 5=Fatal.
[3] Duration of adverse event is calculated in days from Onset Date to Resolution Date.
[4] Drug Related include relationship as Definite or Probable or Possible.
[5] Outcome: 1=Recovered/Resolved, 2=Recovered/Resolved with sequelae, 3=Recovering/Resolving, 4=Not Recovered /Not Resolved, 5=Fatal, 6=Unknown.
Cross-References: Listing 16.2.7.1, 16.2.7.2.3, 16.2.7.4

PROGRAMMERS NOTES:
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.

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Table 14.3.2.4
Patient Listing of Dose Limiting Toxicities
DLT Evaluable (N=n)

Patient/ Age/Sex	Study Part	NBF-006 Dose (mg/kg)	MedDRA Preferred Term	Day [1]	Grade [2]	Duration (Days) [3]	Drug Related[4]	Outcome [5]
ccc-pppp/ xx/x	x	xx	MedDRA PT	x	xx	xx	Possible	x
			MedDRA PT	x	xx	xx	Related	x
ccc-pppp/ xx/x	x	xx	MedDRA PT	x	xx	xx	Unrelated	x
			MedDRA PT	x	xx	xx	Possible	x
			MedDRA PT	x	xx	xx	Related	x
ccc-pppp/ xx/x	x	xx	MedDRA PT	x	xx	xx	Possible	x

MedDRA version 21.1
DLT= Dose Limiting Toxicity
[1] Day is relative to the first dose date.
[2] Grade: 1=Mild, 2=Moderate, 3=Severe, 4=Life threatening, 5=Fatal.
[3] Duration of Adverse Event calculated in days from the Onset Date to the Resolution Date.
[4] Drug Related include relationship as Definite or Probable or Possible.
[5] Outcome: 1=Fatal, 2= Not Recovered/Not Resolved, 3= Recovered/Resolved, 4= Recovered/Resolved with sequelae, 5=Recovering/Resolving, 6=Unknown
Cross-References: Listing 16.2.7.1, 16.2.7.4

PROGRAMMER'S NOTES:
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.

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14.3.3 Adverse Events of Special Interest

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Table 14.3.3.1
Summary of Dose Limiting Toxicities by System Organ Class and Preferred Term During Cycle One
DLT Evaluable (N=n)

MedDRA System Organ Class	NBF-006 Dose Level (mg/kg) for Escalation (Part A)					
MedDRA Preferred Term [1]	0.15	0.3	0.6	1.2	1.6	Overall
Number of Patients	nnn	nnn	nnn	nnn		nnn
Patients with Any DLT [2][3]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA System Organ Class	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA System Organ Class	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)

DLT= Dose Limiting Toxicity
[1] MedDRA version 21.1
[2] Number of Patients used as denominator to calculate percentages.
[3] Only those DLTs occurring during Cycle 1 will be used to make decisions regarding dose escalation and tolerability.
Cross-References: Table 14.3.2.4, Listing 16.2.7.1, 16.2.7.4

PROGRAMMER'S NOTES:
Sort System Organ Class and then Preferred term in descending order using 'Overall' frequency column.
Excludes events with incomplete information for grade or drug relationship. Add footnote if required: See Listing 16.2.7.4 for excluded events.

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Table 14.3.3.2
Summary of Infusion-Related Reaction by Maximum Severity Grade, System Organ Class and Preferred Term (Dose Escalation Part A)
Safety Evaluable (N=n)

MedDRA System Organ Class MedDRA Preferred Term	NBF-006 Dose Level (mg/kg) for Escalation (Part A)				NBF-006 Dose Expansion (mg/kg) (Part B)			
Maximum Severity Grade [1][2]	0.15	0.3	onwards	Overall	0.6	1.2	1.6	Overall
Number of Patients	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Patients with Any TEAE [3]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA System Organ Class	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
MedDRA Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
< Grade 3	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 1	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 2	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 3	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 4	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 5	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
>= Grade 3	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)

[1] MedDRA version 21.1
[2] Number of Patients used as denominator to calculate percentages.
[3] Infusion-related reaction (IRR) signs and symptoms include back pain, fever and/or shaking chills, flushing and/or itching, alterations in heart rate and blood pressure, dyspnea or chest discomfort, skin rashes, or anaphylaxis (e.g., generalized urticaria, angioedema, wheezing, hypotension, tachycardia, etc.).
Cross-References: Listing 16.2.7.1, 16.2.7.4

PROGRAMMER'S NOTES:
Sort System Organ Class and then Preferred term in descending order using "Overall" frequency column.
Excludes events with incomplete information for grade or drug relationship. Add footnote if required: See Listing 16.2.7.4 for excluded events.
Present Part A and Part B output separately, adjust title for Part B accordingly.

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14.3.4 Abnormal Laboratory Value Listing

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Table 14.3.4
Patient Listing of Grade 3 and 4 Abnormal Laboratory Values During Treatment
Safety Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Abnormal Laboratory Test (unit)	Baseline Grade [1]	Grade Grade [1]	Day [2]	Lab Result	Reference Range Indicator
ccc-pppp /xx/x	x	xx	Test Name (xxx)	x	x	xx	x	High
		xx	Test Name (xxx)	x	x	xx	xx	Low
ccc-pppp /xx/x	x	xx	Test Name (xxx)	x	x	xx	x	Low
		xx	Test Name (xxx)	x	x	xx	xx	High
		xx	Test Name (xxx)	x	x	xx	xx	High
ccc-pppp /xx/x	x	xx	Test Name (xxx)	x	x	xx	xx	Low
		xx	Test Name (xxx)	x	x	xx	xx	Low

[1] Grade: 3= Severe, 4= Life threatening, 5= Fatal.
[2] Day is relative to the first dose date.
Cross-References: Listing 16.2.8.1-16.2.8.3

PROGRAMMER'S NOTES:
Sort "Patient" in ascending order using "pppp", and then "ccc" and "ll" portions of patient number.
During Treatment is the period from first dose up to 30 days post last dose study drug.

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14.3.5 Other Safety Data Summary Tables

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Table 14.3.5.1.1
Summary of NBF-006 Administration and Compliance for Cycle One (Dose Escalation Part A)
Safety Evaluable (N=n)

	NBF-006 Dose Level (mg/kg) for Escalation (Part A)			
NBF-006 Administration	0.15	0.3	onwards	Overall
Number of Patients	nnn	nnn	nnn	nnn
Duration of Exposure [1]				
N	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx
Maximum	xx	xx	xx	xx
Total Actual Dose (mg) [2]				
N	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx
Maximum	xx	xx	xx	xx
Total Target Dose (mg/kg) [3]				
N	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx
Maximum	xx	xx	xx	xx
Compliance (%) [4][5]				
>100%	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
100%	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
<100%	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)

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Cycle one length = 6 weeks (42 days)
[1] Duration of Exposure is the duration between the first dose and last dose of NBF-006 during the study.
[2] Total Actual Dose is the sum of all NBF-006 administered over the entire course of the study.
[3] Total Target Dose is the sum of intended NBF-006 doses during the duration of exposure, based on no modifications to dose or schedule.
[4] Percent Compliance is the total actual NBF-006 dose divided by total target NBF-006 dose multiplied by 100% for each patient.
[5] Number of patients used as denominator to calculate percentages.
Cross-References: Listing 16.2.5.1

PROGRAMMERS NOTES:
Compliance categories may need to be modified based on the data.

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Table 14.3.5.1.2
Summary of NBF-006 Administration and Compliance for All Treatment Cycles (Dose Escalation Part A)
Safety Evaluable (N=n)

	NBF-006 Dose Level (mg/kg) for Escalation (Part A)				NBF-006 Dose Expansion (mg/kg) (Part B)			
NBF-006 Administration	0.15	0.3	onwards	Overall	0.6	1.2	1.6	Overall
Number of Patients	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Number of Cycles [1]								
N	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx	xx	xx
Duration of Exposure [2]								
N	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx	xx	xx
Total Actual Dose (mg) [3]								
N	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx	xx	xx
Total Target Dose (mg) [4]								
N	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx

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Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx	xx	xx
Compliance (%) [5]								
>100%	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
100%	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
<100%	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)

[1] Incomplete treatment cycles are included in counts.
[2] Duration of Exposure is the duration between the first dose and last dose of NBF-006 during the study.
[3] Total Dose is the sum of all NBF-006 administered over the entire course of the study.
[4] Total Intended Dose is the sum of intended NBF-006 doses during the duration of exposure, based on no modifications to dose or schedule.
[5] Percent Compliance is the total NBF-006 dose divided by Total Intended NBF-006 dose multiplied by 100% for each patient.
Cross-References: Listing 16.2.5.1

PROGRAMMER'S NOTES:
Compliance categories may need to be modified based on the data.
Present Part A and Part B output separately, adjust title for Part B accordingly.

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Table 14.3.5.1.3
Summary of NBF-006 Dose Delayed/Interrupted/Withdrawn (Dose Escalation Part A)
Safety Evaluable (N=n)

	NBF-006 Dose Level (mg/kg) for Escalation (Part A)				NBF-006 Dose Expansion (mg/kg) (Part B)			
NBF-006 Administration	0.15	0.3	onwards	Overall	0.6	1.2	1.6	Overall
Number of Patients	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Patients with Dose Delayed [1]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Yes	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Adverse Event	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Non-compliance	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Other	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
No	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Patients with Dose Interrupted [1]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Yes	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Adverse Event	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Non-compliance	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Other	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
No	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Patients with Dose Skipped[1]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Yes	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Adverse Event	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Non-compliance	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Other	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
No	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Patients with NBF-006 Withdrawn Due to								
Adverse Event	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
xxxxxx	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
xxxxxx	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)

[1] Number of Patients used as denominator to calculate percentages.
Cross-References: Listing 16.2.7.2.1-3

PROGRAMMER'S NOTES:
Based on the CRF NBF-006 Exposure page and Adverse Events page.
Present Part A and Part B output separately, adjust title for Part B accordingly.
Present Dose Skipped after Cycle 3 only data is available.

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Table 14.3.5.1.4
Summary of Concomitant Measures (Dose Escalation Part A)
Safety Evaluable (N=n)

WHO-DD ATC Class Category Level II	NBF-006 Dose Level (mg/kg) for Escalation (Part A)				NBF-006 Dose Expansion (mg/kg) (Part B)			
WHO-DD Preferred Term [1][2]	0.15	0.3	onwards	Overall	0.6	1.2	1.6	Overall
Number of Patients	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Number of Patients Taking Concomitant Measures[3][4]	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
WHO-DD ATC Class Category Level II	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
WHO-DD Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
WHO-DD Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
WHO-DD Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
WHO-DD Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
WHO-DD ATC Class Category Level II	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
WHO-DD Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
WHO-DD Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
WHO-DD Preferred Term	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)

[1] World Health Organization Drug Dictionary (WHO-DD) version 2018
[2] Number of Patients used as denominator to calculate percentages.
[3] Patients may be counted in more than one therapeutic class; patients are only counted once within a therapeutic class.
[4] Summarizes medications (except for study drug) taken on or after the date of the first study drug dose up to last dose+30 days.
Cross-References: Listing 16.2.10.1, 16.2.10.2

PROGRAMMER'S NOTES:
Include all "Therapeutic Class" categories found in the database.
Sort "Therapeutic Class" column in descending order based on "Overall" column frequency count.
Present Part A and Part B output separately, adjust title for Part B accordingly

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Table 14.3.5.2.1
Summary of Change from Baseline during Treatment Period for Hematology Tests (Dose Escalation Part A)
Safety Evaluable (N=n)

Hematology Test	NBF-006 Dose Level (mg/kg) for Escalation (Part A)											
Timepoint	0.15			0.3			onwards			Overall		
Statistics	Actual	Change	%Change	Actual	Change	%Change	Actual	Change	%Change	Actual	Change	%Change
Lab Parameter 1 (unit)												
Baseline												
N	nnn			nnn			nnn			nnn		
Mean	xx.x			xx.x			xx.x			xx.x		
Standard Deviation	x.xx			x.xx			x.xx			x.xx		
Median	xx.x			xx.x			xx.x			xx.x		
Minimum	xx			xx			xx			xx		
Maximum	xx			xx			xx			xx		
Timepoint												
N	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Median	xx.x			xx.x			xx.x			xx.x	xx.x	
Minimum	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Lab Parameter 2 (unit)												

Cross-Reference: Listing 16.2.8.1

PROGRAMMERS NOTES:
Hematology Tests: hemoglobin, hematocrit, platelets, RBC and WBC and differentials, combined other cells.
Protocol Study Event Schedule and windowing will be used.

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Table 14.3.5.2.1
Summary of Change from Baseline during Treatment Period for Hematology Tests (Dose Expansion Part B)
Safety Evaluable (N=n)

Hematology Test	NBF-006 Dose Expansion (mg/kg) (Part B)											
Timepoint	0.6			1.2			1.6			Overall		
Statistics	Actual	Change	%Change	Actual	Change	%Change	Actual	Change	%Change	Actual	Change	%Change
Lab Parameter 1 (unit)												
Baseline												
N	nnn			nnn			nnn			nnn		
Mean	xx.x			xx.x			xx.x			xx.x		
Standard Deviation	x.xx			x.xx			x.xx			x.xx		
Median	xx.x			xx.x			xx.x			xx.x		
Minimum	xx			xx			xx			xx		
Maximum	xx			xx			xx			xx		
Timepoint												
N	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Lab Parameter 2 (unit)												

Cross-Reference: Listing 16.2.8.1

PROGRAMMERS NOTES:
Hematology Tests: hemoglobin, hematocrit, platelets, RBC and WBC and differentials, combined other cells.
Protocol Study Event Schedule and windowing will be used.
Present Part A and Part B output separately, adjust title for Part B accordingly.

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Table 14.3.5.2.2
Summary of Change from Baseline during Treatment Period for Blood Chemistry Tests (Dose Escalation Part A)
Safety Evaluable (N=n)

Chemistry Test	NBF-006 Dose Level (mg/kg) for Escalation (Part A)											
Timepoint	0.15			0.3			onwards			Overall		
Statistics	Actual	Change	%Change	Actual	Change	%Change	Actual	Change	%Change	Actual	Change	%Change
Lab Parameter 1 (unit)												
Baseline												
N	nnn			nnn			nnn			nnn		
Mean	xx.x			xx.x			xx.x			xx.x		
Standard Deviation	x.xx			x.xx			x.xx			x.xx		
Median	xx.x			xx.x			xx.x			xx.x		
Minimum	xx			xx			xx			xx		
Maximum	xx			xx			xx			xx		
Timepoint												
N	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Lab Parameter 2 (unit)												

Cross-Reference: Listing 16.2.8.2

PROGRAMMERS NOTES:
Blood Chemistry Tests: BUN, Sodium, Chloride, Phosphatase, Bicarbonate, Uric Acid, Direct Bilirubin, Total Bilirubin, Alkaline Phosphatase, SGPT/ALT, SGOT/AST, GGT, Creatine, Potassium, Calcium, Magnesium, Creatine Kinase, Total Protein, Albumin, Glucose.
Protocol Study Event Schedule and windowing will be used.

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Table 14.3.5.2.2
Summary of Change from Baseline during Treatment Period for Blood Chemistry Tests (Dose Expansion Part B)
Safety Evaluable (N=n)

Chemistry Test	NBF-006 Dose Expansion (mg/kg) (Part B)											
Timepoint	0.6			1.2			1.6			Overall		
Statistics	Actual	Change	%Change	Actual	Change	%Change	Actual	Change	%Change	Actual	Change	%Change
Lab Parameter 1 (unit)												
Baseline												
N	nnn			nnn			nnn			nnn		
Mean	xx.x			xx.x			xx.x			xx.x		
Standard Deviation	x.xx			x.xx			x.xx			x.xx		
Median	xx.x			xx.x			xx.x			xx.x		
Minimum	xx			xx			xx			xx		
Maximum	xx			xx			xx			xx		
Timepoint												
N	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Lab Parameter 2 (unit)												

Cross-Reference: Listing 16.2.8.2

PROGRAMMERS NOTES:
Blood Chemistry Tests: BUN, Sodium, Chloride, Phosphatase, Bicarbonate, Uric Acid, Direct Bilirubin, Total Bilirubin, Alkaline Phosphatase, SGPT/ALT, SGOT/AST, GGT, Creatine, Potassium, Calcium, Magnesium, Creatine Kinase, Total Protein, Albumin, Glucose.
Protocol Study Event Schedule and windowing will be used.
Present Part A and Part B output separately, adjust title for Part B accordingly.

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Table 14.3.5.2.3
Summary of Change from Baseline during Treatment Period for Urinalysis Tests (Dose Escalation Part A)
Safety Evaluable (N=n)

Urinalysis Test	NBF-006 Dose Level (mg/kg) for Escalation (Part A)											
Timepoint	0.15			0.3			onwards			Overall		
Statistics	Actual	Change	%Change	Actual	Change	%Change	Actual	Change	%Change	Actual	Change	%Change
Lab Parameter 1 (unit)												
Baseline												
N	nnn			nnn			nnn			nnn		
Mean	xx.x			xx.x			xx.x			xx.x		
Standard Deviation	x.xx			x.xx			x.xx			x.xx		
Median	xx.x			xx.x			xx.x			xx.x		
Minimum	xx			xx			xx			xx		
Maximum	xx			xx			xx			xx		
Timepoint												
N	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Lab Parameter 2 (unit)												

Cross-Reference: Listing 16.2.8.3

PROGRAMMERS NOTES:
Urinalysis Test: Specific gravity, pH, Glucose, Protein, Ketones, Nitrite, and Leukocyte Esterase, and microscopic tests.
Protocol Study Event Schedule and windowing will be used.

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Table 14.3.5.2.3
Summary of Change from Baseline during Treatment Period for Urinalysis Tests (Dose Expansion Part B)
Safety Evaluable (N=n)

Urinalysis Test	NBF-006 Dose Expansion (mg/kg) (Part B)											
Timepoint	0.6			1.2			1.6			Overall		
Statistics	Actual	Change	%Change	Actual	Change	%Change	Actual	Change	%Change	Actual	Change	%Change
Lab Parameter 1 (unit)												
Baseline												
N	nnn			nnn			nnn			nnn		
Mean	xx.x			xx.x			xx.x			xx.x		
Standard Deviation	x.xx			x.xx			x.xx			x.xx		
Median	xx.x			xx.x			xx.x			xx.x		
Minimum	xx			xx			xx			xx		
Maximum	xx			xx			xx			xx		
Timepoint												
N	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Lab Parameter 2 (unit)												
Baseline												

Cross-Reference: Listing 16.2.8.3

PROGRAMMERS NOTES:
Urinalysis Test: Specific gravity, pH, Glucose, Protein, Ketones, Nitrite, and Leukocyte Esterase, and microscopic tests.
Protocol Study Event Schedule and windowing will be used.
Present Part A and Part B output separately, adjust title for Part B accordingly.

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Table 14.3.5.3.1
Summary of Shift from Baseline to Maximum CTCAE Grade during Treatment Period for Hematology Tests (Dose Escalation Part A)
Safety Evaluable (N=n)

Hematology Test	Baseline Severity Grade					
NBF-006 Dose Maximum CTCAE Grade [1][2]	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Overall
Lab Parameter 1 (unit)						
0.15 mg/kg						
Grade 0	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 1	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 2	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 3	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 4	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Overall	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nnn (100.0%)
0.3 mg/kg						
Grade 0	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 1	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 2	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 3	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 4	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
onwards						
Overall	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nnn (100.0%)
Lab Parameter 2 (unit)						
Overall for All Dose Levels						

[1] Number of patients with both a baseline evaluation and an on-study evaluation used as denominator to calculate percentages.
[2] Maximum CTCAE Grade was defined as the highest CTCAE Grade reported for a patient after first dose.
Cross-References: Listing 16.2.8.1

PROGRAMMER'S NOTES:
Grand total used as denominator to calculate percentages within each category.
Hematology Parameters: hemoglobin, hematocrit, platelets, RBC and WBC and differentials, combined other cells.
Only gradable parameters are included in the table.
Present Part A and Part B output separately, adjust title for Part B accordingly.

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Table 14.3.5.3.2
Summary of Shift from Baseline to Maximum CTCAE Grade during Treatment Period for Blood Chemistry Tests (Dose Escalation Part A)
Safety Evaluable (N=n)

Blood Chemistry Test	Baseline Severity Grade					
NBF-006 Dose Maximum CTCAE Grade [1][2]	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Overall
Lab Parameter1 (unit)						
0.15 mg/kg						
Grade 0	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 1	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 2	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 3	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 4	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Overall	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nnn (100.0%)
0.3 mg/kg						
Grade 0	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 1	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 2	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 3	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 4	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
onwards						
Overall	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nnn (100.0%)
Lab Parameter2 (unit)						
Overall for All Dose Levels						

[1] Number of patients with both a baseline evaluation and an on-study evaluation used as denominator to calculate percentages.
[2] Maximum CTCAE Grade was defined as the highest CTCAE Grade reported for a patient after first dose.
Cross-References: Listing 16.2.8.2

PROGRAMMER'S NOTES:
Grand total used as denominator to calculate percentages within each category.
Blood Chemistry tests: BUN, Sodium, Chloride, Phosphatase, Bicarbonate, Uric Acid, Direct Bilirubin, Total Bilirubin, Alkaline Phosphatase, SGPT/ALT, SGOT/AST, GGT, Creatine, Potassium, Calcium, Magnesium, Creatine Kinase, Total Protein, Albumin, Glucose.
Only gradable parameters are included.
Present Part A and Part B output separately, adjust title for Part B accordingly.

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Table 14.3.5.3.3
Summary of Shift from Baseline to Maximum CTCAE Grade during Treatment Period for Urinalysis Tests (Dose Escalation Part A)
Safety Evaluable (N=n)

Urinalysis Test	Baseline Severity Grade					
NBF-006 Dose Maximum CTCAE Grade [1][2]	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Overall
Lab Parameter1 (unit)						
0.15 mg/kg						
Grade 0	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 1	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 2	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 3	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 4	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Overall	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nnn (100.0%)
0.3 mg/kg						
Grade 0	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 1	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 2	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 3	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Grade 4	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
onwards						
Overall	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nnn (100.0%)
Lab Parameter2 (unit)						
Overall for All Dose Levels						

[1] Number of patients with both a baseline evaluation and an on-study evaluation used as denominator to calculate percentages.
[2] Maximum CTCAE Grade was defined as the highest CTCAE Grade reported for a patient after first dose.
Cross-References: Listing 16.2.8.3

PROGRAMMERS NOTES:
Grand total used as denominator to calculate percentages within each category.
Urinalysis Tests: Specific gravity, pH, Glucose, Protein, Ketones, Nitrite, and Leukocyte Esterase, and microscopic tests.
Only gradable parameters are included in the table.
Present Part A and Part B output separately, adjust title for Part B accordingly.

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Table 14.3.5.4
Vital Signs at Baseline Including Weight and Height (Dose Escalation Part A)
Safety Evaluable (N=n)

	NBF-006 Dose Level (mg/kg) for Escalation (Part A)				NBF-006 Dose Expansion (mg/kg) (Part B)			
Vital Signs	0.15	0.3	onwards	Overall	0.6	1.2	1.6	Overall
Number of Patients	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Systolic Blood Pressure (mmHg)								
N	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx	xx	xx
Diastolic Blood Pressure (mmHg)								
N	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx	xx	xx
Pulse (/min)								
N	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx	xx	xx
Temperature (°C)								
N	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx	xx	xx

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Respiration (/min)								
N	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx	xx	xx
Weight (kg)								
N	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx	xx	xx
Height (cm)								
N	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx	xx	xx
BSA								
N	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx	xx	xx

Cross-Reference: Listing 16.2.9.1

PROGRAMMER'S NOTES:
Present Part A and Part B output separately, adjust title for Part B accordingly.

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Table 14.3.5.5.1
Summary of ECG Data and Change from Baseline by Visit (Dose Escalation Part A)
Safety Evaluable (N=n)

ECG Parameter	NBF-006 Dose Level (mg/kg) for Escalation (Part A)											
Timepoint	0.15			0.3			onwards			Overall		
Statistics	Actual	Change	%Change	Actual	Change	%Change	Actual	Change	%Change	Actual	Change	%Change
ECG Parameter 1 (unit)												
Baseline												
N	nnn			nnn			nnn			nnn		
Mean	xx.x			xx.x			xx.x			xx.x		
Standard Deviation	x.xx			x.xx			x.xx			x.xx		
Median	xx.x			xx.x			xx.x			xx.x		
Minimum	xx			xx			xx			xx		
Maximum	xx			xx			xx			xx		
Timepoint												
N	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
<Repeat timepoint>												
ECG Parameter 2 (unit)												

QT=QT interval, QTcF= QT corrected by Fridericia's formula
Cross-Reference: Listing 16.2.9.3

PROGRAMMERS NOTES:
ECG parameters: heart rate, PR, QT, QTcF
Protocol Study Event Schedule and windowing will be used.

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Table 14.3.5.5.2
Summary of ECG Data and Change from Baseline by Visit (Dose Expansion Part B)
Safety Evaluable (N=n)

ECG Parameter	NBF-006 Dose Expansion (mg/kg) (Part B)											
Timepoint	0.6			1.2			1.6			Overall		
Statistics	Actual	Change	%Change	Actual	Change	%Change	Actual	Change	%Change	Actual	Change	%Change
ECG Parameter 1 (unit)												
Baseline												
N	nnn			nnn			nnn			nnn		
Mean	xx.x			xx.x			xx.x			xx.x		
Standard Deviation	x.xx			x.xx			x.xx			x.xx		
Median	xx.x			xx.x			xx.x			xx.x		
Minimum	xx			xx			xx			xx		
Maximum	xx			xx			xx			xx		
Timepoint												
N	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
<Repeat timepoint>												
ECG Parameter 2 (unit)												

QT=QT interval, QTcF= QT corrected by Fridericia's formula
Cross-Reference: Listing 16.2.9.3

PROGRAMMERS NOTES:
ECG parameters: heart rate, PR, QT, QTcF
Protocol Study Event Schedule and windowing will be used.
Present Part A and Part B output separately, adjust title for Part B accordingly.

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Table 14.3.5.6.1
Summary of ECG Parameter QT and QTcF Data by Visit (Dose Escalation Part A)
Safety Evaluable (N=n)

Timepoint	NBF-006 Dose Level (mg/kg) for Escalation (Part A)				NBF-006 Dose Expansion (mg/kg) (Part B)			
ECG Parameter	0.15	0.3	onwards	Overall	0.6	1.2	1.6	Overall
Number of Patients	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Baseline								
QT Interval	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
≤450 msec	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
>450 msec	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
>480 msec	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
>500 msec	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Increase > 30	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Increase > 60	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
QTc Interval								
≤450 msec	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
>450 to 480 msec	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
>480 to 500 msec	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
>500 msec	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Increase > 30	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Increase > 60	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)	nn(xx.x%)
Repeat Timepoint								

QT=QT Interval, QTcF= QT corrected by Fridericia's formula
[1] Number of Patients used as denominator to calculate percentages.
Cross-Reference: Listing 16.2.9.3

PROGRAMMERS NOTES:
ECG parameters: heart rate, PR, QT, QTcF
Present Part A and Part B output separately, adjust title for Part B accordingly.

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Table 14.3.5.7.1
Summary of Shift from Baseline to Maximum ECOG Score (Dose Escalation Part A)
Safety Evaluable (N=n)

NBF-006 Dose Maximum Score [1][2]	Baseline ECOG Performance			
	Score 0	Score 1	Score 2	Overall
0.15 mg/kg				
Score 0	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 1	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 2	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 3	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 4	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 5	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Overall	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Onwards				
Score 0	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 1	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 2	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 3	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 4	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 5	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Overall	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Overall				
Score 0	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 1	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 2	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 3	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 4	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 5	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)

Overall for All Dose Levels

[1] Number of patients with both a baseline evaluation and an on-study evaluation used as denominator to calculate percentages.
[2] Maximum score are the highest ECOG for a patient after first dose.
Cross-References: Listing 16.2.9.4

PROGRAMMER'S NOTES:
Grand total used as denominator to calculate percentages within each category

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Table 14.3.5.7.2
Summary of Shift from Baseline to Maximum ECOG Score (Dose Expansion Part B)
Safety Evaluable (N=n)

NBF-006 Dose Maximum Score [1][2]	Baseline ECOG Performance			
	Score 0	Score 1	Score 2	Overall
0.15 mg/kg				
Score 0	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 1	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 2	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 3	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 4	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 5	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Overall	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Onwards				
Score 0	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 1	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 2	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 3	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 4	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 5	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Overall	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Overall				
Score 0	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 1	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 2	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 3	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 4	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)
Score 5	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)	nnn (xx.x%)

Overall for All Dose Levels

[1] Number of patients with both a baseline evaluation and an on-study evaluation used as denominator to calculate percentages.
[2] Maximum score are the highest ECOG for a patient after first dose.
Cross-References: Listing 16.2.9.4

PROGRAMMERS NOTES:
Grand total used as denominator to calculate percentages within each category.
Present Part A and Part B output separately, adjust title for Part B accordingly.

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14.4 Biomarker Data Summary Tables

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Table 14.4.1.1
Summary of Mean Change from Baseline in TNF-α Overtime (Dose Escalation Part A)
Safety Evaluable (N=n)

	NBF-006 Dose Level (mg/kg) for Escalation (Part A)											
Timepoint	0.15			0.3			onwards			Overall		
Statistics	Actual	Change	%Change	Actual	Change	%Change	Actual	Change	%Change	Actual	Change	%Change
Baseline												
N	nnn			nnn			nnn			nnn		
Mean	xx.x			xx.x			xx.x			xx.x		
Standard Deviation	x.xx			x.xx			x.xx			x.xx		
Median	xx.x			xx.x			xx.x			xx.x		
Minimum	xx			xx			xx			xx		
Maximum	xx			xx			xx			xx		
Timepoint				xx			xx			xx		
N	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
<Repeat timepoint>												

Cross-Reference: Figure 14.4.1.1, Listing 16.2.9.7

PROGRAMMERS NOTES:

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Table 14.4.1.2
Summary of Mean Change from Baseline in TNF-α Overtime (Dose Expansion Part B)
Safety Evaluable (N=n)

	NBF-006 Dose Expansion (mg/kg) (Part B)											
Timepoint	0.6			1.2			1.6			Overall		
Statistics	Actual	Change	%Change	Actual	Change	%Change	Actual	Change	%Change	Actual	Change	%Change
Baseline												
N	nnn			nnn			nnn			nnn		
Mean	xx.x			xx.x			xx.x			xx.x		
Standard Deviation	x.xx			x.xx			x.xx			x.xx		
Median	xx.x			xx.x			xx.x			xx.x		
Minimum	xx			xx			xx			xx		
Maximum	xx			xx			xx			xx		
Timepoint				xx			xx			xx		
N	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn	nnn
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Maximum	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
<Repeat timepoint>												

Present Part A and Part B output separately, adjust title for Part B accordingly.
Present Part B only if data is available (cytokines to be collected if there are symptoms indicative of cytokine induction, e.g., IRRs)

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< Repeat for>

Table 14.4.2.1
Summary of Mean Change from Baseline in IL-1β Overtime (Dose Escalation Part A)
Safety Evaluable (N=n)

Cross-Reference: Figure 14.4.2.1, Listing 16.2.9.7
PROGRAMMER'S NOTES:

Table 14.4.2.2
Summary of Mean Change from Baseline in IL-1β Overtime (Dose Expansion Part B)
Safety Evaluable (N=n)

Cytokines only collected in Part B at 1.6 mg/kg if cytokine induction was seen at 1.6 mg/kg in Part A, or if there are symptoms indicative of cytokine induction.
Cross-References: Figure 14.4.2.2, Listing 16.2.9.7
PROGRAMMER'S NOTES:
Present Part B only if data is available (cytokines to be collected if there are symptoms indicative of cytokine induction, e.g., IRRs).

Table 14.4.3.1
Summary of Mean Change from Baseline in IL-6 Overtime (Dose Escalation Part A)
Safety Evaluable (N=n)

Cross-References: Figure 14.4.3.1, Listing 16.2.9.7
PROGRAMMER'S NOTES:

Table 14.4.3.2
Summary of Mean Change from Baseline in IL-6 Overtime (Dose Expansion Part B)
Safety Evaluable (N=n)

Cytokines only collected in Part B at 1.6 mg/kg if cytokine induction was seen at 1.6 mg/kg in Part A, or if there are symptoms indicative of cytokine induction.
Cross-References: Figure 14.4.3.2, Listing 16.2.9.7
PROGRAMMER'S NOTES:
Present Part B only if data is available (cytokines to be collected if there are symptoms indicative of cytokine induction, e.g., IRRs).

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Table 14.4.4.1
Summary of Mean Change from Baseline in IFN-γ Overtime (Dose Escalation Part A)
Safety Evaluable (N=n)

Cross-References: Figure 14.4.4.1, Listing 16.2.9.7
PROGRAMMER'S NOTES:

Table 14.4.4.2
Summary of Mean Change from Baseline in IFN-γ Overtime (Dose Expansion Part B)
Safety Evaluable (N=n)

Cytokines only collected in Part B at 1.6 mg/kg if cytokine induction was seen at 1.6 mg/kg in Part A, or if there are symptoms indicative of cytokine induction.
Cross-References: Figure 14.4.4.2, Listing 16.2.9.7
PROGRAMMER'S NOTES:
Present Part B only if data is available (cytokines to be collected if there are symptoms indicative of cytokine induction, e.g., IRRs).

Table 14.4.5.1
Summary of Mean Change from Baseline in Complement-CH50 Overtime (Dose Escalation Part A)
Safety Evaluable (N=n)

Cross-References: Figure 14.4.5.1, Listing 16.2.9.8
PROGRAMMER'S NOTES:

Table 14.4.5.2
Summary of Mean Change from Baseline in Complement-CH50 Overtime (Dose Expansion Part B)
Safety Evaluable (N=n)

Cross-References: Figure 14.4.5.2, Listing 16.2.9.8
PROGRAMMER'S NOTES:

Table 14.4.6.1
Summary of Mean Change from Baseline in Complement-Bb Overtime (Dose Escalation Part A)
Safety Evaluable (N=n)

Cross-References: Figure 14.4.6.1, Listing 16.2.9.8
PROGRAMMER'S NOTES:

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Table 14.4.6.2
Summary of Mean Change from Baseline in Complement-Bb Overtime for Dose Expansion (Part B)
Safety Evaluable (N=n)

Cross-References: Figure 14.4.6.2, Listing 16.2.9.8
PROGRAMMER'S NOTES:

Table 14.4.7.1
Summary of Mean Change from Baseline in Complement-C3a Overtime (Dose Escalation Part A)
Safety Evaluable (N=n)

Cross-References: Figure 14.4.7.1, Listing 16.2.9.8
PROGRAMMER'S NOTES:

Table 14.4.7.2
Summary of Mean Change from Baseline in Complement-C3a Overtime (Dose Expansion Part B)
Safety Evaluable (N=n)

Cross-References: Figure 14.4.7.2, Listing 16.2.9.8
PROGRAMMER'S NOTES:

Table 14.4.8.1
Summary of Mean Change from Baseline in Complement-C5a Overtime (Dose Escalation Part A)
Safety Evaluable (N=n)

Cross-References: Figure 14.4.8.1, Listing 16.2.9.8
PROGRAMMER'S NOTES:

Table 14.4.8.2
Summary of Mean Change from Baseline in Complement-C5a Overtime (Dose Expansion Part B)
Safety Evaluable (N=n)

Cross-References: Figure 14.4.8.2, Listing 16.2.9.8
PROGRAMMER'S NOTES:

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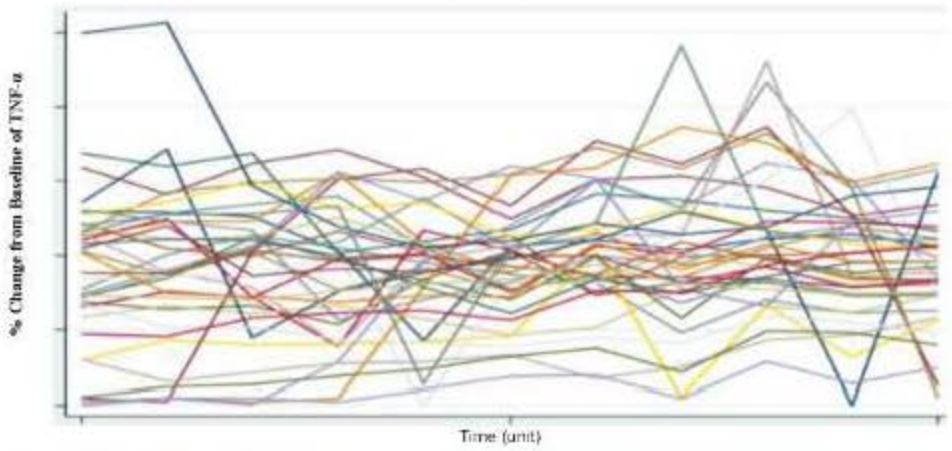
Figure 164.4.1.1: Spaghetti Plot for Individual Change from Baseline in TNF-α Overtime (Dose Escalation Part A)
Safety Evaluable (N=n)



Cross-References: Table 14.4.1.1, Listing 16.2.9.7

PROGRAMMER'S NOTES:
Y-axis scale should always be -100 to 100 to avoid presenting extreme values.
Use line colors/ patterns to represent different dose levels.

Repeat for

Figure 174.4.1.2: Spaghetti Plot for Individual Change from Baseline in TNF-α Overtime (Dose Escalation Part B)

Cross-References: Table 14.4.1.2, Listing 16.2.9.7

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PROGRAMMER'S NOTES:
Y-axis scale should always be -100 to 100 to avoid presenting extreme values.
Use line colors/ patterns to represent different dose levels.
Present Part B only if data is available (cytokines to be collected if there are symptoms indicative of cytokine induction, e.g., IRRs).

Figure 184.4.2.1: Spaghetti Plot for Individual Change from Baseline in IL-1β Overtime (Dose Escalation Part A)

Cross-References: Table 14.4.2.1, Listing 16.2.9.7

PROGRAMMER'S NOTES:
Y-axis scale should always be -100 to 100 to avoid presenting extreme values.
Use line colors/ patterns to represent different dose levels.
Present Part B only if data is available (cytokines to be collected if there are symptoms indicative of cytokine induction, e.g., IRRs).

Figure 194.4.2.2: Spaghetti Plot for Individual Change from Baseline in IL-1β Overtime (Dose Escalation Part B)

Cross-References: Table 14.4.2.2, Listing 16.2.9.7

PROGRAMMER'S NOTES:
Y-axis scale should always be -100 to 100 to avoid presenting extreme values.
Use line colors/ patterns to represent different dose levels.
Present Part B only if data is available (cytokines to be collected if there are symptoms indicative of cytokine induction, e.g., IRRs).

Figure 204.4.3.1: Spaghetti Plot for Individual Change from Baseline in IL-6 Overtime (Dose Escalation Part A)

Cross-References: Table 14.4.3.1, Listing 16.2.9.7

PROGRAMMER'S NOTES:
Y-axis scale should always be -100 to 100 to avoid presenting extreme values.
Use line colors/ patterns to represent different dose levels.
Present Part B only if data is available (cytokines to be collected if there are symptoms indicative of cytokine induction, e.g., IRRs).

Figure 214.4.3.2: Spaghetti Plot for Individual Change from Baseline in IL-6 Overtime (Dose Escalation Part B)

Cross-References: Table 14.4.3.2, Listing 16.2.9.7

PROGRAMMER'S NOTES:
Y-axis scale should always be -100 to 100 to avoid presenting extreme values.
Use line colors/ patterns to represent different dose levels.
Present Part B only if data is available (cytokines to be collected if there are symptoms indicative of cytokine induction, e.g., IRRs).

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Figure 224.4.4.1: Spaghetti Plot for Individual Change from Baseline in IFN-γ Overtime (Dose Escalation Part A)

Cross-References: Table 14.4.4.1, Listing 16.2.9.7

PROGRAMMER'S NOTES:
Y-axis scale should always be -100 to 100 to avoid presenting extreme values.
Use line colors/ patterns to represent different dose levels.
Present Part B only if data is available (cytokines to be collected if there are symptoms indicative of cytokine induction, e.g., IRRs).

Figure 234.4.4.2: Spaghetti Plot for Individual Change from Baseline in IFN-γ Overtime (Dose Escalation Part B)

Cross-References: Table 14.4.4.2, Listing 16.2.9.7

PROGRAMMER'S NOTES:
Y-axis scale should always be -100 to 100 to avoid presenting extreme values.
Use line colors/ patterns to represent different dose levels.
Present Part B only if data is available (cytokines to be collected if there are symptoms indicative of cytokine induction, e.g., IRRs).

Figure 244.4.5.1: Spaghetti Plot for Individual Change from Baseline in Complement-CH50 Overtime (Dose Escalation Part A)

Cross-References: Table 14.4.5.1, Listing 16.2.9.8

PROGRAMMER'S NOTES:
Y-axis scale should always be -100 to 100 to avoid presenting extreme values.
Use line colors/ patterns to represent different dose levels.

Figure 254.4.5.2: Spaghetti Plot for Individual Change from Baseline in Complement-CH50 Overtime (Dose Escalation Part B)

Cross-References: Table 14.4.5.2, Listing 16.2.9.8

PROGRAMMER'S NOTES:
Y-axis scale should always be -100 to 100 to avoid presenting extreme values.
Use line colors/ patterns to represent different dose levels.

Figure 264.4.6.1: Spaghetti Plot for Individual Change from Baseline in Complement-Bb Overtime (Dose Escalation Part A)

Cross-References: Table 14.4.6.1, Listing 16.2.9.8

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PROGRAMMER'S NOTES:
Y-axis scale should always be -100 to 100 to avoid presenting extreme values.
Use line colors/ patterns to represent different dose levels.

Figure 274.4.6.2: Spaghetti Plot for Individual Change from Baseline in Complement-Bb Overtime (Dose Escalation Part B)

Cross-References: Table 14.4.6.2, Listing 16.2.9.8

PROGRAMMER'S NOTES:
Y-axis scale should always be -100 to 100 to avoid presenting extreme values.
Use line colors/ patterns to represent different dose levels.

Figure 284.4.7.1: Spaghetti Plot for Individual Change from Baseline in Complement-C3a Overtime (Dose Escalation Part A)

Cross-References: Table 14.4.7.1, Listing 16.2.9.8

PROGRAMMER'S NOTES:
Y-axis scale should always be -100 to 100 to avoid presenting extreme values.
Use line colors/ patterns to represent different dose levels.

Figure 294.4.7.2: Spaghetti Plot for Individual Change from Baseline in Complement-C3a Overtime (Dose Escalation Part B)

Cross-References: Table 14.4.7.2, Listing 16.2.9.8

PROGRAMMER'S NOTES:
Y-axis scale should always be -100 to 100 to avoid presenting extreme values.
Use line colors/ patterns to represent different dose levels.

Figure 304.4.8.1: Spaghetti Plot for Individual Change from Baseline in Complement-C5a Overtime (Dose Escalation Part A)

Cross-References: Table 14.4.8.1, Listing 16.2.9.8

PROGRAMMER'S NOTES:
Y-axis scale should always be -100 to 100 to avoid presenting extreme values.
Use line colors/ patterns to represent different dose levels.

Figure 314.4.8.2: Spaghetti Plot for Individual Change from Baseline in Complement-C5a Overtime (Dose Escalation Part B)

Cross-References: Table 14.4.8.2, Listing 16.2.9.8

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PROGRAMMER'S NOTES:
Y-axis scale should always be -100 to 100 to avoid presenting extreme values.
Use line colors/ patterns to represent different dose levels.

Figure 324.4.9.1: Spaghetti Plot for Individual Change from Baseline in GSTP1 mRNA Level Overtime (Dose Escalation Part A)

Cross-References: Listing 16.2.9.14

PROGRAMMER'S NOTES:
Y-axis scale should always be -100 to 100 to avoid presenting extreme values.
Use line colors/ patterns to represent different dose levels.

Figure 334.4.9.2: Spaghetti Plot for Individual Change from Baseline in GSTP1 mRNA Level Overtime (Dose Escalation Part B)

Cross-References: Listing 16.2.9.14

PROGRAMMER'S NOTES:
Y-axis scale should always be -100 to 100 to avoid presenting extreme values.
Use line colors/ patterns to represent different dose levels.

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Listing 16.2.1.1
Patient Disposition
All Enrolled (N=n)

Patient/Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Date of Last Dose	Day [1]	Reason	ITT [2]	Safety Evaluable [3]	Efficacy Evaluable [4]
ccc-pppp/xx/x	x	xxx	ddmmmyyyy	xxx	Reason	Yes	Yes	Yes
ccc-pppp/xx/x	x	xxx	ddmmmyyyy	xxx	Reason	Yes	Yes	Yes
ccc-pppp/xx/x	x	xxx	ddmmmyyyy	xxx	Other: Specify	Yes	Yes	Yes
ccc-pppp/xx/x	x	xxx	ddmmmyyyy	xxx	Reason	Yes	Yes	Yes
ccc-pppp/xx/x	x	xxx	ddmmmyyyy	xxx	Reason	Yes	Yes	Yes
ccc-pppp/xx/x	x	xxx	ddmmmyyyy	xxx	Other: Specify	Yes	Yes	Yes
ccc-pppp/xx/x	x	xxx	ddmmmyyyy	xxx	Reason	Yes	Yes	Yes
ccc-pppp/xx/x	x	xxx	ddmmmyyyy	xxx	Reason	Yes	Yes	Yes
ccc-pppp/xx/x	x	xxx	ddmmmyyyy	xxx	Other: Specify	Yes	Yes	Yes

[1] Day is relative to first dose date of NBF-006-001.
[2] Intent-to-Treat (ITT) includes all participants who were enrolled (signed consent) into the study, irrespective of whether study medication was administrated or not.
[3] Safety Evaluable include all patients who received any component of study treatment.
[4] Efficacy Evaluable include patients with measurable disease by RECIST 1.1 who had a baseline assessment and at least one post-baseline assessment.
Cross-References: Case Report Form OFF-STUDY SUMMARY (OF)

PROGRAMMER'S NOTES:
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.

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Listing 16.2.2.1
Inclusion/Exclusion Criteria
All Enrolled (N=n)

Patient/Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Eligibility	Protocol Version Date	Category Not Met	Waiver Number
ccc-pppp/xx/x	x	xxx	Yes	xx		
ccc-pppp/xx/x	x	xxx	Yes	xx		
ccc-pppp/xx/x	x	xxx	No	xx	Inclusion x	
ccc-pppp/xx/x	x	xxx	Yes	xx		
ccc-pppp/xx/x	x	xxx	Yes	xx		
ccc-pppp/xx/x	x	xxx	No, but waiver granted	xx	Exclusion x	xxxxxx
ccc-pppp/xx/x	x	xxx	Yes	xx		
ccc-pppp/xx/x	x	xxx	Yes	xx		
ccc-pppp/xx/x	x	xxx	No	xx	Inclusion x	
ccc-pppp/xx/x	x	xxx	Yes	xx		

Cross-References: Case Report Form INCLUSION/EXCLUSION CRITERIA (IE)

PROGRAMMER'S NOTES:
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Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.

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Listing 16.2.4.1
Demographics
Intent-to-Treat (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Birth Date	Race [1]	Ethnicity	Registration Date	ICF Date	ICF Signature Date	Protocol Amend #	Protocol Amend Date	Withdraw Content from Main Study	Withdraw Content for Biopsies	Date
ccc-pppp/xx/x	x	xxx	xxx	x	xxx	ddmmmyyyy	xxx	xxx	x	ddmmmyyyy	Yes	xxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	x	xxx	ddmmmyyyy	xxx	xxx	x	ddmmmyyyy	No	xxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	x	xxx	ddmmmyyyy	xxx	xxx	x	ddmmmyyyy	No	xxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	x	xxx	ddmmmyyyy	xxx	xxx	x	ddmmmyyyy	Yes	xxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	x	xxx	ddmmmyyyy	xxx	xxx	x	ddmmmyyyy	No	xxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	x	xxx	ddmmmyyyy	xxx	xxx	x	ddmmmyyyy	No	xxx	xxx

[1]Race: A=Asian, W=White, B=Black or African American, N=Native Hawaiian or Pacific Islander, I= American Indian or Alaska native, NR=Not Reported, O=Other
Cross-References: Case Report Form DEMOGRAPHICS (DM), Informed Consent (IC)

PROGRAMMER'S NOTES:
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.

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Listing 16.2.4.2.1
Disease Related Characteristics
Intent-to-Treat (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Primary Site (Site Class)	Initial Diagnosis Date	Day [1]	Duration of Disease (m) [2]	Histology [3]	Disease Stage	EGFR Mutation	ALK/ROS1 Gene Fusion	KRAS Genotype Mutated
ccc-pppp/xx/x	x	xxx	Site (Class)	ddmmmyyyy	xxx.x	xxx.x	xxxx	xxxx	Yes, specify	Yes	Yes
ccc-pppp/xx/x	x	xxx	Site (Class)	ddmmmyyyy	xxx.x	xxx.x	xxxx	xxxx	No	No	No
ccc-pppp/xx/x	x	xxx	Site (Class)	ddmmmyyyy	xxx.x	xxx.x	xxxx	xxxx	No	No	Unknown
ccc-pppp/xx/x	x	xxx	Site (Class)	ddmmmyyyy	xxx.x	xxx.x	xxxx	xxxx	Yes, specify	Yes	Yes
ccc-pppp/xx/x	x	xxx	Site (Class)	ddmmmyyyy	xxx.x	xxx.x	Other	xxxx	No	Unknown	No
ccc-pppp/xx/x	x	xxx	Site (Class)	ddmmmyyyy	xxx.x	xxx.x	xxxx	xxxx	Unknown	No	No

[1] Days to first dose date.
[2] Duration of Disease= (Date ICF signed – Initial Diagnosis Date) in month
[3] ICO- version xxx
Cross-References: Case Report Form DEMOGRAPHICS (DM)

PROGRAMMER'S NOTES:
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.

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Listing 16.2.4.2.2
Baseline KRAS Mutation Assessment
Intent-to-Treat (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Assessment Completed?	Genomic Tumor Profile Available?	Date of Analysis	Archived Tissue Sample Obtained?	Sample Date	Fresh Sample Required	Sample Date	Biopsy Performed?	If not, Reason	KRAS Mutation Type
ccc-pppp/xx/x	x	xxx	Yes	Yes	ddmmmyyyy	Yes	ddmmmyyyy	Yes	ddmmmyyyy	Yes		xxxxx
ccc-pppp/xx/x	x	xxx	Yes	Yes	ddmmmyyyy	Yes	ddmmmyyyy	Yes	ddmmmyyyy	Yes		xxxxx
			Yes	Yes	ddmmmyyyy	Yes	ddmmmyyyy	Yes	ddmmmyyyy	Yes		xxxxx
ccc-pppp/xx/x	x	xxx	Yes	Yes	ddmmmyyyy	Yes	ddmmmyyyy	No				xxxxx
			Yes	Yes	ddmmmyyyy	Yes	ddmmmyyyy	No				xxxxx
ccc-pppp/xx/x	x	xxx	No	No		Yes	ddmmmyyyy	Yes	ddmmmyyyy	Yes		
ccc-pppp/xx/x	x	xxx	Yes	Yes	ddmmmyyyy	Yes	ddmmmyyyy	Yes	ddmmmyyyy	Yes		xxxxx
			Yes	Yes	ddmmmyyyy	Yes	ddmmmyyyy	Yes	ddmmmyyyy	Yes		xxxxx
			Yes	Yes	ddmmmyyyy	Yes	ddmmmyyyy	Yes	ddmmmyyyy	Yes		xxxxx
ccc-pppp/xx/x	x	xxx	Yes	Yes	ddmmmyyyy	Yes	ddmmmyyyy	Yes	ddmmmyyyy	No	xxxxx	xxxxx

Cross-References: Case Report Form KRAS MUTATION ASSESSMENT (TM5)

PROGRAMMER'S NOTES:
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.

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Listing 16.2.4.3
Medical History
Intent-to-Treat (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Start Date	Study Day [1]	Condition (Preferred Term) (System Organ Class) [2]	Ongoing	Grade	Related to Study Disease	Therapy Given
ccc-pppp /xx/x	x	xxx	ddmmmyyyy	-xx	Condition (MedDRA Preferred Term) (MedDRA System Organ Class)	No	Mild	No	No
					Condition (MedDRA Preferred Term) (MedDRA System Organ Class)	No	Moderate	No	Yes
ccc-pppp /xx/x	x	xxx	ddmmmyyyy	-xx	Condition (MedDRA Preferred Term) (MedDRA System Organ Class)	Yes	Mild	No	No

[1] Day is relative to the first dose date of NBF-006 or ongoing.
[2] MedDRA version 21.1
Cross-References: Case Report Form MEDICAL HISTORY (MH)

PROGRAMMER'S NOTES:
Grade: 1=Mild, 2=Moderate, 3=Severe, Unknown, and Not Applicable.
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.

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Listing 16.2.4.4
Prior Cancer Therapy
Intent-to-Treat (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Regimen Number	Agent/Treatment	Therapy Type	Start Date	Stop Date	Stop Day [1]	Reason	Best Response
ccc-pppp/xx/x	x	xxx	x	Prior Therapy Name	Type	ddmmmyyyy	ddmmmyyyy	-xx	xxx	Response
ccc-pppp/xx/x	x	xxx	x	Prior Therapy Name	Type	ddmmmyyyy	ddmmmyyyy	-xx	xxx	Response
			x	Prior Therapy Name	Type	ddmmmyyyy	ddmmmyyyy	-xx	xxx	Response
ccc-pppp/xx/x	x	xxx	x	Prior Therapy Name	Type	ddmmmyyyy	ddmmmyyyy	-xx	xxx	Response
			x	Prior Therapy Name	Type	ddmmmyyyy				
ccc-pppp/xx/x	x	xxx	x	NO PRIOR THERAPY						
ccc-pppp/xx/x	x	xxx	x	Prior Therapy Name	Type	ddmmmyyyy	ddmmmyyyy	-xx	xxx	Response
			x	Prior Therapy Name	Type	ddmmmyyyy	ddmmmyyyy	-xx	xxx	Response
			x	Prior Therapy Name	Type	ddmmmyyyy	ddmmmyyyy	-xx	xxx	Response
ccc-pppp/xx/x	x	xxx	x	Prior Therapy Name	Type	ddmmmyyyy	ddmmmyyyy	-xx	xxx	Response

[1] Stop day is relative to the first dose date of NBF-006 or ongoing.
Cross-References: Case Report Form PRIOR CANCER THERAPY (PT)

PROGRAMMERS NOTES:
Prior Therapy Type includes: Chemotherapy, Hormonal Therapy, Immunotherapy, and Other.
Best Response includes: Complete Response, Partial Response, Stable Disease, Progressive Disease, Unknown, and Not Applicable.
When "No Prior Therapy" is indicated, enter "NO PRIOR THERAPY" in the 'Agent/Treatment' column.
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Start Date" in ascending order within "Patient".

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Listing 16.2.4.5
Prior Medications
Intent-to-Treat (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Agent/Treatment	Start Date	Stop Date	Stop Day [1]	Time	Dose	Unit	Route	Other Route
ccc-pppp/xx/x	x	xxx	Prior Therapy Name	ddmmmyyyy	ddmmmyyyy	-xx	hh:mm	xx.x	xxx	xxx	
ccc-pppp/xx/x	x	xxx	Prior Therapy Name	ddmmmyyyy	ddmmmyyyy	-xx	hh:mm	xx.x	xxx	xxx	
			Prior Therapy Name	ddmmmyyyy	ddmmmyyyy	-xx	hh:mm	xx.x	xxx	xxx	
ccc-pppp/xx/x	x	xxx	Prior Therapy Name	ddmmmyyyy	ddmmmyyyy	-xx	hh:mm	xx.x	xxx	xxx	
			Prior Therapy Name	ddmmmyyyy	ddmmmyyyy	-xx	hh:mm	xx.x	xxx	Other	xxx
ccc-pppp/xx/x	x	xxx	NO PRIOR THERAPY								
ccc-pppp/xx/x	x	xxx	Prior Therapy Name	ddmmmyyyy	ddmmmyyyy	-xx	hh:mm	xx.x	xxx	xxx	
			Prior Therapy Name	ddmmmyyyy	ddmmmyyyy	-xx	hh:mm	xx.x	xxx	xxx	
			Prior Therapy Name	ddmmmyyyy	ddmmmyyyy	-xx	hh:mm	xx.x	xxx	xxx	
ccc-pppp/xx/x	x	xxx	Prior Therapy Name	ddmmmyyyy	ddmmmyyyy	-xx	hh:mm	xx.x	xxx	xxx	

[1] Stop day is relative to the first dose date of NBF-006 or ongoing.
Cross-References: Case Report Form PRIOR MEDICATIONS (PM)

PROGRAMMER'S NOTES:
Prior Therapy Type includes: Chemotherapy, Hormonal Therapy, Immunotherapy, and Other.
Best Response includes: Complete Response, Partial Response, Stable Disease, Progressive Disease, Unknown, and Not Applicable.
When "No Prior Therapy" is indicated, enter "NO PRIOR THERAPY" in the 'Agent/Treatment' column.
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Start Date" in ascending order within "Patient".

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Listing 16.2.4.6
Prior Cancer Radiation
Intent-to-Treat (N=n)

Patient/Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Site	Start Date	Stop Date	Stop Day [1]	Best Response
ccc-pppp/xx/x	x	xxx	NO PRIOR RADIATION				
ccc-pppp/xx/x	x	xxx	Reported Site	ddmmmyyyy	ddmmmyyyy	-xx	xxx
ccc-pppp/xx/x	x	xxx	Reported Site	ddmmmyyyy	ddmmmyyyy	-xx	xxx
ccc-pppp/xx/x	x	xxx	Reported Site	ddmmmyyyy	ddmmmyyyy	-xx	xxx
ccc-pppp/xx/x	x	xxx	Reported Site	ddmmmyyyy	ddmmmyyyy	-xx	xxx
ccc-pppp/xx/x	x	xxx	Reported Site	ddmmmyyyy	ddmmmyyyy	-xx	xxx
ccc-pppp/xx/x	x	xxx	Reported Site	ddmmmyyyy	ddmmmyyyy	-xx	xxx
ccc-pppp/xx/x	x	xxx	Reported Site	ddmmmyyyy	ddmmmyyyy	-xx	xxx

[1] Stop day is relative to the first dose of NBF-006 or ongoing.
Cross-References: Case Report Form PRIOR CANCER RADIATION (PR)

ROGRAMMER'S NOTES:
When "No Prior Radiation" is indicated, enter "NO PRIOR RADIATION" in the 'Site' column.
Best Response includes: Complete Response, Partial Response, Stable Disease, Progressive Disease, Unknown, and Not Applicable
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Start Date" in ascending order within "Patient".

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Listing 16.2.4.7
Prior Cancer Surgeries
Intent-to-Treat (N=n)

Patient/Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Procedure (including site)	Procedure Date	Study Day [1]	Findings (Pathology/Cytology)
ccc-pppp/xx/x	x	xxx	Procedure and Site	ddmmmyyyy	-xx	Description of Findings
			Procedure and Site	ddmmmyyyy	-xx	Description of Findings
ccc-pppp/xx/x	x	xxx	Procedure and Site	ddmmmyyyy	-xx	Description of Findings
			Procedure and Site	ddmmmyyyy	-xx	Description of Findings
			Procedure and Site	ddmmmyyyy	-xx	Description of Findings
ccc-pppp/xx/x	x	xxx	Procedure and Site	ddmmmyyyy	-xx	Description of Findings
			Procedure and Site	ddmmmyyyy	-xx	Description of Findings
			Procedure and Site	ddmmmyyyy	-xx	Description of Findings
ccc-pppp/xx/x	x	xxx	Procedure and Site	ddmmmyyyy	-xx	Description of Findings
			Procedure and Site	ddmmmyyyy	-xx	Description of Findings

[1] Day is relative to the first dose date of NBF-006.
Cross-References: Case Report Form: PRIOR CANCER SURGERIES (SG)

PROGRAMMER'S NOTES:
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Procedure Date" in ascending order within "Patient".

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Listing 16.2.4.8
Pregnancy Test
Intent-to-Treat (N=n)

Patient/Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Visit	Date	Study Day [1]	Method	Result	Reason Not Done
ccc-pppp/xx/x	x	xxx	xxx	dd/mm/yyyy	-xx	Urine	Negative	
			xxx	dd/mm/yyyy	xx	Serum	Negative	
			xxx	dd/mm/yyyy	xx	Serum	Negative	
ccc-pppp/xx/x	x	xxx	xxx	dd/mm/yyyy	-xx	Serum	Negative	
			xxx	dd/mm/yyyy	xx	Urine	Negative	
			xxx	dd/mm/yyyy	xx	Urine	Negative	
ccc-pppp/xx/x	x	xxx	xxx	dd/mm/yyyy	-xx	Urine	Negative	
			xxx	NOT PERFORMED				Post-Menopausal
			xxx	dd/mm/yyyy	-xx	Urine	Negative	

[1] Day is relative to the first dose date of NBF-006.
Cross-References: Case Report Form PREGNANCY (RP)

PROGRAMMER'S NOTES:
If Pregnancy Test is not performed, enter "NOT PERFORMED" in the 'Sample Date' column.
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.

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Listing 16.2.5.1
NBF-006 Administration
Safety Evaluable (N=n)

Patient /Age/Sex	Study Part	Visit	Start Date	Day [1]	Start Time	Stop Time	Dose Level (mg/kg)	Lot No.	Total Infused Dose (mg)	Infusion Rate	Dose Delay[2]	Reason	Dose Interrupted[3]	Reason	AE #
ccc-pppp	x	xx	ddmmmyyyy	xx	hh:mm	hh:mm	xxx	x	xxx	xxx	Yes	xxx	No		
			ddmmmyyyy	xx	hh:mm	hh:mm	xxx	x	xxx	xxx	No	xxx	No		
/xx/x			ddmmmyyyy	xx	hh:mm	hh:mm	xxx	x	xxx	xxx	No		Yes	xxx	xx
		xx	ddmmmyyyy	xx	hh:mm	hh:mm	xxx	x	xxx	xxx	No		No		
			ddmmmyyyy	xx	hh:mm	hh:mm	xxx	x	xxx		No		No		
			ddmmmyyyy	xx	hh:mm	hh:mm	xxx	x	xxx	xxx	Yes	xxx	No		
ccc-pppp	x	xx	ddmmmyyyy	xx	hh:mm	hh:mm	xxx		xxx	xxx	No		No		
/xx/x			ddmmmyyyy	xx	hh:mm	hh:mm	xxx	x	xxx	xxx	No		No		
		xx	ddmmmyyyy	xx	hh:mm	hh:mm	xxx	x	xxx	xxx	No		Yes	xxx	xx

[1] Day is relative to first dose date of NBF-006.
[2] Dose is not administrated on protocol scheduled timepoint.
[3] The infusion is temporarily interrupted and then resumed when symptoms are resolved.
Cross-Reference: Case Report Form NBF-006 ADMINISTRATION (EX)

PROGRAMMER'S NOTES:
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Start Date" in ascending order within "Patient", specify other.
There are 3 infusion rates, each subject may have 3 rows for 3 infusion rates.
The infusion will be implemented as a stepwise infusion:
(1) 0.5 mL/min for 10 minutes.
(2) then 1.5 mL/min for 10 minutes, and
(3) finally 6 mL/min for the remaining volume

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Listing 16.2.6.1
Extent of Disease: Target and Non-Target Lesions
Efficacy Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Visit	Date of Procedure	Day [1]	Lesion Type	Lesion Number	Organ (Other, specify)	Procedure	Previous RT to Lesion	Progression Since RT
ccc-pppp /xx/x	x	xxx	Screening	ddmmmyyyy	-xx	Target	x	Other: Specify	X-Ray		
						Target	x	Reported Organ	Other: Specify	Yes	Yes
						Target	x	Reported Organ	PET/CT		
						Non-Target	x	Reported Organ	Other: Specify		
			xxx	ddmmmyyyy	xx	Target	x	Reported Organ	X-Ray		
						Target	x	Reported Organ	Other: Specify		
						Target	x	Reported Organ	CT Scan		
						Non-Target	x	Reported Organ	Other: Specify		
						Non-Target	x	Reported Organ	CT Scan		
						Non-Target	x	Reported Organ	X-Ray		
ccc-pppp /xx/x		xxx	xxx	ddmmmyyyy	xx	Target	x	Reported Organ	CT Scan		

[1] Day is relative to the first dose date of NBF-006.
Cross-References: Case Report Forms TARGET LESIONS ASSESSMENT (TR1, TR2), NON-TARGET LESIONS ASSESSMENT (TR3, TR4), NEW LESIONS (TR5)
PROGRAMMER'S NOTES:
When "No Target Lesions at Pretreatment", enter 'NO TARGET LESIONS' in the 'Lesion Type' column.
When "No Non-Target Lesions at Pretreatment", enter 'NO NON-TARGET LESIONS' in the 'Lesion Type' column.
Data is presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portions of patient number.
Sort "Date" in ascending order within "Patient".
Sort "Lesion Type" in descending order within "Date".
Sort "Lesion Number" in ascending order within "Lesion Type".

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Listing 16.2.6.1
Extent of Disease: Target and Non-Target Lesions
Efficacy Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Visit	Date of Procedure	Day [1]	Lesion Type	Lesion Number	Anatomical Location	Lesion Assessable/ Non-Target Lesion Evaluation	RECIST Measure (mm)	Total Sum (mm)
ccc-pppp /xx/x	x	xxx	Screening	ddmmmyyyy	-xx	Target	x	Reported Location	Yes	xx	
						Target	x	Reported Location	Yes	xx	
						Target	x	Reported Location	Yes	xx	xxx
						Non-Target	x	Reported Location			
						Non-Target	x	Reported Location			
			xxx	ddmmmyyyy	xx	Target	x	Reported Location	Yes	xx	
						Target	x	Reported Location	Yes	xx	
						Target	x	Reported Location	Yes	xx	xxx
						Non-Target	x	Reported Location			
						Non-Target	x	Reported Location			
						New Lesion	x	Reported Location			
ccc-pppp /xx/x		xxx	xxx	ddmmmyyyy	xx	Target	x	Reported Location	Yes	xx	

[1] Day is relative to the first dose date of NBF-006.
Cross-References: Case Report Forms TARGET LESIONS ASSESSMENT (TR1, TR2), NON-TARGET LESIONS ASSESSMENT (TR3, TR4), NEW LESIONS (TR5)

PROGRAMMER'S NOTES:
When "No Target Lesions at Pretreatment", enter "NO TARGET LESIONS" in the 'Lesion Type' column.
When "No Non-Target Lesions at Pretreatment", enter "NO NON-TARGET LESIONS" in the 'Lesion Type' column.
Data is presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portions of patient number.
Sort "Date" in ascending order within "Patient".
Sort "Lesion Type" in descending order within "Date".
Sort "Lesion Number" in ascending order within "Lesion Type".

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Listing 16.2.6.2
Cycle Response Assessment
Efficacy Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Visit	Date of Procedure	Day [1]	Target Lesion Response	Non-Target Lesion Response	New Lesions	Symptomatic Deterioration	Deterioration Date	Overall Response for this Cycle
ccc-pppp	x	xxx	xxx	ddmmmyyyy	xx	Stable Disease	NON-CR/NON-PD	No			Stable Disease
			xxx	ddmmmyyyy	xx	Stable Disease	NON-CR/NON-PD	No			Stable Disease
			xxx	ddmmmyyyy	xx	Complete Response	Complete Response	No			Complete Response
			xxx	ddmmmyyyy	xx	Complete Response	Complete Response	No			Complete Response
ccc-pppp	x	xxx	xxx	ddmmmyyyy	xx	Stable Disease	NON-CR/NON-PD	No			Stable Disease
			xxx	ddmmmyyyy	xx	Stable Disease	NON-CR/NON-PD	No	Yes	ddmmmyyyy	Stable Disease
			xxx	ddmmmyyyy	xx	Complete Response	Complete Response	No			Complete Response
			xxx	ddmmmyyyy	xx	Complete Response	Complete Response	No			Complete Response
ccc-pppp	x	xxx	xxx	ddmmmyyyy	xx	Stable Disease	NON-CR/NON-PD	No			Stable Disease
/xx/x			xxx	ddmmmyyyy	xx	Stable Disease	NON-CR/NON-PD	No			Stable Disease
			xxx	ddmmmyyyy	xx	Progression	Progression	No			Progression

[1] Day is relative to the first dose date of NBF-006.

Cross-References: Case Report Form CYCLE RESPONSE ASSESSMENT (RS)

PROGRAMMER'S NOTES:
Data is presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portions of patient number.

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Listing 16.2.7.1
Adverse Events
Safety Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Adverse Event (MedDRA Preferred Term) (MedDRA System Organ Class)	DLT [1]	Onset Resolved Dates	Day [2]	Grade	Ser [3]	Drug Related	Act [4]	Therapy Given	Out [5]	Alternate Cause Primary Disease	Alternate Cause Comment
ccc-pppp /xx/x	x	xxx	ADVERSE EVENT (MedDRA Preferred Term) (MedDRA System Organ Class)		ddmmmyyyy ddmmmyyyy	xx	Mild	x	probably	1	Yes	x		
			ADVERSE EVENT (MedDRA Preferred Term) (MedDRA System Organ Class)		ddmmmyyyy ongoing	xx	Mild	x	Unlikely	3	Yes	x	Yes	xxxxxx
ccc-pppp /xx/x	x	xxx	ADVERSE EVENT (MedDRA Preferred Term) (MedDRA System Organ Class)	Yes	ddmmmyyyy	xx	Severe		Unrelated	2	No	x	Yes	xxxxxx

MedDRA version 21.1
[1] DLT= Dose Limiting Toxicity
[2] Day is relative to the first dose date of NBF-006 .
[3] Ser=Serious: 1=Not Serious, 2=Results in Death, 3=Life Threatening, 4=Requires or Prolongs Hospitalization, 5=Persistent or Significant Disability/Incapacity, 6=Congenital Anomaly or Birth Defect, 7=Other Medically Important Serious Event.
[4] Act=Action Taken: 1=Dose NOT Changed, 2=Dose Interrupted, 3= Dose Delayed, 4= Drug Withdrawn.
[5] Out=Outcome: 1=Recovered/Resolved, 2=Recovered/Resolved with sequelae, 3=Recovering/Resolving, 4=Not Recovered/Not Resolved, 5=Fatal, 6=Unknown.
DLT= Dose Limiting Toxicity
Cross-References: Case Report Form ADVERSE EVENTS (AE)

PROGRAMMER'S NOTES:
Grade: 1=Mild, 2=Moderate, 3=Severe, 4=Life threatening, 5=Fatal. Use maximum grade for summary.
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Onset Date" in ascending order within "Patient".

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Listing 16.2.7.2.1
Treatment-Emergent Adverse Events Leading to Dose Interrupted
Safety Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose(mg/kg)	Adverse Event (MedDRA Preferred Term)	Day [1]	Last Dose to Onset [2]	Treatment Duration [3]	Duration of TEAE (day)	Grade	Serious [5]	Drug Related
ccc-pppp /xx/x	x	xxx	Adverse Event (MedDRA Preferred Term)	xx	xxx	xxx	xxx	Mild	No	Possible
ccc-pppp /xx/x	x	xxx	Adverse Event (MedDRA Preferred Term)	xx	xxx	xxx	xxx	Severe	Yes	Unrelated

[1] Day is relative to the first dose date of NBF-006.
[2] Last Dose to Onset is calculated in days.
[3] Treatment Duration is calculated from first dose to discontinuation of study drug.
[4] Duration of adverse event is calculated in days from Onset Date to Resolution Date.
[5] Ser=Serious:1=Not Serious, 2=Results in Death, 3=Life Threatening, 4=Requires or Prolongs Hospitalization, 5=Persistent or Significant Disability/Incapacity, 6=Congenital Anomaly or Birth Defect, 7=Other Medically Important Serious Event.
Cross-References: Case Report Form ADVERSE EVENTS (AE)

PROGRAMMER'S NOTES:
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.

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Listing 16.2.7.2.2
Treatment-Emergent Adverse Events Leading to Dose Delayed
Safety Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose(mg/kg)	Adverse Event (MedDRA Preferred Term)	Day [1]	Last Dose to Onset [2]	Treatment Duration [3]	Duration of TEAE (day)	Grade	Serious [5]	Drug Related
ccc-pppp /xx/x	x	xxx	Adverse Event (MedDRA Preferred Term)	xx	xxx	xxx	xxx	Mild	No	Possible
ccc-pppp /xx/x	x	xxx	Adverse Event (MedDRA Preferred Term)	xx	xxx	xxx	xxx	Severe	Yes	Unrelated

[1] Day is relative to the first dose date of NBF-006.
[2] Last Dose to Onset is calculated in days.
[3] Treatment Duration is calculated from first dose to discontinuation of study drug.
[4] Duration of adverse event is calculated in days from Onset Date to Resolution Date.
[5] Ser=Serious:1=Not Serious, 2=Results in Death, 3=Life Threatening, 4=Requires or Prolongs Hospitalization, 5=Persistent or Significant Disability/Incapacity, 6=Congenital Anomaly or Birth Defect, 7=Other Medically Important Serious Event.
Cross-References: Case Report Form ADVERSE EVENTS (AE)

PROGRAMMER'S NOTES:
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.

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Listing 16.2.7.2.3
Treatment-Emergent Adverse Events Leading to Drug Withdrawn
Safety Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose(mg/kg)	Adverse Event (MedDRA Preferred Term)	Day [1]	Last Dose to Onset [2]	Treatment Duration [3]	Duration of TEAE (day)	Grade	Serious [5]	Drug Related
ccc-pppp /xx/x	x	xxx	Adverse Event (MedDRA Preferred Term)	xx	xxx	xxx	xxx	Mild	No	Possible
ccc-pppp /xx/x	x	xxx	Adverse Event (MedDRA Preferred Term)	xx	xxx	xxx	xxx	Severe	Yes	Unrelated

[1] Day is relative to the first dose date of NBF-006.
[2] Last Dose to Onset is calculated in days.
[3] Treatment Duration is calculated from first dose to discontinuation of study drug.
[4] Duration of adverse event is calculated in days from Onset Date to Resolution Date.
[5] Ser=Serious:1=Not Serious, 2=Results in Death, 3=Life Threatening, 4=Requires or Prolongs Hospitalization, 5=Persistent or Significant Disability/Incapacity, 6=Congenital Anomaly or Birth Defect, 7=Other Medically Important Serious Event.
Cross-References: Case Report Form ADVERSE EVENTS (AE)

PROGRAMMER'S NOTES:
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.

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Listing 16.2.7.3
Serious Adverse Events
Safety Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	SAE MedDRA PT [1]	Previously Reported	Onset Resolved Dates	Day [2]	Hospitalized Admission Discharge Date	Date Met SAE Criteria	Rechallenge	Study Drug Administrated?	Off-Treatment Prior to SAE?	Patient Withdrawn
ccc-pppp /xx/x	x	xxx	SAE (PT)	No	ddmmmyyyy ddmmmyyyy	xx xx	ddmmmyyyy	ddmmmyyyy	Yes	Yes	x	Yes
ccc-pppp /xx/x	x	xxx	SAE (PT)	Yes	ddmmmyyyy ddmmmyyyy	xx xx	ddmmmyyyy	ddmmmyyyy	NA	No	x	No

[1] MedDRA version 21.1
[2] Day is relative to the first dose date of NBF-006.
Cross-References: Case Report Form SERIOUS ADVERSE EVENTS (SAE)

PROGRAMMERS NOTES:
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Onset Date" in ascending order within "Patient".

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Listing 16.2.7.4
Patients with Incomplete Adverse Event Information Excluded from Summary Tables
Safety Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose(mg/kg)	Adverse Event (MedDRA Preferred Term) (MedDRA System Organ Class) [1]	DLT [2]	Onset Resolved Dates	Day [3]	Grade	Ser [4]	Drug Related	Act [5]	Therapy Given	Out [6]	Alternate Cause: Primary Disease	Alternate Cause: Comment
ccc-pppp /xx/x	x	xxx	ADVERSE EVENT (MedDRA Preferred Term) (MedDRA System Organ Class)		ddmmmyyyy ddmmmyyyy	xx xx	Mild	x	probably	1	Yes	x		
			ADVERSE EVENT (MedDRA Preferred Term) (MedDRA System Organ Class)		ddmmmyyyy ongoing	xx	Mild	x	Unlikely	3	Yes	x	Yes	xxxxxx
ccc-pppp /xx/x	x	xxx	ADVERSE EVENT (MedDRA Preferred Term) (MedDRA System Organ Class)	Yes	ddmmmyyyy ddmmmyyyy	xx xx	Severe		Unrelated	2	No	x	Yes	xxxxxx

[1] MedDRA version 21.1
[2] DLT= Dose Limiting Toxicity
[3] Day is relative to the first dose date of NBF-006 .
[4] Ser=Serious: 1=Not Serious, 2=Results in Death, 3=Life Threatening, 4=Requires or Prolongs Hospitalization, 5=Persistent or Significant Disability/Incapacity, 6=Congenital Anomaly or Birth Defect, 7=Other Medically Important Serious Event.
[5] Act=Action Taken: 1=Dose NOT Changed, 2=Dose Interrupted, 3= Dose Delayed, 4= Drug Withdrawn.
[6] Out=Outcome: 1=Recovered/Resolved, 2=Recovered/Resolved with sequelae, 3=Recovering/Resolving, 4=Not Recovered/Not Resolved, 5=Fatal, 6=Unknown.
Cross-References: Case Report Form ADVERSE EVENTS (AE)

PROGRAMMER'S NOTES:
Grade: 1=Mild, 2=Moderate, 3=Severe, 4=Life threatening, 5=Fatal. Use maximum grade for summary
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Onset Date" in ascending order within "Patient".

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Listing 16.2.7.5
Death Summary
Safety Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Date of Death	Primary Cause	Date of First Dose	Date of Last Dose	Date off-Study	Treatment Duration (Day) [1]	First Dose to Death (Day)	Last Dose to Death (Day)	Off-Study to Death (Day)
ccc-pppp /xx/x	x	xxx	ddmmmyyyy	xxxxxx	ddmmmyyyy	ddmmmyyyy	ddmmmyyyy	xx	xx	xx	xx
ccc-pppp /xx/x	x	xxx	ddmmmyyyy	xxxxxx	ddmmmyyyy	ddmmmyyyy	ddmmmyyyy	xx	xx	xx	xx

[1] Treatment duration is calculated from the first dose date to discontinuation date of study drug in days.
Cross-References: Case Report Form Case Report Forms DEATH SUMMARY (DS), NBF-006 ADMINISTRATION (EX) and OFF-STUDY SUMMARY (OF)

PROGRAMMER'S NOTES:
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.

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Listing 16.2.8.1
Clinical Laboratory Tests - Hematology
Safety Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Visit	Sample Date	Sample Time	Day [1]	Lab Code	Laboratory Test 1 (unit) [2] Results	Laboratory Test 1 (unit) [2] Normal Range	Laboratory Test 2 (unit) [2] Results	Laboratory Test 2 (unit) [2] Normal Range
ccc-pppp	x	xxx	xx	ddmmmyyyy	hhmm	-xx	xxxx	xx.x H G1	xx.x - xx.x	xx.x H G1	xx.x - xx.x
/xx/x			xx	ddmmmyyyy	hhmm	xx	xxxx	xx.x	xx.x - xx.x	xx.x	xx.x - xx.x
			xx	ddmmmyyyy	hhmm	xx	xxxx	xx.x	xx.x - xx.x	xx.x	xx.x - xx.x
ccc-pppp	x	xxx	xx	ddmmmyyyy	hhmm	-xx	xxxx	xx.x	xx.x - xx.x	xx.x	xx.x - xx.x
/xx/x			xx	ddmmmyyyy	hhmm	xx	xxxx	xx.x L G1	xx.x - xx.x	xx.x L G1	xx.x - xx.x
			xx	ddmmmyyyy	hhmm	xx	xxxx	xx.x	xx.x - xx.x	xx.x	xx.x - xx.x
			xx	ddmmmyyyy	hhmm	xx	xxxx	xx.x	xx.x - xx.x	xx.x	xx.x - xx.x

[1] Day is relative to the first dose date of NBF-006.
[2] Reported Result; H = High (Above Normal Range), L = Low (Below Normal Range); Calculated CTCAE version 5 Grade 1 to 4.
Cross-References: Case Report Form HEMATOLOGY (HM)

PROGRAMMER'S NOTES:
Onwards page as required.
Include following Hematology Tests: Hemoglobin, Hematocrit, Platelets, WBC, and WBC differential.
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Date" in ascending order within "Patient".
Remove footnote 'Calculated CTCAE version 5 Grade 1 to 4 if not needed.

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Listing 16.2.8.2
Clinical Laboratory Tests - Blood Chemistry
Safety Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Visit	Sample Date	Sample Time	Day [1]	Lab Code	Laboratory Test 1(unit) [2] Results	Laboratory Test 1(unit) [2] Normal Range	Laboratory Test 2 (unit) [2] Results	Laboratory Test 2 (unit) [2] Normal Range
ccc-pppp	x	xxx	xx	ddmmmyyyy	hh:mm	-xx	xxxx	xx.x H G1	xx.x - xx.x	xx.x H G1	xx.x - xx.x
/xx/x			xx	ddmmmyyyy	hh:mm	xx	xxxx	xx.x	xx.x - xx.x	xx.x	xx.x - xx.x
			xx	ddmmmyyyy	hh:mm	xx	xxxx	xx.x	xx.x - xx.x	xx.x	xx.x - xx.x
			xx	ddmmmyyyy	hh:mm	-xx	xxxx	xx.x	xx.x - xx.x	xx.x	xx.x - xx.x
ccc-pppp	x	xxx	xx	ddmmmyyyy	hh:mm	xx	xxxx	xx.x L G1	xx.x - xx.x	xx.x L G1	xx.x - xx.x
/xx/x			xx	ddmmmyyyy	hh:mm	xx	xxxx	xx.x	xx.x - xx.x	xx.x	xx.x - xx.x
			xx	ddmmmyyyy	hh:mm	xx	xxxx	xx.x	xx.x - xx.x	xx.x	xx.x - xx.x

[1] Day is relative to the first dose date of NBF-006.
[2] Reported Result: H = High (Above Normal Range), L = Low (Below Normal Range); Calculated CTCAE version 5 Grade 1 to 4.
Cross-References: Case Report Form BLOOD BIOCHEMISTRY (BC)

PROGRAMMER'S NOTES:
Coagulation collected only Pre-Study; revise footnote [1].
Onwards page as required.
Include following Blood Chemistry Tests: BUN, sodium, potassium, calcium, total bilirubin, total protein, ALT, AST, ALP, albumin, creatinine, and glucose.
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Date" in ascending order within "Patient".
Remove footnote 'Calculated CTCAE version 5 Grade 1 to 4 if not needed.

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Listing 16.2.8.3
Clinical Laboratory Tests - Urinalysis
Safety Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Visit	Sample Date	Sample Time	Day [1]	Lab Code	Laboratory Test 1[2] Results	Laboratory Test 1[2] Normal Range	Laboratory Test 2[2] Results	Laboratory Test 2[2] Normal Range
ccc-pppp /xx/x	x	xxx	xx	ddmmmyyyy	hh:mm	-xx	xxx	xx.x H G1	xx.x - xx.x	xx.x H G1	xx.x - xx.x
			xx	ddmmmyyyy	hh:mm	xx	xxx	xx.x	xx.x - xx.x	xx.x	xx.x - xx.x
			xx	ddmmmyyyy	hh:mm	xx	xxx	xx.x	xx.x - xx.x	xx.x	xx.x - xx.x
			xx	ddmmmyyyy	hh:mm	-xx	xxx	xx.x	xx.x - xx.x	xx.x	xx.x - xx.x
ccc-pppp /xx/x	x	xxx	xx	ddmmmyyyy	hh:mm	xx	xxx	xx.x L G1	xx.x - xx.x	xx.x L G1	xx.x - xx.x
			xx	ddmmmyyyy	hh:mm	xx	xxx	xx.x	xx.x - xx.x	xx.x	xx.x - xx.x
			xx	ddmmmyyyy	hh:mm	xx	xxx	xx.x	xx.x - xx.x	xx.x	xx.x - xx.x
			xx	ddmmmyyyy	hh:mm	xx	xxx	xx.x	xx.x - xx.x	xx.x	xx.x - xx.x

[1] Day is relative to the first dose date of NBF-006.
[2] Reported Result: H = High (Above Normal Range), L = Low (Below Normal Range); Calculated CTCAE version 5 Grade 1 to 4.
Cross-References: Case Report Form URINALYSIS (US)

PROGRAMMER'S NOTES:
Onwards page as required.
Include following Urinalysis Tests: Specific gravity, pH, Glucose, Protein, Ketones, Nitrite, and Leukocyte Esterase, and microscopic tests.

Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.

Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Date" in ascending order within "Patient".
Remove footnote 'Calculated CTCAE version 5 Grade 1 to 4 if not needed.

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Listing 16.2.9.1
Vital Signs
Safety Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose(mg/kg)	Visit	Examination Date	Time	Day [1]	Infusion Time		Blood Pressure(mmHg)		Temperature (°C)	Heart Rate (/min)	Respiratory (/min)
							Start	Stop	Systolic	Diastolic			
ccc-pppp /xx/x	x	xxx	xx	ddmmmyyyy	hh:mm	xx	hh:mm	hh:mm	xxx	xx	xx.x	xxx	xx
									xxx	xx	xx.x	xxx	xx
									xxx	xx	xx.x	xxx	xx
									xxx	xx	xx.x	xxx	xx
			xx	ddmmmyyyy	hh:mm	xx	hh:mm	hh:mm	xxx	xx	xx.x	xxx	xx
									xxx	xx	xx.x	xxx	xx
									xxx	xx	xx.x	xxx	xx
									xxx	xx	xx.x	xxx	xx
ccc-pppp /xx/x	x	xxx	xx	ddmmmyyyy	hh:mm	xx	hh:mm	hh:mm	xxx	xx	xx.x	xxx	xx
									xxx	xx	xx.x	xxx	xx
									xxx	xx	xx.x	xxx	xx

[1] Day is relative to the first dose date of NBF-006.
Cross-References: Case Report Form VITAL SIGNS (VS, VS1)

PROGRAMMER'S NOTES:
When "Not done" is indicated, enter "NOT DONE" in the 'Time' column.
Add records for "Other unscheduled timepoints" within a day if necessary.
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Date Performed" in ascending order within "Patient". Sort "Time" in ascending order within "Date".
Present Infusion Time only data is available or can be derived.

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Listing 16.2.9.2
Physical Examination
Safety Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Visit	Examination Date	Day [1]	Any Clinically Significant Findings
ccc-pppp/xx/x	x	xxx	Screening	ddmmmyyyy	-xx	No
			xx	ddmmmyyyy	xx	No
			xx	ddmmmyyyy	xx	No
			xx	ddmmmyyyy	xx	No
ccc-pppp/xx/x	x	xxx	Screening	ddmmmyyyy	-xx	No
			xx	ddmmmyyyy	xx	No
			xx	ddmmmyyyy	xx	No
			xx	ddmmmyyyy	xx	Yes
ccc-pppp/xx/x	x	xxx	Screening	ddmmmyyyy	-xx	No
			xx	ddmmmyyyy	xx	No
			xx	ddmmmyyyy	xx	No
			xx	ddmmmyyyy	xx	No

[1] Day is relative to the first dose date of NBF-006.
Cross-References: Case Report Form PHYSICAL EXAMINATION (PE)

PROGRAMMER'S NOTES:
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.

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Listing 16.2.9.3
Electrocardiogram
Safety Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Visit	Visit Date	Day [1]	Planned Timepoint	Time	Infusion Time Start	Infusion Time End	Heart Rate (bpm)	PR (ms)	QT (ms)	QTcF (ms)
ccc-pppp/xx/x	x	xxx	Screening	ddmmmyyyy	-xx	xxx	hh:mm	hh:mm	hh:mm	xx	xx.x	xx.x	xx.x
						xxx	hh:mm	hh:mm	hh:mm	xx	xx.x	xx.x	xx.x
						xxx	hh:mm	hh:mm	hh:mm	xx	xx.x	xx.x	xx.x
			xxx	ddmmmyyyy	xx	xxx	hh:mm	hh:mm	hh:mm	xx	xx.x	xx.x	xx.x
			xxx	ddmmmyyyy	xx	xxx	hh:mm	hh:mm	hh:mm	xx	xx.x	xx.x	xx.x
ccc-pppp/xx/x	x	xxx	Screening	ddmmmyyyy	-xx	xxx	hh:mm	hh:mm	hh:mm	xx	xx.x	xx.x	xx.x
						xxx	hh:mm	hh:mm	hh:mm	xx	xx.x	xx.x	xx.x
						xxx	hh:mm	hh:mm	hh:mm	xx	xx.x	xx.x	xx.x
			xxx	ddmmmyyyy	xx	xxx	hh:mm	hh:mm	hh:mm	xx	xx.x	xx.x	xx.x
			xxx	ddmmmyyyy	xx	xxx	hh:mm	hh:mm	hh:mm	xx	xx.x	xx.x	xx.x

QT=QT interval, QTcF= QT corrected by Fridericia's formula
[1] Day is relative to the first dose date of NBF-006.
Cross-References: Case Report Form ELECTROCARDIOGRAM (EG, EG1, EG2, EG3, EG4)

PROGRAMMER'S NOTES:
When "Not done" is indicated, enter "NOT DONE" in the 'Time' column.
Add records for "Other unscheduled timepoints" within a day if necessary.
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Date Performed" in ascending order within "Patient". Sort "Time" in ascending order within "Date".
Present Visit only if data are available.
Present Infusion Time only data is available or can be derived.

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Listing 16.2.9.3
Electrocardiogram
Safety Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose(mg/kg)	Visit	Date	Day [1]	Planned Timepoint	Time	Clinical Interpretation	Clinical Significance	Conclusion	Collection Status
ccc-pppp/xx/x	x	xxx	Screening	dd/mm/yyyy	-xx	dd/mm/yyyy	hh:mm	dd/mm/yyyy	xxx	xxx	xxx
						dd/mm/yyyy	hh:mm	dd/mm/yyyy	xxx	xxx	xxx
						dd/mm/yyyy	hh:mm	dd/mm/yyyy	xxx	xxx	xxx
			xxx	dd/mm/yyyy	xx	dd/mm/yyyy	hh:mm	dd/mm/yyyy	xxx	xxx	xxx
			xxx	dd/mm/yyyy	xx	dd/mm/yyyy	hh:mm	dd/mm/yyyy	xxx	xxx	xxx
ccc-pppp/xx/x	x	xxx	Screening	dd/mm/yyyy	-xx	dd/mm/yyyy	hh:mm	dd/mm/yyyy	xxx	xxx	xxx
						dd/mm/yyyy	hh:mm	dd/mm/yyyy	xxx	xxx	xxx
						dd/mm/yyyy	hh:mm	dd/mm/yyyy	xxx	xxx	xxx
			xxx	dd/mm/yyyy	xx	dd/mm/yyyy	hh:mm	dd/mm/yyyy	xxx	xxx	xxx
			xxx	dd/mm/yyyy	xx	dd/mm/yyyy	hh:mm	dd/mm/yyyy	xxx	xxx	xxx

[1] Day is relative to the first dose date of NBF-006.

Cross-References: Case Report Forms SCREENING ELECTROCARDIOGRAM (EG, EG1, EG2, EG3, EG4)

PROGRAMMER'S NOTES:
When "Not done" is indicated, enter "NOT DONE" in the 'Time' column.
Add records for "Other unscheduled timepoints" within a day if necessary.
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Date Performed" in ascending order within "Patient". Sort "Time" in ascending order within "Date".
Remove "Collection Status" if not populated.

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Listing 16.2.9.4
ECOG Performance Status
Safety Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Visit	Date Assessed	Day [1]	ECOG Performance Status
ccc-pppp /xx/x	x	xxx	Screening	ddmmmyyyy	-xx	0 Fully active, able to carry on all pre-disease activities without restriction.
			xxx	ddmmmyyyy	xx	1 Restricted in physically strenuous activity but ambulatory and able to carry work of a light or sedentary nature, e.g., light housework, office work.
			xxx	ddmmmyyyy	xx	2 Ambulatory and capable of all self-care but unable to carry out work activities. Up and about more than 50% of waking hours.
			xxx	ddmmmyyyy	xx	3 Capable of only limited self-care, confined to bed or chair more than 50% of waking hours.
			xxx	ddmmmyyyy	xx	4 Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.
			xxx	ddmmmyyyy	xx	5 Dead.
ccc-pppp /xx/x	x	xxx	Screening	ddmmmyyyy	-xx	0 Fully active, able to carry on all pre-disease activities without restriction.
			xxx	ddmmmyyyy	xx	1 Restricted in physically strenuous activity but ambulatory and able to carry work of a light or sedentary nature, e.g., light housework, office work.
			xxx	ddmmmyyyy	xx	2 Ambulatory and capable of all self-care but unable to carry out work activities. Up and about more than 50% of waking hours.
			xxx	ddmmmyyyy	xx	3 Capable of only limited self-care, confined to bed or chair more than 50% of waking hours.

[1] Day is relative to the first dose date of NBF-006.
Cross-References: Case Report Form PERFORMANCE STATUS (ES)

PROGRAMMER'S NOTES:
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Date Performed" in ascending order within "Patient".

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Listing 16.2.9.5
Infusion-Related Reactions
Safety Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Adverse Event (MedDRA Preferred Term) (MedDRA System Organ Class)	DLT [1]	Onset Resolved Date/Time	Day [2]	Grade	Ser [3]	Drug Related	Act [4]	Therapy Given	Infusion Time Start	Infusion Time Stop
ccc-pppp /xx/x	x	xxx	ADVERSE EVENT (MedDRA Preferred Term) (MedDRA System Organ Class)		xx:xxx/xxxx xx:xxx/xxxx	xx	Mild	x	probably	1	Yes	hh:mm	hh:mm
			ADVERSE EVENT (MedDRA Preferred Term) (MedDRA System Organ Class)		xx:xxx/xxxx xx:xxx/xxxx	xx	Mild	x	Unlikely	3	Yes	hh:mm	hh:mm
ccc-pppp /xx/x	x	xxx	ADVERSE EVENT (MedDRA Preferred Term) (MedDRA System Organ Class)	Yes	xx:xxx/xxxx xx:xxx/xxxx	xx	Severe		Unrelated	2	No	hh:mm	hh:mm

MedDRA version 21.1
[1] DLT= Dose Limiting Toxicity
[2] Day is relative to the first dose date of NBF-006 .
[3] Ser=Serious: 1=Not Serious, 2=Results in Death, 3=Life Threatening, 4=Requires or Prolongs Hospitalization, 5=Persistent or Significant Disability/Incapacity, 6=Congenital Anomaly or Birth Defect, 7=Other Medically Important Serious Event.
[4] Act=Action Taken: 1=Dose NOT Changed, 2=Dose Interrupted, 3= Dose Delayed, 4= Drug Withdrawn.
DLT= Dose Limiting Toxicity
Infusion-related reactions includes back pain, fever and/or shaking chills, flushing and/or itching, alterations in heart rate and blood pressure, dyspnea or chest discomfort, skin rashes, or anaphylaxis (e.g. generalized urticaria, angioedema, wheezing, hypotension, tachycardia, etc.)
Cross-References: Case Report Form ADVERSE EVENTS (AE)

PROGRAMMER'S NOTES:
Grade: 1=Mild, 2=Moderate, 3=Severe, 4=Life threatening, 5=Fatal. Use maximum grade for summary.
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Onset Date" in ascending order within "Patient".
Infusion-related reactions includes back pain, fever and/or shaking chills, flushing and/or itching, alterations in heart rate and blood pressure, dyspnea or chest discomfort, skin rashes, or anaphylaxis (e.g. generalized urticaria, angioedema, wheezing, hypotension, tachycardia, etc.)
Present Infusion Time only data is available or can be derived.

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Listing 16.2.9.6
Pain Assessment
Safety Evaluable (N=n)

Patient /Age/Sex	Study Part	Dose (mg/kg)	Visit	Visit Date	Infusion Start /Stop Time	MedDRA Preferred Term	Date Collected	Day [1]	Time Collected	Pain Rate[2]	Grade [3]	Where	Duration (unit)	Drug Relationship	Trigger
ccc-pppp /xx/x	x	xxx	xxx	xxx	hh:mm /hh:mm	MedDRA PT	ddmmmyyyy	xx	hh:mm	xxx	x	xxx	xx.x	Unrelated	xxxxxx
					hh:mm /hh:mm	MedDRA PT	ddmmmyyyy	xx	hh:mm	xxx	x	xxx	xx.x	Unlikely	xxxxxx
ccc-pppp /xx/x	x	xxx	xxx	xxx	hh:mm /hh:mm	MedDRA PT MedDRA PT	ddmmmyyyy ddmmmyyyy	xx xx	hh:mm hh:mm	xxx xxx		xxx xxx	xx.x xx.x	Possible	xxxxxx

Pain rate scale of 0-10, 0 is no pain, 10 is the worst pain.
[1] Day is relative to the first dose date of NBF-006.
[2] Pain scale 0-10
[3] Grade: 1=Mild, 2=Moderate, 3=Severe, 4=Life threatening, 5=Fatal.
Cross-References: Case Report Form Pain Assessment (PA)

PROGRAMMER'S NOTES:
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Date Performed" in ascending order within "Patient".
Infusion-related reactions includes back pain, fever and/or shaking chills, flushing and/or itching, alterations in heart rate and blood pressure, dyspnea or chest discomfort, skin rashes, or anaphylaxis (e.g. generalized urticaria, angioedema, wheezing, hypotension, tachycardia, etc.)
Present Visit/Visit Date only if data are available. Present pain rate only if data is available.
Added 3 columns MedDRA PT, Grade, Drug Relationship, but they are not on CRF Pain Assessment page, present only if they can be populated

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Listing 16.2.9.7
Immune Activation Markers - Cytokines Assessment
Intent-to-Treat (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose(mg/kg)	Visit	Sample Date	Day [1]	Scheduled Timepoint	Time	TNF-α		IL-1β		IL-6		IFN-γ	
								Actual	%Change	Actual	%Change	Actual	%Change	Actual	%Change
ccc-pppp/xx/x	x	xxx	Screening	xxx	xx	xxx	hh:mm	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
						xxx	hh:mm	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
						xxx	hh:mm	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
ccc-pppp/xx/x	x	xxx	Screening	xxx	xx	xxx	hh:mm	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
						xxx	hh:mm	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
						xxx	hh:mm	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

Cytokines only collected in Part B at 1.6 mg/kg if cytokine induction was seen at 1.6 mg/kg in Part A, or if there are symptoms indicative of cytokine induction.
[1] Day is relative to the first dose date of NBF-006.
[2] Change = Change from baseline. Baseline is defined as the last value prior to first dose of study drug.
Cross-References: Case Report Form IMMUNE ACTIVATION MARKERS - CYTOKINES ASSESSMENT (TM4)

PROGRAMMER'S NOTES:
When "Not done" is indicated, enter "NOT DONE" in the 'Time' column.
Add records for "Other unscheduled timepoints" within a day if necessary.
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Date Performed" in ascending order within "Patient". Sort "Time" in ascending order within "Date".

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Listing 16.2.9.8
Immune Activation Markers - Complement Assessment
Intent-to-Treat (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose(mg/kg)	Visit	Sample Date	Day [1]	Scheduled Timepoint	Time	CH50 Actual	CH50 %Change	Bb Actual	Bb %Change	C3a Actual	C3a %Change	C5a Actual	C5a %Change
ccc-pppp/xx/x	x	xxx	xxx	xxx	xxxxxx	xx	hh:mm	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
						xx	hh:mm	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
						xx	hh:mm	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
ccc-pppp/xx/x	x	xxx	xxx	xxx	xxxxxx	xx	hh:mm	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
						xx	hh:mm	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
						xx	hh:mm	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

[1] Day is relative to the first dose date of NBF-006.
[2] Change = Change from baseline. Baseline is defined as the last value prior to first dose of study drug.
Cross-References: Case Report Form IMMUNE ACTIVATION MARKERS - COMPLEMENT (TM)

PROGRAMMER'S NOTES:
When "Not done" is indicated, enter "NOT DONE" in the 'Time' column.
Add records for "Other unscheduled timepoints" within a day if necessary.
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Date Performed" in ascending order within "Patient". Sort "Time" in ascending order within "Date".

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Listing 16.2.9.9
Anti-Drug Antibody (ADA) Assay
Intent-to-Treat (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Visit	Test	Sample Date	Day [1]	Scheduled Timepoint	Time	Result	Titer
ccc-pppp/xx/x	x	xxx	xxx	Screening	ddmmmyyyy	xx	xx	hh:mm	Negative	
	x	xxx	xxx	Confirmatory	N/A					
	x	xxx	xxx	Titration	N/A					
ccc-pppp/xx/x	x	xxx	xxx	Screening	ddmmmyyyy	xx	xx	hh:mm	Positive	
	x	xxx	xxx	Confirmatory	ddmmmyyyy	xx	xx	hh:mm	Positive	
	x	xxx	xxx	Titration	ddmmmyyyy	xx	xx	hh:mm	Positive	xxxx
	x	xxx	xxx	xxx	ddmmmyyyy	xx	xx	hh:mm	Positive	
	x	xxx	xxx	Confirmatory	ddmmmyyyy	xx	xx	hh:mm	Negative	
	x	xxx	xxx	Titration	N/A					

[1] Day is relative to the first dose date of NBF-006.
Cross-References: Case Report Form ANTI-DRUG ANTIBODY (ADA) ASSAY (TM1, TM2)

PROGRAMMER'S NOTES:
When "Not done" is indicated, enter "NOT DONE" in the 'Time' column.
Add records for "Other unscheduled timepoints" within a day if necessary.
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Date Performed" in ascending order within "Patient". Sort "Time" in ascending order within "Date".
If Screening result is positive, the same sample will be tested again as a confirmatory assay. Assume that if only tier 1 done on sample, then would next result be blank or N/A.

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Listing 16.2.9.10
KRAS Mutation Assessment
Intent-to-Treat (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Visit	Assessment Completed	Genomic Tumor Profile at Screen	Date of Analysis	Day [1]	Result	Archival Tissue Sample	Date	Fresh Sample	Date	If Yes, Biopsy Performed	KRAS Mutation Type
ccc-pppp/xx/x	x	xxx	xxx	Yes	Yes	ddmmmyyyy	-xx	xxx	Yes	xxx	Yes	xxx	Yes	xxx
ccc-pppp/xx/x	x	xxx	xxx	Yes	Yes	ddmmmyyyy	-xx	xxx	Yes	xxx	Yes	xxx	Yes	xxx
ccc-pppp/xx/x	x	xxx	xxx	Yes	Yes	ddmmmyyyy	-xx	xxx	Yes	xxx	Yes	xxx	Yes	xxx
ccc-pppp/xx/x	x	xxx	xxx	Yes	Yes	ddmmmyyyy	-xx	xxx	Yes	xxx	Yes	xxx	Yes	xxx
ccc-pppp/xx/x	x	xxx	xxx	No	No	NOT DONE	-xx	xxx	No		No		No, xxx	
ccc-pppp/xx/x	x	xxx	xxx	Yes	Yes	ddmmmyyyy	-xx	xxx	Yes	xxx	Yes	xxx	Yes	xxx
ccc-pppp/xx/x	x	xxx	xxx	Yes	Yes	ddmmmyyyy	-xx	xxx	Yes	xxx	Yes	xxx	Yes	Other, specify

[1] Day is relative to the first dose date of NBF-006.
Cross-References: Case Report Form KRAS MUTATION ASSESSMENT (TM8)

PROGRAMMER'S NOTES:
When "Not done" is indicated, enter "NOT DONE" in the 'Time' column.
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Present Visit only if it is applicable.

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Listing 16.2.9.11
GSTT1 Genotyping
Intent-to-Treat (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Visit	Whole Blood Collected	Date Collected	Day [1]	Time Collected	Test	Result
ccc-pppp/xx/x	x	xxx	xxx	Yes	ddmmmyyyy	-xx	hh:mm	GSTT1 Ct Value	xx.xx
ccc-pppp/xx/x	x	xxx	xxx	Yes	ddmmmyyyy	-xx	hh:mm	RNASE Ct Value	xx.xx
ccc-pppp/xx/x	x	xxx	xxx	Yes	ddmmmyyyy	-xx	hh:mm	GSTT1 Genotype	GSTT1 Positive
ccc-pppp/xx/x	x	xxx	xxx	Yes	ddmmmyyyy	-xx	hh:mm	GSTT1 Ct Value	Undetermined
ccc-pppp/xx/x	x	xxx	xxx	Yes	ddmmmyyyy	-xx	hh:mm	RNASE Ct Value	xx.xx
ccc-pppp/xx/x	x	xxx	xxx	Yes	ddmmmyyyy	-xx	hh:mm	GSTT1 Genotype	GSTT1 Positive
ccc-pppp/xx/x	x	xxx	xxx	No					

GSTT1= Glutathione S-Transferase theta class
[1] Day is relative to the first dose date of NBF-006.
Cross-References: Case Report Form GSTT1 GENOTYPING (BS)

PROGRAMMER'S NOTES:
When "Not done" is indicated, enter "NOT DONE" in the 'Time' column.
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Date Performed" in ascending order within "Patient". Sort "Time" in ascending order within "Date".
Present Visit only if it is applicable. Present result if data collected.

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Listing 16.2.9.12
Exploratory Tumor Biopsy
Intent-to-Treat (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Visit	Date Collected	Day [1]	Reason Not Collected	Time	Tumor Biopsy Location
ccc-pppp/xx/x	x	xxx	xxx	ddmmmyyyy	-xx		hh:mm	xxx
ccc-pppp/xx/x	x	xxx	xxx	ddmmmyyyy	-xx		hh:mm	xxx
ccc-pppp/xx/x	x	xxx	xxx	ddmmmyyyy	-xx		hh:mm	xxx
ccc-pppp/xx/x	x	xxx	xxx	ddmmmyyyy	-xx		hh:mm	xxx
ccc-pppp/xx/x	x	xxx	xxx	ddmmmyyyy	-xx		hh:mm	xxx
ccc-pppp/xx/x	x	xxx	xxx	ddmmmyyyy	-xx		hh:mm	xxx
ccc-pppp/xx/x	x	xxx	xxx	NOT DONE		xxxxxx		

[1] Day is relative to the first dose date of NBF-006.
Cross-References: Case Report Form EXPLORATORY TUMOR BIOPY (PR1, PR2)

PROGRAMMER'S NOTES:
When "Not done" is indicated, enter "NOT DONE" in the 'Time' column.
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Date Performed" in ascending order within "Patient". Sort "Time" in ascending order within "Date".
Present Visit only if it is applicable.

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Listing 16.2.9.13
GSTP mRNA KD Sample
Intent-to-Treat (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Visit	Schedule Timepoint	Sample Date	Day [1]	Time	Result	Unit
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxxx

[1] Day is relative to the first dose date of NBF-006.
Cross-References: Case Report Form GSTP MRNA KD SAMPLE (TM6, TM7)

PROGRAMMER'S NOTES:
When "Not done" is indicated, enter "NOT DONE" in the 'Time' column.
Add records for "Other unscheduled timepoints" within a day if necessary.
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Date Performed" in ascending order within "Patient". Sort "Time" in ascending order within "Date".
Present Visit only if it is applicable. Present result if data collected.
For any of the PBMC read-outs (GST mRNA levels), there will be some time points that fail due to insufficient sample. So for unit we may have to indicate ND and then footnote that sample insufficient for analysis.

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Listing 16.2.9.14
GST Family - GSTP1 mRNA Level
Intent-to-Treat (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Visit	Schedule Timepoint	Sample Date	Day [1]	Time	GSTP1 mRNA Level	Unit
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx

[1] Day is relative to the first dose date of NBF-006.
Cross-References: Case Report Form GSTP MRNA KD SAMPLE (TM6, TM7)

PROGRAMMER'S NOTES:
When "Not done" is indicated, enter "NOT DONE" in the 'Time' column.
Add records for "Other unscheduled timepoints" within a day if necessary.
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Date Performed" in ascending order within "Patient". Sort "Time" in ascending order within "Date".
Present Visit only if it is applicable. Data will be from outside vendor.
For any of the PBMC read-outs (GST mRNA levels), there will be some time points that fail due to insufficient sample. So for unit we may have to indicate ND and then footnote that sample insufficient for analysis.

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Listing 16.2.9.15
GST Family - GSTT1 mRNA Level
Intent-to-Treat (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (/mg/kg)	Visit	Schedule Timepoint	Sample Date	Day [1]	Time	GSTT1 mRNA Level	Unit
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx

GSTT1= Glutathione S-Transferase theta class
[1] Day is relative to the first dose date of NBF-006.
Cross-References:

PROGRAMMER'S NOTES:
When "Not done" is indicated, enter "NOT DONE" in the 'Time' column.
Add records for "Other unscheduled timepoints" within a day if necessary.
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Date Performed" in ascending order within "Patient". Sort "Time" in ascending order within "Date".
Present Visit only if it is applicable. Data will be from outside vendor.
For any of the PBMC read-outs (GST mRNA levels), there will be some time points that fail due to insufficient sample. So for unit we may have to indicate ND and then footnote that sample insufficient for analysis.

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Listing 16.2.9.16
GST Family - MGST3 mRNA Level
Intent-to-Treat (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (/mg/kg)	Visit	Schedule Timepoint	Sample Date	Day [1]	Time	MGST3 mRNA Level	Unit
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx

[1] Day is relative to the first dose date of NBF-006.
Cross-References:

PROGRAMMER'S NOTES:
When "Not done" is indicated, enter "NOT DONE" in the 'Time' column.
Add records for "Other unscheduled timepoints" within a day if necessary.
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Date Performed" in ascending order within "Patient". Sort "Time" in ascending order within "Date".
Present Visit only if it is applicable. Data will be from outside vendor.
For any of the PBMC read-outs (GST mRNA levels), there will be some time points that fail due to insufficient sample. So for unit we may have to indicate ND and then footnote that sample insufficient for analysis.

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Listing 16.2.9.17
GST Family – GSTM3 mRNA Level
Intent-to-Treat (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (/mg/kg)	Visit	Schedule Timepoint	Sample Date	Day [1]	Time	GSTM3 mRNA Level	Unit
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxxxx	xxx

[1] Day is relative to the first dose date of NBF-006.
Cross-References:

PROGRAMMER'S NOTES:
When "Not done" is indicated, enter "NOT DONE" in the 'Time' column.
Add records for "Other unscheduled timepoints" within a day if necessary.
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Date Performed" in ascending order within "Patient". Sort "Time" in ascending order within "Date".
Present Visit only if it is applicable. Data will be from outside vendor.
For any of the PBMC read-outs (GST mRNA levels), there will be some time points that fail due to insufficient sample. So for unit we may have to indicate ND and then footnote that sample insufficient for analysis.

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Listing 16.2.9.16
Pharmacokinetics Data Collection
Safety Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Visit	Planned Timepoint	Date Collected	Day [1]	Time Collected	siRNA (ng/mL)	Infusion Time Start	Infusion Time Stop
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxx	hh:mm	hh:mm
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxx	hh:mm	hh:mm
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxx	hh:mm	hh:mm
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxx	hh:mm	hh:mm
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxx	hh:mm	hh:mm
ccc-pppp/xx/x	x	xxx	xxx	xxx	ddmmmyyyy	-xx	hh:mm	xxx	hh:mm	hh:mm
ccc-pppp/xx/x	x	xxx	xxx	xxx	NOT DONE					

[1] Day is relative to the first dose date of NBF-006.
Cross-References: Case Report Form PHARMACOKINETICS (PK, PK1), PHARMACOKINETICS DATA COLLECTION (PK1-2)

PROGRAMMER'S NOTES:
When "Not done" is indicated, enter "NOT DONE" in the 'Time' column.
Add records for "Other unscheduled timepoints" within a day if necessary.
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Date Performed" in ascending order within "Patient". Sort "Time" in ascending order within "Date".
Present Visit only if it is applicable. Present result if data collected.
Present Infusion Time only data is available or can be derived.

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Listing 16.2.10.1
Concomitant Measures
Safety Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Start Date Stop Date	Start Day Stop Day [1]	Drug Name or Treatment (WHO-DD Preferred Term) (WHO-DD ATC Class Category Level I I) [2]	Dose	Unit	Route	Reason For Use	AE Number
ccc-pppp /xx/x	x	xxx	ddmmmyyyy Ongoing	-xx -xx	Concomitant Measure (WHO-DD Preferred Term) (WHO-DD ATC Class Category Level I I)	xxx	xxx	Route	Reason	xx
		xxx	ddmmmyyyy ddmmmyyyy	xx xx	Concomitant Measure (WHO-DD Preferred Term) (WHO-DD ATC Class Category Level I I)	xxx	xxx	Route	Reason	xx
ccc-pppp /xx/x	x	xxx	ddmmmyyyy Ongoing	-xx xx	Concomitant Measure (WHO-DD Preferred Term) (WHO-DD ATC Class Category Level I I)	xxx	xxx	Other: specify	Reason	xx

[1] Day is relative to the first dose date of NBF-006.
[2] WHO-DDE version 2018
Cross-References: Case Report Form CONCOMITANT MEASURES (CM)

PROGRAMMER'S NOTES:
When "None" is indicated, enter "NO CONCOMITANT MEASURES" in the 'Drug Name or Treatment' column.
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Start Date" in ascending order within "Patient".

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Listing 16.2.10.2
Concomitant Measures - Palliative Radiotherapy
Safety Evaluable (N=n)

Patient /Age/Sex	Study Part	NBF-006 Dose (mg/kg)	Start Date Stop Date	Start Day Stop Day [1]	Drug Name or Treatment (WHO-DD Preferred Term) (WHO-DD ATC Class Category Level II) [2]	Dose	Unit	Route	Reason For Use	On Target Lesion
ccc-pppp /xx/x	x	xxx	dd/mmmyyyy Ongoing	-xx -xx	Concomitant Measure (WHO-DD Preferred Term) (WHO-DD ATC Class Category Level II)	xxx	xxx	Route	Reason	No
		xxx	dd/mmmyyyy dd/mmmyyyy	xx xx	Concomitant Measure (WHO-DD Preferred Term) (WHO-DD ATC Class Category Level II)	xxx	xxx	Route	Reason	No
ccc-pppp /xx/x	x	xxx	dd/mmmyyyy Ongoing	-xx xx	Concomitant Measure (WHO-DD Preferred Term) (WHO-DD ATC Class Category Level II)	xxx	xxx	Other: specify	Reason	Yes

Palliative radiotherapy is allowed as medically indicated after completion of the first treatment cycle, and after discussion with medical monitor.
[1] Day is relative to the first dose date of NBF-006.
[2] WHO-DDE version 2018
Cross-References: Case Report Form CONCOMITANT MEASURES (CM)

PROGRAMMER'S NOTES:
When "None" is indicated, enter "NO CONCOMITANT MEASURES" in the 'Drug Name or Treatment' column.
Data will be presented in mixed case for formatted variables and upper case only for unformatted variables.
Sort "Patient" in ascending order using "pppp", and then "ccc" portion of patient number.
Sort "Start Date" in ascending order within "Patient".
May removed some columns if data is not available.

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Nitto NBF-006-001_TLF Plan Part A & B Final 2.0_clean_14Mar2023

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