

# Complex Surgery Pancreas and Peri-Ampullary Region - Registration form

*Dataset established by the Expert Working Group and approved by the “Stuurgroep Complexe Chirurgie - Groupe de Pilotage Chirurgie Complexe” on 30/04/2019. – Revision April 2021*



All variables are required to be filled out unless stated otherwise (e.g. 'if possible', 'if applicable', 'not mandatory').

- Single-select variables: only one answer can be selected
- Multi-select variables: one or more answers can be selected

## Administrative patient data

Hospital: .....  
Health insurance institution: .....  
National number for social security (INSZ/NISS)\*: .....

*\* if filled out in the WBCR application, the following variables will be completed automatically:*

Last name: .....  
First name: .....  
Postal code: .....  
City: .....  
Country: .....  
Health insurance number: ..... (if possible)  
Date of birth: ...../...../..... (dd/mm/yyyy)  
Date of death: ...../...../..... (dd/mm/yyyy) (if applicable)  
Sex:  Male  
 Female

## General information

Did the patient undergo surgery?

No

- Indication:

- Malignant tumour °
- Adenoma
- Cystadenoma
- Intraductal Papillary Mucinous Neoplasm (IPMN) with low grade or moderate dysplasia (8453/0)
- Other benign tumour, specify: .....
- Chronic pancreatitis
- Other, specify: .....

*° Only to be filled out for a malignant tumour:*

- Lesion to treat (in (peri-)pancreas)
  - Primary tumour §
  - Relapse of primary tumour
  - Metastasis (primary tumour not located in/near (peri-)pancreas) §
- Incidence date primary tumour/relapse: ..... /..... /..... (dd/mm/yyyy)
- Primary tumour/relapse localisation: .....
- Histological diagnosis primary tumour/relapse: .....

*§ Only to be filled out for a primary tumour or metastasis, not a relapse:*

- Clinical TNM primary tumour (cTNM): cT: ..... cN: ..... cM: .....
- Pathological TNM primary tumour (pTNM): pT: ..... pN: ..... pM: .....

- MC/CM date: ...../...../..... (dd/mm/yyyy)
- MC/CM report, without patient identification variables (e.g. name, INSZ/NISS):  
..... (include as text)



- Was the patient referred?
  - No
  - Yes
    - Referring hospital: Belgian: ..... or foreign: .....

*If the patient did not undergo surgery, the registration can be terminated here.*

- Yes

*If the patient underwent surgery, please fill out the following variables*

Indication:

- Malignant tumour \*
- Adenoma
- Cystadenoma
- Intraductal Papillary Mucinous Neoplasm (IPMN) with low grade or moderate dysplasia (8453/0)
- Other benign tumour, specify: .....
- Chronic pancreatitis
- Other, specify: .....

*\* Only to be filled out for a malignant tumour:*

- Lesion to treat (in (peri-)pancreas)
  - Primary tumour §
  - Relapse of primary tumour
  - Metastasis (primary tumour not located in/near (peri-)pancreas) §
- Incidence date primary tumour/relapse: ..... /..... /..... (dd/mm/yyyy)
- Primary tumour/relapse localisation: .....
- Histological diagnosis primary tumour/relapse: .....

*§ Only to be filled out for a primary tumour or metastasis, not a relapse:*

- Clinical TNM primary tumour (cTNM):      cT: .....      cN: .....      cM: .....
- Pathological TNM primary tumour (pTNM):      pT: .....      pN: .....      pM: .....

Type of FIRST diagnostic method:

- CT
- MRI
- PET
- PET/CT
- ERCP (endoscopic retrograde cholangio-pancreatography)
- EUS (endoscopic ultrasound)/endoscopy
- Surgery (laparoscopy/laparotomy)
- Date: ...../...../..... (dd/mm/yyyy)

Method to obtain first tissue sample for histopathological evaluation:

- ERCP (endoscopic retrograde cholangio-pancreatography)
- EUS (endoscopic ultrasound)/endoscopy
- Surgery (laparoscopy/laparotomy/'complex' surgery)
- CT
- MRI
- Date: ...../...../..... (dd/mm/yyyy)



MC/CM date: ...../...../..... (dd/mm/yyyy)

Surgeon 1: number RIZIV/INAMI: ..... (not mandatory)

Surgeon 2: number RIZIV/INAMI: ..... (not mandatory, if applicable)

Please upload the following reports without patient identification variables (e.g. name, INSZ/NISS):

- MC/CM report: ..... (include as text)
- Pathology report: ..... (include as text)
- Surgery report: ..... (not mandatory, include as text)

Was the patient referred?

- No
- Yes

- Referring hospital: Belgian: ..... or foreign: .....
- Was there a M(O)C/C(O)M at the referring hospital?
  - No
  - Yes
    - Date: ...../...../..... (dd/mm/yyyy)
- Was the patient hospitalized at the referring hospital (before referral)?
  - No
    - Date of last consultation before referral: ...../...../..... (dd/mm/yyyy)
  - Yes
    - Date of discharge at the referring hospital: ...../...../..... (dd/mm/yyyy)

## Patient characteristics

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Height: ..... cm

Weight at time of surgery: ..... kg

WHO performance status at time of surgery:

- 0 - Asymptomatic, normal activity
- 1 - Symptomatic, but ambulant
- 2 - Symptomatic, bedbound <50% of the day
- 3 - Symptomatic, bedbound >50% of the day
- 4 - Completely dependent, 100% bedbound

ASA score (pre-operative risk):

- 1 - Healthy person
- 2 - Mild systemic disease, normal activity
- 3 - Serious systemic disease, limited activity
- 4 - Life-threatening illness, handicapped
- 5 - Dying

Comorbidity (prior to surgery) - Charlson Modified Index (not the current surgery indication!):

- No
- Yes
  - Myocardial infarction
  - Peripheral vascular disease
  - Cerebrovascular disease
  - Congestive heart failure
  - Connective tissue disease



- Mild liver disease
- Moderate-severe liver disease
- Moderate-severe renal disease
- Chronic pulmonary disease
- Peptic ulcer
- Hemiplegia
- Dementia
- Diabetes without any damage to end-organs
- Diabetes with damage to end-organs
- Any tumour (without metastasis)
- Leukaemia (acute or chronic)
- Lymphoma
- Metastatic solid tumour
- AIDS (not just HIV positive)

Is the patient currently (= at time of surgery) treated with antithrombotic medication?

- No
- Yes
  - B01AA: Vitamin K antagonists (e.g. warfarin)
  - B01AB: Heparin group (e.g. heparin)
  - B01AC: Platelet aggregation inhibitors excluding heparin (e.g. acetylsalicylic acid)
  - B01AD: Enzymes (e.g. streptokinase)
  - B01AE: Direct thrombin inhibitors (e.g. desirudin)
  - B01AF: Direct Xa inhibitors (e.g. rivaroxaban)
  - B01AX: Other antithrombotic agents (e.g. dermatan sulfate)

## Surgery

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Did the patient receive any other treatment modality before this surgical procedure?

- No
- Yes
  - Chemotherapy <sup>oo</sup>
    - Start date: ...../...../..... (dd/mm/yyyy)
    - Date latest treatment: ...../...../..... (dd/mm/yyyy)
    - Type of chemotherapy:
      - Gemcitabine-based regimen
      - FOLFIRINOX (5-Fluorouracil, Leucovorin, Irinotecan and Oxaliplatin)-based regimen
      - Other, specify: .....
  - Radiotherapy <sup>oo</sup>
    - Start date: ...../...../..... (dd/mm/yyyy)
    - Date latest treatment: ...../...../..... (dd/mm/yyyy)
  - Prior abdominal surgery
    - Type of surgery: .....
    - Date latest surgery: ...../...../..... (dd/mm/yyyy)
  - Other treatment modality (that could affect the pancreas), specify: .....

<sup>oo</sup> Only to be filled out in case of neoadjuvant chemo- and/or radiotherapy:

- Resectability status of the (peri-)pancreatic lesion before neoadjuvant treatment:
  - Upfront resectable
  - Borderline resectable
  - Unresectable



Date of surgery: ...../...../..... (dd/mm/yyyy)

*\* Only to be filled out for a malignant tumour:*

- Resectability status of the (peri-)pancreatic lesion before surgery:
  - Upfront resectable
  - Borderline resectable
  - Unresectable

Type of surgery:

- Minimally invasive surgery (MIS)
  - Total laparoscopic
  - Total robotic
  - Hybrid (laparoscopic + robotic)
- Open
- Conversion from MIS to open surgery
  - Reason for conversion: .....

Nomenclature code:

- 242830-242841: Pancreaticoduodenectomy
  - Pancreaticoduodenectomy
  - Total pancreatectomy
    - Localisation lesion:
      - Pancreatic head / peri-ampullary region
      - Pancreatic body or tail
- 242852-242863: Hemipancreatectomy left with jejunal anastomosis of the resection plane of the pancreas, or almost total pancreatectomy (95 pct)
- 242874-242885: Hemipancreatectomy left
- 242896-242900: Enucleation of a pancreatic tumour
  - Localisation tumour:
    - Pancreatic head / peri-ampullary region
    - Pancreatic body or tail

Simultaneous vascular resection?

- No
- Yes
  - Superior mesenteric vein/portal vein (SMV/PV) resection
    - Type of SMV/PV reconstruction:
      - with primary wedge-reconstruction
      - with primary end-to-end reconstruction
      - with vascular autograft interposition
      - with vascular allograft interposition
      - with synthetic/prosthetic interposition
      - with peritoneal patch wedge-reconstruction
      - without reconstruction
  - Arterial resection
    - Type of arterial resection:
      - Hepatic artery
      - Coeliac trunk
      - Superior mesenteric artery (SMA)
    - Type of arterial reconstruction:
      - with primary wedge-reconstruction
      - with primary end-to-end reconstruction
      - with vascular autograft interposition
      - with vascular allograft interposition



- with synthetic/prosthetic interposition
- without reconstruction

Simultaneous other organ resection?

- No
- Yes
  - Colon
  - Stomach
  - Sur-renal gland
  - Spleen
  - Other, specify: .....

*\* Only to be filled out for a malignant tumour:*

- Residual disease - resection margins:
  - R0: tumour-free resection margin > 1 mm
  - R1 indirect: tumour-free resection margin  $\leq$  1 mm
  - R1 direct: tumour involvement of the resection margin
  - R2: macroscopic tumour transection

Lymphadenectomy:

- No
- Yes
  - Region:
    - Peri-tumoural
    - Coeliac trunk
    - SMA origin (superior mesenteric artery)
    - Para-aortic
  - Number of lymph nodes retrieved: .....
  - Number of lymph nodes with tumoural involvement: .....

## Post-surgery

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Postoperative complications (90 days post-op, in-hospital complications):

- No
- Yes
  - Type of postoperative complication(s):
    - Clinically relevant pancreatic fistula [cf. Bassi *et al.* (ISGPS), Surgery, 2017]
      - ISGPS grade B
      - ISGPS grade C
    - Haemorrhage [cf. Wente *et al.* (ISGPS), Surgery, 2007]
      - ISGPS grade A
      - ISGPS grade B
      - ISGPS grade C
    - Delayed gastric emptying [cf. Wente *et al.* (ISGPS), Surgery, 2007]
      - ISGPS grade A
      - ISGPS grade B
      - ISGPS grade C
    - Bile leakage [cf. Koch *et al.* (ISGLS), Surgery, 2011]
      - ISGLS grade A
      - ISGLS grade B
      - ISGLS grade C
    - Intra-abdominal abscess
    - Other, specify: .....



- General Clavien-Dindo classification (90 days post-op, in-hospital complications): ([https://www.baus.org.uk/patients/surgical\\_outcomes/grading\\_of\\_surgical\\_complications.aspx](https://www.baus.org.uk/patients/surgical_outcomes/grading_of_surgical_complications.aspx))
  - TOSGS grade 1
  - TOSGS grade 2
  - TOSGS grade 3a
  - TOSGS grade 3b
  - TOSGS grade 4a
  - TOSGS grade 4b
  - TOSGS grade 5

Re-operation necessary?

- No
- Yes

- Type of surgery: .....

Please upload the following reports without patient identification variables:

- MC/CM report (if applicable): ..... (include as text)
- Pathology report (if applicable): ..... (include as text)
- Surgery report: ..... (not mandatory, include as text)

Was the patient discharged after surgery during the 90-day post-op period?

- No
- Yes

- Discharge date after surgery: ...../...../..... (dd/mm/yyyy)

- Destination?

- Home
- Rehabilitation centre
- Nursing home
- Transfer to another hospital

- Name: .....

- Because of complications?

- No
- Yes

- Re-admission within 30 days after discharge (from the centre that performed the surgery):

- No
- Unknown
- Yes, in the hospital where the surgery was performed

- Reason for re-admission: .....

Yes, in another hospital

- Reason for re-admission: .....

Did the patient die during the 90-day post-op period?

- No
- Yes

- In-hospital?

- No
- Yes

- Date of death: ...../...../..... (dd/mm/yyyy)

- Cause of death: .....





*\* Only to be filled out for a malignant tumour:*

- Was there adjuvant therapy after surgery?
  - No
  - Yes
    - Systemic therapy
    - Radiotherapy
    - Combined therapy (systemic + radiotherapy)

Was the patient included in a clinical trial for (neo)adjuvant therapy or surgery?

- No
- Unknown
- Yes
  - EudraCT number: ..... or NCT number: .....



## Registration form - version overview

Version	Changes
v1.0	Original document (28/06/2019)
v1.1	<ul style="list-style-type: none"> <li>- The variable 'Nomenclature code' changed from multi- to single-select variable</li> <li>- The variable 'Re-admission within 30 days after discharge' was moved under the variable 'Was the patient discharged after surgery during the 90-day post-op period' – option 'Yes', so that it should only be answered when the patient was discharged</li> </ul>
v1.2	<ul style="list-style-type: none"> <li>- The symbols related to the variable 'Indication' in case surgery is performed, were altered to * for malignant tumoural indications</li> <li>- The answer option 'EUS (endoscopic ultrasound)' was expanded to 'EUS (endoscopic ultrasound)/endoscopy' for the variables 'Type of FIRST diagnostic method' and 'Method to obtain first tissue sample for histopathological evaluation'</li> <li>- The variable 'Was the patient hospitalized at the referring hospital' was further clarified by adding: (before referral) to the question</li> <li>- The variable 'Comorbidity (prior to surgery) - Charlson Modified Index' was further clarified by adding: 'not the current surgery indication!'</li> <li>- The MC/CM report (if applicable), pathology report (if applicable) and surgery report are requested when re-operation was necessary</li> <li>- The variable 'Re-admission within 30 days after discharge' was further clarified by adding: 'from the centre that performed the surgery'</li> <li>- The variable 'Was there adjuvant therapy after surgery?' and the variable to specify the adjuvant therapy were moved further down the document</li> </ul>
v1.3 (Aug/2019)	<ul style="list-style-type: none"> <li>- For the nomenclature code '242830-242841: Pancreaticoduodenectomy', the answering option 'Whipple' has been changed to 'Pancreaticoduodenectomy'</li> <li>- For the nomenclature code '242830-242841: Pancreaticoduodenectomy' and '242896-242900: Enucleation of a pancreatic tumour', the answering option 'Pancreatic tail' has been changed to 'Pancreatic body or tail'</li> <li>- The option 'without reconstruction' has been added in case of a SMV/PV resection</li> <li>- A question has been added regarding the type of reconstruction in case of an arterial resection</li> <li>- The definitions corresponding to R0 and R1 resection margins have been changed: <ul style="list-style-type: none"> <li>o From 'R0: no residual disease' to 'R0: tumour-free resection margin &gt; 1 mm'</li> <li>o From 'R1 indirect: R0 with magnitude of resection margin &lt; 1 mm' to 'R1 indirect: tumour-free resection margin &lt; 1 mm'</li> <li>o From 'R1 direct: microscopic tumour positive margin' to 'R1 direct: tumour involvement of the resection margin'</li> </ul> </li> <li>- The question on lymph node retrieval has been changed from 'number of loco-regional lymph nodes retrieved' to 'number of lymph nodes retrieved'</li> <li>- The question on the number of involved lymph nodes has been changed from 'number of metastatic loco-regional lymph nodes' to 'number of lymph nodes with tumoural involvement'</li> </ul>
v2.0 (Sep/2020)	<ul style="list-style-type: none"> <li>- Added additional question in case of malignant indication (lesion to treat): primary tumour, relapse of primary tumour or metastasis</li> <li>- Added specific variables from the MOC/COM cancer registration (bijlage/annexe 55) in case of a malignant indication: incidence date primary tumour/relapse, primary tumour/relapse localization, histological diagnosis primary tumour/relapse, cTNM and pTNM in case of primary tumour or</li> </ul>



	metastasis - MC/CM date - RIZIV numbers surgeon(s)
v3.0 (Apr/2021)	- RIZIV numbers surgeon(s) not mandatory - Surgery report not mandatory - Added additional question in case of malignant indication and neoadjuvant chemo- or radiotherapy (resectability status before neoadjuvant treatment): upfront resectable, borderline resectable or unresectable - Added additional question in case of malignant indication (resectability status before surgery): upfront resectable, borderline resectable or unresectable - The option 'R1 indirect: tumour-free resection margin < 1 mm' was further specified as being ' $\leq 1$ mm' - Surgery report re-operation not mandatory