Belgian Cancer Registry

Complex Surgery Pancreas and Peri-Ampullary Region

-

Project manual + FAQ

Contents

1. General Project Information

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 or 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.

For all questions or comments concerning the variables to be registered, the timeline or the registration procedure, please contact us at 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:

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

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.

1.2. General MOC/COM and specific complex surgery registration

The mandatory registration consists of two types of datasets:

1. **The general MOC/COM registration (bijlage/annexe 55), only for malignant tumours (see Chapter 2)**
   The complete, structured MOC/COM dataset should accompany the project-specific registration **for all malignant tumours** (including the pTNM in case of surgery). This registration is also mandatory to be performed by the expert centre in case of a referral, where the MOC/COM was held in the referring

centre. MOC/COM registrations are already ongoing in the Belgian hospitals (obliged since 2003), but the delivery to the BCR will become more frequent (from once a year to 4 times per year).
Please contact the person(s) that are already responsible for this registration within your centre to arrange the practicalities for the MOC/COM registrations related to complex surgery.
The MOC/COM dataset and the accompanying registration manual can be found here:

- Dutch version: "MOC-formulier (bijlage 55)" (p.2-3) and "Handleiding voor registratie - NEW 2017" (p.1-10), online available via: https://kankerregister.org/downl-vr-zorgprogramma
- French version: "Formulaire COM (annexe 55)" (p.5-6) and "Manuel de l'enregistrement - NEW 2017" (p.1-10), online available via: https://kankerregister.org/downl_pour_progrdesoins

2. **The project-specific complex surgery registration (see Chapter 3)**
   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. The dataset can be accessed via https://kankerregister.org/ComplexSurgery_nl or http://www.kankerregister.org/ComplexSurgery_fr. All requested variables are discussed in detail in Chapter 3 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.

1.3. Modes of registration

The registrations can be delivered to the BCR in two ways (which may or may not be the same for the specific and the MOC/COM registration):

1. Via the online **WBCR** application
2. Via structured **batch** deliveries (in a predefined format)

Example: An expert centre may choose to deliver the data via batch for the MOC/COM registration and via WBCR for the specific complex surgery registration.

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 or 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 the MOC/COM registration is always listed as the first module in the online platform ('Standaard kankerregistratie' / 'Enregistrements généraux').

The WBCR module for project-specific registrations of complex surgery can be found as one of the next modules in 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.
- 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 and per type of dataset (MOC/COM or project-specific), in a predefined order and format.

For the MOC/COM dataset, all necessary batch file specifications can be found in the following documents:

- Dutch version: "Dataset kankerregistratiegegevens" and "Checklist BATCH",
  online available via: https://kankerregister.org/downl-vr-zorgprogramma
- French version: "Variables demandées" and "Checklist BATCH",
  online available via: https://kankerregister.org/downl_pour_progrdesoins

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 or http://www.kankerregister.org/ComplexSurgery_fr). The template has three 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 10-step checklist to verify whether your batch file was set up according to the requested format.

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 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 or not surgery was performed:

- 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!
  The MOC/COM registrations (only for malignant tumours) can only be completed when the pTNM and the finally performed or planned adjuvant therapy are known. Therefore, it is recommended to complete the MOC/COM registrations also after 90 days post-surgery.

- 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.
  The MOC/COM registration (only for malignant tumours) must include the cTNM and the performed or planned therapy and should only be completed when this therapy (plan) is known.

Registrations (both the MOC/COM and the project-specific dataset) should thus be **completed** year-round. However, **delivery** of these completed registrations to the BCR will be restricted to 4 mandatory delivery time points per year (with the same deadlines for WBCR and batch file deliveries).

Only **completed registrations** can be delivered to the BCR. The registrations (including the MOC/COM for malignant indications) will need to be transferred to the BCR by every **last day of March/June/September/December**, with the exception of the first quarterly delivery time point being **October 2019** instead of September 2019. The following table indicates the exact deadlines for sending in the complete registrations to BCR for each delivery time point, depending on whether or not complex surgery took place.

If **complex surgery**	**Registrations mandatory to be delivered to BCR in the specified quartile (> 100 days post-op)** Surgery on or before …	**Registrations that can be delivered to BCR but are not yet mandatory in the specified quartile (90-100 days post-op)** Surgery in the time period …	**Registrations that cannot yet be delivered to BCR (< 90 days post-op)** Surgery on or after…
Q1 – **March 31st**	21/12	22/12 to 31/12	01/01
Q2 – **June 30th**	22/03	23/03 to 01/04	02/04
Q3 – **September 30th**	22/06	23/06 to 02/07	03/07
Q4 – **December 31st**	22/09	23/09 to 02/10	03/10
October 31st, 2019*	01/07/2019 to 23/07/2019	24/07/2019 to 02/08/2019	03/08/2019

If **no complex surgery**	**Registrations mandatory to be delivered to BCR in the specified quartile (> 60 days post-MC/CM)** MC/CM on or before …	**Registrations that can be delivered to BCR but are not yet mandatory in the specified quartile (< 60 days post-MC/CM)** MC/CM in the time period …
Q1 – **March 31st**	30/01	31/01 to 31/03
Q2 – **June 30th**	01/05	02/05 to 30/06
Q3 – **September 30th**	01/08	02/08 to 30/09
Q4 – **December 31st**	01/11	02/11 to 31/12
October 31st, 2019*	01/07/2019 to 01/09/2019	02/09/2019 to 31/10/2019

Q: quartile

* For 2019, the delivery time points will be 31/10/2019 (not Q3: 30/09) and 31/12/2019.

2. The obligatory MOC/COM cancer registration (bijlage/annexe 55)

The general, 'classic' cancer (MOC/COM) registration for malignant tumours (both in situ and invasive) is obliged since 2003 for all oncological care programs and is thus already ongoing in the Belgian hospitals.

The structured dataset that should be registered (via the online WBCR application or via batch file) is specified in 'bijlage/annexe 55' (Appendix D). The variables that should be registered, are the following:

1. Incidence date
2. Basis of diagnosis
3. WHO score at diagnosis
4. Localisation of the tumour (ICD-O-3)
5. Laterality
6. Histological diagnosis (ICD-O-3)
7. Differentiation grade
8. Clinical TNM (UICC TNM 8th edition)
9. Pathological TNM (UICC TNM 8th edition)
10. Other classification
11. Date start first treatment
12. Treatments already performed
13. Further treatment plan (intention to)

Also for the complex surgery registration project, it will be important to correctly and completely fill out all variables related to the MOC/COM registration. Please make sure that the pTNM (after surgery) is completed and that the treatment plan is filled out correctly and chronologically. This will be important for evaluation of the data.

Normally, the delivery to the BCR of the MOC/COM registrations is requested once per year, but in the context of the convention for complex surgery, this will become four times per year. The practicalities for this registration should be discussed with the person(s) responsible for the MOC/COM registration that is already ongoing within each hospital.

More information about the MOC/COM registration can be found on the BCR website, including the registration manual (Dutch/French), the MOC/COM registration form (D/F) and, in case of batch delivery, the batch dataset (D/F) and a checklist (D/F) to help send in complete registrations:

- Dutch: https://kankerregister.org/downl-vr-zorgprogramma
- French: https://kankerregister.org/downl_pour_progrdesoins

3. Complex surgery registration form

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: variable that has a specific format (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 3.6. General comments field).

3.1. 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.

3.2. 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 or not surgery was performed, the surgery indication, patient reports and referral information.

3.2.1. The patient did not undergo surgery

Name variable	Type	Answer options
Did the patient undergo surgery?	SS	No*
		Yes
*Indication:	SS (+ Text)	Malignant tumour
		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…
*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 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!

- In case the option 'Malignant tumour' was selected, **the obligatory MOC/COM cancer registration ('bijlage/annexe 55' - see chapter 2) should be performed for this tumour within 60 days following the Multidisciplinary Consult (MC/CM).**
- In case the option 'Other benign tumour' was chosen, the type of tumour should be further specified in a text field.
- If the option 'Other' was chosen, the precise non-tumoural indication (full name) should also be filled out in a text field.

Next, the **report of the MC/CM** where the decision was made to not perform surgery, should be provided in a large text field. Please copy and paste the complete textual report from the electronic patient dossier.

- For batch deliveries, the complete text can be included as one variable by pasting 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.

3.2.2. The patient underwent surgery

Name variable	Type	Answer options
Did the patient undergo surgery?	SS	No
		Yes¥
¥Indication:	SS (+Text)	Malignant tumour
		Adenoma
		Cystadenoma
		Intraductal Papillary Mucinous Neoplasm with low grade or moderate dysplasia (8453/0)
		Other benign tumour. Please specify…
		Chronic pancreatitis
		Other. Please specify…
¥Type of FIRST diagnostic method:	SS	CT
		MRI
		PET
		PET/CT
		ERCP (Endoscopic Retrograde Cholangio-Pancreatography)
		EUS (Endoscopic UltraSound)
		Surgery (laparoscopy/laparotomy)
¥Date (of first diagnostic method):	Date	(dd/mm/yyyy)
¥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
¥Date (on which the first tissue sample was obtained):	Date	(dd/mm/yyyy)
¥MC/CM report, without patient identification variables:	Text	… (include as text)
¥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¥¥
¥¥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°
°Date of the M(O)C/C(O)M at referring hospital:	Date	(dd/mm/yyyy)

¥¥Was the patient hospitalised at the referring hospital?	SS	No†
		Yes‡
†Date of last consultation prior to referral:	Date	(dd/mm/yyyy)
‡Date of discharge at the referring hospital:	Date	(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 diagnosis of the patient) should be specified. This variable is the same as in case of no surgery (section 3.2.1), with the exception that for a 'malignant tumour' **the obligatory MOC/COM cancer registration ('bijlage/annexe 55' - see chapter 2) should be performed within 100 days following the date of surgery.**

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.
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 3.4.2).
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 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 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 pasting 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

3.3. Patient characteristics

3.3.1. 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.

3.3.2. 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 (≥ 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

3.3.3. 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.

3.3.4. 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 (**Charlson Modified index**):	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.

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

Name variable	Type	Answer options
Is the patient currently (= 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). 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.

3.4. Surgery

3.4.1. 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¥
		Prior abdominal surgery§
		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…
¥Start date radiotherapy:	Date	(dd/mm/yyyy)
¥Date latest radiotherapy treatment:	Date	(dd/mm/yyyy)
§Type of the prior abdominal surgery:	Text	…
§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.

3.4.2. 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.

3.4.3. 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.

3.4.4. 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§
*Pancreaticoduodenectomy?	SS	Pancreaticoduodenectomy
		Total pancreatectomy¥
¥Localisation lesion:	SS	Pancreatic head/peri-ampullary region
		Pancreatic body or tail
§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'.

3.4.5. 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§
**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
§Specify the type of 'arterial resection'	SS	Hepatic artery
		Coeliac trunk
		Superior mesenteric artery (SMA)
§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).

3.4.6. 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).

3.4.7. 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.

3.4.8. 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).

3.5. Post-surgery

3.5.1. 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[§]
		Haemorrhage°
		Delayed gastric emptying[¥]
		Bile leakage[‡]
		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 3.5.2) 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):
  - 'Grade B' requires a change in the postoperative management; drains are either left in place >3 weeks or repositioned through endoscopic or percutaneous procedures.
  - '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 '**hemorraghe**', 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):
  - 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.

3.5.2. Post-operative complications: the Clavien-Dindo grade

This variable should only be filled out if the patient had post-operative complications (see section 3.5.1).

Name variable	Type	Answer options
* General 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
Grade I	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
Grade II	Complications requiring drug treatments other than those allowed for Grade I complications; this includes blood transfusion and total parenteral nutrition (TPN)
Grade III	Complications requiring surgical, endoscopic or radiological intervention - **Grade IIIa** - intervention not under general anaesthetic - **Grade IIIb** - intervention under general anaesthetic
Grade IV	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) - **Grade IVa** - single-organ dysfunction (including dialysis) - **Grade IVb** - multi-organ dysfuncton
Grade V	Death of the patient

3.5.3. 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.

3.5.4. 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 3.5.5). 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.

3.5.5. Re-admission within 30 days after discharge

This variable should only be filled out if the patient was discharged after surgery (see section 3.5.4).

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

3.5.6. 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.

3.5.7. 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.

3.5.8. 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.

3.6. General comments field

A general ‘comments’ field is provided, both in the WBCR application and in the batch file (for both the MOC/COM and specific dataset). 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.

4. Frequently asked questions (FAQ)

4.1. Registration in general

4.1.1. 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 or http://www.kankerregister.org/ComplexSurgery_fr.

4.1.2. 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. As a result, there is a 10-day window to complete the registrations for patients who underwent complex surgery.
- 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.

Please note that the obligatory MOC/COM cancer registration (bijlage/annexe 55) should also be performed within this time frame in case of a malignant tumour.

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

The BCR will ask to deliver all completed registrations **4 times per year**, for both modes of delivery (WBCR and batch file). Complete registrations (including the MOC/COM in case of malignant indications) will need to be transferred to the BCR **every 3 months**, by every **last day of March/June/September/December**, with the exception of the first quarterly delivery time point being **October 2019** instead of September 2019. More information can be found in section "1.4. Registration time points". The complex surgery registration can only be send in after the 90-day post-op period has been completed.

Only completed registrations can be delivered to the BCR at the quarterly time points (see section 1.4 for a detailed overview), implying that:

- In case of surgery: all registrations of patients for whom the 100-day post-op period has ended at the latest on the quarterly delivery time point, should be included.

  Example: for the quarterly time point 31/12/2019:
  - All registrations of patients who had surgery on or before 22/09/2019 should be delivered to BCR.

- All registrations of patients who had surgery in the period 23/09/2019 - 02/10/2019 can be delivered to BCR (but this is not mandatory and can be postponed until the next quarterly time point).
- All registrations of patients who had surgery after 02/10/2019 cannot be delivered to BCR because the 90-day post-op period has not yet ended.

- In case of no surgery: all registrations of patients for whom the MC/CM took place at the latest 60 days before the quarterly delivery time point should be included.

  Example: for the quarterly time point 31/12/2019:
  - All registrations of patients who were discussed on a MC/CM on or before 01/11/2019 should be delivered to BCR.
  - All registrations of patients who were discussed on a MC/CM in the period 02/11/2019 - 31/12/2019 can be delivered to BCR (but this is not mandatory and can be postponed until the next quarterly time point).

4.1.4. 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.

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

- The general **MOC/COM registration** (bijlage/annexe 55) (see chapter 2 for more information)
  ⇨ only in case of a malignant indication, even if no complex surgery eventually took place
- The **project-specific registration** of the variables related to complex surgery (see chapter 3 for detailed information)
  ⇨ for all indications, even if no complex surgery eventually took place

More information about the MOC/COM registration can be found on the BCR website, including the registration manual, the MOC/COM registration form and, in case of batch delivery, the batch dataset and a checklist to help send in complete registrations:

- Dutch: https://kankerregister.org/downl-vr-zorgprogramma
- French: https://kankerregister.org/downl_pour_progrdesoins

The dataset for the specific registrtion of complex surgery is available on the website of BCR: https://kankerregister.org/ComplexSurgery_nl or 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)

4.1.6. 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: Once you ‘double click’ on a cell, the complete textual report can be copy-pasted 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 “3.5.3. Re-operation necessary?”).

4.1.7. 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
- Textual MC/CM report
- Referral + referring hospital

Note: This minimal dataset is additional to the obligatory MOC/COM registration (bijlage/annexe 55) in case of a malignant indication.

Note: Only complete registrations (MOC/COM + specific dataset) can be taken into account to calculate the minimal activity for the 3-year convention period.

4.1.8. 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 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 3.6).

4.1.9. 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 3.6), 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.

4.1.10. 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).

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

After each quarterly 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.

4.1.12. 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. 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 steps can be undertaken to correct the erroneous data:

- Communication to your Cancer Registry contact person via telephone (only if it concerns few errors).
- 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 number (which is automatically assigned to each sent registration) to identify the registration in which corrections need to be carried out.
- Via our secured online sFTP server (especially if it concerns a larger number of corrections). Please contact the BCR to ask for a sFTP login name and password so the data can be send.
  For registrations sent via WBCR, please also include the WBCR reference number.

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.

Only in exceptional circumstances it will be asked to resubmit the complete registration, mentioning in the general comments field: “corrected version”.

4.1.13. 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.

4.1.14. 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 only these patients/reimbursements/registrations are taken into account for the (final) analyses. 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.

4.1.15. 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 (and a MOC/COM registration in case of a malignant tumour) 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), with for malignant tumours also a new MOC/COM registration in which the pTNM and possible adjuvant therapy should be specified.

4.1.16. In case of a collaboration in which not all centres perform their own registrations, how should the centre that performed the MC/CM and/or surgery be identified?

- WBCR: Please include for each registration the name of the hospital that performed the MC/CM and/or surgery in the general comments field (see section 3.6) 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 MC/CM and/or 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).

4.1.17. Should all delivered MOC/COM registrations be resubmitted in June (for the mandatory, yearly registration for the Oncological Care Programs)?

In case of malignant indications, the MOC/COM registration, which is already ongoing in all centres with oncological care programs (obliged since 2003, see chapter 2) and which is requested by BCR once a year in June, should now be included at the corresponding quarterly time points, together with the project-specific registration.

As such, it will not be 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.

4.1.18. Should the pathology report be resubmitted in February (for the mandatory, yearly registration for the Oncological Care Programs)?

Yes. Once a year, in February, pathology reports of malignant indications are submitted to BCR by the pathology labs. This data delivery is completely separate from the data deliveries in the context of complex surgery. For complex surgery, we ask the responsible registration officer(s) to deliver all the necessary documents, including the pathology report, to BCR at the indicated quarterly time points for this specific registration project.

4.2. Registration form variables

4.2.1. Where can I enter additional information?

This can be entered in the general comments field (see section 3.6), 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.

4.2.2. 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.

4.2.3. 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.

4.2.4. 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 "3.3.4. 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 **(only codes related to AIDS, not HIV+)**

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.whocc.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 Tioclomarol
- 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 Treprostinil
- 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

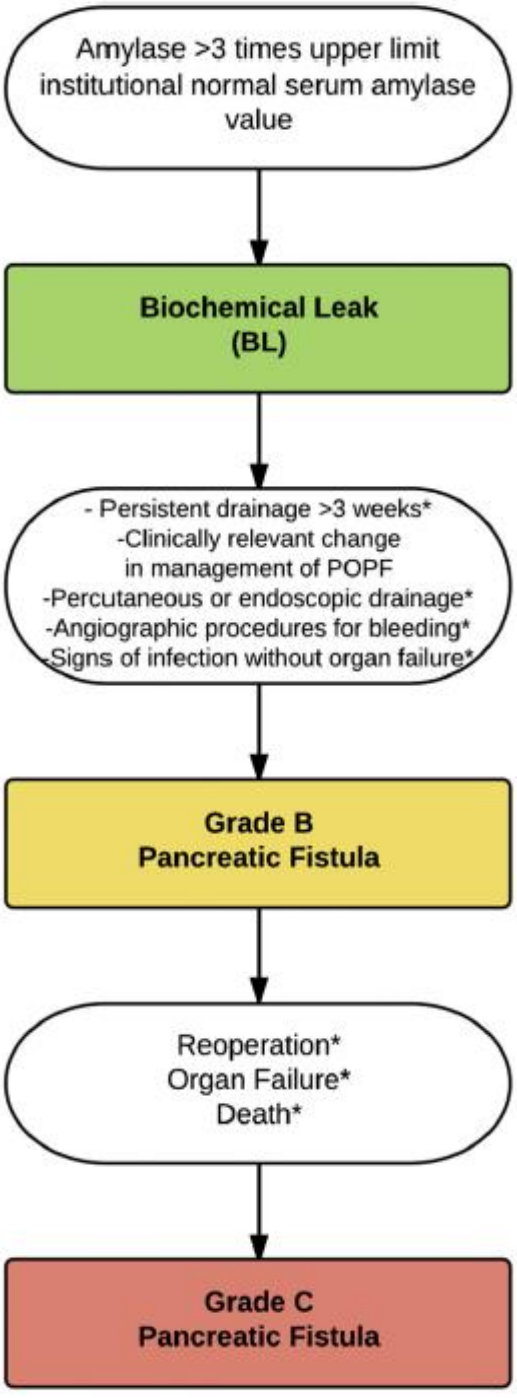
- B01AF01 Rivaroxaban
- B01AF02 Apixaban
- B01AF03 Edoxaban

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	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. 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.
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, *or* a Grade A bile leakage lasting for >1 week
C	Bile leakage requiring relaparotomy

Appendix D: 'Bijlage 55 - Annexe 55'

Bijlage 55

KANKERREGISTRATIEFORMULIER VOOR EEN NIEUWE DIAGNOSE

Patiënt : ..... Geb. datum : .....
Nationaal nr./Ziekenfondsnr. : ..... Geslacht : .....

1. INCIDENTIEDATUM (DD-MM-YYYY) .....
volgorde afnemende prioriteit : 1=eerste hist/cyto bevestiging. 2=klin. evaluatie/opname ziekenhuis. 3=overlijden

2. BASIS VOOR DIAGNOSE (omcirkelen, meerdere items aan te duiden) :
1 = autopsie (niet van toepassing bij MOC)
2 = histologie primaire tumor
3 = histologie metastase
4 = cytologie/hematologie
5 = technisch onderzoek (bv. RX, endoscopie, …)
6 = klinisch
7 = tumormerker (bv. PSA, HCG, AFP, Ig, …)
9 = onbekend

3. WHO-SCORE BIJ DIAGNOSE (omcirkelen)
0 = asymptomatisch, normale activiteit
1 = symptomatisch, maar ambulant
2 = symptomatisch, bedlegerig <50% per dag
3 = symptomatisch, bedlegerig >50% per dag
4 = aangewezen op volledige verzorging, 100% bedlegering

4. PRIMAIRE TUMORLOKALISATIE (invullen).....

5. LATERALITEIT bij pare organen (omcirkelen) 1. links 2. rechts 3. onbekend

6. HISTOLOGISCHE DIAGNOSE (invullen) :

7. DIFFERENTIATIEGRAAD (omcirkelen) : 1=goed 2=matig 3=weinig 4=ongediff/anapl 9=onbekend

8. KLINISCHE TNM (UICC 2002) : cT ..... cN ..... cM .....

9. PATHOLOGISCHE TNM (UICC 2002) : pT ..... pN ..... pM .....

10. ANDERE CLASSIFICATIE (omcirkelen) :
1.Ann Arbor, [2], 3.Figo, 4.Salmon Dury, 5.Clark, 6.Breslow, andere (invullen) :.....

Stadium (invullen) :.....

11. DATUM START EERSTE BEHANDELING (DD-MM-YYYY) :.....

12. REEDS UITGEVOERDE BEHANDELINGEN :
chronologisch invullen vanaf datum eerste behandeling

10 : heelkunde
20 : externe radiotherapie/curietherapie
25 : concomitant chemoradiotherapie
40 : chemotherapie
80 : andere vorm van behandeling (invullen) :.....
15 : beenmergtransplantatie
30 : isotopen
50 : hormonale therapie
60 : Immunotherapie
70 : symptomatisch
90 : geen therapie
95 : weigering therapie
90 : onbekend

13. VERDER BEHANDELINGSPLAN (intentie tot)

codes chronologisch invullen zie punt 12 | | | | | | | |

14. REDEN MOC (aankruisen)
- ☐ patiënt met een nieuwe diagnose van kanker
- ☐ voorafgaand aan een oncologische behandeling die afwijkt van de geschreven en door het oncologisch centrum aanvaarde richtlijnen
- ☐ voorafgaand aan een herhaling van een bestralingsreeks van éénzelfde doelgebied binnen de twaalf maanden, te rekenen vanaf de aanvangsdatum van de eerste bestralingsreeks
- ☐ voorafgaand aan een chemotherapeutische behandeling met een geneesmiddel dat in een fase van verzekeringstegemoetkoming door de Commissie Tegemoetkoming Geneesmiddelen werd aangeduid voor monitoring via het multidisciplinair oncologisch consult
- ☐ andere (invullen) : .....

ARTS COORDINATOR (stempel)
Dr :.....RIZIV-nr :.....
Instelling :.....
Datum :.....

Annexe 55

FORMULAIRE D'ENREGISTREMENT DU CANCER : *NOUVEAU DIAGNOSTIC*

Patient : ..... Date de naissance : .....
N° national / N° organisme assureur : ..... Sexe : .....

1. DATE D'INCIDENCE (JJ-MM-AAAA) .....
ordre de priorité décroissante : 1 = première confirmation histo/cyto, 2 = évaluation clinique/hospitalisation, 3 = décès

2. MOYEN DE DIAGNOSTIC (entourer, plusieurs items sont permis) :
1 = autopsie (pas d'application pour la CMO)
2 = histologie tumeur primitive
3 = histologie métastase
4 = cytologie / hématologie
5 = examen technique (ex. RX, endoscopie, …)
6 = examen clinique
7 = marqueur tumoral (ex. PSA, HCG, AFP, Ig, …)
9 = inconnu

3. SCORE OMS DU DIAGNOSTIC (entourer)
0 = Asymptomatique, activité normale
1 = Symptomatique, mais ambulant
2 = Symptomatique, alité < 50 p.c. de la journée
3 = Symptomatique, alité > 50 p.c. de la journée
4 = Complètement dépendant pour les soins, grabataire

4. LOCALISATION DE LA TUMEUR PRIMITIVE (remplir) : .....

5. LATERALITE uniquement pour organes pairs (entourer) : 1. gauche 2. droite 3. inconnu

6. DIAGNOSTIC HISTOLOGIQUE (remplir) : .....

7. DEGRE DE DIFFERENCIATION (entourer) : 1 = bien 2 = moyen 3 = peu 4 = indiff/anapl 9 = inconnu

8. TNM CLINIQUE (UICC 2002) : cT ..... cN ..... cM .....

9. TNM PATHOLOGIQUE (UICC 2002) : pT ..... pN ..... pM .....

10. AUTRES TYPES DE STADE CLINIQUE (entourer) :
1. Ann Arbor, [2], 3. Figo, 4. Salmon Dury, 5. Clark, 6. Breslow, autre (remplir) :

Stade (remplir) : .....

11. DATE DEBUT DU PREMIER TRAITEMENT (JJ-MM-AAAA) : .....

12. TRAITEMENTS DEJA REÇUS :
remplir chronologiquement à partir de la date du premier traitement

10 : chirurgie
20 : radiothérapie externe/curiethérapie
25 : chimioradiothérapie concomitante
40 : chimiothérapie
15 : greffe moelle osseuse
30 : isotopes
50 : hormonothérapie
60 : immunothérapie
70 : symptomatique
90 : pas de thérapie
95 : refus thérapie
99 : inconnu

80 : autre forme de traitement (remplir) : .....

13. PLAN DE TRAITEMENT ULTERIEUR (intention)
remplir les codes chronologiquement, voir point 12

14. JUSTIFICATION DE LA COM (indiquer)
- ○ prise en charge d'un patient avec un nouveau diagnostic de cancer
- ○ traitement oncologique qui s'écarte des lignes directrices écrites acceptés par le centre oncologique
- ○ répétition d'une série d'irradiations d'une même région cible dans les douze mois, à compter de la date du début de la première série d'irradiations
- ○ chimiothérapie par un médicament qui, dans une première phase de remboursement, a été désigné par la Commission de remboursement des médicaments pour faire l'objet d'un monitoring par la concertation oncologique multidisciplinaire
- ○ autre (remplir) .....

MEDECIN-COORDINATEUR (cachet)
Dr : ..... N° INAMI : .....
Institution : .....
Etabli le : .....