Statistical Analysis Plan

P-VCNA-003

A Phase IIb, Open-label, Randomized Study of Nab-Paclitaxel and Gemcitabine plus/minus VCN-01 in Patients with Metastatic Pancreatic Cancer (VIRAGE)

Simbec-Orion Study ID: 35667

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GLOSSARY OF ABBREVIATIONS

AE	Adverse Event
AR	Adverse Reaction
ATC	Anatomical Therapeutic Chemical
BMI	Body Mass Index
Ca 19.9	Tumor marker carbohydrate antigen (Ca) 19.9
CI	Confidence Interval
CIV	Central Imaging Vendor
CMH	Cochran-Mantel-Haenszel
CR	Complete Response
CRA	Clinical Research Associate
CRF	Case Report Form
CS	Clinically Significant
CSR	Clinical Study Report
CT	Computerized Tomography
DBL	Database Lock
DCR	Disease Control Rate
DMC	Data Monitoring Committee
DoR	Duration of Response
DRM	Data Review Meeting
ECG	Electrocardiogram
ECOG	Eastern Cooperative Oncology Group
EDC	Electronic Data Capture
EORTC	European Organization for Research and Treatment of Cancer
EOS	End of Study
EOT	End of Treatment
EU	European Union
FAS	Full Analysis Set
FU	Follow-up
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Hepatitis B/C and Human Immunodeficiency Virus
ICH	International Conference on Harmonisation

IMP	Investigational Medicinal Product
ITT	Intent-to-Treat set
IV	Intravenously
LS Mean	Least Squares Mean
LVEF	Left Ventricular Ejection Fraction
MedDRA	Medical Dictionary for Regulatory Activities
MRI	Magnetic Resonance Imaging
N	Number of Patients in the Population
n	Number of Patients in the Sample
NA	North America
NCS	Not clinically significant
ORR	Objective Response Rate
OS	Overall Survival
PCR	Polymerase Chain Reaction
PD	Progressive Disease
PDS	Pharmacodynamic Set
PFS	Progression-free Survival
PPS	Per-Protocol Set
PR	Partial Response
PT	Preferred Term
QC	Quality Control
QoL	Quality of Life
RECIST	Response Evaluation Criteria in Solid Tumors
SAE	Serious Adverse Event
SAF	Safety Analysis Set
SAP	Statistical Analysis Plan
SAR	Serious Adverse Reaction
SAS	Statistical Analysis System
SD	Stable Disease
STD	Standard Deviation
SE	Standard Error
SOC	System Organ Class
SoC	Standard of Care
TB	Tuberculosis
TEAE	Treatment Emergent Adverse Event
TSH	Thyroid Stimulating Hormone

TTP	Time to Progression
WHODD	World Health Organisation Drug Dictionary

1 INTRODUCTION

1.1 GENERAL

This statistical analysis plan (SAP) describes the statistical methods to be used during the reporting and analyses of data collected under Protocol P-VCNA-003 (Simbec-Orion study 35667) sponsored by VCN Biosciences S.L., a wholly-owned subsidiary of Theriva Biologics, Inc., and should be read in conjunction with the study protocol and case report form (CRF).

This version of the plan has been developed using the protocol Version 2.1 dated 10 AUG2023 and CRF specifications dated 13Jul2023. Any further changes to the protocol or CRF will be reviewed for potential impact on the SAP which will be amended if it is deemed necessary.

All versions of this plan will be reviewed by the Simbec-Orion project manager, medical writer and statistical reviewer. The SAP will be finalised and approved by the Sponsor prior to database lock.

1.2 CHANGES FROM PROTOCOL

All Randomized Set has been added to analysis sets.

Progression-Free Survival (PFS) and Time to Progression (TTP) will both be analysed as secondary endpoints instead of PFS or TTP. Definitions are included in this SAP.

Per Protocol set to be defined as patients in the FAS without any major protocol deviations that could potentially influence a primary or main secondary study endpoints.

Duration of Response (DoR) will be summarized by Kaplan-Meier estimate of the median with the associated 95 % confidence interval and censoring will be occur in patients without progression or death until EOS.

1.3 CHANGES FROM PREVIOUS VERSIONS OF THE SAP

Changes from SAP version 1.0:

- Updates have been made based on protocol amendment (v2.1 dated 10Aug2023) and eCRF amendment (dated 13Jul2023).
- Summary tables for serious treatment-emergent adverse by relationship to VCN-01, Gemcitabine and Nab-paclitaxel events have been added to the safety analysis.
- Definition of Per Protocol Set has been updated.
- Summary statistics for DoR have been added to use Kaplan-Meier estimate.
- Kaplan-Meier figures have been added to the time-to event endpoints.

Changes from SAP version 2.0:

- Updates on final TFLs shells.
- Kaplan-Meier figures for PFS (FAS), Subgroup analysis for OS and PFS (ITT) and for Duration of Response (FAS) have been added to the efficacy analysis.
- Added demographic and baseline characteristics table to be summarized on Full Analysis Set
- Visit windowing and baseline definition for QoL outcomes have been updated. Baseline for ECOG has been updated.
- Topline TFLs have been selected for the final TFL delivery.

- Adverse Events tables are presented only for Patients with Adverse Events, event counts are deleted from the tables.
- Minor edits throughout the documents.

2 STUDY OBJECTIVES

2.1 PRIMARY OBJECTIVES

This study will enroll patients with metastatic pancreatic cancer into one of two treatment arms (Arm I or Arm II) as detailed in Section 3 Study Design. The primary objectives of the study are:

- To evaluate the time from randomization until death in both arms (Overall Survival)
- To evaluate the safety and tolerability of VCN-01, intravenously (IV) administered at Week 1 and Week 14 in Arm II (VCN-01 in combination with Nab-paclitaxel and Gemcitabine).

2.2 SECONDARY OBJECTIVES

The secondary objectives are:

- To evaluate the Time to Progression (TTP) and Progression-free Survival (PFS)
- To determine the Objective Response Rate (ORR)
- To determine the Disease Control Rate (DCR) (stable disease [SD] + partial response [PR] + complete response [CR])
- To determine the landmark 1-year survival and PFS at the 1-year landmark
- To evaluate the Duration of Response (DoR)
- To assess changes in tumor marker carbohydrate antigen (Ca) 19.9 measured every 4 weeks while on study.

2.3 EXPLORATORY OBJECTIVES

- To evaluate circulating immune markers in serum, VCN-01 genomes in blood, PH20 levels in serum, neutrophil/lymphocyte ratio, and serum levels of neutralizing anti-VCN-01 antibodies (Anti-Ad-NAbs)
- To evaluate radiomic analysis of computerized tomography (CT) images
- To characterize the Quality of Life (QoL) via the validated European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC) QLQ-C30 questionnaire (version 3)
- To determine the disease control rate (DCR) to the subsequent anticancer therapies.

3 STUDY DESIGN

3.1 OVERVIEW

This is a multi-center, open label, randomized, 2-parallel arm, phase IIb study of nab-paclitaxel and gemcitabine as Standard of Care (SoC) plus/minus VCN-01 in patients with metastatic pancreatic cancer.

Approximately 92 patients in about 25 sites in North America (NA) and European Union (EU) will be recruited and randomized in a 1:1 ratio to one of two treatment arms:

- Arm I: Nab-paclitaxel and gemcitabine as SoC (28-day cycles). Patients in this arm will not receive the Investigational Medicinal Product (IMP) (VCN-01).
- Arm II: Two (2) doses of VCN-01 administrated in combination with nab-paclitaxel and gemcitabine as SoC (28-day cycles with exception of the IMP dose cycles, which will be 35-day cycles).

The randomization will be stratified to take account of the patients' baseline Eastern Cooperative Oncology Group (ECOG) performance status (0 or 1) and region (NA or EU).

A Data Monitoring Committee (DMC) will be convened at regular intervals to assess safety and to look at Overall Survival (OS) to determine if the trial can continue, as mentioned in the DMC charter.

See Section 16.1 for the Study Design.

3.2 Inclusion and Exclusion Criteria

To be eligible for inclusion into this study, each patient must fulfil all inclusion criteria and not violate any exclusion criteria within 28 days up to and including Study Day 1 (first day of treatment with IMP/SoC). Details of the inclusion and exclusion criteria are presented in the protocol and amendments.

3.3 Study Treatment

For this study, VCN-01 is considered an IMP while nab-paclitaxel and gemcitabine are considered non-IMPs to be administrated as SoC.

Approximately 92 patients in about 25 sites in NA and EU will be recruited and randomized in a 1:1 ratio to one of the two treatment arms described above. Patients in both arms will continue study treatment until progressive disease (PD), intolerable/unacceptable toxicity or patient's/investigator's decision. This period will be defined as Treatment period.

3.4 Study Timepoints

The trial includes the following periods:

- Screening period (approximately 4 weeks prior to first dose): Days -28 to -1 (Week -4 to -1); there is no Day 0
- Randomization can occur any time during the 28-day Screening period when all the screening assessments are completed, but dosing (D1) must take place no later than 5 days after randomization.
- Treatment period (variable, depending on progression of disease/toxicity and decision of patient/investigator):
    - Arm I: Cycle 1 (28 days); Cycle 2 (28 days); Cycle 3 (28 days); Cycle 4 (28 days) and subsequent nab-paclitaxel / gemcitabine cycles
    - Arm II: Cycle 1 (35 days); Cycle 2 (28 days); Cycle 3 (28 days); Cycle 4 (35 days) and subsequent nab-paclitaxel / gemcitabine cycles
    - End-of-Treatment (EOT) visit: 1 month after last dose (±1 week)
- Follow-up (FU) period:
    - FU without PD (±1 week): every 4 weeks (q4wk) until PD
    - FU due to PD (±1 week): q4wk during the first 6 months; every 2 months (q2mo) until the second year; every 6 months (q6mo) after the second year

- End of Study (EOS): Patients will be followed for survival until the EOS regardless of further treatments, or until the sponsor ends the study. Early trial termination of the study by the Sponsor is only anticipated on the basis of safety.

See Protocol Appendix 7 and 8 for the Study Schedule in Arm I and Arm II.

3.5 Sample Size Considerations

Assuming an accrual time of 18 months with (minimum) 12-month FU for all patients, 1-sided alpha = 0.05, beta= 0.2 (80% power), the median OS=10.6 months for Arm I and the median OS=20.8 for Arm II with 1: 1 randomization, 46 patients would be needed for each study arm to reach the 57 events needed using the logrank test. It is therefore planned to randomize a total of 92 adult patients with metastatic pancreatic cancer into the study for final analysis.

3.6 Randomization

Patients will be randomized in a ratio of 1:1 to receive either SoC or SoC + 2 administrations of VCN-01. The randomization will be stratified to take account of the patients' baseline ECOG performance status (0 or 1) and region (NA or EU).

4 STUDY VARIABLES AND COVARIATES

4.1 Primary Variables

The primary variables are:

- Overall Survival (OS)
- Safety and tolerability of VCN-01 in Arm II

4.2 Secondary Variables

The secondary variables are:

- PFS or TTP
- ORR
- DCR (SD + PR + CR)
- Landmark 1-year survival and PFS at the 1-year landmark
- DoR
- Changes in tumor marker Ca 19.9

4.3 Exploratory Variables

The exploratory variables are:

- Biomarker levels, such as PH20, VCN-01 genomes, neutrophil/lymphocyte ratio, anti-Ad-NAb, circulating immune markers and/or other markers according to the state of the art, may be determined in blood and serum samples collected at different timepoints during the study.
- Image biomarkers (radiomics) assessed from the images of CT scans performed during the study.
- Change from baseline in values of the QoL via the validated EORTC QLQ-C30 questionnaire (version 3).
- DCR (SD + PR + CR) to the subsequent therapies.

4.4 PHARMACOKINETIC VARIABLES

Pharmacokinetic variables are not evaluated in this study.

4.5 PHARMACODYNAMIC VARIABLES

Please refer to Section 4.3 for exploratory Pharmacodynamic variables. No further Pharmacodynamic variables will be evaluated in this study.

4.6 SAFETY VARIABLES

Safety will be evaluated by the following:

- Demographics
- Medical history
- Prior medications and procedures, including standard of care
- Concomitant medications and procedures
- Physical examinations
- Vital signs assessments
- Safety laboratory test – biochemistry, hematology, coagulation profile, thyroid stimulating hormone (TSH), Hepatitis B Virus (HBV)/Hepatitis C Virus (HCV), tuberculosis (TB) test and Human Immunodeficiency Virus (HIV), urinalysis and pregnancy test
- 12-Lead electrocardiogram (ECG)
- COVID-19 testing
- Left ventricular ejection fraction (LVEF)
- Eastern Cooperative Oncology Group (ECOG) score
- Fibroscan (if clinically indicated)
- Adverse event (AE)/serious adverse event (SAE) assessment.

5 DEFINITIONS

Study Drug: Study drug is taken to mean either VCN-01 (considered as IMP) or nab-paclitaxel and gemcitabine (considered as non-IMPs to be administrated as SoC).

Baseline: Baseline is defined by patient and by variable as the last non-missing value (including repeat/unscheduled assessments) before the first dose of study drug except for QoL and ECOG result. The baseline for QoL is C1D1, if not missing, otherwise the closes value which is before C1D1. The baseline ECOG status refers to the ECOG assessment used to determine stratification at randomization. This is always the Screening value. ***Study Day***: Study day is the number of days since start of treatment where the date of first dose is counted as Day 1 (there is no Day 0).

Protocol Deviation: a deviation related to study inclusion or exclusion criteria, conduct of the trial, patient management or patient assessment. This refers to any change, divergence, or departure from the study design or procedures defined in the protocol. Protocol deviations captured in the CRF will be reviewed on a regular basis during the study and discussed at the Data Review Meeting (DRM) before Database Lock (DBL). In addition, any deviations identified during the DRM will be discussed and included in the database as necessary. All protocol deviations within the study database will be classified as either 'Major' or 'Minor' prior to DBL, details of which will be included within the Protocol Deviations Listing.

6 ANALYSIS SETS

Membership of the analysis sets will be reviewed and agreed at a DRM before database lock.

6.1 ALL RANDOMIZED SET

The All Randomized Set is defined as all patients who are randomized.

This analysis set will be used for the summary of disposition.

6.2 SAFETY ANALYSIS SET (SAF)

The Safety Analysis Set (SAF) is defined as all patients who are randomized and take at least any dose of Study Drug.

This analysis set will be used for demographic and safety summaries as well as for study listings. The treatment arm is defined as the treatment that actually treated the patient.

6.3 INTENT-TO-TREAT SET (ITT)

The intent-to-treat (ITT) analysis set is defined as all patients who are randomized and have received any dose of Study Drug. The treatment arm is defined as the treatment that is randomized to treat the patient.

The ITT will be used for demographic and baseline characteristics summary and for all efficacy analyses.

6.4 FULL ANALYSIS SET (FAS)

The Full Analysis Set (FAS) is defined as all patients who are randomized and have received

- at least 1/3 of the planned chemotherapy dose, if allocated to Arm I or
- at least 1/3 of the planned chemotherapy dose and a complete dose of VCN-01, if allocated to Arm II

during the first cycle of the study.

The FAS will be used for the efficacy analyses of the primary and secondary variables and for demographic and baseline characteristics.

6.5 PER-PROTOCOL SET (PPS)

The Per-Protocol Set (PPS) is defined as patients in the FAS without any major protocol deviations that could potentially influence a primary or main secondary study endpoint.

Primary analysis will be repeated for the PPS.

6.6 PHARMACODYNAMIC SET (PDS)

The Pharmacodynamic Set (PDS) will consist of all patients in the FAS who had at least 1 pharmacodynamic measurement, had no major protocol deviations affecting pharmacodynamic parameters and no deviation from pharmacodynamic sampling procedures.

PDS will be used for pharmacodynamic parameters.

7 SAFETY MONITORING

An independent DMC will be established to ensure patient safety, to consider patient risks against the potential for meeting trial objectives, and to provide recommendations to the Sponsor with respect to the conduct of the trial.

The DMC will perform the following major functions:

- The DMC will be responsible for the ongoing review of safety data throughout the trial. Primary among the safety data to be reviewed will be SAEs, any adverse drug reactions and all relevant available clinical laboratory data.
- The DMC may review acute and additional safety data, on a patient-by-patient basis, at their discretion. This would be warranted if significant unexpected events are observed.
- The DMC may request additional safety data if, in the view of the committee, these additional data are needed in order to make an informed, responsible decision about the conduct of the trial.
- The DMC will advise the Sponsor regarding safety of patients and continuing validity and scientific merit of the trial. The DMC will also monitor the number of deaths in both arms of the study.

If emerging data from this unblinded study suggest that an interim analysis for futility or efficacy is warranted, the clinical study protocol, DMC responsibilities, and this SAP may be amended to incorporate such analysis.

All details of the conduct and responsibilities of the study DMC along with the frequency of DMC meetings will be described in the 'DMC Charter', which will be finalized prior to the start of patient enrolment.

8 INTERIM ANALYSES

No interim analysis is planned. If emerging data from this unblinded study suggest that an interim analysis for futility or efficacy is warranted, the clinical study protocol, DMC responsibilities, and this SAP may be amended to incorporate such analysis.

9 DATA

9.1 eCRF DATA

CRF data will be provided by Simbec-Orion data management to the statistics department as Statistical Analysis System (SAS) data sets in Simbec-Orion standard format which will be used for programming

the outputs to be included in the Clinical Study Report (CSR). Populated datasets will be available when programming starts. These may contain dummy data if real data is not yet available.

9.1.1 Laboratory Data

Laboratory tests will be performed at the time points provided in the schedule of assessments of the protocol (APPENDIX 7 and APPENDIX 8 for Arms I and II, respectively).

Laboratory tests include the following:

Hematology (All samples to local laboratory)		
Basophils (absolute and relative)	Monocytes (absolute and relative)	Neutrophils (absolute and relative)
Eosinophils (absolute and relative)	MCH	Platelet count
Hemoglobin	MCV	RBC count
Hematocrit	Mean corpuscular hemoglobin concentration	Lymphocytes (absolute and relative)
D-dimer		White Blood Cell (WBC) count
Coagulation Panel (All samples to local laboratory)		
aPTT	Prothrombin time	INR
Biochemistry (All samples to local laboratory)		
Albumin	Creatine phosphokinase	Sodium
Alkaline phosphatase	CRP	Total protein
ALT	GGT	Phosphorous
AST	Glucose (fasted)	Transferrin
Bilirubin (total) (Direct bilirubin may also be measured at the investigator's discretion if clinically indicated)	Magnesium	Urea or blood urea nitrogen, depending on local practice
Calcium	Lipase	
Chloride	Amylase	Uric acid
Creatinine	Potassium	Lactate dehydrogenase
Blood Borne Viruses (BBVs) (Samples to local laboratory)		
HBV	HCV	HIV
TB	COVID-19	
Serum tumor markers (Samples to local laboratory)		
Ca 19.9 tumor marker		
Hormone levels (Samples to local laboratory)		
TSH		
Pregnancy test in serum and urine (Samples to local laboratory) for women of child-bearing potential		
βHCG (serum)	hCG (urine)	
Urinalysis (All samples to local laboratory)		
Albumin	Creatine	Leukocytes reagent strip result
Bilirubin	Glucose	pH
Blood	Ketones	Sediment
Calcium	Leukocytes per field	Microscopic examination, if needed

Abbreviations: ALT=Alanine aminotransferase; AST=Aspartate aminotransferase; aPTT=Activated partial thromboplastin time; βHCG=Beta human chorionic gonadotropin; BUN=Blood urea nitrogen; CRP=C-reactive protein; COVID-19 = Coronavirus Disease 2019; GGT=Gamma-glutamyl transferase; HBV=hepatitis B virus; HCV=hepatitis C virus; HIV=human immunodeficiency virus; INR=International normalized ratio; MCH=Mean corpuscular hemoglobin; MCV=Mean corpuscular volume; Nabs=Ad-specific neutralizing antibodies; pH=potential of Hydrogen; RBC=Red blood cell; TB=tuberculosis; TSH=thyroid stimulating hormone; WBC=White blood cell

9.2 External Data

9.2.1 Laboratory Data

The following biomarkers will be collected by Central Laboratory:

Biomarkers (All samples to Central laboratory)		
Circulating immune markers (serum)	VCN-01 genomes (blood)	PH20 (serum)
Neutralizing anti-VCN-01 antibodies (Anti-Ad-NAbs) (serum)		

9.2.2 Other non-CRF data

Local Laboratory Reference ranges will be provided by the laboratory before site initiation and the required parameters will be transcribed onto the Data Management Laboratory Reference Range Form by the Clinical Research Associate (CRA). The CRA will provide reference ranges to the Data Manager, who will use them to verify data on CRF.

9.3 Randomization list

The randomization list will be uploaded to a SAS dataset following database lock.

9.4 Programming and Data Review

Programming of analysis datasets, tables, figures and listings will be ongoing during the data management of the study. Outputs for the DMC will be reviewed by Simbec-Orion. Outputs may be reviewed by Sponsor before DBL.

When the final data are considered clean, key listings (to be agreed) will be run and distributed to the study team for review. A data review meeting will be held to discuss the outcome of this review and the protocol deviations. Once all data issues have been resolved and the analysis populations approved, the database will be locked. The final run of outputs and quality control (QC) will then take place.

10 STATISTICAL METHODS

10.1 General Principles

All statistical methods will be based on the International Conference on Harmonisation (ICH) E9 document "Statistical Principles for Clinical Trials".

Data will be summarised by treatment arm. Where appropriate, data will also be summarised by visit with summaries for each visit attended as scheduled and an additional summary for final (last scheduled visit or early withdrawal). The format of the summaries is defined in the shells at the end of this document.

In summary and analysis tables of continuous variables, standard descriptive statistics (N, mean, standard deviation [STD], median, minimum and maximum) will be presented. Least squares mean (LS mean), standard error (SE) and 95% confidence interval (CI) will be presented in the statistical analysis outputs as appropriate. The minimum and maximum statistics will be presented in summary tables to the same number of significant figures as the original data. The mean, median, LS mean, CI, STD and SE will be presented to one more significant than the original data.

In summary tables of categorical variables, the number of non-missing observations by category will be presented with percentages. Unless otherwise specified, the denominator for each percentage will be the number of non-missing observations within the column. All percentages will be presented to one decimal place.

If changes in severity for the same Treatment Emergent Adverse Event (TEAE) have been reported separately but with the same AE number, they will be collapsed to a single AE with maximum severity for the summary tables, but will be listed as reported.

Classifications of medical history, concomitant medication and adverse events will be sorted alphabetically within the summary tables.

If any laboratory assessments are repeated at the same visit, the result from the repeat assessment will be used in summaries. Both values will be listed.

Data collected on the eCRF will be presented within data listings. The data listings will be sorted by treatment arm, patient number and visit. If any patients receive the wrong treatment this will be flagged in all listings. For patients who complete the study, the last visit will be described in the listings as '<Cycle X Day Y>'; for those who withdraw early it will be described as 'End of Study'.

The date format for all output presentations will be 'ddMMMyyyy'.

All statistical analysis will be performed using SAS® Enterprise Guide 8.3 or higher.

All hypothesis testing will be carried out at the 5% (2-sided) significance level unless stated otherwise.

P-values will be rounded to four decimal places. P-values less than 0.0001 will be reported as <0.0001 in tables.

If any of the assumptions underlying the formal statistical methods proposed are violated during the analysis of the final data, alternative statistical methods will be used and any changes documented in the statistical methods section of the CSR, including the rationale for use.

10.2 Stratification and Covariate Adjustment

Randomization is stratified by ECOG (=0 or =1) at baseline and region (=NA or =EU). The primary analysis will be adjusted for the stratification factors.

10.3 Interactions

No interactions are to be performed.

10.4 Missing Data

There will be no imputation of missing data in this study.

10.5 Pooling of Sites

Sites will be pooled for all analyses. There will be no adjustment for centre effect or treatment by centre interaction.

10.6 Multiple Comparisons

A sequential testing will be used to control the overall false positive rate at the 5% (2-sided) significance level for the primary and secondary variables, based on the ITT analysis set. Specifically, the primary variable (OS) will be tested first. If the P-value for OS is < 0.05, then the secondary variables will be tested in the order that is listed in the SAP. The PFS will be tested first. If the P-value for PFS is < 0.05, then ORR will be tested next. If at anytime the P-value is > 0.05, the testing procedure will stop.

10.7 Subgroup Analyses

Analyses for the primary endpoint (OS) and the main secondary endpoints (PFS, TTP and ORR) will be repeated for the following subgroup:

- Arm I: patients who had the first 3 cycles of SoC chemotherapy and started the 4th SoC chemotherapy
- Arm II: patients who had the first 3 cycles of SoC chemotherapy, started the 4th cycle of SoC chemotherapy and received 2 doses of VCN-01.

Subgroup analyses will be performed using the ITT. Subgroup analysis will also be performed for the primary endpoint using the PPS.

11 STATISTICAL OUTPUT

General principles for layout of the statistical output are described in Section 10.1, including specification of the table columns, and these are illustrated for each unique table in the table shells in Section 15. For clarity and brevity in this document the phrase "by treatment arm" is understood to apply to all summaries and is not included within the text of this section.

11.1 Patient Disposition

Information about screening failures will be provided by the project manager and presented in the CSR as a brief summary of the most frequent reasons for failure.

The patient disposition table (*Table 14.1.1*) will summarise the following data:

- The number (%) of patients who withdrew from the study and the associated reasons for withdrawal
- The number (%) of patients in each analysis set.

A listing of all patients with protocol deviations will be presented. A data listing presenting the eligibility for the analysis sets for each patient will also be presented.

11.2 Patient Characteristics at Baseline

11.2.1 Demographic and Baseline Characteristics

Age will be calculated using Year of Birth and Date of first treatment and presented as age at last birthday as an integer.

Body Mass Index (BMI) is the patient's body weight in kilograms divided by the square of the patient's height in metres.

Age, gender, race, ethnicity, region of study site, baseline ECOG status, height, weight and BMI will be summarised using the ITT (*Table 14.1.2.1*) the FAS (*Table 14.1.2.2*) and the SAF (Table 14.1.2.3).

11.2.2 Medical History

All conditions will be coded using the version of the Medical Dictionary for regulatory Activities (MedDRA) defined in the Data Management Plan. Medical history will be summarised by system organ class (SOC) and preferred term (PT). The number (%) of patients reporting each condition will be presented using the FAS (*Table 14.1.3*).

Medical history should include all ongoing medical conditions at the time of Screening.

11.2.3 Substance Use History

Substance use (alcohol, smoking and recreational drug) history will be listed only.

11.3 Efficacy Analyses

All the efficacy analyses will use ITT. The analysis for the primary endpoint will be repeated for the FAS and PPS. Secondary analyses will be repeated using FAS.

Subgroup analyses will be conducted for OS, PFS, TTP and ORR using the ITT, please refer to section 10.7. Subgroup analysis for OS will be repeated for the PPS.

11.3.1 Primary Variable

11.3.1.1 Overall Survival (OS)

The primary efficacy endpoint is survival time (OS), defined as time from randomization until death. Patients who are lost to FU during the trial will be censored at the time of their last visit or contact.

A Cox Proportional Hazards model will be fitted to the data with the Cox adjustment for tied observations. Model terms will include region, baseline ECOG performance status and treatment. A logrank test will be used to test the null hypothesis that there is no difference between the two treatments against the two-sided alternative. An estimate and 95% CI for the hazard ratio will be provided. Analysis will be performed using the ITT (*Table 14.2.1.1*) and will be repeated using the FAS and PPS (*Table 14.2.1.2 and Table 14.2.1.3*). Subgroup analysis will also be performed for patients defined under section 10.7 for ITT (*Table 14.2.1.4*) and for PPS (*Table 14.2.1.5*).

In addition, Kaplan-Meier curves will be plotted, from which median survival times will be estimated (*Figure 14.2.1 - Figure 14.2.3*). Subgroup analysis will also be performed and Kaplan-Meier curve will be plotted (Figure 14.2.4).

11.3.2 Secondary Variables

11.3.2.1 Progression-free Survival (PFS) and Time to Progression (TTP)

Progression-free Survival (PFS) is defined as time from randomization until progression of disease (PD) or death by any cause. Time to Progression (TTP) is defined as time from randomization until disease progression or death due to progression. Progression of Disease (PD) is defined as having progression of disease according to Response Evaluation Criteria in Solid Tumors (RECIST) 1.1.

PFS and TTP will be analysed in the same way as overall survival (see section 11.3.1.1) (*Table 14.2.2.1 and Table 14.2.2.2*). Subgroup analysis will also be performed for patients defined under section 10.7 for ITT (*Table 14.2.2.3*). Patients who are lost to FU prior to having progression of disease will be censored at the time of their last visit or contact.

PFS and TTP will also be analysed using data from central imaging vendor (*Table 14.2.2.4, 14.2.2.5 and 14.2.2.6*).

In addition, Kaplan-Meier curves will be plotted, from which median survival times will be estimated *(Figure 14.2.5 – Figure 14.2.6 and Figure 14.2.8)*. Subgroup analysis will also be performed on PFS and Kaplan-Meier curve will be plotted (Figure 14.2.7).

11.3.2.2 Objective Response Rate (ORR)

ORR is defined as the percentage of patients with CR or PR to study treatment according to RECIST 1.1 at EOT.

ORR will be presented using the number and percentage of patients. Cochran–Mantel–Haenszel (CMH) test stratified by region and ECOG performance status at randomization will be used to test the null hypothesis that there is no difference between the two treatments. CMH adjusting for age group will be conducted as a sensitivity analysis (*Table 14.2.2.7 and Table 14.2.2.8*). Subgroup analysis will also be performed for patients defined under section 10.7 for ITT (*Table 14.2.2.9*).

ORR will also be analysed using data from central imaging vendor (*Table 14.2.2.10, 14.2.2.11 and 14.2.2.12*).

Age group is provisionally defined as <65 and >=65 years of age at enrolment. Should the data present with age groups with too many in either group (>75%) a revised cut-off may be made prior to database lock, but only under the single criteria described above, age group cannot be redefined for any other reason.

11.3.2.3 Disease Control Rate (DCR)

The percentage of patients who have achieved CR, PR, and SD to the study treatment according to RECIST 1.1 at EOT as assessed by CT scan or Magnetic Resonance Imaging (MRI). Refer to protocol APPENDIX 4 for information on tumor response evaluation and definition of CR, PR, and SD.

DCR will be presented using the number and percentage of patients. Cochran–Mantel–Haenszel (CMH) test stratified by region and ECOG performance status at randomization will be used to test the null hypothesis that there is no difference between the two treatments. CMH adjusting for age group will be conducted as a sensitivity analysis (*Table 14.2.2.13 and Table 14.2.2.14*).

DCR will also be analysed using data from central imaging vendor (*Table 14.2.2.15, and 14.2.2.16*).

Age group is provisionally defined as <65 and >=65 years of age at enrolment. Should the data present with age groups with too many in either group (>75%) a revised cut-off may be made prior to database lock, but only under the single criteria described above, age group cannot be redefined for any other reason.

11.3.2.4 Landmark 1-year survival and PFS at the 1-year landmark

Landmark 1-year survival is defined as survival at 1 year from randomization. PFS at 1-year landmark is defined as PFS at 1 year from randomization.

Landmark 1-year survival and PFS at the 1-year landmark will be presented using the number and percentage of patients. Cochran–Mantel–Haenszel (CMH) test will be used to test the null hypothesis that there is no difference between the two treatments. CMH adjusting for age group will be conducted as a sensitivity analysis (*Table 14.2.2.17 and Table 14.2.2.18*).

The above endpoints will also be analysed using data from central imaging vendor (*Table 14.2.2.19, and 14.2.2.20*).

Age group is provisionally defined as <65 and >=65 years of age at enrolment. Should the data present with age groups with too many in either group (>75%) a revised cut-off may be made prior to database lock, but only under the single criteria described above, age group cannot be redefined for any other reason.

11.3.2.5 Duration of Response (DoR)

DoR is defined as the time from the date of first documented response until date of documented disease progression or death in the absence of disease progression for those subjects who reach partial or complete response. The end of response should coincide with the date of progression or death from any cause used for the PFS endpoint. Patients without progression or death until EOS will be censored.

DoR will be analysed in the same way as overall survival (see section 11.3.1.1) (*Table 14.2.2.21 and Table 14.2.2.22*).

In addition, Kaplan-Meier curve will be plotted, from which median survival times will be estimated *(Figure 14.2.9-14.2.10)*. Kaplan-Meier curve must start not from 100% but the respective response rates.

DoR will also be analysed using data from central imaging vendor (*Table 14.2.2.23, and 14.2.2.24*).

11.3.2.6 Changes in Tumor Marker Ca 19.9

Changes in tumor marker Ca 19.9 will be measured every 4 weeks while on study treatment (1st day of each cycle [±1 week]), as a potential prognostic biomarker for pancreatic ductal adenocarcinoma, especially with regards, to predicting survival following clinical treatment.

Absolute and change from baseline values for Tumor Marker CA 19.9 will be summarised using descriptive statistics (n, mean, standard deviation, median, minimum, maximum) (*Table 14.2.2.25 and Table 14.2.2.26*).

11.3.3 Exploratory Variables

11.3.3.1 Quality of Life (QoL)

QoL will be measured via the validated EORTC QLQ-C30 questionnaire (version 3). Absolute scores and change from baseline values will be summarised by scales using descriptive statistics at each month using the following visit windowing (*Table 14.2.3.1*).:

Analysis Visit	Standard	Low window	High window
Month 1	31	17	46
Month 2	61	47	76
Month 3	91	77	106
Month 4	121	107	136

Scoring of the QLQ-C30 questionnaire:

The QLQ-C30 is composed of both multi-item scales and single-item measures. These include five functional scales, three symptom scales, a global health status / QoL scale, and six single items. Each of the multi-item scales includes a different set of items - no item occurs in more than one scale. A summary of the scales can be found in the following figure.

	Scale	Number of items	Item range*	**Version 3.0** Item numbers	Function scales
Global health status / QoL					
Global health status/QoL (revised)†	QL2	2	6	29, 30	
Functional scales					
Physical functioning (revised)†	PF2	5	3	1 to 5	F
Role functioning (revised)†	RF2	2	3	6, 7	F
Emotional functioning	EF	4	3	21 to 24	F
Cognitive functioning	CF	2	3	20, 25	F
Social functioning	SF	2	3	26, 27	F
Symptom scales / items					
Fatigue	FA	3	3	10, 12, 18	
Nausea and vomiting	NV	2	3	14, 15	
Pain	PA	2	3	9, 19	
Dyspnoea	DY	1	3	8	
Insomnia	SL	1	3	11	
Appetite loss	AP	1	3	13	
Constipation	CO	1	3	16	
Diarrhoea	DI	1	3	17	
Financial difficulties	FI	1	3	28	

* *Item range* is the difference between the possible maximum and the minimum response to individual items; most items take values from 1 to 4, giving *range* = 3.
† (revised) scales are those that have been changed since version 1.0, and their short names are indicated in this manual by a suffix "2" – for example, PF2.

All of the scales and single-item measures range in score from 0 to 100. A high scale score represents a higher response level. Thus a high score for a functional scale represents a high / healthy level of functioning, a high score for the global health status / QoL represents a high QoL, but a high score for a symptom scale / item represents a high level of symptomatology / problems.

The principle for scoring these scales is the same in all cases:

1. Estimate the average of the items that contribute to the scale; this is the raw score.
2. Use a linear transformation to standardise the raw score, so that scores range from 0 to 100; a higher score represents a higher ("better") level of functioning, or a higher ("worse") level of symptoms.

Instructions can be found in the following figure.

Technical Summary

In practical terms, if items I_1, I_2, ... I_n are included in a scale, the procedure is as follows:

Raw score

Calculate the raw score

$RawScore = RS = (I_1 + I_2 + ... + I_n)/n$

Linear transformation

Apply the linear transformation to 0-100 to obtain the score S,

Functional scales: $S = \left\{1 - \frac{(RS-1)}{range}\right\} \times 100$

Symptom scales / items: $S = \{(RS-1)/range\} \times 100$

Global health status / QoL: $S = \{(RS-1)/range\} \times 100$

Range is the difference between the maximum possible value of *RS* and the minimum possible value. The QLQ-C30 has been designed so that all items in any scale take the same range of values. Therefore, the range of *RS* equals the range of the item values. Most items are scored 1 to 4, giving *range* = 3. The exceptions are the items contributing to the global health status / QoL, which are 7-point questions with *range* = 6, and the initial yes/no items on the earlier versions of the QLQ-C30 which have *range* = 1.

11.3.3.2 Disease Control Rate (DCR) to the subsequent therapies

DCR for patients with subsequent anti-cancer therapies will be presented using the number and percentage of patients (*Table 14.2.3.2*).

DCR will also be analysed using data from central imaging vendor (*Table 14.2.3.3*).

11.4 Pharmacokinetic Analyses

Not applicable.

11.5 Pharmacodynamic Analyses

The following pharmacodynamic endpoints will be analysed: VCN-01 genomes in blood (Arm II only); PH20 in serum (Arm II only); circulating immune markers in serum; neutrophil/lymphocyte ratio; neutralizing anti-VCN-01 antibodies (Anti-Ad-NAbs) (Arm II only) in serum; image biomarkers (radiomics) assessed from the images of CT scans performed during the study.

Pharmacodynamic parameters will be summarized using the Pharmacodynamic Set (*Table 14.5.1*). For parameters applicable only for Arm II, paired t-test will be used to compare baseline and post baseline values for continuous variables, and CMH or Chi-square test will be used for categorical variables. If both Arms have values for a parameter, t-test will be used to compare change from baseline values at each visit for continuous variables, and Chi-square test to compare the two Arms at each visit. Depending on the findings, additional exploratory analyses may be conducted.

11.6 Safety Analyses

SAF will be used for all safety analyses.

11.6.1 Adverse Events

All adverse events will be classified using the version of the MedDRA coding dictionary defined in the Data Management Plan.

Events will be classified as treatment-emergent if they started or increased in severity on or after the first date of Study Drug dosing and up to study closure or withdrawal date. If an event start date is partial, then the start day, month, year or stop date will be used to determine if the event is treatment-emergent. If the classification of the AE cannot be determined from the data available, then the event will be considered treatment-emergent.

Adverse Reaction (AR) is defined as all untoward and unintended responses to an investigational medicinal product (IMP) that are definitely related to any IMP dose administered. Serious Adverse Reaction (SAR) is an AR which, in the eyes of the Investigator or the Sponsor:

- Results in death
- Is life-threatening adverse event (life-threatening means that the patient was at risk of death at the time of the event and does not refer to a hypothetical situation where the event might have caused death if it were more severe)
- Requires in-patient hospitalisation or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect
- Is a significant medical/surgical event, e.g. an event that jeopardises the patient or requires intervention to prevent one of the above outcomes.

An overall summary of AEs will be produced (*Table 14.3.1.1*) including the number and % of patients reporting at least 1 TEAE, the number and % of patients reporting at least 1 serious TEAE (where SAE is reported as 'Yes'), the number and % of patients reporting at least 1 AR, the number and % of patients reporting at least 1 SAR, the number and % of patients reporting TEAEs by severity and relationship to study treatment. A patient with multiple occurrences of any AE is counted only once at the maximum level of severity or the strongest relationship to study treatment.

Adverse events will be described by primary system organ class and preferred term. Numbers and percentage of patients, and number of occurrences of adverse event will be presented for:

- TEAE by SOC and PT (*Table 14.3.1.2*)
- TEAE by severity (*Table 14.3.1.3*)
- TEAE by relationship to VCN-01 (*Table 14.3.1.4*)
- TEAE by relationship to Gemcitabine (*Table 14.3.1.5*)
- TEAE by relationship to Nab-paclitaxel (*Table 14.3.1.6*)
- Serious TEAEs (*Table 14.3.1.7*)
- Drug-related TEAEs (where relationship is recorded as 'Definitely Related', 'Probably Related' or 'Possibly Related' for IMP or SoC) (*Table 14.3.1.8*)
- TEAEs leading to permanent discontinuation of study drug (where action is recorded as 'Drug Withdrawn' for IMP or SoC) (*Table 14.3.1.9*)
- Serious TEAE by SOC, PT and relationship to VCN-01 (*Table 14.3.1.10*)
- Serious TEAE by SOC, PT and relationship to Gemcitabine (*Table 14.3.1.11*)

- Serious TEAE by SOC, PT and relationship to Nab-paclitaxel (*Table 14.3.1.12*)

All adverse events will be listed.

Adverse events due to disease progression will not be summarised, these adverse events will be listed in a separate listing only.

If a patient has multiple AEs with the same preferred term, these will be summarised once within the count for N (%) of patients, but each event will be counted within the number of reports n of each AE. Changes in severity of the same AE (if collected) will be counted only once within the number of reports n of each AE.

The following will be presented in listing format within the data summaries:

- Adverse Events leading to Deaths (*Table 14.3.2.1*)
- Serious Adverse Events (*Table 14.3.2.2*)
- Adverse Events which Led to Withdrawal (*Table 14.3.2.3*)
- Serious Adverse Reactions (*Table 14.3.2.4*)

11.6.2 Laboratory Data

Safety laboratory tests will be performed at the time points provided in the schedule of assessments in the protocol (refer to APPENDIX 7 and APPENDIX 8 for Arms I and II, respectively). All laboratory assessments are outlined in Section 9.2.1.

Laboratory data listings will be presented in two ways:

- Abnormal values (presented within the data summaries) (*Table 14.3.3*)
- All laboratory data (presented within the data listings)

The absolute values of each laboratory parameter (Biochemistry, Hematology, Coagulation, TSH, Urinalysis) will be summarised at each visit along with the change from baseline to each post baseline timepoint (*Table 14.3.4.1 – Table 14.3.4.5*). In addition, shift tables from baseline to each post baseline timepoint will be presented (*Table 14.3.4.6 – Table 14.3.4.10*) to show Normal/ Abnormal Clinically Significant (CS)/ Abnormal Not Clinically Significant (NCS) results.

If lab results are repeated at the same visit, the repeated result will be used in summaries (instead of the original one) provided the sample was taken within the visit window, otherwise the original result will be used. All results will be listed.

Lab results at unscheduled visits will be included in the listings but will not be summarised.

Serology and Pregnancy results will be listed only.

11.6.3 Vital Signs

Vital signs will be assessed at the time points provided in the schedule of assessments in the protocol (refer to APPENDIX 7 and APPENDIX 8 for Arms I and II, respectively).

Vital signs will include supine systolic and diastolic blood pressure (mmHg), pulse (bpm), body temperature (°C) and respiration rate. Body weight (kg) will also be recorded along with vital signs (pre-dose only).

The absolute values of the vital signs including weight will be summarised at each visit along with the change from baseline to each post baseline timepoint (*Table 14.3.5.1*). Height will be summarised within the demography data. Shift tables will be presented showing changes from baseline to each visit for normal, abnormal NCS and abnormal CS vital signs results (*Table 14.3.5.2*).

11.6.4 Physical Examination

Full and abbreviated physical examinations will be performed at the time points provided in the schedule of assessments in the protocol (refer to APPENDIX 7 and APPENDIX 8 for Arms I and II, respectively).

Shift tables will be presented showing changes from baseline to each visit for normal, abnormal NCS and abnormal CS physical examination results by body system (*Table 14.3.6*).

11.6.5 Electrocardiogram

The absolute values of Heart rate, PR interval, RR interval, QRS width, QT interval and QTcF interval will be summarised at each visit along with the change from baseline to each post baseline timepoint (*Table 14.3.7.1*).

Shift tables will be presented showing changes from baseline to each visit for normal, abnormal NCS and abnormal CS ECG results (*Table 14.3.7.2*).

11.6.6 COVID-19 Testing

The patients will be required to undergo polymerase chain reaction (PCR) test to check for active COVID-19 infection during the study.

COVID-19 testing results will be listed only.

11.6.7 Left Ventricular Ejection Fraction (LVEF)

LVEF assessments will be performed at Screening and at other timepoints only if clinically indicated.

LVEF results will be listed only.

11.6.8 Eastern Cooperative Oncology Group (ECOG) Score

ECOG score will be assessed at the time points provided in the schedule of assessments in the protocol (refer to APPENDIX 7 and APPENDIX 8 for Arms I and II, respectively).

The ECOG Performance score is recorded at baseline (randomization) and at every visit thereafter. For each level of the ECOG score, the proportion of patients continuing on that or a better score will be estimated for each visit using Kaplan-Meier estimates. At death the patient will be assumed to have risen to the highest ECOG score. This method of presentation will ignore those cases where a patient's ECOG score climbs and then falls again.

These proportions will be plotted for each treatment arm across time, a time to event figure will be created. (*Figure 14.3.1*).

ECOG scores will be presented using number and percentage of patients by visit (*Table 14.3.8*).

11.6.9 Fibroscan

Fibroscan results will be listed only.

11.6.10 Anticancer treatment

Anticancer treatment after discontinuation in the trial will be summarized by treatment arms using Anatomical Therapeutic Chemical 4 (ATC4) term and preferred term (*Table 14.3.9)*.

11.7 Study Drug Exposure and Compliance

Treatment duration (days), number of doses administered, total dose administered, dose intensity (represents the amount of a drug administered per dosing day) and relative dose intensity (actual dose intensity delivered to the standard planned dose intensity per dosing day) will be described by descriptive statistics for each of the treatments (VCN-01, Nab-paclitaxel, Gemcitabine) by treatment arm.

Incidence of dose prolongation (yes, no), dose interruption (yes, no) and dose reduction (yes, no, reason for reduction – applicable for Nab-paclitaxel and Gemcitabine only) will be presented descriptively using number of events, number of patients and percentage.

Treatment compliance, as percentage of injection administered (actual/planned) will be summarized by visit and overall.

Treatment exposure and compliance will be summarised for the FAS (*Table 14.3.10)*.

11.8 Prior and Concomitant Medications and Procedures

Prior medications/medical procedures are defined as any medication taken/any medical procedures performed within 28 days of the Screening visit. Any medication taken at or after the time of the Screening visit, regardless of whether it had started prior to the study or not, until EoS visit is to be recorded as concomitant medication.

Therapies will be classified using the version of the World Health Organisation Drug Dictionary (WHODD) coding dictionary defined in the Data Management Plan. The ATC Classification and WHO-DRUG PT will be used to list and summarise the data.

The number (%) of patients reporting the use of any prior medications and the number (%) of patients taking each drug by ATC classification and PT will be summarised using the SAF (*Table 14.3.11.1)*. This table will be repeated for concomitant medications (*Table 14.3.11.2)*.

11.9 All other data

All other data (Protocol Deviations, Inclusion/ Exclusion Criteria Failures, Obstetric History, Menopausal Status, Drug Administration, Target and Non-Target Lesions) will be listed.

12 VALIDATION

All tables, figures and listings will be subject to independent quality control and visual review. Unique tables will be independently programmed. Findings will be documented in a quality control form and actions taken will also be documented.

The completed form will be reviewed and signed by both programmers and by the lead statistician.

13 LITERATURE CITATIONS/REFERENCES

Not applicable.

14 LIST OF TABLES, FIGURES AND LISTINGS

14.1 LIST OF TABLES

* Top Line TFLs

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*Table 14.2.3.1	QLQ-C30 Questionnaire	Full Analysis Set
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Table 14.2.3.3	Disease Control Rate for Patients with Subsequent Anti-Cancer Therapies - CIV Data	Full Analysis Set

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PK/PD Data

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15 SHELLS FOR TABLES, FIGURES AND LISTINGS

The intended layouts for tables, figures and listings are presented. However, it may be appropriate for the Simbec-Orion programmer to change the layouts, upon review of the data available, for completeness and clarity.

QCd output will be produced as Rich Text Format (.rtf) or MS Word (.docx) files for convenient inclusion in the CSR. All attempts will be made to combine outputs into 3 pdf format files corresponding to tables, listings and figures. Should this not be possible results will be provided in RTF of word document format only.

Subject to this, the following will apply:

- Layout will be landscape, fixed width, font size 9, with margin size 2.54 cm for all sides.
- Each output will have the heading:

  P-VCNA-003 (left); date and time ddMMMyyyy HH:MM(right)
- Table headings will define the analysis set used for the summary/analysis.
- All outputs will have a footer specifying the SAS program path and filename (left); page x/y (right)
- Tables will have a footer specifying the source listing
- Figures will have a footer specifying the source table or listing
- Additional footnotes will be included where appropriate for clarification.
- Treatment arm and patient number and will be included in all listings.

P-VCNA-003 ddMMMyyyy HH:MM

Table 14.1.1 Patient Disposition (All Randomized Set)

	Number of patients (%)
Randomised	xx
Completed study	xx (xx.x%)
Early withdrawal	xx (xx.x%)
Reason for early withdrawal:	
Screening Failure	xx (xx.x%)
Lost to Follow-up	xx (xx.x%)
Withdrawal by Subject	xx (xx.x%)
…	
Analysis Sets:	
Safety Analysis Set (SAF)	xx (xx.x%)
Intent-to-Treat Set (ITT)	xx (xx.x%)
Full Analysis Set (FAS)	xx (xx.x%)
Per-Protocol Set (PPS)	xx (xx.x%)
Pharmacodynamics Set (PDS)	xx (xx.x%)
Subgroup analysis inclusion	xx (xx.x%)

Percentage is the number of patients in the category (n) divided by the number of patients within the column (N).

Source: Listing 16.2.1.2
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Table 14.1.2.1 Demographic and Baseline Characteristics (Intent-to-Treat Set)

			Arm I (Nab-paclitaxel and gemcitabine) (N=xx)	Arm II (VCN-01 with Nab-paclitaxel and gemcitabine) (N=xx)
Age (years)		n	xx	xx
		Mean	xx	xx
		STD	xx	xx
		Median	xx	xx
		Minimum	xx	xx
		Maximum	xx	xx
Gender	Male	n (%)	xx (xx.x%)	xx (xx.x%)
	Female	n (%)	xx (xx.x%)	xx (xx.x%)
Race	Black or African American	n (%)	xx (xx.x%)	xx (xx.x%)
	American Indian or Alaska Native	n (%)	xx (xx.x%)	xx (xx.x%)
	Asian	n (%)	xx (xx.x%)	xx (xx.x%)
	Native Hawaiian or Other Pacific Islander	n (%)	xx (xx.x%)	xx (xx.x%)
	White	n (%)	xx (xx.x%)	xx (xx.x%)
	Other	n (%)	xx (xx.x%)	xx (xx.x%)
Ethnicity	Not Hispanic or Latino	n (%)	xx (xx.x%)	xx (xx.x%)
	Hispanic or Latino	n (%)	xx (xx.x%)	xx (xx.x%)
	Not Reported	n (%)	xx (xx.x%)	xx (xx.x%)
	Unknown	n (%)	xx (xx.x%)	xx (xx.x%)
Region of study site	North America	n (%)	xx (xx.x%)	xx (xx.x%)
	European Union	n (%)	xx (xx.x%)	xx (xx.x%)
ECOG status at randomization	0	n (%)	xx (xx.x%)	xx (xx.x%)
	1	n (%)	xx (xx.x%)	xx (xx.x%)

[Continued overleaf…]

Height (cm)	n	xx	xx
	Mean	xx	xx
	STD	xx	xx
	Median	xx	xx
	Minimum	xx	xx
	Maximum	xx	xx
Weight (kg)	n	xx	xx
	Mean	xx	xx
	STD	xx	xx
	Median	xx	xx
	Minimum	xx	xx
	Maximum	xx	xx
BMI (kg/m2)	n	xx	xx
	Mean	xx	xx
	STD	xx	xx
	Median	xx	xx
	Minimum	xx	xx
	Maximum	xx	xx

Percentage is the number of patients in the category (n) divided by the number of patients within the column (N).
Age was calculated using Year of Birth and date of first treatment and presented as age at last birthday.
BMI is the patient's body weight in kilograms divided by the square of the patient's height in meters.

Source: Listing 16.2.4.1
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Programming Note: This layout also applies to Table 14.1.2.2. (Full Analysis Set) and Table 14.1.2.3 (Safety Analysis Set)

Table 14.1.3 Medical History (Full Analysis Set)

	Arm I (Nab-paclitaxel and gemcitabine) (N=xx)	Arm II (VCN-01 with Nab-paclitaxel and gemcitabine) (N=xx)
Any medical history	xx (xx.x%)	xx (xx.x%)
SOC	xx (xx.x%)	xx (xx.x%)
PT	xx (xx.x%)	xx (xx.x%)
…		
SOC	xx (xx.x%)	xx (xx.x%)
PT	xx (xx.x%)	xx (xx.x%)
…		
…		

Percentage is the number of patients in the category (n) divided by the number of patients within the column (N).
MedDRA version <XX.X>.

Source: Listing 16.2.4.2
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Table 14.2.1.1 Overall Survival (Intent-to-Treat Set)

Parameter/ Test		Arm I (Nab-paclitaxel and gemcitabine) (N=xx)	Arm II (VCN-01 with Nab-paclitaxel and gemcitabine) (N=xx)	Hazard Ratio (95% CI)	p-value
Kaplan-Meier estimate of Survival Time (months)	Median	xx	xx		
	Lower 95% Confidence Interval	xx	xx		
	Upper 95% Confidence Interval	xx	xx		
Cox Proportional-Hazards Model				x.x (x.x , x.x)	xxxxxx
Log-rank test					xxxxxx

Survival time is defined as time from randomization until death. Patients who are lost to follow-up are censored at the time of their last visit or contact.
Model terms include region, ECOG performance status at randomization and treatment.

Source: Listing 16.2.6.3
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Programming Note: This layout also applies to Table 14.2.1.2. Overall Survival (Full Analysis Set), Table 14.2.1.3. Overall Survival (Per-Protocol Set), Table 14.2.1.4 Subgroup Analysis: Overall Survival (Intent-to-Treat Set), Table 14.2.1.5 Subgroup Analysis: Overall Survival (Per Protocol Set), Table 14.2.2.1 Progression-free Survival and Time to Progression – EDC Data (Intent-to-Treat Set), Table 14.2.2.2 Progression-free Survival and Time to Progression – EDC Data (Full Analysis Set), Table 14.2.2.3 Subgroup Analysis: Progression-free Survival and Time to Progression – EDC Data (Intent-to-Treat Set), Table 14.2.2.4 Progression-free Survival and Time to Progression – CIV Data (Intent-to-Treat Set), Table 14.2.2.5 Progression-free Survival and Time to Progression – CIV Data (Full Analysis Set) and Table 14.2.2.6 Subgroup Analysis: Progression-free Survival and Time to Progression – CIV Data (Intent-to-Treat Set),Table14.2.2.21-24 All Duration of Response tables.
Footnotes to be included for Table 14.2.2.1 – 14.2.2.24:

- *EDC data: PFS (Progression-free Survival) and TTP (Time to Progression) were assessed based on EDC (Electronic Data Capture) data.*
- *CIV data: PFS (Progression-free Survival) and TTP (Time to Progression) were assessed based on CIV (Central Imaging Vendor) data.*

Source listing for CIV data: Listing 16.2.6.4

Table 14.2.2.7 Objective Response Rate – EDC Data (Intent-to-Treat Set)

Parameter/ Test	Component		Arm I (Nab-paclitaxel and gemcitabine) (N=xx)	Arm II (VCN-01 with Nab-paclitaxel and gemcitabine) (N=xx)	Odds Ratio (95% CI)	p-value
Objective Response Rate (ORR)		n (%)	xx (xx.x %)	xx (xx.x %)		
	CR	n	xx	xx		
	PR	n	xx	xx		
Cochran-Mantel-Haenszel (CMH) test*					x.x (x.x , x.x)	xxxxxx
Sensitivity analysis**					x.x (x.x , x.x)	xxxxxx

Percentage is the number of patients in the category (n) divided by the number of patients within the column (N).
* CMH test was stratified by region and ECOG performance status at randomization.
** CMH test was stratified by age group (<65 years and >=65 years), region and ECOG performance status at randomization.
CR = Complete Response, PR = Partial Response.

Source: Listing 16.2.6.3
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Programming Note: This layout also applies to Table 14.2.2.8 Objective Response Rate - EDC Data (Full Analysis Set), Table 14.2.2.9 Subgroup Analysis: Objective Response Rate - EDC Data (Intent-to-Treat Set), Table 14.2.2.10 Objective Response Rate - CIV Data (Intent-to-Treat Set), Table 14.2.2.11 Objective Response Rate - CIV Data (Full Analysis Set) and Table 14.2.2.12 Subgroup Analysis: Objective Response Rate - CIV Data (Intent-to-Treat Set)
Footnotes to be included:

- *EDC data: ORR (Objective Response Rate) was assessed based on EDC (Electronic Data Capture) data.*
- *CIV data: ORR (Objective Response Rate) was assessed based on CIV (Central Imaging Vendor) data.*

Source listing for CIV data: Listing 16.2.6.4

Table 14.2.2.13 Disease Control Rate - EDC Data (Intent-to-Treat Set)

Parameter/ Test	Component		Arm I (Nab-paclitaxel and gemcitabine) (N=xx)	Arm II (VCN-01 with Nab-paclitaxel and gemcitabine) (N=xx)	Odds Ratio (95% CI)	p-value
Disease Control Rate (DCR)		n (%)	xx (xx.x %)	xx (xx.x %)		
	CR	n	xx	xx		
	PR	n	xx	xx		
	SD	n	xx	xx		
Cochran-Mantel-Haenszel (CMH) test*					x.x (x.x , x.x)	xxxxxx
Sensitivity analysis**					x.x (x.x , x.x)	xxxxxx

Percentage is the number of patients in the category (n) divided by the number of patients within the column (N).
* CMH test was stratified by region and ECOG performance status at randomization.
** CMH test was stratified by age group (<65 years and >=65 years), region and ECOG performance status at randomization.
CR = Complete Response, PR = Partial Response, SD = Stable Disease.

Source: Listing 16.2.6.3
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Programming Note: This layout also applies to Table 14.2.2.14 Disease Control Rate - EDC Data (Full Analysis Set), Table 14.2.2.15 Disease Control Rate - CIV Data (Intent-to-Treat Set), Table 14.2.2.16 Disease Control Rate - CIV Data (Full Analysis Set), Table 14.2.3.2 Disease Control Rate for Patients with Subsequent Anti-Cancer Therapies - EDC Data (Full Analysis Set) and Table 14.2.3.3 Disease Control Rate for Patients with Subsequent Anti-Cancer Therapies - CIV Data (Full Analysis Set)
Footnotes to be included:

- *EDC data: DCR (Disease Control Rate) was assessed based on EDC (Electronic Data Capture) data.*
- *CIV data: DCR (Disease Control Rate) was assessed based on CIV (Central Imaging Vendor) data.*

Source listing for CIV data: Listing 16.2.6.4

Table 14.2.2.17 Landmark 1-year Survival and PFS at the 1-year Landmark - EDC Data (Intent-to-Treat Set)

Parameter/ Test		Arm I (Nab-paclitaxel and gemcitabine) (N=xx)	Arm II (VCN-01 with Nab-paclitaxel and gemcitabine) (N=xx)	Odds Ratio (95% CI)	p-value
Landmark 1-year survival	n (%)	xx (xx.x %)	xx (xx.x %)		
Cochran-Mantel-Haenszel (CMH) test*				x.x (x.x , x.x)	xxxxxx
Sensitivity analysis**				x.x (x.x , x.x)	xxxxxx
PFS at the 1-year Landmark	n (%)	xx (xx.x %)	xx (xx.x %)		
Cochran-Mantel-Haenszel (CMH) test*				x.x (x.x , x.x)	xxxxxx
Sensitivity analysis**				x.x (x.x , x.x)	xxxxxx

Percentage is the number of patients in the category (n) divided by the number of patients within the column (N).
* CMH test was stratified by region and ECOG performance status at randomization.
** CMH test was stratified by age group (<65 years and >=65 years), region and ECOG performance status at randomization.

Source: Listing 16.2.6.3
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Programming Note: This layout also applies to Table 14.2.2.18 Landmark 1-year Survival and PFS at the 1-year Landmark - EDC Data (Full Analysis Set), Table 14.2.2.19 Landmark 1-year Survival and PFS at the 1-year Landmark - CIV Data (Intent-to-Treat Set) and Table 14.2.2.20 Landmark 1-year Survival and PFS at the 1-year Landmark - CIV Data (Full Analysis Set)
Footnotes to be included:

- *EDC data: Landmark 1-year Survival and PFS (Progression-free Survival) at the 1-year Landmark were assessed based on EDC (Electronic Data Capture) data.*
- *CIV data: Landmark 1-year Survival and PFS (Progression-free Survival) at the 1-year Landmark were assessed based on CIV (Central Imaging Vendor) data.*

Source listing for CIV data: Listing 16.2.6.4

Table 14.2.2.21 Duration of Response - EDC Data (Intent-to-Treat Set)

Parameter		Arm I (Nab-paclitaxel and gemcitabine) (N=xx)	Arm II (VCN-01 with Nab-paclitaxel and gemcitabine) (N=xx)
Kaplan-Meier estimate of Duration of Response (months)	Median	xx	xx
	Lower 95% Confidence Interval	xx	xx
	Upper 95% Confidence Interval	xx	xx

Source: Listing 16.2.6.3
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Programming Note: This layout also applies to Table 14.2.2.22 Duration of Response - EDC Data (Full Analysis Set), Table 14.2.2.23 Duration of Response - CIV Data (Intent-to-Treat Set) and Table 14.2.2.24 Duration of Response - CIV Data (Full Analysis Set)
Footnotes to be included:

- *EDC data: Duration of Response was assessed based on EDC (Electronic Data Capture) data.*
- *CIV data: Duration of Response was assessed based on CIV (Central Imaging Vendor) data.*

Source listing for CIV data: Listing 16.2.6.4

Table 14.2.2.25 Tumor Marker Ca 19.9 (Intent-to-Treat Set)

Ca 19.9 (<*unit*>)

Visit		Arm I (Nab-paclitaxel and gemcitabine) (N=xx)	Arm II (VCN-01 with Nab-paclitaxel and gemcitabine) (N=xx)
Screening	n	xx	xx
	Mean	xx	xx
	STD	xx	xx
	Median	xx	xx
	Minimum	xx	xx
	Maximum	xx	xx
Baseline	n	xx	xx
	Mean	xx	xx
	STD	xx	xx
	Median	xx	xx
	Minimum	xx	xx
	Maximum	xx	xx
<*Visit*>	n	xx	xx
	Mean	xx	xx
	…		
Change from Baseline to <*Visit*>	n	xx	xx
	Mean	xx	xx
	…		
…			

Source: Listing 16.2.6.5
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Programming Note: This layout also applies to Table 14.2.2.26 Tumor Marker Ca 19.9 (Full Analysis Set)
Please start a new page when unit of Ca 19.9 is different (U/mL or KU/L).

Table 14.2.3.1 QLQ-C30 Questionnaire (Full Analysis Set)

<Scale>

Visit		Arm I (Nab-paclitaxel and gemcitabine) (N=xx)	Arm II (VCN-01 with Nab-paclitaxel and gemcitabine) (N=xx)
Screening	n	xx	xx
	Mean	xx	xx
	STD	xx	xx
	Median	xx	xx
	Minimum	xx	xx
	Maximum	xx	xx
Baseline	n	xx	xx
	Mean	xx	xx
	STD	xx	xx
	Median	xx	xx
	Minimum	xx	xx
	Maximum	xx	xx
<*Visit*>	n	xx	xx
	Mean	xx	xx
	…		
Change from Baseline to <*Visit*>	n	xx	xx
	Mean	xx	xx
	…		
…			

Source: Listing 16.2.6.6
Path\Filename

Programming Note: Please summarize values by each scale described in section 11.3.3.1.

Table 14.3.1.1 Summary of Adverse Events (Safety Analysis Set)

		Arm I (Nab-paclitaxel and gemcitabine) (N=xx)	Arm II (VCN-01 with Nab-paclitaxel and gemcitabine) (N=xx)
		n(%)	n(%)
Any Treatment-Emergent Adverse Event (TEAE)		xx (xx.x%)	Xx (xx.x%)
Any Serious TEAE		xx (xx.x%)	xx (xx.x%)
Any Adverse Reaction		xx (xx.x%)	xx (xx.x%)
Any Serious Adverse Reaction		xx (xx.x%)	xx (xx.x%)
		xx (xx.x%)	xx (xx.x%)
TEAEs by Severity	Grade 1	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)
	Grade 5	xx (xx.x%)	xx (xx.x%)
		xx (xx.x%)	xx (xx.x%)
TEAEs by Relationship to VCN-01	Definitely Related	xx (xx.x%)	xx (xx.x%)
	Probably Related	xx (xx.x%)	xx (xx.x%)
	Possibly Related	xx (xx.x%)	xx (xx.x%)
	Unlikely Related	xx (xx.x%)	xx (xx.x%)
	Not Related	xx (xx.x%)	xx (xx.x%)
		xx (xx.x%)	xx (xx.x%)
TEAEs by Relationship to Gemcitabine	Definitely Related	xx (xx.x%)	xx (xx.x%)
	Probably Related	xx (xx.x%)	xx (xx.x%)
	…		
TEAEs by Relationship to Nab-paclitaxel	Definitely Related	xx (xx.x%)	xx (xx.x%)
	Probably Related	xx (xx.x%)	xx (xx.x%)
	…		

A patient with multiple occurrences of any AE is counted only once at the maximum level of severity or the strongest relationship to study treatment.
Percentage is the number of patients in the category (n) divided by the number of patients within the column (N).
MedDRA version <XX.X>.

Source: Listing 16.2.7.1
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Table 14.3.1.2 Treatment-Emergent Adverse Events, by System Organ Class and Preferred Term (Safety Analysis Set)

	Arm I (Nab-paclitaxel and gemcitabine) (N=xx)	Arm II (VCN-01 with Nab-paclitaxel and gemcitabine) (N=xx)
	n (%)	n (%)
Any Treatment-Emergent Adverse Event	xx (xx.x%)	xx (xx.x%)
SOC	xx (xx.x%)	xx (xx.x%)
PT	xx (xx.x%)	xx (xx.x%)
PT	xx (xx.x%)	xx (xx.x%)
SOC	xx (xx.x%)	xx (xx.x%)
…		
…		

The table presents number of patients (n) who have at least one occurrence of the event, and percentage of patients (n %).
Percentage is the number of patients in the category (n) divided by the number of patients within the column (N).
MedDRA version <XX.X>.

Source: Listing 16.2.7.1
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Programming Note: This layout also applies to Table 14.3.1.7 Serious Treatment-Emergent Adverse Events, by System Organ Class and Preferred Term (Safety Analysis Set), Table 14.3.1.8 Drug-related Treatment-Emergent Adverse Events, by System Organ Class and Preferred Term (Safety Analysis Set) and Table 14.3.1.9 Treatment-Emergent Adverse Events Leading to Permanent Discontinuation of Study Drug, by System Organ Class and Preferred Term (Safety Analysis Set)

Table 14.3.1.3 Treatment-Emergent Adverse Events, by System Organ Class, Preferred Term and Severity (Safety Analysis Set)

	Severity	Arm I (Nab-paclitaxel and gemcitabine) (N=xx) n (%)	Arm II (VCN-01 with Nab-paclitaxel and gemcitabine) (N=xx) n (%)
Any Treatment-Emergent Adverse Event	<*Grade X*>	xx (xx.x%)	xx (xx.x%)
	<*Grade X*>	xx (xx.x%)	xx (xx.x%)
	<*Grade X*>	xx (xx.x%)	xx (xx.x%)
	<*Grade X*>	xx (xx.x%)	xx (xx.x%)
	<*Grade X*>	xx (xx.x%)	xx (xx.x%)
SOC	<*Grade X*>	xx (xx.x%)	xx (xx.x%)
	<*Grade X*>	xx (xx.x%)	xx (xx.x%)
	<*Grade X*>	xx (xx.x%)	xx (xx.x%)
PT	<*Grade X*>	xx (xx.x%)	xx (xx.x%)
PT	<*Grade X*>	xx (xx.x%)	xx (xx.x%)
	<*Grade X*>	xx (xx.x%)	xx (xx.x%)
SOC	<*Grade X*>	xx (xx.x%)	xx (xx.x%)
…			
…			

The table presents number of patients (n) who have at least one occurrence of the event, and percentage of patients (n(%)).
Percentage is the number of patients in the category (n) divided by the number of patients within the column (N).
MedDRA version <XX.X>.

Source: Listing 16.2.7.1
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Table 14.3.1.4 Treatment-Emergent Adverse Events, by System Organ Class, Preferred Term and Relationship to VCN-01 (Safety Analysis Set)

	Relationship to VCN-01	Arm I (Nab-paclitaxel and gemcitabine) (N=xx) n (%)	Arm II (VCN-01 with Nab-paclitaxel and gemcitabine) (N=xx) n (%)
Any Treatment-Emergent Adverse Event	<*Relationship*>	xx (xx.x%)	xx (xx.x%)
	<*Relationship*>	xx (xx.x%)	xx (xx.x%)
	<*Relationship*>	xx (xx.x%)	xx (xx.x%)
	<*Relationship*>	xx (xx.x%)	xx (xx.x%)
	<*Relationship*>	xx (xx.x%)	xx (xx.x%)
SOC	<*Relationship*>	xx (xx.x%)	xx (xx.x%)
	<*Relationship*>	xx (xx.x%)	xx (xx.x%)
	<*Relationship*>	xx (xx.x%)	xx (xx.x%)
PT	<*Relationship*>	xx (xx.x%)	xx (xx.x%)
PT	<*Relationship*>	xx (xx.x%)	xx (xx.x%)
	<*Relationship*>	xx (xx.x%)	xx (xx.x%)
SOC	<*Relationship*>	xx (xx.x%)	xx (xx.x%)
…			
…			

The table presents number of patients (n) who have at least one occurrence of the event, and percentage of patients(n(%)).
Percentage is the number of patients in the category (n) divided by the number of patients within the column (N).
MedDRA version <XX.X>.

Source: Listing 16.2.7.1
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Programming Note: This layout also applies to Table 14.3.1.5 Treatment-Emergent Adverse Events, by System Organ Class, Preferred Term and Relationship to Gemcitabine (Safety Analysis Set), Table 14.3.1.6 Treatment-Emergent Adverse Events, by System Organ Class, Preferred Term and Relationship to Nab-paclitaxel (Safety Analysis Set), Table 14.3.1.10 Serious Treatment-Emergent Adverse Events, by System Organ Class, Preferred Term and Relationship to VCN-01 (Safety Analysis Set),), Table 14.3.1.11 Serious Treatment-Emergent Adverse Events, by System Organ Class, Preferred Term and Relationship to Gemcitabine (Safety Analysis Set) and Table 14.3.1.12 Serious Treatment-Emergent Adverse Events, by System Organ Class, Preferred Term and Relationship to Nab-paclitaxel (Safety Analysis Set). Please update second column header according to the table title.

Table 14.3.2.1 Listing of Deaths due to Adverse Events – (1)

Patient Number	Adverse Event SOC PT	Due to PD	Onset date/time/TEAE	Resolution date/time / Ongoing	Serious	Severity	Relationship to VCN-01	Relationship to Gemcitabine	Relationship to Nab-paclitaxel
xxxxxxx	xxxxxxxxx xxxxxxxxx xxxxxxxxx	Due to PD/ Not Due to PD	xxxxxxxx Txx:xx /Yes or Yes[1]	xxxxxxxxT xx:xx/ Ongoing	Yes (criteria)/ No	Grade 1/ Grade 2/ Grade 3/ Grade 4/ Grade 5	Definitely Related (*specify*)/ Probably Related (*specify*)/ Possibly Related (*specify*)/ Unlikely Related/ Not Related	Definitely Related (*specify*)/ Probably Related (*specify*)/ Possibly Related (*specify*)/ Unlikely Related/ Not Related	Definitely Related (*specify*)/ Probably Related (*specify*)/ Possibly Related (*specify*)/ Unlikely Related/ Not Related
	xxxxxxxxx xxxxxxxxx xxxxxxxxx	Due to PD/ Not Due to PD	xxxxxxxx Txx:xx /Yes or Yes[1]	xxxxxxxxT xx:xx/ Ongoing	Yes (criteria)/ No	Grade 1/ Grade 2/ Grade 3/ Grade 4/ Grade 5	Definitely Related (*specify*)/ Probably Related (*specify*)/ Possibly Related (*specify*)/ Unlikely Related/ Not Related	Definitely Related (*specify*)/ Probably Related (*specify*)/ Possibly Related (*specify*)/ Unlikely Related/ Not Related	Definitely Related (*specify*)/ Probably Related (*specify*)/ Possibly Related (*specify*)/ Unlikely Related/ Not Related
	…								
…									

PD = Progressive Disease.
MedDRA version <XX.X>.
TEAE = Treatment Emergent Adverse Event.
Yes = Treatment Emergent for all study drugs. Yes[1] = Treatment Emergent for VCN-01.

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Programming Note: This layout also applies to Table 14.3.2.2 Listing of Serious Adverse Events (please include "Occurred after 1st VCN-01 Dose" and "Occurred after 2nd VCN-01 dose" columns after Due to PD column), Table 14.3.2.3 Listing of Withdrawals Due to Adverse Events and Table 14.3.2.4 Listing of Serious Adverse Reactions (please include "Occurred after 1st VCN-01 Dose" and "Occurred after 2nd VCN-01 dose" columns after Due to PD column).
Please include (1) and (2) pages in one output, for every (1) page there will be a consecutive (2) page.

If the relationship to study treatment is marked as "Definitely Related, Probably Related or Possibly Related" please present the reason for decision in brackets.

Table 14.3.2.1 Listing of Deaths due to Adverse Events – (2)

Patient Number	Adverse Event SOC PT	Outcome	Action taken with VCN-01	Action taken with Gemcitabine	Action taken with Nab-paclitaxel	Other action taken
xxxxxxx	xxxxxxxxx xxxxxxxxx xxxxxxxxx	Fatal/ Not Recovered/Not Resolved / Recovered/Resolved / Recovered/Resolved with Sequelae / Recovering/ Unknown	Dose Not Changed/ Dose Reduced/ Drug Interrupted/ Drug Withdrawn/ Not Applicable/ Unknown	Dose Not Changed/ Dose Reduced/ Drug Interrupted/ Drug Withdrawn/ Not Applicable/ Unknown	Dose Not Changed/ Dose Reduced/ Drug Interrupted/ Drug Withdrawn/ Not Applicable/ Unknown	xxxxxx
	xxxxxxxxx xxxxxxxxx xxxxxxxxx	Fatal/ Not Recovered/Not Resolved / Recovered/Resolved / Recovered/Resolved with Sequelae / Recovering/ Unknown	Dose Not Changed/ Dose Reduced/ Drug Interrupted/ Drug Withdrawn/ Not Applicable/ Unknown	Dose Not Changed/ Dose Reduced/ Drug Interrupted/ Drug Withdrawn/ Not Applicable/ Unknown	Dose Not Changed/ Dose Reduced/ Drug Interrupted/ Drug Withdrawn/ Not Applicable/ Unknown	xxxxxx
	…					
…						

MedDRA version <XX.X>.

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Programming Note:
This layout also applies to Table 14.3.2.2 Listing of Serious Adverse Events (please include "Occurred after 1st VCN-01 Dose" and "Occurred after 2nd VCN-01 dose" columns after Due to PD column), Table 14.3.2.3 Listing of Withdrawals Due to Adverse Events and Table 14.3.2.4 Listing of Serious Adverse Reactions (please include "Occurred after 1st VCN-01 Dose" and "Occurred after 2nd VCN-01 dose" columns after Due to PD column).

Please include (1) and (2) pages in one output, for every (1) page there will be a consecutive (2) page.
If the relationship to study treatment is marked as "Definitely Related, Probably Related or Possibly Related" please present the reason for decision in brackets.

Table 14.3.3 Listing of Abnormal Laboratory Values

Patient Number	Visit	Parameter	Result	Unit	Reference range Lower	Reference range Upper	Interpretation
xxxxxxx	<*Visit*>	xxxxxxxxxxxxxxxxxx	xx	xxxx	xx	xx	Abnormal CS/ Abnormal NCS
		xxxxxxxxxxxxxxxxxx	xx	xxxx	xx	xx	Abnormal CS/ Abnormal NCS
		…					
	…						
…							

NCS = Not Clinically Significant; CS = Clinically Significant.

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Table 14.3.4.1 Summary of Biochemistry Parameters (Safety Analysis Set)

<Parameter (unit)>

Visit		Arm I (Nab-paclitaxel and gemcitabine) (N=xx)	Arm II (VCN-01 with Nab-paclitaxel and gemcitabine) (N=xx)
Screening	n	xx	xx
	Mean	xx	xx
	STD	xx	xx
	Median	xx	xx
	Minimum	xx	xx
	Maximum	xx	xx
Baseline	n	xx	xx
	Mean	xx	xx
	STD	xx	xx
	Median	xx	xx
	Minimum	xx	xx
	Maximum	xx	xx
<*Visit*>	n	xx	xx
	Mean	xx	xx
	…		
Change from Baseline to <*Visit*>	n	xx	xx
	Mean	xx	xx
	…		
…			

Source: Listing 16.2.8.1
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Programming Note: This layout also applies to Table 14.3.4.2 Summary of Hematology Parameters (Safety Analysis Set), Table 14.3.4.3 Summary of Coagulation Parameters (Safety Analysis Set), Table 14.3.4.4 Summary of TSH (Safety Analysis Set), Table 14.3.4.5 Summary of Urinalysis Parameters (Safety Analysis Set), Table 14.3.5.1 Summary of Vital Signs (Safety Analysis Set) and Table 14.3.7.1 Summary of 12-lead Electrocardiogram (Safety Analysis Set). Please update source listings.

Table 14.3.4.6 Shift Table of Biochemistry Parameters (Safety Analysis Set)

<Parameter (unit)>

Visit		Arm I (Nab-paclitaxel and gemcitabine) (N=xx)	Arm II (VCN-01 with Nab-paclitaxel and gemcitabine) (N=xx)
Screening	n	xx	xx
	Normal	xx (xx.x%)	xx (xx.x%)
	Abnormal NCS	xx (xx.x%)	xx (xx.x%)
	Abnormal CS	xx (xx.x%)	xx (xx.x%)
Baseline	n	xx	xx
	Normal	xx (xx.x%)	xx (xx.x%)
	…		
<*Visit*>	n	xx	xx
	…		
Change from Baseline to <*Visit*>	n	xx	xx
	Normal -> Normal	xx (xx.x%)	xx (xx.x%)
	Normal -> Abnormal NCS	xx (xx.x%)	xx (xx.x%)
	Normal -> Abnormal CS	xx (xx.x%)	xx (xx.x%)
	Abnormal NCS -> Normal	xx (xx.x%)	xx (xx.x%)
	Abnormal NCS -> Abnormal NCS	xx (xx.x%)	xx (xx.x%)
	Abnormal NCS -> Abnormal CS	xx (xx.x%)	xx (xx.x%)
	Abnormal CS -> Normal	xx (xx.x%)	xx (xx.x%)
	Abnormal CS -> Abnormal NCS	xx (xx.x%)	xx (xx.x%)
	Abnormal CS -> Abnormal CS	xx (xx.x%)	xx (xx.x%)
…			

Percentage is the number of patients in the category (n) divided by the number of patients within the column (N).

Source: Listing 16.2.8.1
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Programming Note: This layout also applies to Table 14.3.4.7 Shift Table of Hematology Parameters (Safety Analysis Set), Table 14.3.4.8 Shift Table of Coagulation Parameters (Safety Analysis Set), Table 14.3.4.9 Shift Table of TSH (Safety Analysis Set) and Table 14.3.4.10 Shift Table of Urinalysis Parameters (Safety Analysis Set). Please update source listings.

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Table 14.3.5.2 Shift Table of Vital Signs (Safety Analysis Set)

Visit		Arm I (Nab-paclitaxel and gemcitabine) (N=xx)	Arm II (VCN-01 with Nab-paclitaxel and gemcitabine) (N=xx)
Screening	n	xx	xx
	Normal	xx (xx.x%)	xx (xx.x%)
	Abnormal NCS	xx (xx.x%)	xx (xx.x%)
	Abnormal CS	xx (xx.x%)	xx (xx.x%)
Baseline	n	xx	xx
	Normal	xx (xx.x%)	xx (xx.x%)
	…		
<*Visit*>	n	xx	xx
	…		
Change from Baseline to <*Visit*>	n	xx	xx
	Normal -> Normal	xx (xx.x%)	xx (xx.x%)
	Normal -> Abnormal NCS	xx (xx.x%)	xx (xx.x%)
	Normal -> Abnormal CS	xx (xx.x%)	xx (xx.x%)
	Abnormal NCS -> Normal	xx (xx.x%)	xx (xx.x%)
	Abnormal NCS -> Abnormal NCS	xx (xx.x%)	xx (xx.x%)
	Abnormal NCS -> Abnormal CS	xx (xx.x%)	xx (xx.x%)
	Abnormal CS -> Normal	xx (xx.x%)	xx (xx.x%)
	Abnormal CS -> Abnormal NCS	xx (xx.x%)	xx (xx.x%)
	Abnormal CS -> Abnormal CS	xx (xx.x%)	xx (xx.x%)
…			

Percentage is the number of patients in the category (n) divided by the number of patients within the column (N).

Source: Listing 16.2.9
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Programming Note: This layout also applies to Table 14.3.7.2 Shift Table of 12-lead Electrocardiogram (Safety Analysis Set). Please update source listing.

Table 14.3.6 Physical Examination (Safety Analysis Set)

<Body system>

Visit		Arm I (Nab-paclitaxel and gemcitabine) (N=xx)	Arm II (VCN-01 with Nab-paclitaxel and gemcitabine) (N=xx)
Screening	n	xx	xx
	Normal	xx (xx.x%)	xx (xx.x%)
	Abnormal NCS	xx (xx.x%)	xx (xx.x%)
	Abnormal CS	xx (xx.x%)	xx (xx.x%)
Baseline	n	xx	xx
	Normal	xx (xx.x%)	xx (xx.x%)
	…		
<*Visit*>	n	xx	xx
	…		
Change from Baseline to <*Visit*>	n	xx	xx
	Normal -> Normal	xx (xx.x%)	xx (xx.x%)
	Normal -> Abnormal NCS	xx (xx.x%)	xx (xx.x%)
	Normal -> Abnormal CS	xx (xx.x%)	xx (xx.x%)
	Abnormal NCS -> Normal	xx (xx.x%)	xx (xx.x%)
	Abnormal NCS -> Abnormal NCS	xx (xx.x%)	xx (xx.x%)
	Abnormal NCS -> Abnormal CS	xx (xx.x%)	xx (xx.x%)
	Abnormal CS -> Normal	xx (xx.x%)	xx (xx.x%)
	Abnormal CS -> Abnormal NCS	xx (xx.x%)	xx (xx.x%)
	Abnormal CS -> Abnormal CS	xx (xx.x%)	xx (xx.x%)
…			

Percentage is the number of patients in the category (n) divided by the number of patients within the column (N).

Source: Listing 16.2.10
Path\Filename

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Table 14.3.8 ECOG Score (Safety Analysis Set)

Visit		Arm I (Nab-paclitaxel and gemcitabine) (N=xx)	Arm II (VCN-01 with Nab-paclitaxel and gemcitabine) (N=xx)
<*Visit*>	n	xx	xx
	0	xx (xx.x%)	xx (xx.x%)
	1	xx (xx.x%)	xx (xx.x%)
	2	xx (xx.x%)	xx (xx.x%)
	3	xx (xx.x%)	xx (xx.x%)
	4	xx (xx.x%)	xx (xx.x%)
	5	xx (xx.x%)	xx (xx.x%)
<*Visit*>	n	xx	xx
	0	xx (xx.x%)	xx (xx.x%)
	…		
…			

Percentage is the number of patients in the category (n) divided by the number of patients within the column (N).

Source: Listing 16.2.16
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Table 14.3.9 Subsequent Anticancer Treatment (Safety Analysis Set)

	Arm I (Nab-paclitaxel and gemcitabine) (N=xx)	Arm II (VCN-01 with Nab-paclitaxel and gemcitabine) (N=xx)
Any subsequent anticancer treatment	xx (xx.x%)	xx (xx.x%)
ATC4 term	xx (xx.x%)	xx (xx.x%)
PT	xx (xx.x%)	xx (xx.x%)
…		
ATC4 term	xx (xx.x%)	xx (xx.x%)
PT	xx (xx.x%)	xx (xx.x%)
…		
…		

Percentage is the number of patients in the category (n) divided by the number of patients within the column (N).
WHO-DDE version <XXXX>.

Source: Listing 16.2.18
Path\Filename

Table 14.3.10 Study Drug Exposure and Compliance (Safety Analysis Set)

			Arm I (Nab-paclitaxel and gemcitabine) (N=xx)	Arm II (VCN-01 with Nab-paclitaxel and gemcitabine) (N=xx)
Treatment duration (days)		n	xx	xx
		Mean	xx	xx
		STD	xx	xx
		Median	xx	xx
		Minimum	xx	xx
		Maximum	xx	xx
<*Treatment*> administration	Number of doses	n	xx	xx
		Mean	xx	xx
		STD	xx	xx
		Median	xx	xx
		Minimum	xx	xx
		Maximum	xx	xx
	Total dose administered (*unit*)	n	Xx	xx
		Mean	xx	xx
		…		
	Dose intensity (unit)	n	xx	xx
		Mean	xx	xx
		…		
	Relative dose intensity (%)	n	xx	xx
		Mean	xx	xx
		…		
	Dose prolongation[a]	Yes	xx xx (%)	xx xx (%)
		No	xx xx (%)	xx xx (%)

Dose Interruption[a]	Yes	xx xx (%)	xx xx (%)
	No	xx xx (%)	xx xx (%)
Dose Reduction[a]	Yes	xx xx (%)	xx xx (%)
	No	xx xx (%)	xx xx (%)
Reason for dose reduction[a] [b]	xxxxxx	xx xx (%)	xx xx (%)
	xxxxxx	xx xx (%)	xx xx (%)
	xxxxxx	xx xx (%)	xx xx (%)
Treatment compliance[c]	Mean	xx	xx
	STD	xx	xx
	Median	xx	xx
	Minimum	xx	xx
	Maximum	xx	xx

Percentage is the number of patients in the category (n) divided by the number of patients within the column (N) unless otherwise specified below.
[a]: Represents number of events, number of patients with at least one event and percentage of patients with at least one event.
[b]: The denominator for each percentage is the number of patients with dose reduction.
[c]: Treatment compliance = percentage of injection administered (actual/planned).

Source: Listing 16.2.1.3, 16.2.1.4, 16.2.1.5, 16.2.1.6, 16.2.1.7
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Programming Note: Please present summaries by the following treatments: VCN-01, Nab-paclitaxel, Gemcitabine.
Please note that dose reduction is not applicable for VCN-01 administration, this category should be excluded for the treatment.

Table 14.3.11.1 Prior Medications (Safety Analysis Set)

	Arm I (Nab-paclitaxel and gemcitabine) (N=xx)	Arm II (VCN-01 with Nab-paclitaxel and gemcitabine) (N=xx)
Any prior medications	xx (xx.x%)	xx (xx.x%)
X, xxxxxxxxxxxxx	xx (xx.x%)	xx (xx.x%)
X0N, xxxxxxxxxxxxx	xx (xx.x%)	xx (xx.x%)
X0NXX, xxxxxxxxxxx	xx (xx.x%)	xx (xx.x%)
xxxxxxxxxxxxx	xx (xx.x%)	xx (xx.x%)
X0NXX, xxxxxxxxxxx	xx (xx.x%)	xx (xx.x%)
xxxxxxxxxxxx	xx (xx.x%)	xx (xx.x%)
…		
…		

Prior medications/medical procedures are defined as any medication taken/any medical procedures performed within 28 days of the Screening visit.
Data are summarized by: Anatomical main group (ATC level 1); Therapeutic subgroup (ATC level 2); Therapeutic/pharmacological subgroup (ATC level 3); Chemical/therapeutic/pharmacological subgroup (ATC level 4); Preferred term.
Percentage is the number of patients in the category (n) divided by the number of patients within the column (N).
WHO-DDE version <XXXX>.

Source: Listing 16.2.12
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Programming Note: This layout also applies to Table 14.3.11.2 Concomitant Medications (Safety Analysis Set) [Footnote: Concomitant medications are defined as any medication taken at or after the time of the Screening visit.]

Table 14.5.1 Pharmacodynamic Parameters (Pharmacodynamic Set)

<Parameter>

Visit		Arm I (Nab-paclitaxel and gemcitabine) (N=xx)	Arm II (VCN-01 with Nab-paclitaxel and gemcitabine) (N=xx)	p-value
Screening	n	xx	xx	
	Mean	xx	xx	
	STD	xx	xx	
	Median	xx	xx	
	Minimum	xx	xx	
	Maximum	xx	xx	
Baseline	n	xx	xx	
	Mean	xx	xx	
	STD	xx	xx	
	Median	xx	xx	
	Minimum	xx	xx	
	Maximum	xx	xx	
<Visit>	n	xx	xx	
	Mean	xx	xx	
	…			
Change from Baseline to *<Visit>*	n	xx	xx	
	Mean	xx	xx	
	…			
<Test>				x.xxxx
…				

Source: Listing 16.2.6
Path\Filename

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Programming Note: Above layout should be used for parameters where both arms as assessed. Please indicate test used in the first column as appropriate.

<Parameter>

Visit		Arm I (Nab-paclitaxel and gemcitabine) (N=xx)	Arm II (VCN-01 with Nab-paclitaxel and gemcitabine) (N=xx)	p-value
Screening	n	NA	xx	
	Mean		xx	
	STD		xx	
	Median		xx	
	Minimum		xx	
	Maximum		xx	
Baseline	n	NA	xx	
	Mean		xx	
	STD		xx	
	Median		xx	
	Minimum		xx	
	Maximum		xx	
<Visit>	n	NA	xx	
	Mean		xx	
	…			
<Test>				x.xxxx
Change from Baseline to *<Visit>*	n	NA	xx	
	Mean		xx	
	…			
…				

NA = Not applicable.

Source: Listing 16.2.13
Path\Filename

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Programming Note: Above layout should be used for parameters only applicable for Arm II. Please indicate test used in the first column as appropriate. These two layouts should be combined in one output, starting each parameter on a new page.

Figure 14.2.1 Kaplan-Meier Plot of Overall Survival (Intent-to-Treat Set)

Figure Specifications

Procedure: PROC LIFETEST – survival plot

By: Arm

x axis: Time
x axis: Label: Time Post-Dose (months)
x axis: values: As appropriate

Y axis: Survival proportion
Y axis Label: Proportion
Y axis values: As appropriate

Legend:
Arm I (Nab-paclitaxel and gemcitabine) (N=xx) – linestyle = solid, colour = blue
Arm II (VCN-01 with Nab-paclitaxel and gemcitabine) (N=xx) – linestyle = solid, colour = green

Number of patients at risk over time to be presented below the x axis.

Footnote:
Patients who are lost to follow-up are censored at the time of their last visit or contact.

Programming Note: This layout also applies to Figure 14.2.2 Kaplan-Meier Plot of Overall Survival (Full Analysis Set) and Figure 14.2.3 Kaplan-Meier Plot of Overall Survival (Per Protocol Set), Figure 14.2.4 Subgroup Analysis: Kaplan-Meier Plot of Overall Survival (ITT), Figure 14.2.5 Kaplan-Meier Plot of Progression Free Survival (ITT), Figure 14.2.6 Kaplan-Meier Plot of Progression Free Survival (Full Analysis Set), Figure 14.2.7 Subgroup Analysis: Kaplan-Meier Plot of Progression Free Survival (ITT), Figure 14.2.8 Kaplan-Meier Plot of Time to Progression, Figure 14.2.9 Kaplan-Meier Plot of Duration of Response
Programming note for Figure 14.2.6 Kaplan-Meier Plot for Duration of Response: The starting point for both arms is not 100%, but the response rate per arm.

Figure 14.3.1 ECOG Score (Safety Analysis Set)

Figure Specifications

Plot: Kaplan-Meier time to event plot

x axis: Visit
x axis: Label: Visit
x axis: values: As appropriate

Y axis: Percentage
Y axis Label: Percentage of patients
Y axis values: 0 - 100

Footnote:
For each level of the ECOG score, the proportion of patients continuing on that or a better score were estimated for each visit using Kaplan-Meier estimates. At death the patient was assumed to have risen to the highest ECOG score.

Listing 16.2.1.1 Visit Dates

<Arm>

Patient Number	Visit	Date	Type	Reason for Unscheduled Visit
xxxxxxx	xx	xxxxxxxxxxxxx	Site Visit/ Remote Visit	
	xx	xxxxxxxxxxxxx	Site Visit/ Remote Visit	xxxxxxxxxxxxxxxxxxxxxxxxxxx
	xx	xxxxxxxxxxxxx	Site Visit/ Remote Visit	
	xx	xxxxxxxxxxxxx	Site Visit/ Remote Visit	
	…			
…				

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Listing 16.2.1.2 Patient Disposition – (1)

<Arm>

Patient Number	Date/Time of Informed Consent	Informed Consent Version	Protocol Version	Completed Treatment	If no, specify	Completed study	If no, specify	Date of completion/ withdrawal
xxxxxxx	xxxxxxxTxx:xx	x.x	xxxxxxxxxx	Yes/No	xxxxxxxxxxxxxx	Yes/No		xxxxxxx
xxxxxxx	xxxxxxxTxx:xx	x.x	xxxxxxxxxx	Yes/No		Yes/No		xxxxxxx
xxxxxxx	xxxxxxxTxx:xx	x.x	xxxxxxxxxx	Yes/No		Yes/No	xxxxxxxxxxxxxxxxxxxx	xxxxxxx
xxxxxxx	xxxxxxxTxx:xx	x.x	xxxxxxxxxx	Yes/No		Yes/No		xxxxxxx
…								

Completed treatment refers to completed treatment period, completed study refers to completed FU period.

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Programming Note: Please include (1) and (2) pages in one output, for every (1) page there will be a consecutive (2) page.

Listing 16.2.1.2 Patient Disposition – (2)

<Arm>

Patient Number	Safety Analysis Set (SAF)	Intent-to-Treat Set (ITT)	Full Analysis Set (FAS)	Per-Protocol Set (PPS)	Pharmacodynamic Set (PDS)	Subgroup Analysis Inclusion
xxxxxxx	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
xxxxxxx	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
xxxxxxx	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
xxxxxxx	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
…						

Inclusion for subgroup analysis is defined as patients who had the first 3 cycles of SoC chemotherapy and started the 4th SoC chemotherapy in Arm I, and patients who had the first 3 cycles of SoC chemotherapy, started the 4th cycle of SoC chemotherapy and received 2 doses of VCN-01.

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Programming Note: Please include (1) and (2) pages in one output, for every (1) page there will be a consecutive (2) page.

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Listing 16.2.1.3 SoC Administration – Nab-Paclitaxel – (1)

<Arm>

Patient Number	Visit	Administered	Start Date/time (Stop Date/Time)	Protocol Assigned Dose (mg/m2)	Patient BSA (m2) (Calculation Method)	Concentration of Infusion Solution (mg/ml)	Volume to be Infused (ml)	Actual Volume Infused (ml)
xxxxxxx	xxxxxxxxx	Yes/ No (*reason*)	xxxxxxxxTxx:xx (xxxxxxxxTxx:xx)	xxx	xx (method)	xx	xx	xx
	xxxxxxxxx	Yes/ No (*reason*)	xxxxxxxxTxx:xx (xxxxxxxxTxx:xx)	xxx	xx (method)	xx	xx	xx
…								

BSA = Body Surface Area.

Path\Filename

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Programming Note: Please include (1) and (2) pages in one output, for every (1) page there will be a consecutive (2) page.

Listing 16.2.1.3 SoC Administration – Nab-Paclitaxel – (2)

<Arm>

Patient Number	Visit	Actual Assigned Dose	Administered Dose (mg)	Complete Protocol Assigned Dose Administered	Prolongation of Infusion	Dose Reduction/ Interruption
xxxxxxx	xxxxxxxxx	xxxxxxxxx	xx	Yes/ No (*reason*)	Yes (*reason*)/ No	Yes/ No
	xxxxxxxxx	xxxxxxxxx	xx	Yes/ No (*reason*)	Yes (*reason*)/ No	Yes/ No
…						

Path\Filename

Programming Note: Please include (1) and (2) pages in one output, for every (1) page there will be a consecutive (2) page.

Listing 16.2.1.4 SoC Administration – Gemcitabine – (1)

<Arm>

Patient Number	Visit	Neutrophils and Platelets Reviewed prior to Dosing	Premedication Administered	Gemcitabine Administered	Start Date/time (Stop Date/Time)	Protocol Assigned Dose (mg/m2)	Patient BSA (m2) (Calculation Method)	Concentration of Infusion Solution (mg/ml)
xxxxxxx	xxxxxxxxx	Yes/ No	Yes/ No	Yes/ No (*reason*)	xxxxxxxxTxx:xx (xxxxxxxxTxx:xx)	xx	xx (method)	xx
	xxxxxxxxx	Yes/ No	Yes/ No	Yes/ No (*reason*)	xxxxxxxxTxx:xx (xxxxxxxxTxx:xx)	xx	xx (method)	xx
…								

BSA = Body Surface Area.

Path\Filename

Programming Note: Please include (1) and (2) pages in one output, for every (1) page there will be a consecutive (2) page.

Listing 16.2.1.4 SoC Administration – Gemcitabine – (2)

<Arm>

Patient Number	Visit	Volume to be Infused (ml)	Actual Volume Infused (ml)	Actual Assigned Dose	Administered Dose (mg)	Complete Protocol Assigned Dose Administered	Prolongation of Infusion	Dose Reduction/ Interruption
xxxxxxx	xxxxxxxxx	xx	xx	xxxxxxxxx	xx	Yes/ No (*reason*)	Yes (*reason*)/ No	Yes/ No
	xxxxxxxxx	xx	xx	xxxxxxxxx	xx	Yes/ No (*reason*)	Yes (*reason*)/ No	Yes/ No
…								

Path\Filename

Programming Note: Please include (1) and (2) pages in one output, for every (1) page there will be a consecutive (2) page.

Listing 16.2.1.5 SoC Dose Adjustments

<Arm>

Patient Number	Visit	Treatment	Action Taken	Reason for Adjustment/ Modification	Interrupted Dose Administration Continued	Start Date/time (Stop Date/Time)	Administered Volume after Continuation (mg)	Administered Volume after Continuation (ml)
xxxxxxx	xxxxxxxxx	Nap-paclitaxel/ Gemcitabine	Drug Interrupted/ Drug Withdrawn/ Dose Reduced	xxxxxxxxxxx	Yes/ No	xxxxxxxxTxx:xx (xxxxxxxxTxx:xx)	xx	xx
	xxxxxxxxx	Nap-paclitaxel/ Gemcitabine	Drug Interrupted/ Drug Withdrawn/ Dose Reduced	xxxxxxxxxxx	Yes/ No	xxxxxxxxTxx:xx (xxxxxxxxTxx:xx)	xx	xx
…								

Listing 16.2.1.6 VCN-01 Administration – (1)

<Arm>

Patient Number	Visit	Administered	Antipyretic Treatment p.o. Given Prior to Administration	Start Date/time (Stop Date/Time)	Protocol Assigned Volume Infused (mL)	Concentration of Infusion Solution (vp/mL)	Actual Volume Infused (mL)	Administered Dose (x10^13 vp)
xxxxxxx	xxxxxxxxx	Yes/ No (*reason*)	Yes/ No	xxxxxxxxTxx:xx (xxxxxxxxTxx:xx)	xx	xx	xx	xx
	xxxxxxxxx	Yes/ No (*reason*)	Yes/ No	xxxxxxxxTxx:xx (xxxxxxxxTxx:xx)	xx	xx	xx	xx
…								

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Programming Note: Please include (1) and (2) pages in one output, for every (1) page there will be a consecutive (2) page.

Listing 16.2.1.6 VCN-01 Administration - (2)

<Arm>

Patient Number	Visit	Required Dose (vp)	Fraction of Required Dose Administered (%)	Prolongation of Infusion	Dose Interruption
xxxxxxx	xxxxxxxxx	xx	xx	Yes (*reason*)/ No	Yes/ No
	xxxxxxxxx	xx	xx	Yes (*reason*)/ No	Yes/ No
…					

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Programming Note: Please include (1) and (2) pages in one output, for every (1) page there will be a consecutive (2) page.

Listing 16.2.1.7 VCN-01 Dose Interruptions

<Arm>

Patient Number	Visit	Reason for Interruption	Start Date/time (Stop Date/Time)	Administered Volume after Continuation (mL)
xxxxxxx	xxxxxxxxx	xxxxxxxxxxx	xxxxxxxxTxx:xx (xxxxxxxxTxx:xx)	xx
	xxxxxxxxx	xxxxxxxxxxx	xxxxxxxxTxx:xx (xxxxxxxxTxx:xx)	xx
…				

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Listing 16.2.2.1 Protocol Deviations

<Arm>

Patient Number	Deviation Number	Date of Deviation	Type	Protocol Deviation	Major/Minor
xxxxxxx	xx	xxxxxxxxx	xxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	Major/Minor
	xx	xxxxxxxxx	xxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	Major/Minor
xxxxxxx	xx	xxxxxxxxx	xxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	Major/Minor
xxxxxxx	xx	xxxxxxxxx	xxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	Major/Minor
…					

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P-VCNA-003 ddMMMyyyy HH:MM

Listing 16.2.4.1 Demographics and Baseline Characteristics

<Arm>

Patient Number	Year of birth	Age (years)	Gender	Ethnicity	Race	Weight (kg)	Height (cm)	BMI (kg/m^2)	Region of Study Site	ECOG status at randomization
xxxxxxx	xxxx	xx	xxxx	Not Hispanic or Latino/ Hispanic or Latino/ Not Reported/ Unknown	Black or African American/ American Indian or Alaska Native/ Asian/ Native Hawaiian or Other Pacific Islander/ White/ Other (specify)	xx	xx	xx	European Union/ North American	0/ 1
xxxxxxx	xxxx	xx	xxxx	Not Hispanic or Latino/ Hispanic or Latino/ Not Reported/ Unknown	Black or African American/ American Indian or Alaska Native/ Asian/ Native Hawaiian or Other Pacific Islander/ White/ Other (specify)	xx	xx	xx	European Union/ North American	0/ 1
…										

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Listing 16.2.4.2 Medical History

<*Arm*>

Patient Number	Condition SOC PT	Date of diagnosis	Ongoing (End date)	Any medication taken/ treatment given?
xxxxxxx	xxxxxxxxxxxxxx xxxxxxxxxxxxxx xxxxxxxxxxxxxx	xxxxxxx	Yes/ No (ddMMMyyyy)	Yes/ No
	xxxxxxxxxxxxxx xxxxxxxxxxxxxx xxxxxxxxxxxxxx	xxxxxxx	Yes/ No (ddMMMyyyy)	Yes/ No
…				

MedDRA version <XX.X>.

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Listing 16.2.4.3 Substance Use History

<*Arm*>

	Alcohol History		Smoking History			Recreational Drug History	
Patient Number	Average alcohol units per week	Did patient suffer from alcoholism in the past?	Smoking History	Average number of cigarettes per day	Comment	History of recreational drug use	Comment
xxxxxxx	xx	Yes/ No	Never Smoked/ Smoker/ Ex-Smoker (Date stopped smoking: *date*)	xx	xxxxxxxxxxx	Yes/ No	xxxxxxxxxxx
xxxxxxx	xx	Yes/ No	Never Smoked/ Smoker/ Ex-Smoker (Date stopped smoking: *date*)	xx	xxxxxxxxxxx	Yes/ No	xxxxxxxxxxx
…							

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Listing 16.2.4.4 Obstetric History

<Arm>

Patient Number	Childbearing Potential	Contraception Methods	Postmenopausal	Postmenopausal Additional Information	Date of Last Menstrual Period	Surgically Sterile	Surgically Sterile Additional Information	Hysterectomy	Additional Information
xxxxxxx	Yes/ No	xxxxxxxxxxxxxxx	Yes/ No/ Not Reported	xxxxxxxxxxx	xxxxxxxxxx	Yes (date of sterilisation)/ No/ Not Reported	xxxxxxxxxxx	Yes (date)/ No/ Not Reported	xxxxxxxxxxx
xxxxxxx	Yes/ No	xxxxxxxxxxxxxxx	Yes/ No/ Not Reported	xxxxxxxxxxx	xxxxxxxxxx	Yes (date of sterilisation)/ No/ Not Reported	xxxxxxxxxxx	Yes (date)/ No/ Not Reported	xxxxxxxxxxx
…									

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Listing 16.2.4.5 Menopausal Status

<Arm>

Patient Number	Date/Time of Sample	Status
xxxxxxx	xxxxxxxxTxx:xx	Menopausal/ Premenopausal/ Peri-menopausal
xxxxxxx	xxxxxxxxTxx:xx	Menopausal/ Premenopausal/ Peri-menopausal
…		

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Listing 16.2.4.6 Inclusion/ Exclusion Criteria Failures

<Arm>

Patient Number	Visit	Inclusion/ Exclusion	Criteria Number	Result
xxxxxxx	xxxxx	Inclusion/ Exclusion	xx	xxxxxx
	xxxxx	Inclusion/ Exclusion	xx	xxxxxx
xxxxxxx	xxxxx	Inclusion/ Exclusion	xx	xxxxxx
xxxxxxx	xxxxx	Inclusion/ Exclusion	xx	xxxxxx
…				

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Listing 16.2.6.1 Tumor Response Evaluation - EDC Data

<Arm>

Patient Number	Visit	Date of Tumor Assessment	Target Lesion Assessment	Target Lesions: Sum of Diameters (mm)	Non-Target Lesion Assessment	New Lesions	Overall Response
xxxxxxx	xxxxxxxxx	xxxxxxxx	Complete Response (CR)/ Partial Response (PR)/ Stable Disease (SD)/ Not All Evaluated/ Progressive Disease (PD)	xx	Absent (No Non-Target Lesion at Baseline)/ Complete Response (CR)/ Non-CR/Non-PD/ Not Evaluated/ Progressive Disease (PD)	Yes/ No	Complete Response (CR)/ Partial Response (PR)/ Stable Disease (SD)/ Inevaluable (NE)/ Progressive Disease (PD)
	xxxxxxxxx	Yes/ No (*reason*)	Yes/ No	xxxxxxxxTxx:xx (xxxxxxxxTxx:xx)	xx	xx	xx
…							

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Programming Note: This layout also applies to Listing 16.2.6.2 Tumor Response Evaluation - CIV Data.
Footnotes to be included:

- *EDC = Electronic Data Capture.*
- *CIV = Central Imaging Vendor.*

Listing 16.2.6.3 Derived Efficacy Variables - EDC Data

<Arm>

Patient Number	Overall Survival (OS) (months)	Progression – Free Survival (PFS) (months)	Time to Progression (TTP) (months)	Objective Response	Disease Control	Landmark 1-year Survival	New PFS at the 1-year Landmark	Duration of Response (DoR) (months)
xxxxxxx	xx	xx	xx	Yes/ No	Yes/ No	Yes/ No	Yes/ No	xx
	xx	xx	xx	Yes/ No	Yes/ No	Yes/ No	Yes/ No	xx
…								

Path\Filename

Programming Note: This layout also applies to Listing 16.2.6.4 Derived Efficacy Variables - CIV Data.
Footnotes to be included:

- *EDC = Electronic Data Capture.*
- *CIV = Central Imaging Vendor.*

Listing 16.2.6.5 Tumor Marker Ca 19.9

<Arm>

Patient Number	Visit	Date/Time	Result	Unit	Normal Range			Evaluation
					Lower	Upper	Unit	
xxxxxxx	xxxxx	xxxxxxxTxx:xx	xx	xxx	xx	xx	xxx	Normal/ Abnormal NCS/ Abnormal CS
	xxxxx	xxxxxxxTxx:xx	xx	xxx	xx	xx	xxx	Normal/ Abnormal NCS/ Abnormal CS
…								

NCS = Not Clinically Significant; CS = Clinically Significant.

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Below Detectable Value (if any present in the data) should be included in the result column as "BDV' with a footnote for clarification.

Listing 16.2.6.6 QLQ-C30 Questionnaire

<Arm>

Patient Number	Visit	Scale	Score
xxxxxxx	xxxxxx	xxxxxxxxxxxxxxxxxx	xx
		xxxxxxxxxxxxxxxxxx	xx
		xxxxxxxxxxxxxxxxxx	xx
		…	
	xxxxxx	xxxxxxxxxxxxxxxxxx	xx
		…	
	…		
…			

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Listing 16.2.6.7 Target Lesions

<Arm>

Patient Number	Lesion Number	Lesion Site	Date of Scan	Lesion Measurable	Size of Longest Diameter/ Short Axis (mm)
xxxxxxx	xx	xxxxxxxxxxx	xxxxxxxx	Yes/ No (*reason*)	xx
			xxxxxxxx	Yes/ No (*reason*)	xx
	xx	xxxxxxxxxxx	xxxxxxxx	Yes/ No (*reason*)	xx
…					

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Listing 16.2.6.8 Non-Target Lesions

<Arm>

Patient Number	Lesion Number	Lesion Site	Date of Scan	Lesion Assessment
xxxxxxx	xx	xxxxxxxxxxx	xxxxxxxx	Absent/ Present/ Unequivocal progression/ Not evaluable
			xxxxxxxx	Absent/ Present/ Unequivocal progression/ Not evaluable
	xx	xxxxxxxxxxx	xxxxxxxx	Absent/ Present/ Unequivocal progression/ Not evaluable
…				

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Listing 16.2.6.9 Deaths

<Arm>

Patient Number	Date of Death	Primary Cause of Death
xxxxxxx	xxxxxxxx	Progressive Disease/ Other (*specify*)
xxxxxxx	xxxxxxxx	Progressive Disease/ Other (*specify*)
…		

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Listing 16.2.7.1 Adverse Events – (1)

<Arm>

Patient Number	Adverse Event SOC PT	Due to PD	Onset date/time/TEAE	Resolution date/time / Ongoing	Serious	Severity	Relationship to VCN-01	Relationship to Gemcitabine	Relationship to Nab-paclitaxel
xxxxxxx	xxxxxxxxx xxxxxxxxx xxxxxxxxx	Due to PD/ Not Due to PD	xxxxxxxx Txx:xx /Yes or Yes[1]	xxxxxxxxT xx:xx/ Ongoing	Yes (criteria)/ No	Grade 1/ Grade 2/ Grade 3/ Grade 4/ Grade 5	Definitely Related (*specify*)/ Probably Related (*specify*)/ Possibly Related (*specify*)/ Unlikely Related/ Not Related	Definitely Related (*specify*)/ Probably Related (*specify*)/ Possibly Related (*specify*)/ Unlikely Related/ Not Related	Definitely Related (*specify*)/ Probably Related (*specify*)/ Possibly Related (*specify*)/ Unlikely Related/ Not Related
	xxxxxxxxx xxxxxxxxx xxxxxxxxx	Due to PD/ Not Due to PD	xxxxxxxx Txx:xx /Yes or Yes[1]	xxxxxxxxT xx:xx/ Ongoing	Yes (criteria)/ No	Grade 1/ Grade 2/ Grade 3/ Grade 4/ Grade 5	Definitely Related (*specify*)/ Probably Related (*specify*)/ Possibly Related (*specify*)/ Unlikely Related/ Not Related	Definitely Related (*specify*)/ Probably Related (*specify*)/ Possibly Related (*specify*)/ Unlikely Related/ Not Related	Definitely Related (*specify*)/ Probably Related (*specify*)/ Possibly Related (*specify*)/ Unlikely Related/ Not Related
	…								
…									

PD = Progressive Disease.
MedDRA version <XX.X>.
TEAE = Treatment Emergent Adverse Event.
Yes = Treatment Emergent for all study drugs. Yes[1] = Treatment Emergent for VCN-01.

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Programming Note: This layout also applies to Listing 16.2.7.2 Adverse Events Due to Progressive Disease. and Listing 16.2.7.3 TEAE with Grade 4 or 5 (please include "Occurred after 1st VCN-01 Dose" and "Occurred after 2nd VCN-01 dose" columns after Due to PD column)

Please include (1) and (2) pages in one output, for every (1) page there will be a consecutive (2) page.
If the relationship to study treatment is marked as "Definitely Related, Probably Related or Possibly Related" please present the reason for decision in brackets.

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Listing 16.2.7.1 Adverse Events – (2)

<Arm>

Patient Number	Adverse Event SOC PT	Outcome	Action taken with VCN-01	Action taken with Gemcitabine	Action taken with Nab-paclitaxel	Other action taken
xxxxxxx	xxxxxxxxx xxxxxxxxx xxxxxxxxx	Fatal/ Not Recovered/Not Resolved / Recovered/Resolved / Recovered/Resolved with Sequelae / Recovering/ Unknown	Dose Not Changed/ Dose Reduced/ Drug Interrupted/ Drug Withdrawn/ Not Applicable/ Unknown	Dose Not Changed/ Dose Reduced/ Drug Interrupted/ Drug Withdrawn/ Not Applicable/ Unknown	Dose Not Changed/ Dose Reduced/ Drug Interrupted/ Drug Withdrawn/ Not Applicable/ Unknown	xxxxxx
	xxxxxxxxx xxxxxxxxx xxxxxxxxx	Fatal/ Not Recovered/Not Resolved / Recovered/Resolved / Recovered/Resolved with Sequelae / Recovering/ Unknown	Dose Not Changed/ Dose Reduced/ Drug Interrupted/ Drug Withdrawn/ Not Applicable/ Unknown	Dose Not Changed/ Dose Reduced/ Drug Interrupted/ Drug Withdrawn/ Not Applicable/ Unknown	Dose Not Changed/ Dose Reduced/ Drug Interrupted/ Drug Withdrawn/ Not Applicable/ Unknown	xxxxxx
	…					
…						

MedDRA version <XX.X>.

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Programming Note: This layout also applies to Listing 16.2.7.2 Adverse Events Due to Progressive Disease
and Listing 16.2.7.3 TEAE with Grade 4 or 5 (please include "Occurred after 1st VCN-01 Dose" and "Occurred after 2nd VCN-01 dose" columns after Due to PD column)Please include (1) and (2) pages in one output, for every (1) page there will be a consecutive (2) page.
If the relationship to study treatment is marked as "Definitely Related, Probably Related or Possibly Related" please present the reason for decision in brackets.

Listing 16.2.8.1 Biochemistry Parameters

<Arm>

Patient Number	Visit	Date/Time	Parameter	Result	Unit	Normal Range			Evaluation
						Lower	Upper	Unit	
xxxxxxx	xxxxxxxx	xxxxxxxxTxx:xx	xxxxxxxxxx	xx	xxxx	xx	xx	xxxx	Normal/ Abnormal CS/ Abnormal NCS
	xxxxxxxx	xxxxxxxxTxx:xx	xxxxxxxxxx	xx	xxxx	xx	xx	xxxx	Normal/ Abnormal CS/ Abnormal NCS
	xxxxxxxx	xxxxxxxxTxx:xx	xxxxxxxxxx	xx	xxxx	xx	xx	xxxx	Normal/ Abnormal CS/ Abnormal NCS
…									

CS=Clinically Significant; NCS=Not Clinically Significant

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Programming Note: This layout also applies to Listing 16.2.8.2 Hematology Parameters, Listing16.2.8.3 Coagulation Parameters and Listing 16.2.8.4 TSH Below Detectable Value (if any present in the data) should be included in the result column as "BDV' with a footnote for clarification.

Listing 16.2.8.5 Urinalysis Parameters

<Arm>

Patient Number	Visit	Date/Time	Parameter	Result	Unit	Evaluation
xxxxxxx	xxxxxxxx	xxxxxxxxTxx:xx	xxxxxxxxxx	xx	xxxx	Normal/ Abnormal CS/ Abnormal NCS
	xxxxxxxx	xxxxxxxxTxx:xx	xxxxxxxxxx	xx	xxxx	Normal/ Abnormal CS/ Abnormal NCS
	xxxxxxxx	xxxxxxxxTxx:xx	xxxxxxxxxx	xx	xxxx	Normal/ Abnormal CS/ Abnormal NCS
…						

CS=Clinically Significant; NCS=Not Clinically Significant

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Listing 16.2.8.6 Serology Results

<Arm>

Patient Number	Visit	Date/Time	Parameter	Result	Unit
xxxxxxx	xxxxxxxx	xxxxxxxxTxx:xx	xxxxxxxxxx	xx	xxxx
	xxxxxxxx	xxxxxxxxTxx:xx	xxxxxxxxxx	xx	xxxx
	xxxxxxxx	xxxxxxxxTxx:xx	xxxxxxxxxx	xx	xxxx
...					

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Listing 16.2.8.7 Pregnancy Results

<Arm>

Patient Number	Visit	Date/Time	Specimen Type	Result
xxxxxxx	xxxxxxxx	xxxxxxxxTxx:xx	Urine/ Serum	Positive/ Negative
	xxxxxxxx	xxxxxxxxTxx:xx	Urine/ Serum	Positive/ Negative
	xxxxxxxx	xxxxxxxxTxx:xx	Urine/ Serum	Positive/ Negative
...				

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Listing 16.2.9 Vital Signs

<Arm>

Patient number	Visit	Date/ Time	Body Temperature (°C)	Weight (kg)	Systolic BP (mmHg)	Diastolic BP (mmHg)	Pulse rate (bpm)	Respirations (breaths/min)	Review	Comments
xxxxxxx	xxxxx	xxxxxxxxTxx:xx	xx	xx	xx	xx	xx		Normal/ Abnormal NCS/ Abnormal CS	xxxxxxxxx
	xxxxx	xxxxxxxxTxx:xx	xx	xx	xx	xx	xx		Normal/ Abnormal NCS/ Abnormal CS	xxxxxxxxx
	xxxxx	xxxxxxxxTxx:xx	xx	xx	xx	xx	xx		Normal/ Abnormal NCS/ Abnormal CS	xxxxxxxxx
…										

CS=Clinically Significant; NCS=Not Clinically Significant

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Listing 16.2.10 Physical Examination

<Arm>

Patient Number	Visit	Date	Body system	Status	Abnormality	Clinically Significant
xxxxxxx	xxxx	xxxxxx	xxxxxxxx	Normal/ Abnormal/ Not done/ Not Applicable	xxxxxxxxxxxxxxxxxxxxxxxxxx	Yes/ No
			xxxxxxxx	Normal/ Abnormal/ Not done/ Not Applicable	xxxxxxxxxxxxxxxxxxxxxxxxxx	Yes/ No
			xxxxxxxx	Normal/ Abnormal/ Not done/ Not Applicable		

…

CS=Clinically Significant; NCS=Not Clinically Significant

Path\Filename

Listing 16.2.11 12-Lead ECG

<Arm>

Patient Number	Visit	Date/Time	Heart rate (bpm)	PR Interval (msec)	RR Interval (msec)	QRS width (msec)	QT Interval (msec)	QTcF Interval (msec)	Investigator's Interpretation
xxxxxxx	xxxx	xxxxxxTxx:xx	xx	xx	xx	xx	xx	xx	Normal/ Abnormal NCS/ Abnormal CS
	xxxx	xxxxxxTxx:xx	xx	xx	xx	xx	xx	xx	Normal/ Abnormal NCS/ Abnormal CS
	xxxx	xxxxxxTxx:xx	xx	xx	xx	xx	xx	xx	Normal/ Abnormal NCS/ Abnormal CS
…									

CS=Clinically Significant; NCS=Not Clinically Significant

Path\Filename

Listing 16.2.12 Prior and Concomitant Medications – (1)

<Arm>

Patient Number	Medication Name ATC4 PT	Indication	Dose	Unit	Frequency	Route	Start date (Stop date / Ongoing)
xxxxxxx	xxxxxxxxxxxxxxx xxxxxxxxxxxxxxx xxxxxxxxxxxxxxx	xxxxxxx	xx	xxx	xxx	xxx	xxxxxxxxxxxxx (xxxxxxxxxxxxx)
	xxxxxxxxxxxxxxx xxxxxxxxxxxxxxx xxxxxxxxxxxxxxx	xxxxxxx	xx	xxx	xxx	xxx	xxxxxxxxxxxxx (xxxxxxxxxxxxx)
	xxxxxxxxxxxxxxx xxxxxxxxxxxxxxx xxxxxxxxxxxxxxx	xxxxxxx	xx	xxx	xxx	xxx	xxxxxxxxxxxxx (Ongoing)

…

WHO-DDE version <XXXX>.

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Programming Note: Please include (1) and (2) pages in one output, for every (1) page there will be a consecutive (2) page.

Listing 16.2.12 Prior and Concomitant Medications – (2)

<Arm>

Patient Number	Medication Name ATC4 PT	Not Allowed Per Protocol	Prophylactic	Given for Pre-Existing Condition	Given for Adverse Event	Given as Pre-Medication for Gemcitabine	Given as Antipyretic Treatment Prior to Dosing?
xxxxxxx	xxxxxxxxxxxxxxx xxxxxxxxxxxxxxx xxxxxxxxxxxxxxx	Yes/ No	Yes/ No	Yes/ No	Yes/ No	Yes/ No	Yes/ No/ Not Applicable
	xxxxxxxxxxxxxxx xxxxxxxxxxxxxxx xxxxxxxxxxxxxxx	Yes/ No	Yes/ No	Yes/ No	Yes/ No	Yes/ No	Yes/ No/ Not Applicable
	xxxxxxxxxxxxxxx xxxxxxxxxxxxxxx xxxxxxxxxxxxxxx	Yes/ No	Yes/ No	Yes/ No	Yes/ No	Yes/ No	Yes/ No/ Not Applicable

…

WHO-DDE version <XXXX>.

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Programming Note: Please include (1) and (2) pages in one output, for every (1) page there will be a consecutive (2) page.

Listing 16.2.13 Pharmacodynamic Parameters

<Arm>

Patient Number	Visit	Date/Time	Parameter	Result	Unit
xxxxxxx	xxxxxxxx	xxxxxxxxTxx:xx	xxxxxxxxxx	xx	xxxx
	xxxxxxxx	xxxxxxxxTxx:xx	xxxxxxxxxx	xx	xxxx
	xxxxxxxx	xxxxxxxxTxx:xx	xxxxxxxxxx	xx	xxxx
...					

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Listing 16.2.14 COVID-19 Results

<Arm>

Patient Number	Visit	Date/Time	Where was the test Performed?	Result
xxxxxxx	xxxxxxxx	xxxxxxxxTxx:xx	At Study Site/ Other Test Center/ Test not performed	Positive/ Negative/ Indistinct
	xxxxxxxx	xxxxxxxxTxx:xx	At Study Site/ Other Test Center/ Test not performed	Positive/ Negative/ Indistinct
	xxxxxxxx	xxxxxxxxTxx:xx	At Study Site/ Other Test Center/ Test not performed	Positive/ Negative/ Indistinct
…				

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Listing 16.2.15 Left Ventricular Ejection Fraction Results

<Arm>

Patient Number	Visit	LVEF Performed	Date of Scan	Method	Result (%)
xxxxxxx	xxxxxxxx	Yes/ Not applicable (no clinical indication)	xxxxxxxx	Multigated Acquisition Scan/ ECHO	xx
	xxxxxxxx	Yes/ Not applicable (no clinical indication)	xxxxxxxx	Multigated Acquisition Scan/ ECHO	xx
	xxxxxxxx	Yes/ Not applicable (no clinical indication)	xxxxxxxx	Multigated Acquisition Scan/ ECHO	xx
…					

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Listing 16.2.16 ECOG Score

<Arm>

Patient Number	Visit	Date	Grade
xxxxxxx	xxxxxxxx	xxxxxxxx	0 (Fully active, able to carry on all pre-disease performance without restriction)/ 1 (Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework or office work)/ 2 (Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about > 50% of waking hours)/ 3 (Capable of only limited self-care, confined to a bed or chair > 50% of waking hours)/ 4 (Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair)/ 5 (Dead)
	xxxxxxxx	xxxxxxxx	0 (Fully active, able to carry on all pre-disease performance without restriction)/ 1 (Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework or office work)/ 2 (Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about > 50% of waking hours)/ 3 (Capable of only limited self-care, confined to a bed or chair > 50% of waking hours)/ 4 (Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair)/ 5 (Dead)
	xxxxxxxx	xxxxxxxx	0 (Fully active, able to carry on all pre-disease performance without restriction)/ 1 (Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework or office work)/ 2 (Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about > 50% of waking hours)/ 3 (Capable of only limited self-care, confined to a bed or chair > 50% of waking hours)/ 4 (Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair)/ 5 (Dead)
…			

Listing 16.2.17 Fibroscan Results

<Arm>

Patient Number	Visit	Fibroscan Performed	Date of Scan	Result (kPa)
xxxxxxx	xxxxxxxx	Yes/ Not applicable (no clinical indication)	xxxxxxxx	xx
	xxxxxxxx	Yes/ Not applicable (no clinical indication)	xxxxxxxx	xx
	xxxxxxxx	Yes/ Not applicable (no clinical indication)	xxxxxxxx	xx
…				

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Listing 16.2.18 Subsequent Anticancer Treatment

<Arm>

Patient Number	Medication Name ATC4 PT	Indication	Dose	Unit	Frequency	Route	Start date (Stop date / Ongoing)	Reason Therapy Ended
xxxxxxx	xxxxxxxxxxxxxxx xxxxxxxxxxxxxxx xxxxxxxxxxxxxxx	xxxxxxx	xx	xxx	xxx	xxx	xxxxxxxxxxxxx (xxxxxxxxxxxxx)	Death/ Therapy changed/ Other (*specify*)
	xxxxxxxxxxxxxxx xxxxxxxxxxxxxxx xxxxxxxxxxxxxxx	xxxxxxx	xx	xxx	xxx	xxx	xxxxxxxxxxxxx (xxxxxxxxxxxxx)	Death/ Therapy changed/ Other (*specify*)
	xxxxxxxxxxxxxxx xxxxxxxxxxxxxxx xxxxxxxxxxxxxxx	xxxxxxx	xx	xxx	xxx	xxx	xxxxxxxxxxxxx (Ongoing)	Death/ Therapy changed/ Other (*specify*)

…

WHO-DDE version <XXXX>.

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Listing 16.2.19 Study Disease Diagnosis

<Arm>

Patient Number	Date of Diagnosis	Cancer Stage at Diagnosis	Source of Diagnosis	If Other, specify	Location of Primary Pancreatic Tumour	TNM Criteria (T)	TNM Criteria (N)	TNM Criteria (M)	Date of Metastatic Disease Diagnosis	Tumour Grade	Metastasis Location
xxxxxxx	xxxxxxx	xxxxxxx	xx	xxx	xxx	xxx	xxx	xxx	xxxxxxx	xxx	xxxxxxx
	xxxxxxx						xxx	xxx	xxxxxxx	xxx	xxxxxxx
	xxxxxxx	xxxxxxx	xx	xxx	xxx	xxx	xxx	xxx	xxxxxxx	xxx	xxxxxxx
	xxxxxxx						xxx	xxx	xxxxxxx	xxx	xxxxxxx
	xxxxxxx	xxxxxxx	xx	xxx	xxx	xxx	xxx	xxx	xxxxxxx	xxx	xxxxxxx
…											

Path\Filename

16 APPENDICES

16.1 STUDY DESIGN

