

# **Data collection protocol: Pancreatic cancer**

**PancreOS (Pancreatic cancer overall survival registry in Europe)**



**PANCREATIC CANCER EUROPE**  
The European Multi-Stakeholder Platform on Pancreatic Cancer



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## 1. INTRODUCTION

Pancreatic cancer (PC) is an aggressive malignancy with a poor prognosis and short survival (1). Risk factors for developing pancreatic cancer include family history of the disease, some hereditary cancer syndromes, obesity, cigarette smoking, obesity, heavy alcohol intake and non-O blood group, diabetes and chronic pancreatitis (2).

In 2012, a total of 103,845 new cases of PC were diagnosed in Europe and 104,554 deaths from PC were registered (3). There will be more deaths annually from pancreatic cancer in the EU countries than deaths from breast cancer by 2017. It is estimate that PC may become the third most important cause of cancer death in the EU after lung and colorectal cancer in few years (4).

In Europe, the average 5-year relative survival is particularly low, 26% at one year and 7% at five years since diagnosis (5). The poor prognosis of this malignancy depends on several factors, such as: lack of early symptoms, advanced stage at detection, high incidence of metastatic disease at diagnosis, and the lack of successful therapeutic strategies (6) In fact, approximately 60% of patients with pancreatic cancer present metastases at diagnosis, 25% of patients are diagnosed with locally advanced disease, and approximately 15% of patients have resectable tumours. Resection remains the only chance for curing pancreatic adenocarcinoma, and operable patients must undergo surgery promptly and then receive adjuvant treatment. Patients with nonsurgical metastatic or locally advanced pancreatic cancer receive palliative chemotherapy, the median overall survival being 4 to 11 months depending on the stage at time of diagnosis, tumor biology and the therapy received (7).

The objective of the PancreOS (Pancreatic cancer overall survival registry in Europe) is to build up a large **European pancreatic hospital-based cancer registry**, gathering information related to all aspects of the management of patients with pancreatic cancer – from initial symptoms, diagnosis and throughout the treatment continuum.

The data provided by PancreOS would be used:

- To obtain an updated description of trends on pancreatic cancer survival and information on the differences observed between centers and countries.
- To identify areas of improvement (earlier diagnosis, screening programs, better tissue specimens for diagnosis & research, biobanks, clinical research and tailor-made treatments, etc.).
- To study the patterns of prevention, diagnosis, treatment and subsequent outcomes

For instance, some specific objectives linked to PancreOS are to correlate overall survival, the biological behaviour of the tumour, and the resources used for the diagnosis and treatment of

the disease of patients with pancreatic cancer in Europe in order to identify areas of improvement for the benefit of the patients. Additional objectives are:

- Evaluate the performance status, disease-free survival, progression free survival and overall survival in patients with pancreatic cancer in Europe.
- Describe the hospital resources for the diagnosis and treatment of patients with pancreatic cancer in Europe.-
- Describe the biological behaviour of the tumor and clinical outcome of patients diagnosed with pancreatic cancer in Europe
- Establish the prognostic relation of the cancer with the time to diagnosis, biological behaviour of the tumor, clinical outcome of the patient, and hospital resources used for diagnosis and general treatment
- Compare the data collected with that of other databases of available international registries.

As the first step, a data collection protocol was elaborated, including the case definition, the variables to be reported to PancreOS and the codes to be used for each variable.

## **2. DEFINITION OF REPORTABLE CASES**

- All primary malignant pancreatic tumours, exocrine tumours, with or without microscopic verification, based on the judgment of the clinician.
- Primary pancreatic lymphoma and DCO cases are excluded.
- Incident cases

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### 3. DESCRIPTION OF THE VARIABLES

#### Variable name, description, format, coding schema and unknown/missing values

Variable name	Description of the variable	Coding
<b>RECORDING VARIABLES</b>		
ID_CENTRE	Centre identification code assigned by the PancreOS software.	Numeric variable.
ID_PANCREOS	Patient identification code assigned by the PancreOS software.	TBD
CONSENT	Whether consent form was signed (to allow the patient's data collection from the medical records), if needed. If not, "no" must be completed. Depending on the country/center, this does not necessarily preclude data collection.	Numeric variable. 1→Yes 2→No 99→ Unknown/missing value
DATE_CONSENT	The date that the consent form was signed by the patient.	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing
DATE_ENTRY	Date when the data collection of the patient was started in the centre/registry participating in PancreOS.	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing
<b>SOCIODEMOGRAPHIC VARIABLES</b>		
PATIENT_ID	Patient identification code assigned by the centre/registry.	Alphanumeric variable.  According to centre/registry coding
DATE_BIRTH	Date of birth of the patient.	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing
SEX	Sex of the patient. This variable refers to the biological and physiological characteristics that define men and women.	Numeric variable. 1→ male 2→ female 9→ Unknown/missing value
COUNTRY	Country where the patient was residing at the moment of the pancreatic cancer diagnosis.	Alphanumeric variable. According to Eurostat country codes (Two digits) <a href="http://ec.europa.eu/eurostat/statistics-explained/index.php/Glossary:Country_codes">http://ec.europa.eu/eurostat/statistics-explained/index.php/Glossary:Country_codes</a>
MUNICIPALITY	Municipality or equivalent units where the patient was residing at the moment of the pancreatic cancer diagnosis.	Alphanumeric variable. According to Eurostat Local Administrative Units (LAU2 codes) <a href="http://ec.europa.eu/eurostat/web/nuts/local-administrative-units">http://ec.europa.eu/eurostat/web/nuts/local-administrative-units</a>

TOXIC HABITS		
SMOKE_STAT	<p>Smoking status of the patient at pancreatic cancer diagnosis. <b>Smokers</b> are patients having smoked at least one cigarette per week for six months or longer; otherwise, the patient is regarded as <b>non-smoker</b>. <b>Former smokers</b> are patients who were current smokers but quit smoking for more than 1 year before the diagnosis.</p>	<p>Numeric variable.            1 → Non-Smoker            2 → Smoker            3 → Former smoker            9 → Unknown/Missing</p>
SMOKE_DUR	<p><b>For smokers and former smokers:</b> Number of years the patient smoked (considering age of initiation until the age at diagnosis or the age at smoking cessation). This variable will be left blank for non-smokers.</p>	<p>Numeric variable.            99 → Unknown/Missing value</p>
SMOKE_NUM	<p><b>For smokers and former smokers:</b> Number of cigarettes usually smoked per day (considering life-time smoking habit on average).</p> <p>This variable will be left blank for non-smokers. SMOKE_NUM/20 x SMOKE_DUR, whereby 20 is the number of cigarettes contained in a pack. This variable can be either calculated automatically based on SMOKE_DUR and SMOKE_NUM or filled in if the information is available.</p>	<p>Numeric variable.            99 → Unknown/Missing value</p>
PACK_YEARS	<p>This variable will be left blank for non-smokers. SMOKE_NUM/20 x SMOKE_DUR, whereby 20 is the number of cigarettes contained in a pack. This variable can be either calculated automatically based on SMOKE_DUR and SMOKE_NUM or filled in if the information is available.</p>	<p>Numeric variable</p>
CANCER FAMILY HISTORY		
FH_CANCER	<p>Whether the patient has first degree-relatives (parents, siblings and offspring) with cancer. If “no”, no further variables of this section must be completed.</p>	<p>Numeric variable.            1 → Yes            2 → No            9 → Unknown/Missing value</p>
FH_PANCREATIC_CANCER	<p>Whether any first degree relative (parents, siblings and offspring) or several relatives (multiple family members) have ever been diagnosed with pancreatic cancer (C25, according to the International Classification of Diseases for Oncology, third edition (IDC-O-3): <a href="http://codes.iarc.fr/">http://codes.iarc.fr/</a></p>	<p>Numeric variable            1 → not any relative            2 → anyone in the family            5 → multiple family members            9 → Unknown/Missing value</p>
FH_BREAST_CANCER	<p>Whether any first degree relative (parents, siblings and offspring) or several relatives (multiple family members) have ever been diagnosed with breast cancer (C50, according to the IDC-O-3: <a href="http://codes.iarc.fr/">http://codes.iarc.fr/</a></p>	<p>Numeric variable            1 → not any relative            2 → anyone in the family            5 → multiple family members            9 → Unknown/Missing value</p>
FH_OVARIAN_CANCER	<p>Whether any first degree relative (parents, siblings and offspring) or several relatives (multiple family members) have ever been diagnosed with ovarian cancer (C56, according to the IDC-O-3: <a href="http://codes.iarc.fr/">http://codes.iarc.fr/</a></p>	<p>Numeric variable            1 → not any relative            2 → anyone in the family            5 → multiple family members            9 → Unknown/Missing value</p>
FH_CRC_CANCER	<p>Whether any first degree relative (parents, siblings and offspring) or several relatives (multiple family members) have ever been diagnosed with colorectal cancer (C18-C20, according to the IDC-O-3: <a href="http://codes.iarc.fr/">http://codes.iarc.fr/</a></p>	<p>Numeric variable            1 → not any relative            2 → anyone in the family            5 → multiple family members            9 → Unknown/Missing value</p>



**CANCER FAMILY HISTORY**

FH_PROSTATE_CANCER	Whether any first degree relative (parents, siblings and offspring) or several relatives (multiple family members) have ever been diagnosed with prostate cancer (C61, according to the IDC-O-3: <a href="http://codes.iarc.fr/">http://codes.iarc.fr/</a> )	Numeric variable 1 → not any relative 2 → anyone in the family 5 → multiple family members 9 → Unknown/Missing value
FH_LUNG_CANCER	Whether any first degree relative (parents, siblings and offspring) or several relatives (multiple family members) have ever been diagnosed with lung cancer (C34, according to the IDC-O-3: <a href="http://codes.iarc.fr/">http://codes.iarc.fr/</a> )	Numeric variable 1 → not any relative 2 → anyone in the family 5 → multiple family members 9 → Unknown/Missing value
FH_MELANOMA	Whether any first degree relative (parents, siblings and offspring) or several relatives (multiple family members) have ever been diagnosed with melanoma (8720/3-8780/3, according to the International Classification of Diseases for Oncology, third edition (IDC-O-3): <a href="http://codes.iarc.fr/">http://codes.iarc.fr/</a> )	Numeric variable 1 → not any relative 2 → anyone in the family 5 → multiple family members 9 → Unknown/Missing value
FH_OTHER_CANCER	Whether any first degree relative (parents, siblings and offspring) or several relatives (multiple family members) have ever been diagnosed with a certain cancer other than the previously specified.	Numeric variable 1 → not any relative 2 → anyone in the family 5 → multiple family members 9 → Unknown/Missing value

**CHRONIC PANCREATITIS FAMILY HISTORY**

FH_CPANCREATITIS	Whether the patient has first degree-relatives (parents, siblings and offspring) with chronic pancreatitis (SCTID: 235956004)	Numeric variable. 1 → Yes 2 → No 9 → Unknown/Missing value
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**PATIENT MEDICAL HISTORY (BEFORE DIAGNOSIS OF PANCREATIC CANCER)**

DM	Whether the patient has been ever diagnosed with diabetes mellitus. If “no”, no further variables of this section must be completed.	Numeric variable. 1 → Yes 2 → No 9 → Unknown/missing value
DM_TYPE	<p>If there is evidence of diagnosis of diabetes: type of diabetes Excluding:</p> <ul style="list-style-type: none"> <li>• Diabetes mellitus (in): neonatal (International Statistical Classification of Diseases and Related Health Problems 10<sup>th</sup> Revision (ICD-10) code: P70.2) and pregnancy, childbirth and the puerperium (ICD-10 code: O24).</li> <li>• Glycosuria: NOS (ICD-10 code: R81) and renal (ICD-10 code: E74.8)</li> <li>• Impaired glucose tolerance (ICD-10 code: R73.0)</li> <li>• Post-surgical hypoinsulinaemia (ICD-10 code: E89.1)</li> </ul>	<p>Numeric variable.</p> <p>1 → Type 1 diabetes mellitus (ICD-10 code: E10) 2 → Type 2 diabetes mellitus (ICD-10: code E11) 3 → Other specified diabetes mellitus (ICD-10 code: E12 and E13) 4 → Unspecified diabetes mellitus (ICD-10 code: E14) 9 → Unknown/missing value</p>
	This variable will be left blank for patient without diabetes mellitus.	

**PATIENT MEDICAL HISTORY (BEFORE DIAGNOSIS OF PANCREATIC CANCER)**

DM_TREATMENT	If there is evidence of diagnosis of diabetes: control measures used.	Numeric variable. 1 → Only diet 2 → Metformin (The Anatomical Therapeutic Chemical (ATC) classification system code: A10BA02) 3 → Other oral antidiabetics 4 → Insulin (ATC code: A10A) 5 → Both insulin and metformin/other oral antidiabetics 9 → Unknown/missing value
C_PANCREATITIS	Whether the patient has been ever diagnosed with chronic pancreatitis.	Numeric variable. 1 → Yes 2 → No 9 → Unknown/missing
HABITUAL_BMI	Body mass index is a measurement that takes into account weight and height (weight in kg / (height in m) <sup>2</sup> ). Habitual BMI refers to BMI prior to the diagnosis of the pancreatic tumour. A timeframe from 6 to 2 years before diagnosis should be considered.	Numeric variable. 99 → Unknown/missing value
CANCER	Whether the patient has been ever diagnosed with a previous cancer. If “no”, no further variables of this section must be completed.	Numeric variable. 1 → Yes 2 → No 9 → Unknown/Missing value
CANCER_1_TOPO	If there is evidence of diagnosis of a previous malignant tumour: topography. This variable will be left blank for patient without previous malignant tumours.	Alphanumeric variable. According to the ICD-O-3: <a href="http://codes.iarc.fr/">http://codes.iarc.fr/</a> UN → Unknown topography
CANCER_1_MORPHO	If there is evidence of diagnosis of a previous malignant tumour: morphology. This variable will be left blank for patient without previous malignant tumours.	Alphanumeric variable. According to the ICD-O-3 <a href="http://codes.iarc.fr/">http://codes.iarc.fr/</a> 8000/3 → Unknown/Missing value
CANCER_1_DATE	If there is evidence of diagnosis of a previous malignant tumour: date of diagnosis (incidence date) according to the ENCR recommendations <a href="http://www.encl.eu/images/docs/recommendations/incideng.pdf">http://www.encl.eu/images/docs/recommendations/incideng.pdf</a>	YYYY/MM/DD 9999 → Year unknown/missing 99 → Month unknown/missing 99 → Day unknown/missing
CANCER_2_TOPO	This variable will be left blank for patient without previous malignant tumours. If there is evidence of diagnosis of another previous malignant tumour: topography. This variable will be left blank for patient without previous malignant tumours	Alphanumeric variable. According to the ICD-O-3: <a href="http://codes.iarc.fr/">http://codes.iarc.fr/</a> 9 → Unknown/Missing value

**PATIENT MEDICAL HISTORY (BEFORE DIAGNOSIS OF PANCREATIC CANCER)**

CANCER_2_MORPHO	<p>If there is evidence of diagnosis of another previous malignant tumour: morphology.</p> <p>This variable will be left blank for patient without previous malignant tumours.</p>	<p>Alphanumeric variable.</p> <p>According to the ICD-O-3 <a href="http://codes.iarc.fr/">http://codes.iarc.fr/</a></p> <p>8000/3 → Unknown/missing value</p>
CANCER_2_DATE	<p>If there is evidence of diagnosis of another previous malignant tumour: date of diagnosis (incidence date) according to the ENCR recommendations</p> <p><a href="http://www.enrc.eu/images/docs/recommendations/incideng.pdf">http://www.enrc.eu/images/docs/recommendations/incideng.pdf</a></p> <p>This variable will be left blank for patient without previous malignant tumours.</p>	<p>YYYY/MM/DD</p> <p>9999→ Year unknown/missing</p> <p>99→ Month unknown/missing</p> <p>99→ Day unknown/missing</p>

**PANCREATIC CANCER HISTORY**

SYMPTOM_1_AP	<p>The first symptoms of the pancreatic cancer (main motivation to visit the doctor/hospital): abdominal pain (Identification in the SNOMED Clinical Terms (SCTID): 21522001):</p> <p><a href="http://browser.ihtsdotools.org/">http://browser.ihtsdotools.org/</a></p>	<p>Numeric variable.</p> <p>1→ Yes</p> <p>2→ No</p> <p>9→ Unknown/missing value</p>
SYMPTOM_2_BP	<p>The first symptoms of the pancreatic cancer (main motivation to visit the doctor/hospital): back pain (SCTID: 161891005).</p>	<p>Numeric variable.</p> <p>1→ Yes</p> <p>2→ No</p> <p>9→ Unknown/missing value</p>
SYMPTOM_3_AN	<p>The first symptoms of the pancreatic cancer (main motivation to visit the doctor/hospital): anorexia (loss of appetite) (SCTID: 79890006).</p>	<p>Numeric variable.</p> <p>1→ Yes</p> <p>2→ No</p> <p>9→ Unknown/missing value</p>
SYMPTOM_4_WL	<p>The first symptoms of the pancreatic cancer (main motivation to visit the doctor/hospital): weight loss (SCTID: 89362005).</p>	<p>Numeric variable.</p> <p>1→ Yes</p> <p>2→ No</p> <p>9→ Unknown/missing value</p>
SYMPTOM_5_AS	<p>The first symptoms of the pancreatic cancer (main motivation to visit the doctor/hospital): asthenia (fatigue) (SCTID: 13791008).</p>	<p>Numeric variable.</p> <p>1→ Yes</p> <p>2→ No</p> <p>9→ Unknown/missing value</p>
SYMPTOM_6_NV	<p>The first symptoms of the pancreatic cancer (main motivation to visit the doctor/hospital): nausea and vomiting (SCTID: 16932000).</p>	<p>Numeric variable.</p> <p>1→ Yes</p> <p>2→ No</p> <p>9→ Unknown/missing value</p>
SYMPTOM_7_JA	<p>The first symptoms of the pancreatic cancer (main motivation to visit the doctor/hospital): jaundice (SCTID: 18165001), and/or hypo/acolia (lack of colour in faeces) (SCTID: 70396004), and/or itching (SCTID: 418290006), and/or coluria (dark urine) (SCTID: 39575007)</p>	<p>Numeric variable.</p> <p>1→ Yes</p> <p>2→ No</p> <p>9→ Unknown/missing value</p>

**PANCREATIC CANCER HISTORY**

SYMPTOM_8_DE	The first symptoms of the pancreatic cancer (main motivation to visit the doctor/hospital): depression (mental disorders, mood disorders, etc.) (SCTID: 394924000).	Numeric variable 1→ Yes 2→ No 9→ Unknown/missing value
SYMPTOM_9_AC	The first symptoms of the pancreatic cancer (main motivation to visit the doctor/hospital): diarrhoea (SCTID: 62315008).	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
SYMPTOMS_10_FE	The first symptoms of the pancreatic cancer (main motivation to visit the doctor/hospital): fever (SCTID: 386661006).	Numeric variable 1→ Yes 2→ No 9→ Unknown/missing value
SYMPTOM_11_FE	The first symptoms of the pancreatic cancer (main motivation to visit the doctor/hospital): other.	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
FIRST_SYMPTOMS_DATE	Date of initiation of the first symptoms most likely to be related to pancreatic cancer diseases.	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing
FIRST_CONTACT_HEALTH_CARE	The first contact of the patient with the health system concerning pancreatic cancer.	Numeric variable. 1→ primary care 2→ hospital (emergency rooms) 3→ Internal Medicine 4 → Surgeon 5 → Gastroenterologist / Digestive 6 → Oncologist 7 → Other 9→ Unknown/missing value
FIRST_CONTACT_DATE	Date the patient contacted for the first time the health system, either through primary care or hospital visits.	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing
ADMISSION_DATE	Date of the first admission of the patient in the hospital due to pancreatic cancer (if admission took place)	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing
COMMITTEE	Whether the patient was presented in multidisciplinary counselling committee (before starting any treatment).	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
COMMITTEE_DATE	Date when the patient was presented in multidisciplinary counselling committee (before starting any treatment).	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing

PANCREATIC CANCER DIAGNOSIS:PHYSICAL EXAMINATION AND LABORATORY TESTS

HEPATOMEGALY	Hepatomegaly (SCTID: 275296001).	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
ASCITES	Ascites (SCTID: 163309001).	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
FIRST_WEIGHT	The patient's weight at first visit at the medical specialist in kilograms.	Numeric variable. 999→ Unknown/missing value
FIRST_WEIGHT_DATE	Date of the patient's weight at first visit at the medical specialist.	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing
FIRST_HEIGHT	The patient's height at first visit at the medical specialist in centimetres.	Numeric variable. 999→ Unknown/missing value
FIRST_BMI	Body mass index is a measurement that takes into account weight and height (weight in kg / (height in m) <sup>2</sup> ). It will be auto calculated with the weight and height data, if this information is available.	Numeric variable. 99→ Unknown/missing value
FIRST_ECOG	The patient's ECOG performance status at the first visit at medical specialist related to the pancreatic cancer.	Numeric variable. 0→ Fully active, able to carry on all pre-disease performance 1→ Restricted in physically strenuous activity but ambulatory and able to carry out work of light or sedentary nature 2→ Confined to bed less than 50% of waking hours 3→ Confined to bed more than 50% of waking hours 4→ Totally confined to bed 9→ Unknown/missing value
FIRST_ECOG_DATE	Date of ECOG status assessment.	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing
FIRST_KARNOFSKY	The patient's performance status measured through the Karnofsky index at first visit at medical specialist related to pancreatic cancer. Equivalence to ECOG status can be consulted.	Numeric variable. 999→ Unknown/missing value

**PANCREATIC CANCER DIAGNOSIS:PHYSICAL EXAMINATION AND LABORATORY TESTS**

FIRST_KARNOFSKY_DATE	Date of Karnofsky index assessment.	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing
COMORBIDITY	Comorbidity index at the moment of the pancreatic cancer diagnosis. The Charlson index will be filled in (scores from 0 to 40 points). For its calculation the points are accumulated, according to associated diseases, as well as the addition of a single point for each 10 years of age for patients of ages above forty years (in 50 years 1 point, 60 years 2 points etc.). Charlson index calculator, considering age of the patient and presence of diseases: <a href="http://www.samiuc.es/index.php/calculadores-medicos/calculadores-de-evaluadores-pronosticos/indice-de-comorbilidad-de-charlson-cci.html">http://www.samiuc.es/index.php/calculadores-medicos/calculadores-de-evaluadores-pronosticos/indice-de-comorbilidad-de-charlson-cci.html</a>	Numeric variable. 99→ Unknown/missing value
FIRST_CEA	Values of CEA in U/ml at first visit at medical specialist (most likely documented in analytical report from laboratory). If values are not available at the first visit, report the ones before treatment.	Numeric variable. 9999999→ Unknown/missing value
FIRST_CEA_DATE	Date when the CEA test was performed.	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing
FIRST_CA19.9	Values of CA19.9 in U/ml at first clinical at medical specialist (most likely documented in analytical report from laboratory). If values are not available at first visit, report the ones before treatment.	Numeric variable. 9999999→ Unknown/missing value
FIRST_CA19.9_DATE	Date of laboratory test indicating CA19.9 values	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing
FIRST_BILIRUBIN	Values of bilirubin in µmol/L at first visit at medical specialist (most likely documented in analytical report from laboratory). If values are not available at the first visit, report the ones before treatment.	Numeric variable. 9999999→ Unknown/missing value
FIRST_BILIRUBIN_DATE	Date of laboratory test indicating bilirubin values	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing

**PANCREATIC CANCER DIAGNOSIS: IMAGING TECHNIQUES**

CT_SCAN	Computed tomography scan (SCTID: 77477000) performed for pancreatic cancer diagnosis.	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
CT_SCAN_DATE	Date when the computed tomography scan was performed.	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing

**PANCREATIC CANCER DIAGNOSIS: IMAGING TECHNIQUES**

CT_SCAN_RESULTS	Results obtained using the computed tomography scan concerning pancreatic cancer and metastasis.	Numeric variable. 1→ Suspicion for pancreatic cancer 2→ Suspicion for metastasis 3→ Suspicion for pancreatic cancer and metastasis 4→ Negative result 9→ Unknown/missing value
CT_SCAN_SAMPLE	Whether a pancreatic cancer oriented CT scan was carried out to take samples for cytology and/or histology studies.	Numeric variable. 1→ Cytology sample taken 2→ Histology sample taken 3→ Both taken 4→ Samples not taken 9→ Unknown/missing value
MRI	Magnetic resonance imaging (SCTID: 113091000) performed for pancreatic cancer diagnosis.	Numeric variable. 1→ Yes 2→ No 9→ Unknown/Missing
MRI_DATE	Date when the magnetic resonance imaging was performed.	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing
MRI_RESULTS	Results obtained using the magnetic resonance imaging concerning pancreatic cancer and metastasis.	Numeric variable. 1→ Suspicion for pancreatic cancer 2→ Suspicion for metastasis 3→ Suspicion for pancreatic cancer and metastasis 4→ Negative result 9→ Unknown/missing value
END_ULTRASOUND	Endoscopic ultrasound (SCTID: 426808008) performed for pancreatic cancer diagnosis.	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
END_ULTRASOUND_DATE	Date when the endoscopic ultrasound was performed.	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing
END_ULTRASOUND_RESULTS	Results obtained with endoscopic ultrasound concerning pancreatic cancer and metastasis.	Numeric variable. 1→ Suspicion for pancreatic cancer 2→ Suspicion for metastasis 3→ Suspicion for pancreatic cancer and metastasis 4→ Negative result 9→ Unknown/missing value

**PANCREATIC CANCER DIAGNOSIS: IMAGING TECHNIQUES**

END_ULTRASOUND_SAMPLE	Whether samples were taken for cytology and/or histology studies when the endoscopic ultrasound was performed.	Numeric variable. 1→ Cytology sample taken 2→ Histology sample taken 3→ Both taken 4→ Samples not taken 9→ Unknown/missing value
ERCP	Endoscopic retrograde cholangiopancreatography (ERCP) (SCTID: 386718000) performed for pancreatic cancer diagnosis.	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value YYYY/MM/DD
ERCP_DATE	Date when the ERCP was performed.	9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing
ERCP_RESULTS	Results obtained using the ERCP concerning pancreatic cancer and metastasis.	Numeric variable. 1→ Suspicion for pancreatic cancer 2→ Suspicion for metastasis 3→ Suspicion for pancreatic cancer and metastasis 4→ Negative result 9→ Unknown/missing value
ERCP_SAMPLE	Whether samples were taken for cytology and/or histology studies when the ERCP was performed.	Numeric variable. 1→ Cytology sample taken (brush) 2→ Histology sample taken 3→ Both taken 4→ Samples not taken 9→ Unknown/missing value
LAPAROSCOPY	Laparoscopy (SCTID: 76735009) performed for pancreatic cancer diagnosis.	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
LAPAROSCOPY_DATE	Date when the laparoscopy was performed.	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing
LAPAROSCOPY_RESULTS	Results obtained using laparoscopy concerning pancreatic cancer and metastasis.	Numeric variable. 1→ Suspicionfor pancreatic cancer 2→ Suspicionfor metastasis 3→ Suspicionfor pancreatic cancer and metastasis 4→ Negative result 9→ Unknown/missing value



**PANCREATIC CANCER DIAGNOSIS: IMAGING TECHNIQUES**

LAPAROSCOPY _SAMPLE	Whether samples were taken for cytology and/or histology studies when the laparoscopy was performed.	Numeric variable. 1→ Cytology sample taken 2→ Histology sample taken 3→ Both taken 4→ Samples not taken 9→ Unknown/missing value
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**PANCREATIC CANCER DIAGNOSIS: PATHOLOGY REPORTS**

CITOLOGY	Cytology (SCTID: 168440009) performed for pancreatic cancer diagnosis whether from a primary or secondary site.	Numeric variable. 1→ Yes, evidence for pancreatic cancer 2→ Yes, negative result 3→ No performed 9→ Unknown/missing value
CITOLOGY_DATE	Sampling date (the most reliable one used for diagnosis) of the first positive cytology performed whether from a primary or secondary site for pancreatic cancer diagnosis.	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing
PANCREAS_HISTOLOGY	Histology (SCTID: 714797009 ) performed for pancreatic cancer diagnosis from the primary topography (pancreas)	Numeric variable. 1→ Yes, evidence for pancreatic cancer 2→ Yes, negative result 3→ No performed 9→ Unknown/missing value
PANCREAS_HISTOLOGY_DATE	Sampling date (the most reliable one used for diagnosis) of the first positive histology obtained from the primary topography (pancreas) and performed for pancreatic cancer diagnosis.	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing
METASTASES_HISTOLOGY	Histology performed for pancreatic cancer diagnosis from the metastases.	Numeric variable. 1→ Yes, evidence for pancreatic cancer 2→ Yes, negative result 3→ No performed 9→ Unknown/missing value
METASTASES_HISTOLOGY_DATE	Sampling date of the first positive histology obtained from the metastases and performed for pancreatic cancer diagnosis.	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing

**PANCREATIC CANCER DIAGNOSIS: TUMOUR CHARACTERISTICS**

BASIS_DIAGNOSIS	The "most valid basis of diagnosis" is required in this variable. The suggested codes are hierarchical, meaning that the higher number represents the most valid basis, and should thus be used for this purpose.	Numeric variable.  According to the ENCR recommendations: <a href="http://www.encl.eu/images/docs/recommendations/basisd.pdf">http://www.encl.eu/images/docs/recommendations/basisd.pdf</a>
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0→ Death Certificate Only. The only information to the registry is from a death certificate

**Non Microscopic**

1→ Clinical diagnosis made before death, but without the benefit of any of the following (2-7)

2→ Clinical investigation. To include all diagnostic techniques, including x-ray, endoscopy, imaging, ultrasound, exploratory surgery (e.g., laparotomy) and autopsy, without a tissue diagnosis.

4→ Biomarkers

**Microscopic**

5→ Cytology examination of cells whether from a primary or secondary site, including fluids aspirated using endoscopes or needles.

6→ Histology of a metastasis  
Histological examination of tissue from a metastasis, including autopsy specimens.

7→ Histology of a primary tumour  
Histological examination of tissue from the primary tumour, however obtained, including all cutting techniques and bone marrow biopsies. Also to include autopsy specimens of a primary tumour.

9→ Unknown/missing value

8 -> based on autopsy data

The date of the first event (of the six listed below) to occur chronologically. If an event of higher priority occurs within three months of the date initially chosen, the date of the higher priority event should take precedence.

Order of declining priority:

1. Date of first histological or cytological confirmation of this malignancy. This date should be, in the following order:
  - a) date when the specimen was taken (biopsy)
  - b) date of receipt by the pathologist
  - c) date of the pathology report
2. Date of admission to the hospital because of pancreatic cancer.
3. When evaluated at an outpatient clinic only: date of first

INCIDENCE\_DATE

YYYY/MM/DD

**According to the ENCR recommendations:**

<http://www.enccr.eu/images/docs/recommendations/incideng.pdf>

9999→ Year unknown/missing

99→ Month unknown/missing

99→ Day unknown/missing

consultation at the outpatient clinic because of pancreatic cancer.

4. Date of diagnosis, other than 1, 2 or 3.
5. Date of death, if no information is available other than the fact that the patient has died because of pancreatic cancer.
6. Date of death, if the malignancy is discovered at autopsy.

The choice of the date of incidence does not determine the coding of the item "basis of diagnosis".

TOPOGRAPHY

The topography code indicates the site of origin of the pancreatic tumour; in other words, where the tumour arose.

Alphanumeric variable (5 digits).  
According to the ICD-O-3  
<http://codes.iarc.fr/>  
C25.0 Head of pancreas  
C25.1 Body of pancreas  
C25.2 Tail of pancreas  
C25.3 Pancreatic duct  
C25.4 Islets of Langerhans  
C25.7 Other specified parts of pancreas  
C25.8 Overlapping lesion of pancreas  
C25.9 Pancreas, NOS

MORPHOLOGY

The morphology code records the type of cell that has become neoplastic.

At first instance, considering data from histology of the primary tumour. If unavailable, data from histology of the metastasis should be taken as reference, followed by data from cytology.

Alphanumeric variable (6 digits).  
According to the ICD-O-3  
<http://codes.iarc.fr/>

GRADE

The grade describes how abnormal the cells and tissues of a tumour are when compared to normal cells.

The highest grade should be assigned.

Numeric variable.  
According to the ICD-O-3:  
1→ Well differentiated,  
2→ Moderately differentiated  
3→ Poorly differentiated  
4→ Undifferentiated, anaplastic  
9→ Unknown/missing value

CTSIZE

This should represent the maximum tumour diameter in millimetres, and should be based on clinical examination.

Numeric variable.  
999→ Unknown/missing value

CT

This variable encodes information on the extent of the primary tumour, based on clinical evidence. It should be coded according to the 7<sup>th</sup> of the TNM.

Alphanumeric variable.  
According to the 7<sup>th</sup> edition of the TNM classification:  
TX→ Primary tumour cannot be assessed.  
T1→ Tumour limited to the pancreas, ≤ 2 cm in greatest dimension.  
T2→ Tumour limited to the pancreas, > 2 cm in greatest dimension.  
T3→ Tumour extends beyond the

		pancreas but without involvement of the celiac axis or the superior mesenteric artery. T4 → Tumour involves the celiac axis or the superior mesenteric artery (unresectable primary tumour). 9 → Unknown/missing value
cN	This variable provides information on the absence or presence and extent of the regional lymph node metastasis, based on clinical evidence. It should be coded according to the 7 <sup>th</sup> of the TNM.	Alphanumeric variable. According to the 7 <sup>th</sup> edition of the TNM classification: NX → Regional lymph nodes cannot be assessed. N0 → No regional lymph node metastasis. N1 → Regional lymph node metastasis. 9 → Unknown/missing value
cM	This variable describes the absence or presence of distant metastasis, based on clinical evidence. It should be coded according to the 7 <sup>th</sup> of the TNM.	Alphanumeric variable. According to the 7 <sup>th</sup> edition of the TNM classification: M0 → No distant metastasis M1 → Distant metastasis 9 → Unknown/Missing
cSTAGE	This variable encodes information on the TNM stage grouping, based on clinical information. It should be coded according to the 7 <sup>th</sup> of the TNM.	Alphanumeric variable. According to the 7 <sup>th</sup> edition of the TNM classification: IA → T1    N0    M0 IB → T2    N0    M0 IIA → T3    N0    M0 IIB → T1    N1    M0 T2    N1    M0 T3    N1    M0 III → T4    Any N    M0 IV → Any T    Any N    M1 9 → Unknown/missing value
pTSIZE	This should represent the maximum tumour diameter in millimetres, and should be based on pathological data.	Numeric variable. 999 → Unknown/missing value
N_EXAM_NODES	This variable should report the exact number of lymph nodes taken out during surgery (examined), as recorded in the pathological records.	Numeric variable. 99 → Unknown/missing value
N_MET_NODES	This variable should report the exact number of lymph nodes containing tumour cells, as recorded in the pathological records.	Numeric variable. 99 → Unknown/missing value
pT	This variable encodes information on the extent of the primary tumour, based on pathological evidence.	Alphanumeric variable. According to the 7 <sup>th</sup> edition of the TNM classification:

pN

This variable provides information on the absence or presence and extent of the regional lymph node metastasis, based on pathological evidence. It should be coded according to the 7<sup>th</sup> of the TNM.

- TX → Primary tumour cannot be assessed.
- T1 → Tumour limited to the pancreas, ≤ 2 cm in greatest dimension.
- T2 → Tumour limited to the pancreas, > 2 cm in greatest dimension.
- T3 → Tumour extends beyond the pancreas but without involvement of the celiac axis or the superior mesenteric artery.
- T4 → Tumour involves the celiac axis or the superior mesenteric artery (unresectable primary tumour).
- 9 → Unknown/missing value

Alphanumeric variable.  
According to the 7<sup>th</sup> edition of the TNM classification:

- NX → Regional lymph nodes cannot be assessed.
- N0 → No regional lymph node metastasis.
- N1 → Regional lymph node metastasis.
- 9 → Unknown/missing value

pM

This variable describes the absence or presence of distant metastasis, based on pathological evidence.

Alphanumeric variable.  
According to the 7<sup>th</sup> edition of the TNM classification:

- M0 → No distant metastasis
- M1 → Distant metastasis
- 9 → Unknown/missing value

pSTAGE

This variable encodes information on the TNM stage grouping, based on pathological information. It should be coded according to the 7<sup>th</sup> of the TNM.

Alphanumeric variable.  
According to the 7<sup>th</sup> edition of the TNM classification:

- IA → T1    N0    M0
- IB → T2    N0    M0
- IIA → T3    N0    M0
- IIB → T1    N1    M0
- T2    N1    M0
- T3    N1    M0
- III → T4    Any N    M0
- IV → Any T    Any N    M1
- 9 → Unknown/missing value

**TREATMENT: SURGERY**

SURGERY	The patient underwent a surgical procedure of curative or palliative nature.	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
SURGERY_DATE	The date of the first surgical procedure of curative or palliative nature.	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing
SURGERY_TYPE	The type of the first surgical procedure (technique) of curative or palliative nature.	Numeric variable. 1→ Pancreaticoduodenectomy, total pancreatectomy 2→ Pancreaticoduodenectomy, partial pancreatectomy 3→ Partial pancreatectomy, pancreatic body 4→ Partial pancreatectomy, pancreatic tail 5→ Palliative (biliary, drainage, stents, etc.) 9→ Unknown/missing value
INVASION	This variable should be filled only if the patient underwent a resection.	Numeric variable. 1→ Venous 2→ Lymphatic 3→ Perineural 9→ Unknown/missing value
MARGINS	Whether margins of apparently tumorous tissue around a resected pancreatic tumour are present. If not resected, "not applicable" must be completed. R0 and R1 is a pathological criteria. This data should be retrieved from the pathological reports. R2 refers to the surgical criteria (macroscopic evaluation)	Numeric variable 1 → R0 (margin negative) 2 → R1 (microscopic residual tumour) 3 → R2 (macroscopic residual)  4 → Not evaluable 5 → Not applicable 9 → Unknown/missing value

**TREATMENT: RADIOTHERAPY**

RADIOTHERAPY	The patient receives any radiotherapy palliative nature.	Numeric variable 1→ Yes 2→ No 9→ Unknown/missing value
RADIO_FIELD	Radiation field description	Numeric variable. 1→ Primary tumour before surgery 2→ Primary tumour after surgery 3→ Primary tumour, NOS 4→ Metastasis 9→ Unknown/missing value

RADIO_STARTED_DATE	The date of the first session of radiotherapy.	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing
RADIO_ENDED_DATE	The date of the last session of radiotherapy.	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing
RADIO_TOTAL_DOSE	The total dose in Gy.	Numeric variable.

### TREATMENT: CHEMOTHERAPY

CHEMOTHERAPY_1	The patient receives any cancer chemotherapy of curative or palliative nature.	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
CLINICAL TRIAL	The patient participates in a clinical trial.	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
TRIAL_PROTOCOL	The name/number of the trail.	Text
ECOG_STARTED_1	The patient's ECOG performance status at the beginning of chemotherapy (first line).	Numeric variable. 0→ Fully active, able to carry on all pre-disease performance 1→ Restricted in physically strenuous activity but ambulatory and able to carry out work of light or sedentary nature 2→ Confined to bed less than 50% of waking hours 3→ Confined to bed more than 50% of waking hours 4→ Totally confined to bed 9→ Unknown/missing value
CHEMO_INTENT_1	The patient receives any cancer chemotherapy (first line) of curative or palliative nature. Note: chemotherapy for metastatic disease is always palliative. Palliative refers to symptoms management only.	Numeric variable. 1→ Neoadjuvant 2→ Adjuvant 3→ Metastatic first line 4→ Palliative (symptomatic treatment only) 9→ Unknown/missing value
CHEMO_STARTED_DATE_1	Started day of the first line of the chemotherapy.	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing

CHEMO_ENDED_DATE_A_1	Ended date of the first line of the chemotherapy.	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing
DRUG_1_CHEMO_1	Gemcitabine (ATC code: L01BC05)	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
DRUG_2_CHEMO_1	Capecitabine (ATC code: L01BC06)	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
DRUG_3_CHEMO_1	ABRAXANE (Nab-Paclitaxel) (ATC code: L01CD01)	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
DRUG_4_CHEMO_1	Erlotinib (ATC code: L01XE03)	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
DRUG_5_CHEMO_1	Oxaliplatin (ATC code: L01XA03)	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
DRUG_6_CHEMO_1	Irinotecan (ATC code: L01XX19)	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
DRUG_7_CHEMO_1	5-FU (ATC code: )	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
BEST_RESPONSE_1	<p>Response to the first line of chemotherapy.</p> <p>Complete Response (CR): Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to &lt;10 mm.</p> <p>Partial Response (PR): At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.</p> <p>Stable disease: Neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD, taking as reference the smallest sum diameters while on study.</p>	<p>Numeric variable</p> <p>1→ Complete response 2→ Partial response 3→ Stable disease 4→ Progressive disease 5→ Not evaluable 9→ Unknown/missing value</p>
PROGRESSION_DATE_1	The date at which progression is evident, defined as at least a	YYYY/MM/DD 9999→ Year unknown/missing



1

20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. (Note: the appearance of one or more new lesions is also considered progression).

99→ Month unknown/missing  
99→ Day unknown/missing

ECOG\_STARTED\_2

The patient's ECOG performance status at the beginning of chemotherapy (second line).

Numeric variable.

0→ Fully active, able to carry on all pre-disease performance

1→ Restricted in physically strenuous activity but ambulatory and able to carry out work of light or sedentary nature

2→ Confined to bed less than 50% of waking hours

3→ Confined to bed more than 50% of waking hours

4→ Totally confined to bed

9→ Unknown/missing value

CHEMO\_INTENT\_2

The patient receives any cancer chemotherapy (second line) of curative or palliative nature.

Numeric variable.

1→ Metastatic first line

2→ Metastatic second line

3→ Palliative

9→ Unknown/missing value

CHEMO\_STARTED\_DATE\_2

Started day of the second line of the chemotherapy.

YYYY/MM/DD

9999→ Year unknown/missing

99→ Month unknown/missing

99→ Day unknown/missing

CHEMO\_ENDED\_DATE\_2

Ended date of the second line of the chemotherapy.

YYYY/MM/DD

9999→ Year unknown/missing

99→ Month unknown/missing

99→ Day unknown/missing

DRUG\_1\_CHEMO\_2

Gemcitabine (ATC code: L01BC05)

Numeric variable.

1→ Yes

2→ No

9→ Unknown/missing value

DRUG\_2\_CHEMO\_2

Capecitabine (ATC code: L01BC06)

Numeric variable.

1→ Yes

2→ No

9→ Unknown/missing value

DRUG\_3\_CHEMO\_2

ABRAXANE (NabPaclitaxel) (ATC code: L01CD01)

Numeric variable.

1→ Yes

2→ No

9→ Unknown/missing value

DRUG_4_CHEMO_2	Erlotinib (ATC code: L01XE03)	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
DRUG_5_CHEMO_2	Oxaliplatin (ATC code: L01XA03)	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
DRUG_6_CHEMO_2	Irinotecan (ATC code: L01XX19)	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
DRUG_7_CHEMO_2	5-FU (ATC code: )	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
DRUG_8_CHEMO_2	NALIRI (Liposomal Irinotecan) (ATC code: )	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
BEST_RESPONSE_2	Response to the second line of chemotherapy.	Numeric variable 1→ Complete response 2→ Partial response 3→ Stable disease 4→ Progressive disease 5→ Not evaluable 9→ Unknown/missing value
PROGRESSION_DATE_2	The date at which progression is evident, defined as at least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. (Note: the appearance of one or more new lesions is also considered progression).	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing
ECOG_STARTED_3	The patient's ECOG performance status at the beginning of chemotherapy (third line).	Numeric variable. 0→ Fully active, able to carry on all pre-disease performance 1→ Restricted in physically strenuous activity but ambulatory and able to carry out work of light or sedentary nature 2→ Confined to bed less than 50% of waking hours 3→ Confined to bed more than 50% of waking hours 4→ Totally confined to bed 9→ Unknown/missing value

CHEMO_INTENT_3	The patient receives any cancer chemotherapy (third line) of curative or palliative nature.	Numeric variable. 1→ Metastatic second line 2→ Metastatic third line 3→ Palliative 9→ Unknown/missing value
CHEMO_STARTED_DATE_3	Started day of the third line of the chemotherapy.	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing
CHEMO_ENDED_DATE_3	Ended date of the third line of the chemotherapy.	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing
DRUG_1_CHEMO_3	Gemcitabine (ATC code: L01BC05)	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
DRUG_2_CHEMO_3	Capecitabine (ATC code: L01BC06)	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
DRUG_3_CHEMO_3	ABRAXANE (Nab-Paclitaxel) (ATC code: L01CD01)	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
DRUG_4_CHEMO_3	Erlotinib (ATC code: L01XE03)	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
DRUG_5_CHEMO_3	Oxaliplatin (ATC code: L01XA03)	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
DRUG_6_CHEMO_3	Irinotecan (ATC code: L01XX19)	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
DRUG_7_CHEMO_3	5-FU (ATC code: )	Numeric variable. 1→ Yes 2→ No 9→ Unknown/missing value
DRUG_8_CHEMO_3	NALIRI (Liposomal Irinotecan) (ATC code: )	Numeric variable. 1→ Yes 2→ No

ECOG_ENDED_3	The patient's ECOG performance status at the END of chemotherapy.).	9→ Unknown/missing value  Numeric variable. 0→ Fully active, able to carry on all pre-disease performance 1→ Restricted in physically strenuous activity but ambulatory and able to carry out work of light or sedentary nature 2→ Confined to bed less than 50% of waking hours 3→ Confined to bed more than 50% of waking hours 4→ Totally confined to bed 9→ Unknown/missing value
BEST_RESPONSE_3	Response to the third line of chemotherapy.	Numeric variable. 1→ Complete response 2→ Partial response 3→ Stable disease 4→ Progressive disease 5→ Not evaluable 9→ Unknown/missing value
PROGRESSION_DATE_3	The date at which progression is evident, defined as at least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. (Note: the appearance of one or more new lesions is also considered progression).	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing

PATIENT VITAL STATUS	TO BE DISCUSSED
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VITAL_STATUS	This variable describes the <b>last known</b> patient's vital status. If some patients cannot be traced by any active follow-up procedure, their vital status may remain undetermined and should then be coded as "9" (unknown).	YYYY/MM/DD 1→ Alive 2→ Dead 9→ Unknown/missing value
VITAL_STATUS_DATE	Date of last known vital status. If the patient is deceased, the date of last known vital status should be the date of death. If the patient has emigrated or has been lost to follow-up, the last date at which he/she was known to be alive should be reported.	YYYY/MM/DD 9999→ Year unknown/missing 99→ Month unknown/missing 99→ Day unknown/missing
CAUSE_OF_DEATH	This variable may be used to estimate cancer-specific survival	Numeric variable. 0→ Not applicable (the patient is alive) 1→ Pancreatic cancer and/or its complications including treatment toxicities 2→ Cancer, NOS 3→ Other causes of death 9→ Unknown/missing value

PALLIATIVE

Did the patient receive support from a palliative unit?

Numeric variable.

1 → Yes

2 → No

9 → Unknown/missing value

SUPPORT

Did the patient need support during the pancreas cancer treatment?

Numeric variable

1 → no

2 → yes, pain treatment support

3 → yes, psychological support

4 → yes, nutritional support

5 → yes, all kind of support

9 → Unknown/missing value

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#### 4. Quality control

To be defined.

#### 5. Ethics

PancreOS will be conducted according to the protocol, the principles laid down in the latest version of the Declaration of Helsinki and the **Data Protection Directive (95/46/EC)** that regulates the collection, processing and distribution of personal data.

#### 6. REFERENCES

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