

**Official Title  
of the study** **PANOVA-3: Effect of Tumor Treating  
Fields (TTFields, 150 kHz) as Front-Line  
Treatment of Locally-advanced Pancreatic  
Adenocarcinoma Concomitant With  
Gemcitabine and Nab-paclitaxel**

**NCT number** **NCT03377491**

**Document** **October 16, 2024**

**Date**

**Statistical Analysis Plan**

Sponsor Name: NovoCure Ltd.  
Sponsor Protocol ID: EF-27

Study ID: [REDACTED]

**Statistical Analysis Plan**

**Novocure GmbH**

**EF-27**

**PANOVA-3: Pivotal, randomized, open-label study of Tumor  
Treating Fields (TTFields, 150kHz) concomitant with  
gemcitabine and nab-paclitaxel for front-line treatment of  
locally-advanced pancreatic adenocarcinoma**

[REDACTED] Study ID: [REDACTED]

Document Version: [REDACTED]

Document Date: [REDACTED]

[REDACTED]

## Statistical Analysis Plan

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## Reviewers

The following reviews of the SAP were conducted:

Name and Title	Role	Version Last Reviewed	Company/ Organization
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

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## Glossary of Abbreviations

Abbreviation	Term
AE	Adverse Event
ADE	Adverse Device Effect
CA	Competent Authority
CA 19-9	Carbohydrate Antigen 19-9
CI	Confidence Interval
Cm	Centimeter
CR	Complete Response
CRF	Case Report Form
CT	Computed Tomography
CTCAE	Common Terminology Criteria for Adverse Events
DMC	Data and Monitoring Committee
ECOG	Eastern Cooperative Oncology Group
eCRF	Electronic Case Report Form
EORTC	European Organization for Research and Treatment of Cancer
FDA	Food and Drug Administration
ITT	Intent to Treat
mITT	Modified Intent to Treat
LDH	Lactatdehydrogenase
MRI	Magnetic Resonance Imaging
NCI	National Cancer Institute
ORR	Objective Response Rate
OS	Overall Survival
PFS	Progression Free Survival
PR	Partial Response
PT	Preferred Term
QLQ C-30	EORTC's Quality of life Questionnaire C-30
QLQ PAN26	Quality of life questionnaire Pancreatic Cancer Module
RECIST	Response Evaluation Criteria in Solid Tumors
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SAF	Safety Population
SOC	Standard of Care
TEAEs	Treatment-emergence adverse events
TTFields	Tumor Treating Fields
VAS	Visual Analogue Scale

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### 1. SOURCE DOCUMENTS

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

Document	Date	Version
Protocol	[REDACTED]	[REDACTED]
eCRF	[REDACTED]	[REDACTED]

### 2. PROTOCOL DETAILS

#### 2.1. Study Objectives

##### 2.1.1. Primary Objectives

To determine if TTFields concomitant with gemcitabine and nab-paclitaxel in the first line treatment of unresectable, locally advanced pancreatic cancer patients prolongs the overall survival of patients, compared to chemotherapy treatment alone.

##### 2.1.2. Secondary Objectives

1. To determine if TTFields in combination with gemcitabine and nab-paclitaxel in the first line treatment of unresectable, locally advanced pancreatic cancer patients prolongs the progression-free survival of patients, compared to chemotherapy treatment alone.
2. To determine if TTFields in combination with gemcitabine and nab-paclitaxel in the first line treatment of unresectable, locally advanced pancreatic cancer patients prolongs the local progression-free survival of patients, compared to chemotherapy treatment alone.
3. To determine if TTFields in combination with gemcitabine and nab-paclitaxel in the first line treatment of unresectable, locally advanced pancreatic cancer patients leads to a higher rate of objective response rate, compared to chemotherapy treatment alone.
4. To determine if TTFields in combination with gemcitabine and nab-paclitaxel in the first line treatment of unresectable, locally advanced pancreatic cancer patients leads to a higher 1-year survival rate, compared to chemotherapy treatment alone.
5. To assess if TTFields in combination with gemcitabine and nab-paclitaxel in the first line treatment of unresectable, locally advanced pancreatic cancer patients affects the quality of life of patients, compared to chemotherapy treatment alone.
6. To evaluate if TTFields in combination with gemcitabine and nab-paclitaxel in the first line treatment of unresectable, locally advanced pancreatic cancer patients

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prolongs the pain-free survival of patients, compared to chemotherapy treatment alone.

7. To determine if TTFields in combination with gemcitabine and nab-paclitaxel in the first line treatment of unresectable, locally advanced pancreatic cancer patients prolongs the puncture-free survival of patients, compared to chemotherapy treatment alone.
8. To determine if TTFields in combination with gemcitabine and nab-paclitaxel in the first line treatment of unresectable, locally advanced pancreatic cancer patients increases the probability of the cancer becoming resectable (with a curative intention), compared to chemotherapy treatment alone.
9. To determine if TTFields in combination with gemcitabine and nab-paclitaxel in the first line treatment of unresectable, locally advanced pancreatic cancer patients is a safe treatment compared to chemotherapy treatment alone.

### 2.2. Overall Study Design

This is a pivotal, randomized, open-label, two-arm, multicenter study. This randomized study is designed to test the efficacy and safety of gemcitabine and nab-paclitaxel, with or without TTFields, using the NovoTTF-200T System as a front-line therapy for locally-advanced pancreatic adenocarcinoma patients. The study population are the patients with unresectable, locally-advanced adenocarcinoma of the pancreas, and with ECOG 0-2. Patients will be stratified as below:



1. Arm I: Patients receive TTFields using the NovoTTF-200T System together with gemcitabine and nab-paclitaxel.
2. Arm II: Patients receive gemcitabine and nab-paclitaxel alone.

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Patients on both arms should also receive the best supportive care available at each site. Following progression patients may be offered standard pancreatic cancer-directed therapy and salvage therapy based on local practice at each site. Treatment may continue post-radiation therapy if radiation therapy is applied prior to local disease progression, as long as the skin has recovered from the radiation therapy according to the study investigator. Treatment may continue post-surgical resection if patient becomes resectable, as long as the skin has recovered from the surgical wounds according to the study investigator.

The overall schedule of the study is as follows:

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### 2.3. Sample Size and Power

[REDACTED]

[REDACTED]

## 3. EFFICACY AND SAFETY VARIABLES

### 3.1. Primary Efficacy Endpoint

Overall survival (OS) of patients treated with TTFields concomitant with gemcitabine and nab-paclitaxel in the first line treatment of unresectable, locally advanced pancreatic cancer patients, compared to overall survival of patients treated with chemotherapy alone.

OS will be measured from the date of randomization to the date of death (in months).

[REDACTED]

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### 3.2. Secondary Efficacy Endpoints

#### 3.2.1. Progression-free survival (PFS)

PFS of patients treated with TTFields concomitant with gemcitabine and nab-paclitaxel, compared to that of patients treated with chemotherapy alone, using the RECIST V1.1 Criteria.

Progression-free survival is defined as the time from the date of randomization until the date of disease progression for the entire body according to RECIST Criteria Version 1.1 or death (by any cause in the absence of progression). [REDACTED]

#### 3.2.2. Local progression-free survival

Local disease progression is defined as Progressive Disease per revised RECIST version 1.1 in the absence of distant metastasis [REDACTED]

Local progression-free survival is defined as the time from the date of randomization until the date of local disease progression as defined above (by any

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cause in the absence of local disease progression) or death

Term	Percentage
GMOs	85%
Organic	92%
Natural	90%
Artificial	78%
Organic	88%
Natural	85%
Artificial	75%
Organic	95%
Natural	93%
Artificial	80%
Organic	98%
Natural	96%
Artificial	82%
Organic	99%
Natural	97%
Artificial	84%
Organic	100%
Natural	99%
Artificial	86%

[REDACTED]

[REDACTED]

[REDACTED]

### 3.2.3. Objective response rate (ORR)

The objective response to the tumor will be assessed using CT scans and according to the revised RECIST Criteria V1.1. Objective response rate is defined as the proportion of patients with best response of partial-response (PR) or complete response (CR) between the time of randomization and the time of disease progression or death.

### 3.2.4. One-year survival rate

One-year survival rate of patients treated with TTFields concomitant with gemcitabine and nab-paclitaxel in the first line treatment of unresectable, locally advanced pancreatic cancer patients, compared to the one-year survival rate of patients treated with chemotherapy alone. [REDACTED]

\_\_\_\_\_

### 3.2.5. Quality of life

Quality of life of patients are assessed using the EORTC QLQ C30 questionnaire with the PAN26 addendum.

Term	Percentage
Climate change	100
Global warming	98
Green energy	95
Carbon footprint	92
Sustainable development	88
Renewable energy	85
Emissions reduction	82
Green economy	78
Carbon tax	95

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### 3.2.6. Pain-free survival

Pain-free survival measures the duration between the time of randomization until a greater than or equal to [REDACTED] points increase, which means pain increase, from baseline measurement of a patient self-reported visual analogue scale (VAS) is recorded or death, whichever occurs first. [REDACTED]

### 3.2.7. Puncture-free survival

Puncture-free survival will be measured as the duration between randomization until the first need for paracentesis as data collected on the ascitic fluid drainage

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eCRF or death, whichever occurs first. [REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]

### 3.2.8. Resectability rate

Resectability rate will be measured as the percentage of patients whose tumors were deemed resectable. [REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]

PT terms	MEDDRA codes
[REDACTED]	[REDACTED]

## 3.3. Safety Variables

### 3.3.1. Extend of Exposure [REDACTED]

#### 3.3.1.1. Extend exposure to NovoTTF-200T

Extend of exposure to NovoTTF-200T will be summarized descriptively for the patients who randomized to the NovoTTF-200T arm as:

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

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### 3.3.1.2. Exposure to Standard of Care

Standard of care in this study contains two drugs: Nab-paclitaxel and Gemcitabine. For each drug, the following variables will be determined:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

### 3.3.2. Adverse Events (AEs)

All adverse events (AEs) recorded on the eCRF will be coded using the MedDRA dictionary [Version 20.1-23.0]. The adverse event reporting period will begin immediately following randomization. Adverse events will be collected until last study follow up visit and for [REDACTED] following treatment termination

Treatment-emergence adverse events (TEAEs) are events with start date on or after the first date of any study treatment (including SOC or TTFIELDS), or events with start date prior to the date of first treatment whose severity worsens on or after the date first treatment.

Assessment of AE severity will be based on the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

The relationship between an AE and study device is assessed as definite, probable, possible, unlikely, or none. A device-related AE is an AE considered by the investigator as definitely, possibly, or probably related to study device. [REDACTED]

### 3.3.3. Laboratory Evaluations

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Figure 1 consists of three panels, each showing a network structure and a corresponding matrix. The network structure is represented by a grid of black and white pixels. The matrix is represented by a grid of black and white cells. The first panel shows a large black block with a white center. The second panel shows a smaller black block with a white center. The third panel shows a very small black block with a white center. The matrix for the first node has a large black block with a white center. The second has a smaller black block with a white center. The third has a very small black block with a white center. The matrix for the second node has a large black block with a white center. The third has a smaller black block with a white center. The first has a very small black block with a white center. The matrix for the third node has a large black block with a white center. The first has a smaller black block with a white center. The second has a very small black block with a white center.

### 3.3.4. Vital Signs

The following vital signs will be evaluated

Term	Percentage
GMOs	~85%
Organic	~75%
Natural	~70%
Artificial	~45%
Organic	~75%
Natural	~70%
Artificial	~45%
Organic	~75%
Natural	~70%
Artificial	~45%

### 3.3.5. Physical Examination

Physical examination assessments including [REDACTED]  
[REDACTED] will be performed according to the  
study schedule. [REDACTED]  
[REDACTED]

#### 4. PHARMACOKINETIC/PHARMACODYNAMIC VARIABLES

Not applicable.

## 5. ANALYSIS POPULATIONS

## 5.1. Intent-to-treat Population

The Intent-to-treat (ITT) will consist of all randomized subjects regardless of treatment receipt. ITT subjects are analyzed according to their randomized treatment.

## 5.2. Modified Intent-to-treat Population

The Modified Intent-to-treat (mITT) will consist of all patients who received at least one complete cycle of study treatments.

A horizontal bar chart consisting of five solid black bars of increasing height from left to right. The bars are separated by small gaps and are set against a white background.

### 5.3. Safety Population

The safety population (SAF) will include all patients who received any amount of study Standard of Care drugs or TTFields in the experimental arm, and any amount of study Standard of Care drugs in the control arm. [REDACTED]

11. **What is the primary purpose of the *Journal of Clinical Endocrinology and Metabolism*?**

## 6 DATA HANDLING

## 6.1 Time points and Visit Windows

A black and white image showing a series of horizontal bars of varying lengths and positions, suggesting a redacted document. The bars are black and appear to be redacting sensitive information. There are several horizontal bars of different lengths, some shorter and some longer, distributed across the page. The bars are positioned in a way that suggests they are covering specific lines of text.

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## 6.2. Handling of Dropouts, Missing Data, and Outliers

Country	Percentage (2010)
Argentina	~95%
Australia	~90%
Austria	~85%
Belgium	~80%
Brazil	~75%
Bulgaria	~70%
Chile	~65%
China	~60%
Costa Rica	~55%
Czech Republic	~50%
Denmark	~45%
Ecuador	~40%
El Salvador	~35%
Finland	~30%
France	~25%
Germany	~20%
Greece	~15%
Hungary	~10%
Iceland	~5%
India	~4%
Ireland	~3%
Italy	~2%
Japan	~1%
Jordan	~0.5%
Korea	~0.5%
Luxembourg	~0.5%
Malta	~0.5%
Mexico	~0.5%
Netherlands	~0.5%
New Zealand	~0.5%
Norway	~0.5%
Oman	~0.5%
Poland	~0.5%
Portugal	~0.5%
Romania	~0.5%
Russia	~0.5%
Saudi Arabia	~0.5%
Slovakia	~0.5%
Slovenia	~0.5%
Spain	~0.5%
Sweden	~0.5%
Switzerland	~0.5%
Turkey	~0.5%
United Kingdom	~0.5%
United States	~0.5%

## 7. STATISTICAL METHODS

## 7.1. General Principles

All data processing, summarization and analyses will be performed using [REDACTED]  
[REDACTED] of the SAS® statistical software package.

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**Table 1 Statistical Analysis General Principles**

Principle	Value
Principle 1	Value 1
Principle 2	Value 2
Principle 3	Value 3
Principle 4	Value 4
Principle 5	Value 5
Principle 6	Value 6
Principle 7	Value 7
Principle 8	Value 8
Principle 9	Value 9
Principle 10	Value 10
Principle 11	Value 11
Principle 12	Value 12
Principle 13	Value 13
Principle 14	Value 14
Principle 15	Value 15
Principle 16	Value 16
Principle 17	Value 17
Principle 18	Value 18
Principle 19	Value 19
Principle 20	Value 20
Principle 21	Value 21
Principle 22	Value 22
Principle 23	Value 23
Principle 24	Value 24
Principle 25	Value 25
Principle 26	Value 26
Principle 27	Value 27
Principle 28	Value 28
Principle 29	Value 29
Principle 30	Value 30
Principle 31	Value 31
Principle 32	Value 32
Principle 33	Value 33
Principle 34	Value 34
Principle 35	Value 35
Principle 36	Value 36
Principle 37	Value 37
Principle 38	Value 38
Principle 39	Value 39
Principle 40	Value 40
Principle 41	Value 41
Principle 42	Value 42
Principle 43	Value 43
Principle 44	Value 44
Principle 45	Value 45
Principle 46	Value 46
Principle 47	Value 47
Principle 48	Value 48
Principle 49	Value 49
Principle 50	Value 50
Principle 51	Value 51
Principle 52	Value 52
Principle 53	Value 53
Principle 54	Value 54
Principle 55	Value 55
Principle 56	Value 56
Principle 57	Value 57
Principle 58	Value 58
Principle 59	Value 59
Principle 60	Value 60
Principle 61	Value 61
Principle 62	Value 62
Principle 63	Value 63
Principle 64	Value 64
Principle 65	Value 65
Principle 66	Value 66
Principle 67	Value 67
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Principle 70	Value 70
Principle 71	Value 71
Principle 72	Value 72
Principle 73	Value 73
Principle 74	Value 74
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Principle 84	Value 84
Principle 85	Value 85
Principle 86	Value 86
Principle 87	Value 87
Principle 88	Value 88
Principle 89	Value 89
Principle 90	Value 90
Principle 91	Value 91
Principle 92	Value 92
Principle 93	Value 93
Principle 94	Value 94
Principle 95	Value 95
Principle 96	Value 96
Principle 97	Value 97
Principle 98	Value 98
Principle 99	Value 99
Principle 100	Value 100

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Principle	Value
[REDACTED]	[REDACTED]

## 7.2. Subject Disposition and Data Sets Analyzed

Subject disposition will include all subjects and will be listed and summarized by treatment group and overall and will include [REDACTED]

A horizontal bar chart consisting of 12 black bars of varying lengths. The bars are arranged in a staggered, non-overlapping pattern, creating a stepped effect. The lengths of the bars decrease from left to right, with the longest bar on the far left and the shortest bar on the far right. The bars are set against a white background.

### 7.3. Protocol Deviations

All protocol deviations will be listed

## 7.4. Demographics and Other Baseline Characteristics

Demographic and baseline characteristics will be listed and summarized by treatment group and overall for ITT populations.

Standard descriptive statistics will be presented for the continuous variable of:

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

- Gender (Female, Male);
  - Childbearing potential (Yes, No), if female;
  - If no, reason (Surgically sterile, Post-menopausal, Other).

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- Race [REDACTED]
- Ethnicity [REDACTED]
- Cigarette smoking status [REDACTED]
- ECOG performance status [REDACTED]
- Region [REDACTED]  
[REDACTED]  
[REDACTED]

### 7.4.1. Medical History

Medical history will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) [Version 20.1-23.0]. All medical history will be listed, and the number and percentage of subjects with any medical history will be summarized for safety population by system organ class (SOC) and preferred term (PT) for each treatment group and overall. [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

### 7.4.2. Previous and Concomitant Medications

A listing of prior treatments and procedures for pancreatic cancer will be presented.

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

Prior medications and concomitant medications are defined as follows:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

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## 7.5. Efficacy

### 7.5.1. Primary Efficacy Analysis

The primary endpoint is to compare overall survival (OS) of patients treated with TTFields concomitant with standard of care of chemotherapy (SOC) versus patients treated with SOC alone.

The null hypothesis is that the OS is the same in the two study groups, *i.e.*, hazard ratio=1. The alternative hypothesis is that the OS is not the same, *i.e.*, hazard ratio $\neq$ 1.

The primary endpoint will be summarized using Kaplan-Meier (KM) estimate. The treatment difference will be tested using a [REDACTED]

[REDACTED] in ITT population in order to allow for two efficacy analyses of the primary endpoint (interim analysis and final analysis) [REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

### 7.5.2. Secondary Efficacy Analysis

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The secondary endpoint of progression free survival will be tested if the primary endpoint of OS met its significance level. Thus, the entire alpha of 0.05 will be allocated to the progression free survival endpoint and no adjustment will be made for multiple hypothesis testing.

#### 7.5.2.1. Progression-free Survival

A [REDACTED] test at an alpha level of 0.05 will be used to compare the difference of progression-free survival between the patients treated with TTFIELDS concomitant with SOC and the patients treated with SOC alone [REDACTED]

[REDACTED]

[REDACTED]

The median, 25th and 75th percentiles of progression-free survival with 95% CIs will be estimated using the Kaplan-Meier method for the two treatment groups [REDACTED]

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### 7.5.2.2. Local Progression-free Survival

A [REDACTED] test at an alpha level of 0.05 will be used to evaluate if the local PFS will be significantly greater in the TTFields + SOC arm than in the SOC alone arm [REDACTED]

The median, 25th and 75th percentiles of local progression-free survival with 95% CIs will be estimated using the Kaplan-Meier method for the two treatment groups.

### 7.5.2.3. One Year Overall Survival Rate

One-year overall survival (OS) rate is the proportions of patients who are alive at 12 months in each arm of the study. The Kaplan-Meier estimates of survival at Year 1 will be presented with number at risk, number with events, and estimated survival probability.

The one-year OS rates will be compared using [REDACTED]

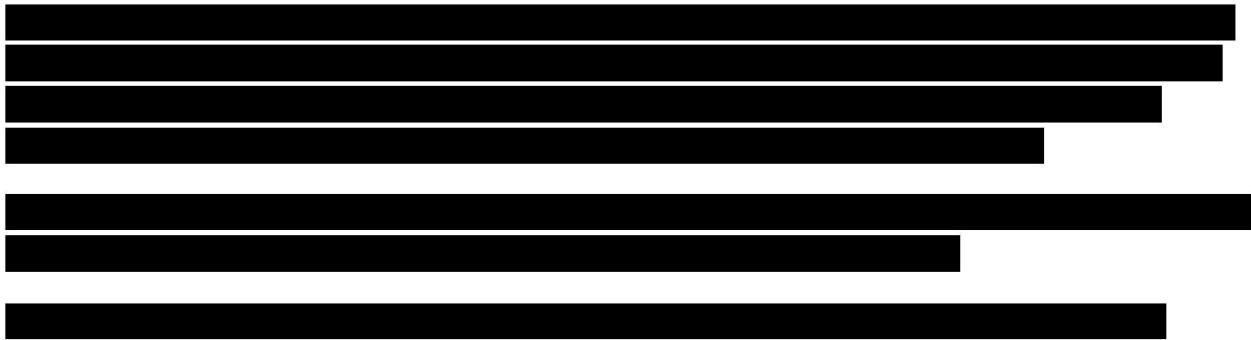
### 7.5.2.4. Objective Radiological Response Rate

Objective radiological response rate (ORR) and its two-sided 95% confidence interval, which is based on [REDACTED], will be presented.

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### 7.5.2.5. Quality of Life Questionnaire Scores

Scores from 0-100 will be derived for all multi-item or single item scales of the EORTC QLQ-C30 and QLQ-PAN26.



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**Table 2. Clinically meaningful change and categories**

Questionnaire	Score	Change from baseline	Visit
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

### 7.5.2.6. Pain-free Survival

A [REDACTED] test at an alpha level of 0.05 will be used to evaluate if TTFields + SOC prolongs the pain-free survival of patients, compared to SOC treatment alone. [REDACTED]

The median, 25th and 75th percentiles of pain-free survival with 95% CIs will be estimated using the Kaplan-Meier method for the two treatment groups. [REDACTED]

### 7.5.2.7. Puncture-free Survival

A [REDACTED] test at an alpha level of 0.05 will be used to evaluate if TTFields + SOC prolongs the puncture-free survival of patients, compared to SOC

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treatment alone

The median, 25th and 75th percentiles of puncture-free survival with 95% CIs will be estimated using the Kaplan-Meier method for the two treatment groups [REDACTED]

### 7.5.2.8. Resectability Rate

Resectability rate and its [REDACTED], which is based on the [REDACTED] will be presented.

The resectability rate between the patients treated with TTFields concomitant with SOC and the patients treated with SOC alone will be compared using [REDACTED] [REDACTED] assuming the TTFields plus the chemotherapy arm would have a higher resectability rate than the chemotherapies alone arm.

### 7.5.3. Sensitivity Analysis

#### 7.5.4. Subgroup Analysis



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### **7.6.1.2. Exposure to Standard of Care**

Standard of care in this study contains two drugs: Nab-paclitaxel and Gemcitabine. For each drug, total dose administered, and duration of exposure will be summarized by each treatment group in safety population using continuous descriptive statistics. Duration of exposure will be calculated as the total number of weeks from the first date of dose to the last date of dose plus 1 day:

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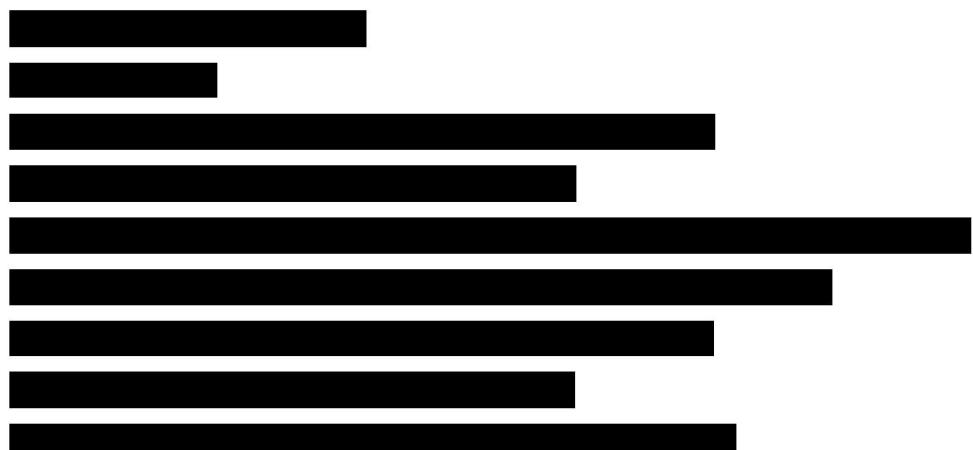
### 7.6.2. Adverse Events

An overview table will summarize the number and percentage of subjects with at least one of the following AEs by treatment group and overall, where subjects with more than one AE in a particular category are counted only once in that category:



A similar overall table summarizing treatment emergent AE will also be created.

The number and percentage of subjects reporting each AE will be summarized [REDACTED] for the Safety population. Tables will be sorted alphabetically by SOC. PTs will be sorted by descending overall total. The following summaries will be produced:



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A series of horizontal black bars of increasing length, starting from a single pixel and ending with a bar that is approximately 10 pixels wide. The bars are positioned at regular intervals vertically.

### 7.6.3. Laboratory Evaluations

Data for the following [REDACTED] analyses recorded in the eCRF will be listed and summarized [REDACTED]. [REDACTED]

Figure 1 consists of three panels arranged horizontally. Each panel is a square divided into a grid of smaller squares. The left panel shows a complex, jagged black shape on a white background. The middle panel shows a more elongated, horizontal black shape. The right panel shows a simplified, more rectangular black shape. Each panel has a thin black border and is set against a light gray background.

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All laboratory data will be reported in International System of Units (SI) units.

[REDACTED]

Laboratory data will be summarized

[REDACTED] for the Safety population.

[REDACTED]

For each laboratory analytic,

[REDACTED]

### 7.6.4. Vital Signs

The following vital signs

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Vital signs data and changes from baseline in vital signs will be summarized

[REDACTED] for the Safety

population.

[REDACTED]

[REDACTED]

### 7.6.5. Physical Examination

Physical examination data will be listed.

[REDACTED].

## 7.7. Interim Analysis

One interim analysis will be performed on the OS data available

Term	Percentage
Climate change	100
Global warming	95
Green energy	92
Carbon footprint	88
Sustainable development	85
Renewable energy	82
Emissions reduction	78
Green economy	75
Carbon tax	75

Term	Percentage
Climate change	98
Global warming	100
Green energy	95
Carbon footprint	92
Sustainable development	88
Renewable energy	85
Emissions reduction	82
Green economy	78
Carbon tax	75
Carbon pricing	95

## 8. CHANGES IN PLANNED ANALYSIS

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## 9. REFERENCES

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2. Hammel P, Huguet F, van Laethem J-L, et al. Effect of Chemoradiotherapy vs Chemotherapy on Survival in Patients With Locally Advanced Pancreatic Cancer Controlled After 4 Months of Gemcitabine With or Without Erlotinib. *JAMA*. 2016;315(17). doi:10.1001/jama.2016.4324.
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4. Anne AE, Paul K, Mithat G, et al. Psychometric Validation of the EORTC QLQ-PAN26 Pancreatic Cancer Module for Assessing Health Related Quality of Life after Pancreatic Resection. *J Pancreas*. 2017; 1027;18(1):19-25

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Study ID: [REDACTED]

### 10. APPENDICES

#### 10.1. Scoring algorithm for the EORTC-QLQC30



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A black and white image showing a series of horizontal bars of varying lengths, suggesting a bar chart or a series of measurements. The bars are positioned against a dark background. The bars are of different lengths, with some being very short and others being quite long, creating a visual representation of data distribution.

## 10.2. Scoring algorithm for the PAN26

The figure consists of a 7x4 grid of black bars on a white background. The bars are of varying lengths and are positioned in a staggered, non-overlapping manner. The grid is bounded by a thin black line.

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