



Belgian Cancer Registry

# **Complex Surgery Pancreas and Peri-Ampullary Region**

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## **Project manual + FAQ**

*Revision September 2020*



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# 1. General Project Information

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This manual has been composed as a guide and reference for filling out the specific registration form for 'Complex Surgery of the Pancreas and Peri-Ampullary Region'.

Starting from 01/07/2019, hospitals have entered into a convention with the National Institute for Health and Disability Insurance (RIZIV/INAMI) about complex surgery of the pancreas and peri-ampullary region. These hospitals are hereafter termed '**expert centres**'. The convention includes an additional registration of surgery-related variables via the Belgian Cancer Registry (BCR). Based on this registration, the result of this convention will be evaluated. More information and all relevant documents can be found on the BCR website: [https://kankerregister.org/ComplexSurgery\\_nl](https://kankerregister.org/ComplexSurgery_nl) or [http://www.kankerregister.org/ComplexSurgery\\_fr](http://www.kankerregister.org/ComplexSurgery_fr), including a link to the RIZIV/INAMI website, from which the written convention can be consulted. For questions about the content of the convention, please contact the RIZIV/INAMI via [medicomut@riziv-inami.fgov.be](mailto:medicomut@riziv-inami.fgov.be).

For all questions or comments concerning the variables to be registered, the timeline or the registration procedure, please contact us at [ComplexSurgery@kankerregister.org](mailto:ComplexSurgery@kankerregister.org) or 02/250 10 10.

## 1.1. Inclusion criteria

Article 3 of the convention defines the requirements for patient inclusion, which can be translated into the following concrete inclusion criteria for registration:

- patients with a Belgian health insurance;
- with a benign, premalignant or malignant disorder of the pancreas and/or peri-ampullary region (ICD-O-3 topography codes: C17.0, C24.0-24.1, C25.0-25.9), such as chronic pancreatitis (benign non-tumoural), adenocarcinoma (cancer), neuro-endocrine tumours, cystic tumours (cystadenoma, IPMN (Intraductal Papillary Mucinous Neoplasm)), stromal tumours (GIST or GastroIntestinal Stromal tumour, schwannoma a.o.);
- for whom 'complex surgery' **is being considered** at the multidisciplinary consult (MC/CM).

Complex surgery, according to the convention, includes the following nomenclature codes:

<b>242830-242841</b>	Pancreaticoduodenectomy
<b>242852-242863</b>	Hemipancreatectomy left with jejunal anastomosis of the resection plane of the pancreas, or almost total pancreatectomy (95 pct)
<b>242874-242885</b>	Hemipancreatectomy left
<b>242896-242900</b>	Enucleation of a pancreatic tumour

This means that all patients for whom complex surgery is considered, should be registered, also if no surgery is performed eventually. Please note that the required variables to be registered in case of 'no surgery' are limited to a minimal specific dataset.

Also, every complex surgery (with the above-mentioned nomenclature codes) must be registered, even if the disorder is not within the defined topographies (e.g. extension/invasion from a nearby location or metastasis from a primary tumour not located in/near the (peri-)pancreas).

## 1.2. Complex surgery registration dataset

This dataset was established by the Expert Working Group and approved by the “Stuurgroep Complexe Chirurgie - Groupe de Pilotage Chirurgie Complexe” on 30/04/2019 and revised in September 2020.

The dataset can be accessed via [https://kankerregister.org/ComplexSurgery\\_nl](https://kankerregister.org/ComplexSurgery_nl) or [http://www.kankerregister.org/ComplexSurgery\\_fr](http://www.kankerregister.org/ComplexSurgery_fr). All requested variables are discussed in detail in Chapter 2 of this manual. Note that this registration includes the written multidisciplinary consult (MC/CM) report, pathology report and surgery report, which should be included as large text variables.

The revised dataset from September 2020 (version v2.0) includes the following changes:

- Inclusion of a few variables from the general MOC/COM (bijlage/annexe 55) dataset, only to be completed for malignant tumours. Hereby the bijlage/annexe 55 registration does not need to accompany the complex surgery dataset anymore.  
**Please note that the complete bijlage/annexe 55 dataset for malignant tumours (both in situ and invasive) still needs to be sent to the BCR by June 30<sup>th</sup> in the context of the general, ‘classic’ cancer (MOC/COM) registration, which is obliged since 2003 for all oncological care programs in Belgium.**
- New variable: Type of malignant lesion to treat (primary tumour, relapse, metastasis)
- New variable: Date of MC/CM
- New variable: RIZIV/INAMI number of the treating (surgeon)s

## 1.3. Modes of registration

The registrations can be delivered to the BCR in two ways:

1. Via the online **WBCR** application (preferred)
2. Via structured **batch** deliveries (in a predefined format, after automated data extraction from the patient’s electronic medical dossier)

### 1.3.1. WBCR

The online Web Based Cancer Registration (WBCR) application of the BCR can be accessed via the BCR website. More information about the login procedure and general operation of this application can be found in the Complex Surgery WBCR manual (see [http://www.kankerregister.org/ComplexSurgery\\_nl](http://www.kankerregister.org/ComplexSurgery_nl) or [http://www.kankerregister.org/ComplexSurgery\\_fr](http://www.kankerregister.org/ComplexSurgery_fr)). Registration via WBCR is the preferred mode of registration because the data are immediately validated, which reduces the number of errors and incomplete registrations.

The WBCR module for project-specific registrations of complex surgery can be found as one of the first modules on the online platform. Please note that there are two different modules for complex surgery (oesophagus and pancreas).

#### Notes:

- Access to WBCR is granted via the **(Main) Access Administrator of your hospital**.
- The login procedure is via the eHealth platform. You will need your electronic identity card and PIN code. Alternatively, you could use the ‘itsme app’.
- It is possible to save and modify (in)complete registrations at any time, before sending them to the BCR. After sending, the registrations can no longer be modified. The registrations can be delivered to the BCR one by one or altogether. The data you have access to, can be downloaded into a CSV file. Please check FAQ 3.1.12 to see how corrections can be sent to the BCR afterwards.

- Quality control checks have been added to the online registration form, e.g. to ensure that the dates are filled out chronologically. Possible errors need to be resolved before the registration can be validated and delivered to the BCR.
- Please keep in mind to save a registration within the hour. After staying on the same WBCR page for more than 1 hour, you will be logged off automatically and unsaved data will be lost.

### 1.3.2. Batch file

Registrations can also be delivered in a predefined 'batch file'. The required variables should be registered in one batch file per hospital, in a predefined order and format.

**Please note that this delivery option is only meant for hospitals that perform automated data extraction from the patient's electronic medical dossier to generate the batch file datasets.**

For the specific complex surgery dataset, all necessary specifications can be found in the 'Complex Surgery Batch file template', which is accessible via our website ([http://www.kankerregister.org/ComplexSurgery\\_nl](http://www.kankerregister.org/ComplexSurgery_nl) or [http://www.kankerregister.org/ComplexSurgery\\_fr](http://www.kankerregister.org/ComplexSurgery_fr)). The template has four Excel sheets:

- **Requested format:** All specifications concerning the structure of the batch file and format of the variables is listed. The first column specifies which variable should be put in which column in the batch file.
- **Batch file example:** This example shows the requested format of the batch file. It is filled out for three test patients to illustrate how the file should be set up.
- **Checklist!:** Please consult the 9-step checklist to verify whether your batch file was set up according to the requested format.
- **Overview hospitals:** Hospital names to be used for the Belgian referring hospitals. Please note that these names might not be the official hospital names.

It is important to use the correct order, format and answer options to ensure that BCR can uniformly process the data and add it correctly to the main database. Note that it is possible that the BCR will send back registrations to complete missing variables, correct mistakes or verify unlikely information.

The data transfer will be performed via BCR's 'secure file transfer protocol (sFTP)' server (<https://sftp.kankerregister.be/>). A sFTP login and password will be provided to the person responsible for the registrations in the two weeks before each registration time point.

## 1.4. Registration time points

The time frame in which registrations should be **completed** is defined in the convention and depends on whether surgery was performed or not:

- **If surgery:** the registration forms should be completed at the latest **100 days after surgery** for patients that underwent surgery.  
**Note that the "90-day post-op complications" are requested. This means that the registrations can only be completed and sent 90 days after surgery and not before!**
- **If no surgery:** the registration forms for patients who did not undergo surgery should be completed at the latest **60 days after the date of the multidisciplinary consult (MC/CM)**, i.e. where the decision was made in the expert centre not to perform surgery.

**It is the responsibility of the expert centre to keep these time frames in mind and to make sure the registered information is complete. In case of surgery, if you deliver a registration before the end of the 90-day post-op period and afterwards it turns out that additional information should have been included (e.g. a very late complication, redo surgery or death within 90 days after the surgery), it is the responsibility of the expert centre to complete the missing information. See FAQ 3.1.12 for how this can be communicated to BCR.**



Registrations should thus be **completed** year-round. However, **delivery** of these completed registrations to the BCR will be restricted to 2 mandatory delivery time points per year (with the same deadlines for WBCR and batch file deliveries). Please note that in the September 2020 revision, this number of delivery time points was reduced from 4 times per year (end of March, June, September, December) to 2 times per year (beginning of April, end of September).

Only **completed registrations** can be delivered to the BCR. Starting from September 2020, the registrations will need to be transferred to the BCR by a specific Friday in:

- The **beginning of April (9/04/2021 and 8/04/2022)**, for the following registrations:
  - o If surgery: until surgery date 31/12
  - o If no surgery: until MC/CM date 31/01
- The **end of September (1/10/2021 and 30/09/2022)**, for the following registrations:
  - o If surgery, until surgery date 30/06
  - o If no surgery, until MC/CM date 31/07/2021 or 30/06/2022

The following table indicates the exact deadlines for sending in the complete registrations to BCR for each delivery time point, depending on whether complex surgery took place or not.

<b>Registration deadline:</b>		<b>If complex surgery:</b> Surgery date on or before:	<b>If no complex surgery:</b> MC/CM date on or before:
2021	Friday 9/04/2021	31/12/2020	31/01/2021
	Friday 1/10/2021	30/06/2021	31/07/2021
2022	Friday 8/04/2022	31/12/2021	31/01/2022
	Friday 30/09/2022	30/06/2022	30/06/2022

The 3-year convention ends on 30/06/2022, with 30/09/2022 as a final delivery time point.

Other registrations than the ones mentioned above can be sent already at the registrations deadlines on the condition that they are complete, but this is not mandatory!

## 2. Complex surgery registration form

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The following types of variables are used in the project:

- Autocomplete (AC): variable is automatically completed when it is entered (only in WBCR for the variable “Belgian referring hospital” in case of surgery).
- Date: variable containing 8 digits: 2 for the day, 2 for the month, 4 for the year (dd/mm/yyyy)
- Decimal: decimal number (1 decimal); **a point ‘.’ should be used as decimal separator in WBCR!**
- Multi-select (MS): variable that is to be chosen out of a limited selection list; multiple options can be selected. This variable is indicated by the following symbol in the registration form:
- Number (NUM): integer number
- Single-select (SS): variable that is to be chosen out of a limited selection list; only one option can be selected. This variable is indicated by the following symbol in the registration form:
- Text: free text field. Short text fields are limited to 255 characters, while large text fields can contain up to 32,750 characters. The large text fields are reserved for the MC/CM report, surgery report and pathology report.
- Formatted text (FT): variable that has a specific format (e.g. for the clinical trial variables EudraCT number and NCT number).

All variables are ‘necessary’ variables (mandatory to be filled out) unless stated otherwise (e.g. denoted by ‘if possible’ or ‘if applicable’). **It is strongly encouraged to fill out the free text fields in English as much as possible.**

Exception: the reports (MC/CM, pathology, surgery) should stay in their original language.

Additional, relevant information may be added to the registration in the **general comments field** (see section 2.6. General comments field).

### 2.1. Administrative patient data

For each new registration, the administrative patient data need to be provided.

In WBCR, when the national number for social security (INSZ/NISS) is filled out, the rest of the mandatory administrative patient data will be automatically completed. The health insurance number is only a mandatory variable if the patient does not have an INSZ/NISS.

## 2.2. General information

If no surgery has been performed, only this section should be completed, after which the registration can be terminated. This section includes general information on the patient: whether surgery was performed or not, the surgery indication, patient reports and referral information.

### 2.2.1. The patient did not undergo surgery

Name variable	Type	Answer options
Did the patient undergo surgery?	SS	No* Yes
*Indication:	SS (+Text)	Malignant tumour <sup>°</sup> Adenoma Cystadenoma Intra-ductal Papillary Mucinous Neoplasm with low grade or moderate dysplasia (8453/0) Other benign tumour. Please specify... Chronic pancreatitis Other. Please specify...
<sup>°</sup> Lesion to treat (in (peri-)pancreas):	SS	Primary tumour § Relapse of primary tumour Metastasis (primary tumour not located in/near (peri-)pancreas)) §
<sup>°</sup> Incidence date primary tumour/relapse:	Date	(dd/mm/yyyy)
<sup>°</sup> Primary tumour/relapse localisation:	FT	CXX.X (C00.0 - C80.9)
<sup>°</sup> Histological diagnosis primary tumour/relapse:	FT	XXXX/X (8000 - 9992)/(0-3)
<sup>°</sup> ,§ Clinical TNM primary tumour (cTNM):	FT	Complement cT, cN and cM
<sup>°</sup> ,§ Pathological TNM primary tumour (pTNM):	FT	Complement pT, pN and pM (if applicable)
*MC/CM date:	Date	(dd/mm/yyyy)
*MC/CM report, without patient identification variables:	Text	... (include as text)
*Was the patient referred?	SS	No Yes**
**Please specify the referring hospital (Belgian):	Text	...
**OR Please specify the referring hospital (Foreign):	Text	...

In case **the patient did not undergo 'complex' surgery** (i.e. when the patient was considered for surgery at the multidisciplinary consult, but the option 'surgery' was rejected or when surgery was initiated, but no 'complex' surgery was eventually performed), the option 'No' should be selected to the question: 'Did the patient undergo surgery?'.  
}

Secondly, the precise **indication** for which surgery was considered (i.e. the initial diagnosis of the patient) should be specified. Here, one out of seven options can be chosen, consisting of five tumoural conditions: 'Malignant tumour', 'Adenoma', 'Cystadenoma', 'Intraductal Papillary Mucinous Neoplasm with low grade or moderate dysplasia (8453/0)' or 'Other benign tumour', and two non-tumoural conditions: 'Chronic pancreatitis' and 'Other'. **Please note that a tumour with 'high grade dysplasia' or an 'in-situ' tumour should be registered as a malignant tumour!** To help distinguish between a malignant or benign tumour, an overview of the most common histological codes for malignant pancreatic tumours can be found in Appendix D.

- For the option 'Other benign tumour', the type of tumour should be further specified in a text field.
- For the option 'Other', the precise non-tumoural indication (full name) should also be filled out in a text field.
- For the option 'Malignant tumour', it must be specified if the **lesion to treat** in (peri-)pancreas is either:
  - a primary tumour,
  - a relapse of a previously diagnosed primary tumour (i.e. after a disease-free interval)
  - a metastasis of a primary tumour not located in or near the (peri-)pancreas.

Furthermore, several characteristics concerning the primary tumour (relapse) are asked, as listed in section "2.2.1.1 Malignant tumour characteristics".

Next, the **MC/CM date** and the report of the MC/CM where the decision was made to not perform surgery, should be provided.

Please extract/copy and paste the complete **textual MC/CM report** from the electronic patient dossier.

- For batch deliveries, the complete text can be included as one variable by extracting it as a whole into one Excel cell.
- For WBCR, in case of an error (e.g. via Ctrl + V), please paste the report via right-clicking within the large text field and selecting "Paste".

It is recommended to delete all patient identification variables from these reports (e.g. name, date of birth, address, INSZ/NISS number). If this would not be feasible, the BCR will have the means to do so. Hospital and doctor information can stay present.

Lastly, it should be indicated **whether the patient was referred**. The name of the hospital that referred the patient needs to be specified in one of two free text fields, depending on whether it was a **Belgian hospital** or a **hospital abroad** that referred the patient. For the hospital abroad, please also specify the country.

**The registration of patients who did not undergo surgery ends here (after completing the malignant tumour characteristics as mentioned in the next section).**

#### 2.2.1.1. Malignant tumour characteristics

Please note that the following variables should be completed differently depending on the type of lesion:

- Primary tumour: fill out for the primary tumour
- Relapse: fill out for the relapse (not the initial newly diagnosed primary tumour)
- Metastasis: fill out for the primary tumour (NOT the metastasis)

In WBCR, 4 of the 5 following variables are formatted text fields (FT) in case of no surgery and autocomplete variables (AC) in case of surgery. When you want to use the autocomplete function in case of no surgery, you can briefly select "Yes (surgery)" to find the correct answering option and then go back to "No (no surgery)" to fill out the correct answer (see WBCR help functions and this manual for format requirements).

The **incidence date of the primary tumour/relapse** is the date of the first diagnosis of the tumour (relapse). This is the date of (with decreasing priority):

1. First microscopic (histological/cytological) confirmation of the tumour (relapse)
  - a. Date of biopsy/cytology
  - b. Date of delivery of the biopsy/cytology by pathologist
  - c. Date that protocol was written by pathologist
2. First hospitalisation for the tumour (relapse)
3. First consultation for the tumour (relapse) (when there was no hospitalisation/ambulatory care)
4. First clinical or technical examination
5. Start of the treatment for the tumour (relapse)
6. Date of death (when no other information is available)

The following principles are kept in mind:

- The incidence date cannot be after the date of the first treatment for the primary tumour (relapse)
- In case of a **relapse**, this is the date of diagnosis of **the same tumour after a disease-free interval**
- Please provide the **exact date** of diagnosis for this variable! Whenever the date is unknown, e.g. in case of a referred patient, the expert centre should undertake the necessary steps to determine the exact date of diagnosis, e.g. by calling the referring hospital.

The **primary tumour/relapse localisation** (format CXX.X) is the organ or tissue ('exact' location) where the tumour or tumour relapse originated (this is not the location of metastasis). In case of a relapse, the localisation of the relapse must be entered here.

To code the primary tumour location the 'International Classification of Diseases for Oncology' (ICD-O-3) is used. Avoid the use of general codes (e.g. C80.9). If possible, please specify the exact location of the tumour (e.g. C25.1 body of pancreas) instead of a general organ code (e.g. C25.0 pancreas, NOS).

The **histological diagnosis of the primary tumour/relapse** (format XXXX/X) gives information about the cell type of the tumour and consists of 4 characters, ranging from 8000 to 9992 (histology), followed by / and 1 character which ranges from 0 to 3 (behaviour):

- The **histology** code is determined by examining the cells or tissue, preferably by microscopy. When a biopsy or surgery is performed, await the results of the microscopic examination. Please be as specific as possible.
- The **behaviour** indicates the degree of invasiveness of the tumour (2 = *in situ*; 3 = invasive). When a histological component is present within the tumour but showing a different index of behaviour, choose the highest index of behaviour.

If you cannot find the correct histological description or code, please use '8000' and specify further in the comment field. The histology is coded according to the ICD-O-3 (starting since incidence year 2002). For every tumour from 01/01/2020, the new ICD-O-3.2 update has to be used (see [http://www.iacr.com.fr/index.php?option=com\\_content&view=article&id=149:icd-o-3-2&catid=80&Itemid=545](http://www.iacr.com.fr/index.php?option=com_content&view=article&id=149:icd-o-3-2&catid=80&Itemid=545)). An overview of the most common histological codes can be found in Appendix D.

The **clinical (cTNM) and/or pathological TNM (pTNM)** should only be completed in case of a primary tumour or metastasis (not a relapse). The TNM describes the anatomical extent of the malignant disease and is based on the assessment of three components:

- T - the extent of the primary tumour
- N - the absence or presence and extent of regional lymph node metastasis
- M - the absence or presence of distant metastasis

It should be filled out according to the UICC guidelines, as described in the booklet 'TNM classification of malignant tumours' (TNM 7<sup>th</sup> edition for incidence years 2010-2016; TNM 8<sup>th</sup> edition starting from incidence year 2017). The addition of numbers (e.g. T1) and/or letters (T1a) to these three components indicates the extent of the malignant disease, for example:

Tis, T0, T1, T2, T3, T4                      N0, N1, N2, N3                      M0, M1

The letters cT, cN, cM, pT, pN, pM should not be entered or delivered.

The **cTNM** is the pre-treatment TNM which is determined at the time of diagnosis and is essential to select and evaluate therapy. The cTNM is based on evidence acquired before treatment and cannot be modified after the start of the treatment. The evidence arises from physical examination, imaging, endoscopy, biopsy, surgical exploration and other relevant examinations.

The **pTNM** is the postsurgical TNM which is used to guide adjuvant therapy and provide additional information for estimating the prognosis. The pTNM is based on evidence acquired before treatment, supplemented or modified by additional evidence acquired from surgery and pathological examination. It can only be fully completed when the patient received a complete resection of the primary tumour.

Please note:

- pTx = Primary tumour cannot be assessed histologically (e.g. no surgery was performed)
- pNx = Regional lymph nodes cannot be assessed histologically
- pM0 and pMx are not valid categories (i.e. the pM has 2 valid options: pM1 or being left open)
- If no information is available (e.g. no surgery performed), please register Tx Nx M (empty)
- It is often possible that the cTNM and pTNM are not the same
- If you want to register a ypTNM (i.e. after neoadjuvant treatment), register the information in the pTNM variable and include "ypTNM" in the general comments field.

## 2.2.2. The patient underwent surgery

Name variable	Type	Answer options
Did the patient undergo surgery?	SS	No Yes <sup>‡</sup>
<sup>‡</sup> Indication:	SS (+Text)	Malignant tumour* Adenoma Cystadenoma Intra-ductal Papillary Mucinous Neoplasm with low grade or moderate dysplasia (8453/0) Other benign tumour. Please specify... Chronic pancreatitis Other. Please specify...
* Lesion to treat (in (peri-)pancreas):	SS	Primary tumour § Relapse of primary tumour Metastasis (primary tumour not located in/near (peri-)pancreas) §
* Incidence date primary tumour/relapse:	Date	(dd/mm/yyyy)
* Primary tumour/relapse localisation:	AC	CXX.X (C00.0 - C80.9)
* Histological diagnosis primary tumour/relapse	AC	XXXX/X (8000 - 9992)/(0-3)
* ,§ Clinical TNM primary tumour (cTNM)	AC	Complement cT, cN and cM
* ,§ Pathological TNM primary tumour (pTNM)	AC	Complement pT, pN and pM
<sup>‡</sup> Type of FIRST diagnostic method:	SS	CT MRI PET PET/CT ERCP (Endoscopic Retrograde Cholangio-Pancreatography) EUS (Endoscopic UltraSound) Surgery (laparoscopy/laparotomy)
<sup>‡</sup> Date (of first diagnostic method):	Date	(dd/mm/yyyy)
<sup>‡</sup> Method to obtain first tissue sample for histopathological evaluation:	SS	ERCP (Endoscopic Retrograde Cholangio-Pancreatography) EUS (Endoscopic UltraSound) Surgery (laparoscopy/laparotomy/ 'Complex' Surgery) CT MRI
<sup>‡</sup> Date (on which the first tissue sample was obtained):	Date	(dd/mm/yyyy)
<sup>‡</sup> MC/CM date	Date	(dd/mm/yyyy)
<sup>‡</sup> Surgeon 1: number RIZIV/INAMI:	Number	... (11 numbers)
<sup>‡</sup> Surgeon 2: number RIZIV/INAMI:	Number	... (11 numbers, if applicable)
<sup>‡</sup> MC/CM report, without patient identification variables:	Text	... (include as text)

Name variable	Type	Answer options
¥Pathology report, without patient identification variables:	Text	... (include as text)
¥Surgery report, without patient identification variables:	Text	... (include as text)
¥Was the patient referred?	SS	No Yes <sup>¥¥</sup>
¥¥Please specify the referring hospital (Belgian):	AC (WBCR) Text (batch)	...
¥¥OR Please specify the referring hospital (Foreign):	Text	...
¥¥Was there a M(O)C/C(O)M at the referring hospital?	SS	No Yes <sup>°</sup>
<sup>°</sup> Date of the M(O)C/C(O)M at referring hospital:	DT	(dd/mm/yyyy)
¥¥Was the patient hospitalised at the referring hospital?	SS	No <sup>†</sup> Yes <sup>‡</sup>
<sup>†</sup> Date of last consultation prior to referral:	DT	(dd/mm/yyyy)
<sup>‡</sup> Date of discharge at the referring hospital:	DT	(dd/mm/yyyy)

If the patient underwent ‘complex’ surgery, one needs to fill out all the following variables of the registration form.

The precise **indication** for which surgery was performed (i.e. the initial diagnosis of the patient) should be specified. This variable is the same as in case of no surgery, with text fields to further specify the type of benign tumour or the other non-tumoural indication (full name) (section 2.2.1).

In case of a malignant tumour, it has to be specified if the **lesion to treat** is a primary tumour, a relapse of a previously diagnosed primary tumour (i.e. after a disease-free interval), or a metastasis of a primary tumour not located in or near the (peri-) pancreas. Furthermore, several characteristics concerning the primary tumour (relapse) are asked, as listed in section “2.2.1.1 Malignant tumour characteristics” (**incidence date, localisation, histological diagnosis, cTNM and pTNM**). Since all patients received complex surgery, **the pTNM is a mandatory variable** (if the TNM classification is applicable, after complete resection and if it does not concern a relapse). Please note that these variables should be completed: in case of a relapse for the relapse (not the initial newly diagnosed primary tumour); and in case of a metastasis for the primary tumour and NOT the metastasis.

The type of **FIRST diagnostic method** used, should be indicated, i.e. the ‘imaging’ method that was used at first diagnosis of the (peri-)pancreatic condition. Also, **the date of the first diagnostic method** is requested. The type of first diagnostic method is the first detection of a tumour or mass and not the confirmation of a malignancy or a more specific diagnosis. Please provide the **exact date** for this variable! Whenever the date is unknown, e.g. in case of a referred patient, the expert centre should undertake the necessary steps to determine the exact date of diagnosis, e.g. by calling the referring hospital.

Next, **the method to obtain the first tissue sample for histopathological evaluation** should be selected. It is possible that the first tissue sample was collected during the ‘complex surgery’ itself. The requested **date of the tissue sample** should then be the same as the date of surgery (see section 2.4.2).

Please provide the **exact date** for this variable! Whenever the date is unknown, e.g. in case of a referred patient, the expert centre should undertake the necessary steps to determine the exact date of diagnosis, e.g. by calling the referring hospital.

Next, the **date of the MC/CM** where the decision was made to perform surgery must be registered. In case of an emergency surgery, the date of surgery can be entered as the date of MC. More information has to be provided in the general comments field (“No MC performed because emergency surgery”). Also, the RIZIV/INAMI numbers of the **surgeon(s)** are asked (11 numbers).

The following three written reports should be provided in three large text fields:

- **MC/CM report** where the decision was made to perform surgery
- **Pathology report** of the resection specimen(s) from the complex surgery
- **Surgery report** of the complex surgery

Please extract/copy and paste the complete textual reports from the electronic patient dossier.

- For batch deliveries, the complete text can be included as one variable by extracting it as a whole into one Excel cell.
- For WBCR, in case of an error (e.g. via Ctrl + V), please paste the report via right-clicking within the large text field and selecting “Paste”.

It is recommended to delete all patient identification variables from these reports (e.g. name, date of birth, address, INSZ/NISS number). If this would not be feasible, the BCR will have the means to do so. Hospital and doctor information can stay present.

If **the patient was referred**, the following variables should be filled out:

- The name of the hospital that referred the patient needs to be specified, depending on whether it is a **Belgian hospital** or a **hospital abroad**. For the hospital abroad, please also specify the country. (In WBCR, an autocompleting list of Belgian hospitals is provided instead of a text field.)
- If there was a **M(O)C/C(O)M at the referring hospital**, the date of the M(O)C/C(O)M needs to be filled out.
- Finally, it should be indicated whether the patient was **hospitalised** at the referring hospital. In each case (answer option ‘No’ or ‘Yes’), an additional date should be provided: either ‘the date of discharge at the referring hospital’ for those patients that were effectively hospitalised, or ‘the date of last consultation prior to referral’ for those patients that were not hospitalised.

! Please note that we are aware of the fact that some of these referral data are not easily obtained. Nevertheless, experts have emphasised the importance of these variables to post-factum determine the time to treatment. Therefore, these variables are required to be filled out. Suggestions to acquire these data more easily:

- Ask the patient upon entry/first consultation and include the information in the medical dossier
- Ask the referring centre to include this information in the referral letter

## 2.3. Patient characteristics

### 2.3.1. Height and weight of the patient at the time of surgery

Name variable	Type	Answer options
Height:	DEC	... cm
Weight at time of surgery:	DEC	... kg

The patient's **height** (in cm) and **body weight** (in kg) at the time of surgery can be filled out as numeric values, up to one decimal.

### 2.3.2. WHO performance status at time of surgery

Name variable	Type	Answer options
WHO performance status at time of surgery:	SS	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

The **WHO (ECOG) performance score** is a classification system which evaluates the general welfare and daily activity of the patient. The answer options normally run from 0 to 5, where a score of 0 indicates a healthy person, while a score of 5 equals death. In this registration form, the answer options are limited from 0 to 4.

**Note:** In contrast with the MOC/COM registration (bijlage/annexe 55), this WHO status is the one at time of surgery and not the one at time of diagnosis of the malignant tumour.

Score 0	Asymptomatic, normal activity	Fully active, able to carry out all activities, as before the disease.
Score 1	Symptomatic, but ambulant	Limited in heavy physical activity but ambulatory and able to perform light or sedentary work (e.g. small house chores, office job).
Score 2	Symptomatic, bedbound <50% of the day	Ambulatory and able to take care of themselves, but impossible to perform work activities. 'Active' more than 50% of the day.
Score 3	Symptomatic, bedbound >50% of the day but not 100% bedbound	Only able to carry out a limited number of self-sufficiency tasks. Confined to bed or chair for 50% or more of the waking hours.
Score 4	Completely dependent (on caretakers): 100% bedbound	Totally disabled. Can no longer take care of themselves. Totally confined to chair or bed.

**Note:** When the WHO performance score is not specified but a Lansky or Karnofsky score is available, please use the following conversion table to determine the WHO performance score:

WHO score	Lansky/ Karnofsky score	Lansky level of performance ( $< 16$ years)	Karnofsky level of performance ( $\geq 16$ years)
0	100	Fully active; normal	Normal, no complaints or signs of disease
1	90	Minor restrictions in physically strenuous activities	Able to carry on normal activities; minor signs or symptoms of disease
	80	Active, but tires more quickly	Normal activity with effort
2	70	Restriction in and less time spent in active play	Care for self; unable to carry on normal activity or to do active work
	60	Up and around; minimal active play; keeps busy with quieter activities	Requires occasional assistance, but able to care for most of his needs
3	50	Gets dressed but lies around much of the day; no active play; able to participate in all quiet play and activities	Requires considerable assistance and frequent medical care
	40	Mostly in bed; participates in quiet activities	Disabled; requires special care and assistance
4	30	In bed; needs assistance even with quiet play	Severely disabled; hospitalisation indicated though death non-imminent
	20	In bed, often sleeping; play limited to very passive activities	Very sick; hospitalisation necessary; active supportive treatment necessary
	10	Does not get out of bed; does not play	Moribund

### 2.3.3. ASA score (pre-operative risk)

Name variable	Type	Answer options
ASA score (pre-operative risk):	SS	1 - Healthy person
		2 - Mild systemic disease, normal activity
		3 - Serious systemic disease, limited activity
		4 - Life-threatening illness, handicapped
		5 - Dying

The American Society of Anesthesiologists or **ASA score** is a global score that assesses the physical status of patients before surgery. Therefore, this score estimates the pre-operative risk.

### 2.3.4. Comorbidity - Charlson Modified Index

Name variable	Type	Answer options
Comorbidity (prior to surgery) - Charlson Modified Index (not the current surgery indication!):	SS	No
		Yes*
*Type of comorbidity ( <b>Charlson Modified index</b> ):	MS	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 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)		

'Comorbidity' is described as the presence of one or more additional medical conditions, co-occurring with the primary condition (here: the surgery indication) but not caused by it. The comorbidities should already be present prior to the complex surgery (e.g. (another) malignant tumour). These comorbidities are important to register because they may affect patient outcome. **The comorbidities do not include the current surgery indication!**

The **Charlson Comorbidity Index** (CCI) is used to collect the comorbidity information. It is among the best-known and widely used indices of comorbidity and consists out of 19 conditions. A single comorbidity score for a patient can be calculated based on the indicated comorbidities. The index is based on the International Classification of Diseases (ICD) diagnosis codes found in administrative data. For your information, a non-exhaustive list of ICD-10 codes for each comorbidity is provided in Appendix A.

Please indicate which of the specified conditions could have an influence at the time of surgery. The timeframe in which the comorbidity was or should be present, is dependent on the type of comorbidity:

- Most items relate to the past medical history of the patient (e.g. myocardial infarction, peptic ulcer, ...) and should not necessarily be active at the time of surgery.
- For some items related to specific organ functions (e.g. renal disease, diabetes) the situation at the time of surgery should be considered. For example: acute kidney failure in the past medical history with a complete normal kidney function at the time of surgery is not an increased risk factor and should not be registered. The same is true for gestational diabetes.
- Only indicate a tumour or malignancy when it is diagnosed or treated within 5 years of the complex surgery. In this case, please also specify the type of malignancy and the incidence date in the general comments field.



**Note:** Other comorbidities or additional information can be specified in the general **comments field** of every registration.

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

Name variable	Type	Answer options
Is the patient <u>currently</u> (= at time of surgery) treated with antithrombotic medication?	SS	No
		Yes*
*Please specify the type of medication (ATC-codes):	MS	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)

For a limited number of patients treated with **antithrombotics**, this treatment cannot be stopped before/during surgery. This can complicate the surgery and increase the risk of post-operative complications, such as bleeding. If the patient is being treated with antithrombotics or if the antithrombotics therapy was not stopped in a timely manner according to evidence-based practices for the specific drug (please consult the responsible surgeon when unsure), the answer option ‘Yes’ should be indicated and the **type(s) of medication (ATC codes)** should be provided. The ATC code of a specific drug can be found on the website of the WHO ([https://www.whocc.no/atc\\_ddd\\_index/?code=B01A](https://www.whocc.no/atc_ddd_index/?code=B01A)). A non-exhaustive list has been added in Appendix B.

*Example:* Treatment with warfarin should be stopped at least 5 to 7 days before complex surgery. When treatment is stopped less than 5 days to surgery, it might not be long enough to ensure normal clotting, therefore, this also presents an increased risk factor. In this case, the options “Yes” and “B01AA: Vitamin K antagonists (e.g. warfarin)” should be selected.

## 2.4. Surgery

### 2.4.1. Prior treatment modalities

Name variable	Type	Answer options
Did the patient receive any other treatment modality before this surgical procedure?	SS	No Yes*
*Please specify the other treatment modality:	MS (+Text)	Chemotherapy** Radiotherapy <sup>‡</sup> Prior abdominal surgery <sup>§</sup> Other treatment modality. Please specify...
**Start date chemotherapy:	Date	(dd/mm/yyyy)
**Date latest (chemo) treatment:	Date	(dd/mm/yyyy)
**Type of chemotherapy:	SS (+Text)	Gemcitabine-based regimen FOLFIRINOX-based regimen (5-Fluorouracil, Leucovorin, Irinotecan and Oxaliplatin) Other. Please specify...
<sup>‡</sup> Start date radiotherapy:	Date	(dd/mm/yyyy)
<sup>‡</sup> Date latest radiotherapy treatment:	Date	(dd/mm/yyyy)
<sup>§</sup> Type of the prior abdominal surgery:	Text	...
<sup>§</sup> Date of the latest abdominal surgery:	Date	(dd/mm/yyyy)

Because **prior treatments of the patient** might significantly affect the outcome of complex surgery, it is important to indicate any other treatment modality prior to surgery. The type of treatment(s) should be specified (multi-select variable with min. 1, max. 4 answer options):

- If the patient previously received **chemotherapy** and/or **radiotherapy** for this tumour/indication, the start date of the treatment and the date of the latest treatment should be provided. For chemotherapy also the type of treatment should be specified.
- If the patient previously had abdominal **surgery** (for this or another indication), the type of prior surgery and the date of the latest surgery should be provided.
- If the patient previously received **any other treatment modality** that could affect the pancreas and/or peri-ampullary region, the name and the date of the treatment are requested.

### 2.4.2. Date of surgery

Name variable	Type	Answer options
Date of surgery	Date	(dd/mm/yyyy)

The **date of surgery** is the date on which the 'complex' (peri-)pancreatic surgery was performed in the expert centre.

### 2.4.3. Type of surgery

Name variable	Type	Answer options
Type of surgery:	SS	Minimally Invasive Surgery (MIS)* Open Conversion from MIS to open surgery**
*Please specify the type of 'minimally invasive surgery':	SS	Total laparoscopic Total robotic Hybrid (laparoscopic + robotic)
**Reason for conversion?	Text	...

For the **type of surgery**, one of three answer options are possible. Open surgery is standard today, but minimally invasive surgery (MIS) can be performed as well. In case of a **MIS**, it should be further specified whether the surgery was 'total laparoscopic', 'total robotic' or 'hybrid' (i.e. a surgery that is partially laparoscopic and partially robotic). Hybrid MIS usually involves laparoscopic resection and robotic reconstruction. In case of a **conversion**, the reason should be provided in a short text field.

### 2.4.4. Nomenclature code

Name variable	Type	Answer options
Nomenclature code:	SS	242830-242841: Pancreaticoduodenectomy* 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 <sup>§</sup>
*Pancreaticoduodenectomy?	SS	Pancreaticoduodenectomy Total pancreatectomy <sup>‡</sup>
<sup>‡</sup> Localisation lesion:	SS	Pancreatic head/peri-ampullary region Pancreatic body or tail
<sup>§</sup> Localisation tumour:	SS	Pancreatic head/peri-ampullary region Pancreatic body or tail

This single-select variable indicates the **nomenclature codes** that are used in the convention between the RIZIV/INAMI and the expert centre. For '**pancreaticoduodenectomy**', it should be further indicated whether a pancreaticoduodenectomy ('Whipple' procedure) was performed or a 'total pancreatectomy'. The Whipple procedure is a major surgical operation most often performed to remove tumours of the head of the pancreas. It can also be used for the treatment of chronic pancreatitis. Surgical removal of the head of the pancreas also necessitates removal of the duodenum, proximal jejunum, gallbladder and, occasionally, part of the stomach. In case a 'total pancreatectomy' was performed, it should be specified whether the lesion was located in the pancreatic head/peri-ampullary region or in the pancreatic body/tail. For '**enucleation of a pancreatic tumour**', the localisation of the tumour should be indicated: 'pancreatic head/peri-ampullary region' or 'pancreatic tail'.

### 2.4.5. Simultaneous vascular resections

Name variable	Type	Answer options
Simultaneous vascular resection?	SS	No
		Yes*
*Please specify the type of vascular resection:	MS	Superior mesenteric vein/portal vein (SMV/PV) resection**
		Arterial resection <sup>§</sup>
**Specify the type of 'superior mesenteric vein/portal vein (SMV/PV) reconstruction':	SS	Primary wedge reconstruction
		Primary end-to-end reconstruction
		Vascular autograft interposition
		Vascular allograft interposition
		Synthetic/prosthetic interposition
		Peritoneal patch wedge-reconstruction
		No reconstruction
<sup>§</sup> Specify the type of 'arterial resection'	SS	Hepatic artery
		Coeliac trunk
		Superior mesenteric artery (SMA)
<sup>§</sup> Specify the type of 'arterial reconstruction'	SS	Primary wedge reconstruction
		Primary end-to-end reconstruction
		Vascular autograft interposition
		Vascular allograft interposition
		Synthetic/prosthetic interposition
		No reconstruction

(Peri-)pancreatic surgery may involve **simultaneous vascular resection** (e.g. in the case of vascular tumour contact). This may affect patient outcome. If a '**superior mesenteric vein/portal vein (SMV/PV) resection**' was performed, the method of reconstruction should be indicated. If there was an '**arterial resection**', it should be specified whether it involved the 'hepatic artery', the 'coeliac artery' a.k.a. coeliac 'trunk' or the 'superior mesenteric artery' (SMA). Also here, the type of reconstruction should be indicated. Both types of resection can be indicated (multi-select variable with min. 1, max. 2 options).

### 2.4.6. Simultaneous other organ resections

Name variable	Type	Answer options
Simultaneous other organ resection?	SS	No
		Yes*
*Please specify the other organ resection:	MS (+Text)	Colon
		Stomach
		Sur-renal gland
		Spleen
		Other. Specify...

The (peri-)pancreatic surgery can be accompanied by the simultaneous resection of other organs, for example in the case of metastasis of a malignant tumour. The answer option 'sur-renal gland' should be indicated when one or both adrenal gland(s) was/were removed. If the other resection(s) do not apply to these listed organs, the option 'other' should be indicated and further specified in a short text field. This is a multi-select variable (min. 1, max. 5 options).

In case of a classical Whipple surgery in which (part of) the stomach was also removed, please indicate for the question ‘Simultaneous other organ resection?’ ‘Yes’ and select the option ‘Stomach’. In this way a clear distinction can be made between a classical Whipple procedure and a pylorus-preserving pancreaticoduodenectomy (PPPD).

#### 2.4.7. Resection (pathology)

The following variable only needs to be filled out for a malignant tumour.

Name variable	Type	Answer options
Was there residual disease (at the resection margins)?	SS	R0: tumour-free resection margin > 1mm
		R1 indirect: tumour-free resection margin < 1mm
		R1 direct: tumour involvement of the resection margin
		R2: macroscopic tumour transection

Normally, the resection margin is classified according to the UICC TNM classification (8th Edition): R0, R1 or R2. However, as the magnitude of the resection margin has a significant impact on the survival of patients who underwent pancreatic cancer resection, the resection margin in case of pancreatic cancer is classified as defined by the table above. The option R0 is applicable when the tumour-free resection margin is > 1 mm and the option R1 indirect for when the tumour-free resection margin is > 0 mm but ≤ 1 mm.

#### 2.4.8. Lymphadenectomy

Name variable	Type	Answer options
Lymphadenectomy?	SS	No
		Yes*
*Region lymphadenectomy:	MS	Peri-tumoural
		Coeliac trunk
		SMA origin (superior mesenteric artery)
		Para-aortic
Number of lymph nodes retrieved:	NUM	...
Number of lymph nodes with tumoural involvement:	NUM	....

If **lymph node removal** was performed, the **region(s) of the lymphadenectomy** should be further specified. This is a multi-select variable with min. 1, max. 4 answer options.

Also, the total number of **lymph nodes retrieved** and **lymph nodes with tumoural involvement** needs to be indicated if there was a lymphadenectomy (no decimals allowed).

## 2.5. Post-surgery

### 2.5.1. Post-operative complication(s)

Name variable	Type	Answer options
Postoperative complications (90 days post-op, in-hospital complications):	SS	No
		Yes*
*Please specify the type of post-operative complication(s):	MS (+text)	Clinically relevant pancreatic fistula <sup>§</sup>
		Haemorrhage <sup>°</sup>
		Delayed gastric emptying <sup>¥</sup>
		Bile leakage <sup>‡</sup>
		Intra-abdominal abscess
		Other. Please specify...
§Please specify the grade of the clinical pancreatic fistula:	SS	ISGPS grade B
		ISGPS grade C
°Please specify the grade of the haemorrhage:	SS	ISGPS grade A
		ISGPS grade B
		ISGPS grade C
¥Please specify the grade of the delayed gastric emptying:	SS	ISGPS grade A
		ISGPS grade B
		ISGPS grade C
‡Please specify the grade of the bile leakage:	SS	ISGLS grade A
		ISGLS grade B
		ISGLS grade C

In this section of the registration form, the possible **post-operative complications during the 90 days post-operative period** are evaluated. All complications (of any Clavien-Dindo grade or 'TOSGS', see also section 2.5.2) that occurred during the 90-day post-operative period should be registered if they occurred or were present during a hospital stay, whether it was during the hospitalisation after the complex surgery or during re-admission in the same or another hospital than where the complex surgery was performed.

*Example:* A patient was discharged after surgery but re-admitted with delayed gastric emptying in the expert centre on post-op day 44. The complication delayed gastric emptying should be registered.

The type of post-operative complication(s) should be indicated (multi-select variable with min. 1, max. 6 answer options).

- For a '**clinically relevant pancreatic fistula**', the postoperative pancreatic fistula (POPF) should be graded according to the 2016 update of the ISGPS (International Study Group of Pancreatic Fistula) cfr. Bassi et al. (ISGPS), *Surgery*, 2017 (see Flow Chart in Appendix C):
  - o 'Grade B' requires a change in the postoperative management; drains are either left in place >3 weeks or repositioned through endoscopic or percutaneous procedures.
  - o 'Grade C' refers to those POPFs that require reoperation or lead to single or multiple organ failure and/or mortality attributable to the pancreatic fistula.
- For a '**hemorrhage**', the postpancreatectomy haemorrhage (PPH) should be graded according to the ISGPS definitions cfr. Wente et al. (ISGPS), *Surgery*, 2007 (see Table 1 in Appendix C):
  - o The three different grades of PPH ('Grade A', 'Grade B' and 'Grade C') were defined according to the time of onset, site of bleeding, severity and clinical impact.
- '**Delayed Gastric Emptying**' (DGE) after pancreatic surgery should be graded according to ISGPS grades cfr. Wente et al. (ISGPS), *Surgery*, 2007 (see Table 2 in Appendix C):

- The three different grades ('Grade A', 'Grade B' and 'Grade C') were defined based on the impact on the clinical course and on postoperative management.
- '**Bile leakage**' should be graded according to the International Study Group of Liver Surgery (ISGLS) cfr. Koch et al. (ISGLS), *Surgery*, 2011 (see Table 3 in Appendix C):
  - 'Grade A' causes no change in patients' clinical management.
  - 'Grade B' requires active therapeutic intervention but is manageable without relaparotomy.
  - 'Grade C' requires relaparotomy.

## 2.5.2. Post-operative complications: the Clavien-Dindo grade

This variable should only be filled out if the patient had post-operative complications (see section 2.5.1).

Name variable	Type	Answer options
* <u>General</u> Clavien-Dindo classification (90 days post-op, in-hospital complications) :	SS	TOSGS grade 1
		TOSGS grade 2
		TOSGS grade 3a
		TOSGS grade 3b
		TOSGS grade 4a
		TOSGS grade 4b
		TOSGS grade 5

The **Clavien-Dindo (CD) system** or therapy-oriented severity grading system (TOSGS), originally described in 2004 (cfr. Dindo et al., *Annals of Surgery*, 2004), is widely used for grading adverse events (i.e. complications) which occur as a result of surgical procedures. It has become the standard classification system for many surgical specialties. One general CD grade needs to be provided for the indicated complications of the patient, if at least one post-operative complication was indicated. **The highest CD grade during the 90-day post-op period should be indicated.** The specifications of the grading system are shown below:

Grade	Definition
<b>Grade I</b>	Any deviation from the normal post-operative course not requiring surgical, endoscopic or radiological intervention. This includes the need for certain drugs (e.g. anti-emetics, antipyretics, analgesics, diuretics and electrolytes), treatment with physiotherapy and wound infections that are opened at the bedside
<b>Grade II</b>	Complications requiring drug treatments other than those allowed for Grade I complications; this includes blood transfusion and total parenteral nutrition (TPN)
<b>Grade III</b>	Complications requiring surgical, endoscopic or radiological intervention <ul style="list-style-type: none"> <li>- <b>Grade IIIa</b> - intervention not under general anaesthetic</li> <li>- <b>Grade IIIb</b> - intervention under general anaesthetic</li> </ul>
<b>Grade IV</b>	Life-threatening complications; this includes CNS complications (e.g. brain haemorrhage, ischaemic stroke, subarachnoid haemorrhage) which require intensive care, but excludes transient ischaemic attacks (TIAs) <ul style="list-style-type: none"> <li>- <b>Grade IVa</b> - single-organ dysfunction (including dialysis)</li> <li>- <b>Grade IVb</b> - multi-organ dysfunction</li> </ul>
<b>Grade V</b>	Death of the patient

### 2.5.3. Re-operation

Name variable	Type	Answer options
Re-operation necessary?	SS	No Yes*
*Type of surgery:	Text	...
*MC/CM report, without patient identification variables (if applicable):	Text	... (include as text)
*Pathology report, without patient identification variables (if applicable):	Text	... (include as text)
*Surgery report, without patient identification variables:	Text	... (include as text)

In some cases, **re-operation** can be necessary. When a re-operation was performed during the 90 days post-operation period, it should be indicated. The type of re-operation should be specified in a short text field. Furthermore, the following reports of this surgery should be included, preferably without patient identification variables:

- **The MC/CM report (if applicable)** where the decision was made to perform the redo surgery
- **The pathology report (if applicable)** of the resection specimen(s) from the redo surgery
- **The surgery report** of the redo surgery

In case the MC/CM and/or pathology report are not available, N/A should be written in the text fields of the WBCR application or in Excel for batch deliveries.

### 2.5.4. Discharge date after surgery

Name variable	Type	Answer options
Was the patient discharged after surgery during the 90-day post-op period?	SS	No Yes*
*Discharge date after surgery:	Date	(dd/mm/yyyy)
*Destination?	SS	Home Rehabilitation centre Nursing home Transfer to another hospital**
**Name of the hospital:	Text	...
**Because of complications?	SS	No Yes

It should be indicated whether the patient was **discharged** from the expert centre after the surgery during the 90-day post-operative period. If so, at least three extra questions will have to be completed in the registration form: the discharge date (from the expert centre) after surgery, the destination of the patient after the discharge and whether there has been a re-admission within 30 days after discharge (see section 2.5.5). With respect to the destination of the patient, four answer options are possible. If the destination cannot be indicated in one of these options, please indicate 'Home' and specify the destination in the general comments field. In case the patient was transferred to another hospital, the name of the hospital should be specified. In addition, it should be indicated whether the transfer was because of complications or not.

### 2.5.5. Re-admission within 30 days after discharge

This variable should only be filled out if the patient was discharged after surgery (see section 2.5.4).

Name variable	Type	Answer options
Re-admission within 30 days after discharge?	SS	No
		Unknown
		Yes, in the hospital where the surgery was performed <sup>°</sup>
		Yes, in another hospital <sup>¥</sup>
<sup>°</sup> Reason for re-admission	Text	...
<sup>¥</sup> Reason for re-admission	Text	...

In case there was a **re-admission within 30 days after discharge**, it should be indicated whether this re-admission was in the expert centre or in another hospital, and the reason for re-admission should be specified in a short text field. **Please note that the option 'Unknown' should be selected if the patient was discharged from the expert centre later than post-op day 60 and less than 30 days before the completion of the registration form!**

### 2.5.6. Did the patient die during the post-operative period?

Name variable	Type	Answer options
Did the patient die during the 90-day post-op period?	SS	No
		Yes*
*In-hospital?	SS	No
		Yes
*Date of death	Date	(dd/mm/yyyy)
*Cause of death	Text	...

In order to be able to evaluate the **30-day, 90-day, and in-hospital post-operative mortality**, the death of the patient should be indicated if this occurred within 90 days of complex surgery. It should be specified whether the death was in-hospital or not. Moreover, the date of death should be provided as well as the cause of death.

### 2.5.7. Adjuvant therapy

This variable only needs to be filled out for a malignant indication.

Name variable	Type	Answer options
Was there adjuvant therapy after surgery?	SS	No
		Yes*
*Please specify the type of adjuvant therapy:	SS	Systemic therapy
		Radiotherapy
		Combined therapy (systemic + radiotherapy)

This variable informs about **adjuvant therapy** after the surgery (with no specification about the timing of the onset of the adjuvant therapy). The type of adjuvant therapy should be specified. Answer options are 'systemic therapy' (e.g. chemotherapy), 'radiotherapy' or 'combined therapy' (i.e. systemic and radiotherapy). Please note that the option 'Yes' only needs to be indicated if the patient effectively received adjuvant therapy. If adjuvant therapy was planned, but the patient did not effectively receive the therapy, the option 'No' should be indicated.



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

Name variable	Type	Answer options
Was the patient included in a clinical trial for (neo)adjuvant therapy or surgery?	SS	No
		Unknown
		Yes*
*Please specify the EudraCT number:	FT	YYYY-NNNNNN-CC
*OR Please specify the NCT number:	FT	NCTNNNNNNNN

The last variable from this registration form evaluates whether the patient was included in a **clinical trial** for (neo)adjuvant therapy or surgery. If this is not clear, the answer option 'Unknown' should be selected. In case the option 'Yes' was chosen, the EudraCT or the NCT number of the clinical trial should be specified:

- The EudraCT number has the format YYYY-NNNNNN-CC, where: 1) YYYY is the year in which the number is issued. 2) NNNNNN is a six digit sequential number. 3) CC is a check digit.
- The format for the ClinicalTrials.gov registry number is "NCT" followed by an 8-digit number, e.g.: NCT00000419.

If a patient was included in more than 1 clinical trial, the one for surgery should be registered in this variable and the remaining should be mentioned in the general comments field.

### 2.6. General comments field

A general 'comments' field is provided, both in the WBCR application and in the batch file. All relevant, additional information may be added to the registration in this field.

This 'comments' field can be found here:

- WBCR: at the bottom of the online registration form
- Batch file: at the end of the registration

Please fill out this field in English as much as possible.

## 3. Frequently asked questions (FAQ)

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### 3.1. Registration in general

#### 3.1.1. How can registrations be delivered to BCR?

Two modes of registration are possible for this project, either delivery via the online WBCR application or through batch file (see section 1.3 for all specifications).

- It is recommended to send in patient registrations through **WBCR** as several checks have been built into the registration application to reduce the frequency of registration errors. Please consult our Complex Surgery WBCR manual for more information on how to access and work in WBCR.
- If registrations are delivered to BCR in **batch**, we request using the specific order of variables and the predefined names, as provided in the Excel template. This will allow us to uniformly process the data and lowers the risk of errors. The data transfer itself will occur through BCR's 'secure file transfer protocol (sFTP)' server (<https://sftp.kankerregister.be/>). An sFTP login and password will be provided to the person who is responsible for delivering the registrations to BCR.

Both the WBCR manual and the Excel batch file template can be consulted and downloaded from the BCR website: [https://kankerregister.org/ComplexSurgery\\_nl](https://kankerregister.org/ComplexSurgery_nl) or [http://www.kankerregister.org/ComplexSurgery\\_fr](http://www.kankerregister.org/ComplexSurgery_fr).

#### 3.1.2. What is the timeframe in which registrations should be completed at the expert centre?

These timeframes have been defined in the RIZIV/INAMI convention (see section 1.4 for more information):

- For patients who underwent complex surgery, registrations should be completed within 100 days after surgery.  
It should be noted that **registrations can only be completed at the earliest 90 days after surgery**, because the 90-day post-operative complications need to be evaluated. If registrations are delivered before the end of the 90-day post-op period, it is the responsibility of the expert centre to complete potentially missing information if necessary (see FAQ 3.1.12).
- For patients who did not undergo surgery, registrations should be completed within 60 days after the multidisciplinary consult (MC/CM), where it was decided not to perform surgery.

#### 3.1.3. At what time should registrations be delivered to the BCR?

The BCR will ask to deliver all completed registrations **2 times per year**, for both modes of delivery (WBCR and batch file). Note that before the September 2020 update, this used to be 4 times per year. Complete registrations will need to be transferred to the BCR **every 6 months**, more specifically at the latest on a specific Friday in the beginning of April or the end of September:

- Friday 9/04/2021
- Friday 1/10/2021
- Friday 8/04/2022
- Friday 30/09/2022

More information and specifications can be found in section "1.4. Registration time points". The complex surgery registration can only be sent in after the 90-day post-op period has been completed.

Only completed registrations can be delivered to the BCR at the bi-yearly time points (see section 1.4 for a detailed overview). On each time point, the following registrations are mandatory to be delivered:

- In case of surgery:
  - o Surgery date until 31/12 (for the deadline in the beginning of April)
  - o Surgery date until 30/06 (for the deadline at the end of September)
- In case of no surgery:
  - o MC/CM date until 31/01 (for the deadline in the beginning of April)
  - o MC/CM date until 31/07/2021 or 30/06/2022 (for the deadline at the end of September)

Other registrations than the ones mentioned above can be sent already at the registration deadlines on the condition that they are complete, but this is not mandatory!

### 3.1.4. For which patients should registrations be delivered to the BCR at the quarterly time points?

The inclusion criteria have been defined in the convention and are summed up in section 1.1. Please note that all patients for whom complex surgery of the (peri-)pancreas has been considered, should be registered, even if it has been decided not to perform surgery.

### 3.1.5. What kind of information should be delivered to BCR at the quarterly time points?

Since the September 2020 update, only the **project-specific dataset** of the variables related to complex surgery should be delivered to the BCR (see chapter 2 for detailed information on the requested variables).

Please note that this dataset should be completed for all indications, even if no complex surgery eventually took place and that every complex surgery has to be registered, even if the disorder is not within the defined topographies!

The dataset for the specific registration of complex surgery (v2.0) is available on the website of BCR: [https://kankerregister.org/ComplexSurgery\\_nl](https://kankerregister.org/ComplexSurgery_nl) or [http://www.kankerregister.org/ComplexSurgery\\_fr](http://www.kankerregister.org/ComplexSurgery_fr). Within this dataset, the following textual reports are required:

- The written MC/CM report
- The written surgery report (in case of surgery)
- The written pathology report (in case of surgery)

### 3.1.6. How should I send in the MC/CM, pathology and surgery reports to BCR?

**It is recommended to delete all patient identification variables from these reports (e.g. name, date of birth, address, INSZ/NISS number).** If this would not be feasible, the BCR will have the means to do so. It is recommended to keep hospital and doctor information.

These reports should be delivered as one text variable in the following manner:

- In WBCR: Large text fields are provided wherein the complete textual report can be copy-pasted from the electronic patient dossier (maximum 32,750 characters). In case of an error (e.g. via Ctrl + V), please paste the report via right-clicking within the large text field and selecting "Paste".
- In the batch file: The complete textual report can be included as one variable by extracting it as a whole into one Excel cell from the electronic patient dossier. A cell in Excel can hold up to 32,750 characters.

**Note:** If a re-operation was performed, the surgery report and if applicable the follow-up MC/CM and pathology report should be included in a similar manner (see section "2.5.3. Re-operation necessary?").

### 3.1.7. Should patients be registered who were discussed at the MC/CM, but for whom no surgery was performed?

Yes, also for these patients a specific but minimal dataset should be registered, consisting of:

- Indication + in case of a malignancy some malignant tumour characteristics
- Textual MC/CM report
- Referral + referring hospital

### 3.1.8. How to register a case for which the complex surgery was started but could not be completed?

This situation can arise when during or at the start of the surgery it becomes clear that for example the lesion is too close to certain important anatomical structures to perform a resection (e.g. heart, trachea, blood vessels). In this case, for the question 'Did the patient undergo surgery?' the option 'No' should be chosen and the specific situation should be explained in the general comments field (see section 2.6).

### 3.1.9. What if no complete follow-up information is available for the 90-day post-operative period?

The aim of the convention is that patients are actively followed up by the expert centre that performed the complex surgery. Even if the patient is transferred to or re-admitted in another hospital, the expert centre should be kept up to date about the follow-up of the patient, so that all the necessary information can be registered.

Please note that the convention mentions "Service Level Agreements (SLA)" between the expert centre and the referring hospital(s), in which the follow-up of the patient can be arranged in detail. It is useful to also include agreements about the communication of the follow-up information into the SLA.

When it is impossible to obtain all follow-up information (i.e. the patient is "lost to follow-up"), this should be explicitly mentioned in the general comments field (see section 2.6), together with the reason and the date after which the patient was lost to follow-up. The number of patients that is lost to follow-up should be extremely low.

Please note that an extra effort should be made to register all follow-up information for the foreign patients (with a Belgian health insurance), because for these patients we have no means to gather information afterwards.

### 3.1.10. In what language should I register?

Please fill out all text variables in English, as well as the general comments field.

Exception: The MC/CM, surgery and pathology reports do not have to be in English and can be provided in Dutch or French (the original language).

### 3.1.11. Will I receive feedback on the patient registrations that were sent to BCR?

After each delivery time point, feedback will be sent about the completeness of the registrations. If data are missing, you can be asked to complete this information.

### 3.1.12. How can I make corrections to sent registrations?

Once a registration has been sent to BCR, it is impossible to modify the registered information in the BCR database yourself. The BCR should be contacted to make the necessary corrections in the database. **For WBCR users, please note that these corrections will not be visible when performing a WBCR download.**

Depending on the mode of data delivery, the following options are possible:

#### WBCR and batch:

- Preferred: Via our secured online sFTP server (especially if it concerns a large number of corrections). Please include the full registration (batch format or WBCR download format) and indicate the changes in colour. Please contact the BCR to ask for a sFTP login name and password to send the data.
- Preferred: Perform a new, complete and corrected registration, mentioning in the general comments field: "corrected version".
- Changes can be communicated via telephone to your Cancer Registry contact person (only if it concerns few errors). You will also be asked to confirm the changes via email, using ONLY the following information to identify the correct registration, **without other patient identification variables:**
  - o WBCR: WBCR ID (see next paragraph)
  - o Batch: the batch file row location or another unique batch identifier, with MC/CM date as control variable

#### WBCR only:

- Only if the registration in question was sent via WBCR: via email to the project email address.  
**Very important: Patient identification information (such as name, INSZ/NISS, date of birth, ...) cannot be communicated via email for privacy and confidentiality reasons!** Please only mention the WBCR reference/ID number (which is automatically assigned to each sent registration) to identify the registration in which corrections need to be carried out. If you download your registrations in an Excel file from WBCR, the WBCR reference/ID number can be found in column A.

In all cases, please clearly state for each registration which variable needs to be corrected, which incorrect information was first registered and to what this should be corrected.

### 3.1.13. What if the patient does not have an INSZ/NISS number?

Only in very rare cases a patient will not have an INSZ/NISS number. In this case, please make sure to include all other requested administrative patient data, so that the patient can unambiguously be identified. If the patient is not domiciled in Belgium, please indicate the other country and the foreign zip code.

For delivery via WBCR it will also be required to fill out the health insurance number or another unique identification number.

### 3.1.14. Should patients not domiciled in Belgium or without a Belgian health insurance be registered?

Only patients with a Belgian health insurance are eligible for reimbursement and are mandatory to be registered. The country of residence or the availability of a National number for social security (INSZ/NISS) does not matter.

Patients without a Belgian health insurance that undergo complex surgery, may be registered but this is not mandatory.

### 3.1.15. Is it possible to have multiple registrations for one patient?

Yes, it is possible that multiple complex surgery registrations need to be performed. However, please note that the RIZIV/INAMI will only reimburse 1 MC/CM per patient for the duration of the convention (3 years), and this once for the oesophagus and once for the pancreas.

*Example:* When complex surgery has been considered for a patient at the MC/CM, but not performed or planned at that time, a specific registration should be performed within 60 days of the MC/CM, in which for the question 'Did the patient undergo surgery?' the answer option 'No' should be selected. However, if the patient was later reconsidered for complex surgery at another MC/CM (e.g. salvage after post-radical chemo- and/or radiotherapy), a second specific registration should be performed ('Did the patient undergo surgery?' → 'Yes')

### 3.1.16. In case of a collaboration in which not all centres perform their own registrations, how should the centre that performed the surgery be identified?

This question is only relevant in case of a collaboration and for patients discussed at an MC/CM or with surgery in the period June-December 2019:

- **WBCR:** Please include for each registration the name of the hospital that performed the surgery in the general comments field (see section 2.6) in a structured way: "Registration for *Hospital X*". The name of the registering hospital is automatically transferred to BCR.
- **Batch:** Indicate the correct hospital (i.e. where the complex surgery took place) for the variable 'Hospital'. Do not indicate the hospital that performed the registration (if this is different from where the complex surgery took place).

Starting from 2020 the RIZIV/INAMI convention mentions that solely the head expert centres within the collaborations will still perform complex surgeries. For new cases from 2020 onwards, only the head expert centre within a collaboration will thus perform new registrations. The last delivery time point for collaborating centres will be at the end of March 2020.

### 3.1.17. How does the September 2020 update affect the general MOC/COM registrations to be submitted in June (for the mandatory, yearly registration for the Oncological Care Programs)?

For all malignant tumours, the MOC/COM registration, which is ongoing in all centres with oncological care programs since 2003 is requested by BCR once a year in June

For WBCR registrations started before the September 2020 update, it is not necessary to send in these completed MOC registrations a second time (at the general query in June), provided that they are complete (including the full treatment (plan) and pTNM if possible). Nevertheless, double registrations would certainly not be a problem.

For registrations after the September 2020 update, there is no impact anymore on the general MOC/COM registrations: All malignant tumours should be delivered yearly in June, even if this case was registered in the context of complex surgery.

### 3.1.18. Does this project registration impact the mandatory registration of all malignancies by the pathology labs?

No, there is no impact. The pathology registration of malignancies stays mandatory for all cases at the usual time points and is completely separate from the data deliveries in the context of complex surgery.



## 3.2. Registration form variables

### 3.2.1. Where can I enter additional information?

This can be entered in the general comments field (see section 2.6), which can be found:

- In WBCR: At the bottom of the online registration form.
- In the batch file: In the last column of the batch file.

Please include all information that is considered relevant to this registration, e.g. additional information on comorbidities or comorbidities other than those included in the provided list.

### 3.2.2. Should 90-day post-op in-hospital complications be registered if they happened after readmission?

Yes, all complications that occur during the 90-day post-operative period should be registered if they occurred or were present during a hospital stay, whether it was during the hospitalisation after the complex surgery or during re-admission in the same or another hospital than where the complex surgery was performed. In case of re-admission, the complications should be registered by the centre who performed the complex surgery, whether the complications occurred after readmission to the expert centre or to another hospital. It is important that the expert centre is informed about these complications, even when the patient is hospitalised in a different centre.

Please note that the convention mentions “Service Level Agreements (SLA)” between the expert centre and the referring hospital(s), in which the follow-up of the patient can be arranged in detail. It is useful to also include agreements about the communication of the follow-up information into the SLA.

### 3.2.3. Which indication should be registered when the final diagnosis was different from the initial indication for which surgery was considered?

For example, when complex surgery was performed because of a benign condition and it turned out to be malignant. In this case the original benign indication must be selected with all information about the final diagnosis in the general comments field.

### 3.2.4. Readmission within 30 days: the patient was discharged from the expert centre less than 30 days before the completion of the registration form

In the registration form, it should be indicated whether there was a re-admission within 30 days after discharge. Please note that the option ‘Unknown’ should be selected if the patient was discharged from the expert centre less than 30 days before the completion of the registration form!

*Example:* A patient was discharged on post-op day 85. The registration is performed on post-op day 100. At that time, it is unknown if the patient will be readmitted within 30 days after discharge, since this 30-day period is between post-op day 85 and 115. The option ‘Unknown’ should be indicated.

### 3.2.5. What if not enough information is available to fill out the requested variables?

It could be that the required information cannot be found in the available patient files. Please consult the responsible physician or the hospital from which the patient was referred to be able to fill out all requested variables.

! Please note that we are aware of the fact that some of these referral data are not easily obtained. Nevertheless, the experts have emphasised the importance of these variables to post-factum determine the time to treatment. Therefore, these variables are required to be filled out.



Suggestions to acquire these data more easily:

- Ask the patient upon entry/first consultation and include this in the medical dossier
- Ask the referring centre to include this information in the referral letter



## Appendix A: ICD-10 codes

A suggestion of related ICD-10 codes to the possible comorbidities, as discussed in section “2.3.4. Comorbidity - Charlson Modified Index” of this manual (based on Quan et al., *Medical Care*, 2005). Please note that this list is not exhaustive.

Comorbidity	ICD-10
Myocardial infarction	I21.x, I22.x, I25.2
Peripheral vascular disease	I70.x, I71.x, I73.1, I73.8, I73.9, I77.1, I79.0, I79.2, K55.1, K55.8, K55.9, Z95.8, Z95.9
Cerebrovascular disease	G45.x, G46.x, H34.0, I60.x - I69.x
Congestive heart failure	I09.9, I11.0, I13.0, I13.2, I25.5, I42.0, I42.5 - I42.9, I43.x, I50.x, P29.0
Connective tissue disease	M05.x, M06.x, M31.5, M32.x - M34.x, M35.1, M35.3, M36.0
Mild liver disease	B18.x, K70.0 - K70.3, K70.9, K71.3 - K71.5, K71.7, K73.x, K74.x, K76.0, K76.2 - K76.4, K76.8, K76.9, Z94.4
Moderate-severe liver disease	I85.0, I85.9, I86.4, I98.2, K70.4, K71.1, K72.1, K72.9, K76.5, K76.6, K76.7
Moderate-severe renal disease	I12.0, I13.1, N03.2 - N03.7, N05.2 - N05.7, N18.x, N19.x, N25.0, Z49.0 - Z49.2, Z94.0, Z99.2
Chronic pulmonary disease	I27.8, I27.9, J40.x - J47.x, J60.x - J67.x, J68.4, J70.1, J70.3
Peptic ulcer	K25.x - K28.x
Hemiplegia	G04.1, G11.4, G80.1, G80.2, G81.x, G82.x, G83.0 - G83.4, G83.9
Dementia	F00.x - F03.x, F05.1, G30.x, G31.1
Diabetes without any damage to end-organs	E10.0, E10.1, E10.6, E10.8, E10.9, E11.0, E11.1, E11.6, E11.8, E11.9, E12.0, E12.1, E12.6, E12.8, E12.9, E13.0, E13.1, E13.6, E13.8, E13.9, E14.0, E14.1, E14.6, E14.8, E14.9
Diabetes with damage to end-organs	E10.2 - E10.5, E10.7, E11.2 - E11.5, E11.7, E12.2 - E12.5, E12.7, E13.2 - E13.5, E13.7, E14.2 - E14.5, E14.7
Any tumour (without metastasis)	C00.x - C26.x, C30.x - C34.x, C37.x - C41.x, C43.x, C45.x - C58.x, C60.x - C76.x, C81.x - C85.x, C88.x, C90.x - C97.x
Leukaemia (acute or chronic)	
Lymphoma	
Metastatic solid tumour	C77.x - C80.x
AIDS (not just HIV positive)	B20.x ( <b>only codes related to AIDS, not HIV+</b> )

## Appendix B: ATC codes

A list is provided with corresponding ATC codes to anti-thrombotic medication. Alternatively, the ATC code can be searched on the website [https://www.whooc.no/atc\\_ddd\\_index/](https://www.whooc.no/atc_ddd_index/) to convert the drug to ATC code.

### **B01AA Vitamin K antagonists**

B01AA01 Dicoumarol  
B01AA02 Phenindione  
B01AA03 Warfarin  
B01AA04 Phenprocoumon  
B01AA07 Acenocoumarol  
B01AA08 Ethyl biscoumacetate  
B01AA09 Clorindione  
B01AA10 Diphenadione  
B01AA11 Tiocloमारol  
B01AA12 Fluindione

### **B01AB Heparin group**

B01AB01 Heparin  
B01AB02 Antithrombin III  
B01AB04 Dalteparin  
B01AB05 Enoxaparin  
B01AB06 Nadroparin  
B01AB07 Parnaparin  
B01AB08 Reviparin  
B01AB09 Danaparoid  
B01AB10 Tinzaparin  
B01AB11 Sulodexide  
B01AB12 Bemiparin  
B01AB51 Heparin, combinations

### **B01AC Platelet aggregation inhibitors excluding heparin**

B01AC01 Ditazole  
B01AC02 Cloricromen  
B01AC03 Picotamide  
B01AC04 Clopidogrel  
B01AC05 Ticlopidine  
B01AC06 Acetylsalicylic acid  
B01AC07 Dipyridamole  
B01AC08 Carbasalate calcium  
B01AC09 Epoprostenol  
B01AC10 Indobufen  
B01AC11 Iloprost  
B01AC13 Abciximab  
B01AC15 Aloxiprin  
B01AC16 Eptifibatide  
B01AC17 Tirofiban  
B01AC18 Triflusal

B01AC19 Beraprost  
B01AC21 Treprostiniil  
B01AC22 Prasugrel  
B01AC23 Cilostazol  
B01AC24 Ticagrelor  
B01AC25 Cangrelor  
B01AC26 Vorapaxar  
B01AC27 Selexipag  
B01AC30 Combinations  
B01AC56 Acetylsalicylic acid, combinations with proton pump inhibitors

### **B01AD Enzymes**

B01AD01 Streptokinase  
B01AD02 Alteplase  
B01AD03 Anistreplase  
B01AD04 Urokinase  
B01AD05 Fibrinolysin  
B01AD06 Brinase  
B01AD07 Reteplase  
B01AD08 Saruplase  
B01AD09 Ancrod  
B01AD10 Drotrecogin alfa (activated)  
B01AD11 Tenecteplase  
B01AD12 Protein C

### **B01AE Direct thrombin inhibitors**

B01AE01 Desirudin  
B01AE02 Lepirudin  
B01AE03 Argatroban  
B01AE04 Melagatran  
B01AE05 Ximelagatran  
B01AE06 Bivalirudin  
B01AE07 Dabigatran etexilate

### **B01AF Direct factor Xa inhibitors**

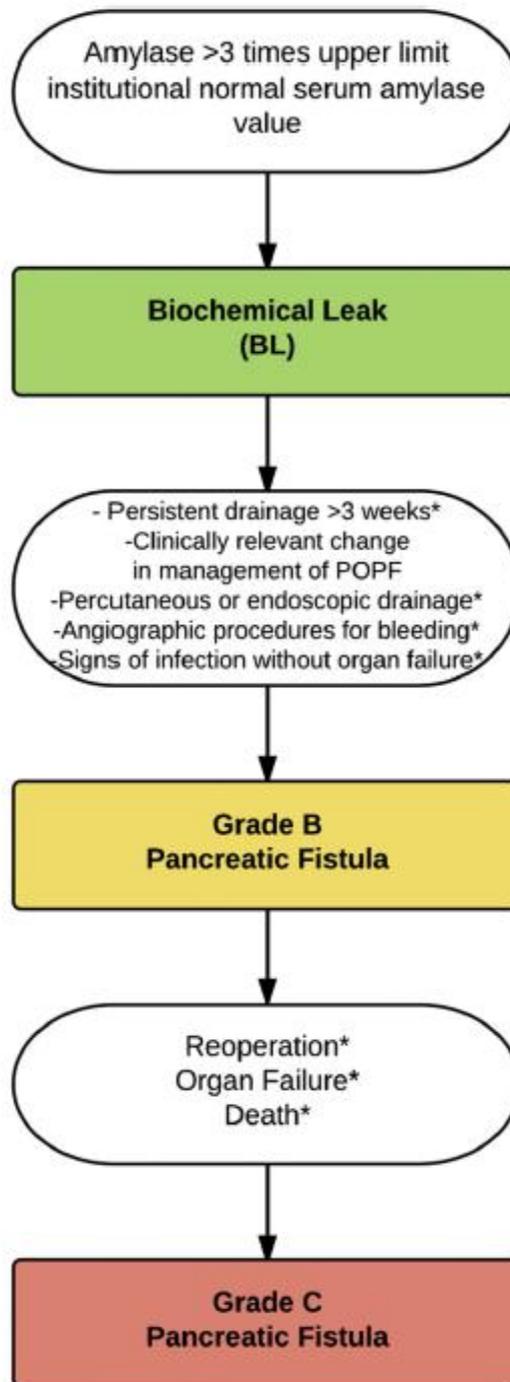
B01AF01 Rivaroxaban  
B01AF02 Apixaban  
B01AF03 Edoxaban

### **B01AX Other antithrombotic agents**

B01AX01 Defibrotide  
B01AX04 Dermatan sulfate  
B01AX05 Fondaparinux  
B01AX07 Caplacizumab

## Appendix C: Criteria for grading of post-operative complications in (peri-) pancreatic surgery

Flow Chart: BL and POPF grade definition (from Bassi et al, *Surgery*, 2017)



*\*Treatment/Event POPF related*

Table 1: Proposed classification of PPH: clinical condition, diagnostic and therapeutic consequences (from Wente et al, *Surgery*, 2007)

Grade	Time of onset, location, severity and clinical impact of bleeding		Clinical condition	Diagnostic consequence	Therapeutic consequence
A	Early, intra- or extraluminal, mild		Well	Observation, blood count, ultrasonography and, if necessary, computed tomography	No
B	Early, intra- or extraluminal, severe	Late, intra- or extraluminal, mild*	Often well/intermediate, very rarely life-threatening	Observation, blood count, ultrasonography, computed tomography, angiography, endoscopy†	Transfusion of fluid/blood, intermediate care unit (or ICU), therapeutic endoscopy,† embolization, relaparotomy for early PPH
C		Late, intra- or extraluminal, severe	Severely impaired, life-threatening	Angiography, computed tomography, endoscopy†	Localization of bleeding, angiography and embolization, (endoscopy†) or relaparotomy, ICU

ICU, Intensive care unit; PPH, pstpancreatectomy hemorrhage.

\*Late, intra- or extraluminal, mild bleeding may not be immediately life threatening to patient but may be a warning sign for later severe hemorrhage ("sentinel bleed") and is therefore Grade B.

†Endoscopy should be performed when signs of intraluminal bleeding are present (melena, hematemesis, or blood loss via nasogastric tube).

Table 2: DGE grading (from Wente et al, *Surgery*, 2007)

DGE	Grade A	Grade B	Grade C
Clinical condition	Well	Often well/minor discomfort	Ill/bad/severe discomfort (increased overall risk owing to complications and procedures)
Comorbidities	No	Possibly yes (pancreatic leak or fistula, intraabdominal abscess)	Possibly yes (pancreatic leak or fistula, intraabdominal abscess)
Specific treatment	Possibly yes (prokinetic drugs)	Yes (prokinetic drugs, potential reinsertion of NGT)	Yes (prokinetic drugs, NGT)
Nutritional support (enteral or parenteral)	Possibly yes (slower return to solid food intake)	Yes (partial parenteral nutrition)	Yes (total parenteral or enteral nutrition via NGT, prolonged, i.e., >3 weeks postoperatively)
Diagnostic evaluation	No	Possibly yes (endoscopy, upper GI contrast study, CT)	Yes (endoscopy, upper GI contrast study, CT)
Interventional treatment	No	No	Possibly yes (e.g., abscess drainage, relaparotomy for complication, relaparotomy for DGE)
Prolongation of hospital stay	Possibly yes	Yes	Yes
Delay of potential adjuvant therapy	No	No	Yes

CT, Computed tomography; DGE, Delayed gastric emptying; GI, Gastrointestinal; NGT, nasogastric tube.

Table 3: Consensus proposal of the ISGLS for a definition and grading of bile leakage after hepatobiliary and pancreatic surgery (Koch et al, *Surgery*, 2011)

Definition	<p>Bile leakage is defined as fluid with an increased bilirubin concentration in the abdominal drain or in the intra-abdominal fluid on or after postoperative day 3, or as the need for radiologic intervention (ie, interventional drainage) because of biliary collections or relaparotomy resulting from bile peritonitis.</p> <p>Increased bilirubin concentration in the drain or intra-abdominal fluid is defined as a bilirubin concentration at least 3 times greater than the serum bilirubin concentration measured at the same time.</p>
Grade	
A	Bile leakage requiring no or little change in patients' clinical management
B	Bile leakage requiring a change in patients clinical management (eg, additional diagnostic or interventional procedures) but manageable without relaparotomy, <i>or</i> a Grade A bile leakage lasting for >1 week
C	Bile leakage requiring relaparotomy

## Appendix D: Morphology codes

This non-exhaustive shortlist of morphology codes of malignant tumours of the (peri-) pancreas can be used to correctly code the histological diagnosis in case of a malignancy.

<b>PANCREAS</b>	
<b><u>Invasive carcinomas</u></b>	
Acinar cell carcinoma	8550/3
Acinar cell cystadenocarcinoma	8551/3
Adenosquamous carcinoma	8560/3
Carcinoma, undifferentiated, NOS	8020/3
Colloid adenocarcinoma	8480/3
Ductal adenocarcinoma	8500/3
Hepatoid adenocarcinoma	8576/3
Intraductal oncocytic papillary neoplasm with an associated invasive carcinoma	8455/3
Intraductal papillary mucinous neoplasm with an associated invasive carcinoma	8453/3
Intraductal papillary neoplasm with an associated invasive carcinoma	8503/3
Large cell carcinoma with rhabdoid phenotype	8014/3
Medullary carcinoma, NOS	8510/3
Mixed acinar-ductal carcinoma	8552/3
Mixed acinar-endocrine-ductal carcinoma	8154/3
Mixed acinar-neuroendocrine carcinoma	8154/3
Mucinous cystic neoplasm (MCN) with an associated invasive carcinoma	8470/3
Poorly cohesive carcinoma	8490/3
Serous cystadenocarcinoma, NOS	8441/3
Signet-ring cell adenocarcinoma	8490/3
Solid pseudopapillary neoplasm of pancreas	8452/3
Undifferentiated carcinoma with osteoclast-like (stromal) giant cells	8035/3
<b><u>(Neuro)endocrine tumour/carcinoma (NET/NEC)</u></b>	
Neuroendocrine tumour, NOS	8240/3
Neuroendocrine tumour, grade 1	8240/3
Neuroendocrine tumour, grade 2	8249/3
Neuroendocrine tumour, grade 3	8249/3
Pancreatic neuroendocrine tumour, non-functioning	8150/3
Oncocytic neuroendocrine tumour, non-functioning, pancreatic	8150/3
Pleomorphic neuroendocrine tumour, non-functioning, pancreatic	8150/3
Clear cell neuroendocrine tumour, non-functioning, pancreatic	8150/3
Cystic neuroendocrine tumour, non-functioning, pancreatic	8150/3
Pancreatic neuroendocrine tumour, functioning	
ACTH-producing tumour	8158/3
Enterochromaffin-cell carcinoid	8241/3
Gastrinoma	8153/3
Glucagonoma	8152/3
Insulinoma	8151/3
Large cell neuroendocrine carcinoma	8013/3
Mixed acinar-endocrine carcinoma	8154/3
Mixed acinar-endocrine-ductal carcinoma	8154/3
Mixed acinar-neuroendocrine carcinoma	8154/3

Mixed neuroendocrine-non-neuroendocrine neoplasm (MiNEN)	8154/3
Neuroendocrine carcinoma, NOS	8246/3
Serotonin-producing tumour	8241/3
Small cell neuroendocrine carcinoma	8041/3
Somatostatinoma	8156/3
VIPoma	8155/3
<b><u>In situ malignancies</u></b>	
Intraductal oncocytic papillary neoplasm, NOS	8455/2
Intraductal papillary mucinous neoplasm with high-grade dysplasia (IPMT / IPMN)	8453/2
Intraductal tubulopapillary neoplasm (high grade dysplasia) (ITPN)	8503/2
Mucinous cystic neoplasm (MCN) with high-grade dysplasia	8470/2
Pancreatic glandular intraepithelial neoplasia, high grade	8148/2
<b><u>Other malignancies</u></b>	
Pancreatoblastoma	8971/3
Lymphoma	Check list hemato

<b>SMALL INTESTINE &amp; AMPULLARY REGION</b>	
<b><u>Invasive carcinomas</u></b>	
Adenocarcinoma, NOS	8140/3
Adenocarcinoma, intestinal type	8144/3
Adenosquamous carcinoma, NOS	8560/3
Medullary carcinoma	8510/3
Mucinous adenocarcinoma	8480/3
Mucin-producing adenocarcinoma	8481/3
Pancreatobiliary-type carcinoma	8163/3
Signet ring cell carcinoma	8490/3
Tubular adenocarcinoma	8211/3
<b><u>(Neuro)endocrine tumour/carcinoma (NET/NEC)</u></b>	
Neuroendocrine tumour, NOS	8240/3
Enterochromaffin-cell carcinoid	8241/3
Extra-adrenal paraganglioma, NOS	8693/3
Gastrinoma	8153/3
Neuroendocrine tumour, grade 1	8240/3
Neuroendocrine tumour, grade 2	8249/3
Neuroendocrine tumour, grade 3	8249/3
Somatostatinoma	8156/3
Neuroendocrine carcinoma, NOS	8246/3
Large cell neuroendocrine carcinoma	8013/3
Small cell neuroendocrine carcinoma	8041/3
Mixed neuroendocrine-non-neuroendocrine neoplasm (MiNEN)	8154/3
<b><u>In situ malignancies</u></b>	
Adenomatous polyp, high-grade dysplasia	8210/2
Intestinal-type adenoma, high grade	8144/2
Intra-ampullary papillary-tubular neoplasm	8163/2
Glandular intraepithelial neoplasia, high grade, HGIN (severe dysplasia)	8148/2
Non-invasive pancreatobiliary papillary neoplasm with high-grade dysplasia	8163/2
Serrated dysplasia, high grade	8213/2
<b><u>Other malignancies</u></b>	
Angiosarcoma, NOS	9120/3
Gastrointestinal stromal tumour (GIST)	8936/3



Inflammatory myofibroblastic tumour, malignant	8825/3
Kaposi sarcoma	9140/3
Leiomyosarcoma, NOS	8890/3
Myofibroblastic tumour, Malignant	8825/3
Undifferentiated sarcoma	8805/3
Lymphoma	Check list hemato

## GALLBLADDER AND EXTRAHEPATIC BILE DUCTS

### Invasive carcinomas

Adenocarcinoma, intestinal type	8144/3
Adenocarcinoma, NOS	8140/3
Adenosquamous carcinoma, NOS	8560/3
Carcinoma, undifferentiated, NOS	8020/3
Cholangiocarcinoma	8160/3
Clear cell adenocarcinoma, NOS	8310/3
Intracystic papillary neoplasm with an associated invasive carcinoma	8503/3
Intraductal papillary neoplasm with an associated invasive carcinoma	8503/3
Klatskin tumour	8162/3
Mucinous adenocarcinoma	8480/3
Mucinous cystic neoplasm (MCN) with an associated invasive carcinoma	8470/3
Mucin-producing adenocarcinoma	8481/3
Poorly cohesive carcinoma	8490/3
Sarcomatoid carcinoma	8033/3
Signet ring cell adenocarcinoma	8490/3
Squamous cell carcinoma, NOS	8070/3

### (Neuro)endocrine tumour/carcinoma (NET/NEC)

Neuroendocrine tumour, NOS	8240/3
Neuroendocrine tumour, grade 1	8240/3
Neuroendocrine tumour, grade 2	8249/3
Neuroendocrine tumour, grade 3	8249/3
Neuroendocrine carcinoma, NOS	8246/3
Large cell neuroendocrine carcinoma	8013/3
Small cell neuroendocrine carcinoma	8041/3
Mixed neuroendocrine-non-neuroendocrine neoplasm (MiNEN)	8154/3

### In situ malignancies

Biliary (glandular) intraepithelial neoplasia, high grade	8148/2
Intracystic papillary neoplasm with high-grade intraepithelial neoplasia	8503/2
Intraductal papillary neoplasm with high-grade intraepithelial neoplasia	8503/2
Mucinous cystic neoplasm (MCN) with high-grade dysplasia	8470/2

### Other malignancies

Angiosarcoma, NOS	9120/3
Carcinosarcoma	8980/3
Embryonal sarcoma (undifferentiated sarcoma)	8991/3
Endodermal sinus tumour (Yolk sac tumour)	9071/3
Epithelioid haemangi endothelioma	9133/3
Hepatoblastoma	8970/3
Hepatoblastoma (mixed epithelial-mesenchymal)	8970/3
Kaposi sarcoma	9140/3
Leiomyosarcoma, NOS	8890/3
Liposarcoma, NOS	8850/3



Malignant rhabdoid tumour	8963/3
Paraganglioma, NOS	8680/3
Rhabdomyosarcoma, NOS	8900/3
Solitary fibrous tumour, Malignant	8815/3
Synovial sarcoma, NOS	9040/3
Teratoma, immature (extratesticular)	9080/3
Undifferentiated sarcoma	8805/3
Yolk sac tumour	9071/3
Lymphoma	Check list hemato

