Belgian Cancer Registry

Barrett Esophagus - RadioFrequency Ablation (BE-RFA) - Project manual + FAQ

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1 General project information

This document has been composed as a guide and reference for filling out the online registration forms for the 'Barrett Esophagus - RadioFrequency Ablation (BE-RFA)' registration project via the Web Based Cancer Registration (WBCR) application of the Belgian Cancer Registry. More information about the login procedure and general operation of this application can be found in the BE-RFA WBCR manual (see http://www.kankerregister.org/BERFA).

The BE-RFA registration project was founded to audit outcomes of all patients undergoing RFA, performed in one of the medical centers with an agreement with the RIZIV/INAMI for the reimbursement of RFA in Barrett esophagus starting from 1/04/2016 (or since the later date of inclusion in the list of recognized medical centers, see the RIZIV/INAMI document "Omzendbrief aan de ziekenhuizen 2016/05" - "Circulaire aux hôpitaux 2016/05").

For questions or problems concerning the BE-RFA project (variables), please contact us at BERFA@kankerregister.org / BERFA@registreducancer.org or 02/250 10 10.

1.1 Inclusion criteria

All Belgian residents (eligible for RFA reimbursement by the RIZIV/INAMI):

- with Barrett esophagus with as histology type either **high grade dysplasia** (HGIN) or **invasive carcinoma of the type T1** (determined according to the modified Vienna classification)
- of which the diagnosis is confirmed by 2 pathologists of 2 different centers of which at least one has an agreement with the RIZIV/INAMI regarding RFA
- with one or more RFA treatment sessions performed since 1/04/2016 (or the later date of inclusion)

In addition, also the RFA treatments performed in patients with Barrett esophagus with **low grade dysplasia** (LGIN) or with an **invasive carcinoma of a type higher than T1** can be registered in this project. We strongly encourage their registration, since these data may contain valuable information for future scientific purposes.

The RIZIV/INAMI additionally specified the following:

- If for one and the same lesion RFA treatment sessions were performed before as well as after 1/04/2016 (or the later date of inclusion), all RFA treatment sessions should be registered.
  Note: Only treatment sessions performed after this date are eligible for reimbursement.
- All RFA treatment sessions performed since the introduction of the reimbursement (1/04/2016 or the later date of inclusion) should be registered retrospectively.

1.2 Registration time points

The **primary registration form** needs to be filled out for every RFA treatment from which one or more sessions were performed after April 1st, 2016 (or the later date of inclusion in the list of recognized medical centers) and can include up to 8 RFA treatment sessions. The primary registration

form consists out of 2 parts that each need to be completed and sent separately and at a different timepoint.

- **Part I** collects information regarding patient's medical history and the first RFA treatment session (RFA1). This part needs to be completed and send as soon as possible (preferably within 3 months after performing RFA1).
- **Part II** collects information regarding additional RFA treatment session(s) (RFA2-8). If more than 1 RFA session is performed in a patient's treatment, a new primary registration form in which Part II should be started. This primary Part II registration can only be completed 1 year after the last RFA session in this treatment (i.e. the patient should be 1 year RFA-free).

The first follow-up registration form should be filled out and sent 1 year after the last RFA session.

The **follow-up registration form** needs to be filled out yearly for the first two years and every two years afterwards (i.e. 1, 2, 4, 6, 8, … years after the last RFA session). It should include information about all follow-up endoscopies that were performed during that follow-up period and can include up to 8 follow-up endoscopies.
In case of recurrence of Barrett's esophagus for which it is decided to perform a new RFA treatment, the follow-up registration form should be closed (including the data from the endoscopy after which the decision was made to start the new RFA treatment). Then a new primary registration form should be initiated (see example at section 4.1.2).

Note: Follow-up endoscopies can be performed by the center that performed the RFA treatment or by another hospital (e.g. that referred the patient to the RFA center). It is the responsibility of the hospital where the RFA was performed to collect the follow-up data of patients that are followed-up by the referring hospital.

Note: The registration forms can be filled out and saved multiple times before submission. After staying on the same WBCR page for more than 1 hour, you will automatically be logged off and unsaved data will be lost! Please keep in mind to save the registration within the hour.

Registrations can be **completed** year-round. However, **delivery** of these completed registrations to the BCR will be restricted to 1 mandatory delivery time point per year, i.e. October 1st. Which registrations need to be delivered to the BCR is summarized in the table below:

Which registrations should be sent?	**Deadline 1/10/20xx**	**Example: Deadline 1/10/2021**
Primary Part I	All patients with RFA1 until 30/06/20xx	All patients with RFA1 until 30/06/2021
Primary Part II	All patients with last RFA until 30/06/20xx-1	All patients with last RFA until 30/06/2020
FU 1 year	All patients with last RFA until 30/06/20xx-1	All patients with last RFA until 30/06/2020
FU 2 years	All patients with last RFA until 30/06/20xx-2	All patients with last RFA until 30/06/2019
FU 4 years	All patients with last RFA until 30/06/20xx-4	All patients with last RFA until 30/06/2017
FU 6 years	All patients with last RFA until 30/06/20xx-6	NA (because project only started 1/04/2016)
FU **Y** years	All patients with last RFA until 30/06/20xx-**Y**	

As a support BCR will provide yearly each center a list indicating which primary PART II and FU registrations should be registered by the next deadline.

1.3 Project variable types

The following types of variables are used in the project:

- Date: variable containing 8 digits: 2 for the day, 2 for the month, 4 for the year (dd/mm/yyyy)
- Decimal (x): decimal number, with x being the number of decimals; a point '.' should be used as decimal separator
- Number: integer number
- Single select (SS): variable that is to be chosen out of a limited selection list; only one option can be selected
- Multi select (MS): variable that is to be chosen out of a limited selection list; multiple options can be selected
- Text: free text field, limited to 255 characters, please fill out in English (as well as the comment box at the bottom of the online registration form)

All variables are 'necessary' variables (mandatory to fill in) unless stated otherwise (denoted by 'if possible' or 'if applicable'). When certain numbers are unknown or not mentioned in the medical report, **'-99'** can be filled out, as mentioned in this manual. If a date is not exactly known, please fill out **15/mm/yyyy** if only the month and year are known and **01/07/yyyy** if only the year is known.

Note: Checks have been added to the online registration forms to ensure that the dates are filled out chronologically and that the Prague C-value is not greater than the M-value.

2 Primary registration

For each new registration the administrative patient data need to be provided. When the national number for social security (INSZ/NISS) is filled out in the online application, the rest of the administrative patient data will be automatically completed. When going to the next page, the actual primary registration form begins.

2.1 General

The primary registration document consists out of two parts that each need to be completed at a different timepoint. PART I collects information regarding the patient's medical history and first RFA treatment session and should be sent as soon as possible after the first RFA treatment session (preferably within 3 months after first RFA session).

If the patient receives a second RFA treatment session, PART II can be started. One year after completion of the last RFA treatment session the registration form can be send. Part I and Part II are considered as a separate primary registration and need to be sent separately.

Name variable	Type	Answer options
Which RFA treatment session(s) will be registered?	SS	First RFA session (RFA1, start of a new treatment)
		Subsequent RFA session(s) (RFA 2-8)

2.2 Part I: Patient history and first RFA treatment session

2.2.1 Patient history (prior to the start of this registration)

Please fill out the date when the initial diagnosis of Barrett esophagus was made (if uncertain: 15/mm/yyyy or 1/07/yyyy; if unknown: leave blank). When the patient received any previous RFA treatments prior to this registration which led to complete remission of the lesions, fill out the date of the last RFA session of the (last) previous RFA treatment.

Name variable	Type	Answer options
Date of the initial diagnosis of Barrett esophagus, if possible:	date	dd/mm/yyyy
Did the patient already receive a RFA treatment after which complete remission was determined?	SS	No
		Yes*
*Date of last RFA session of previous RFA treatment, if possible:	date	dd/mm/yyyy

2.2.2 *Endoscopic and histological diagnosis of the current dysplasia/neoplasia*

The **date** on which the **current dysplasia or neoplasia** was firstly, macroscopically diagnosed via endoscopy should be provided, as well as the Prague classification at that endoscopy.

The **Prague classification** is a standardized system for grading the endoscopic appearance of Barrett esophagus. The Prague classification consists of two values: the C- and the M-value. These values are the circumferential extent (C) and the maximum extent (M) of the suspected columnar metaplasia and are determined by different measurements (Figure 1).
The **C-value** is the depth of endoscopic insertion at the top of the gastric mucosal folds/sphincter pinch (in cm) minus the depth of endoscope insertion at the most proximal circumferential extent of suspected columnar metaplasia (in cm).
The **M-value** is the depth of endoscopic insertion at the top of the gastric mucosal folds/sphincter pinch (in cm) minus the depth of endoscopic insertion at the maximum extent of suspected columnar metaplasia (in cm).

Note: Both the C- and the M-value should be between 0 and 20 cm. The C-value can never be higher than the M-value (and they will rarely be the same).

Note: If the values are unknown, '-99' can be registered (not for the Prague classification at the day of RFA treatment; then it is a required variable).

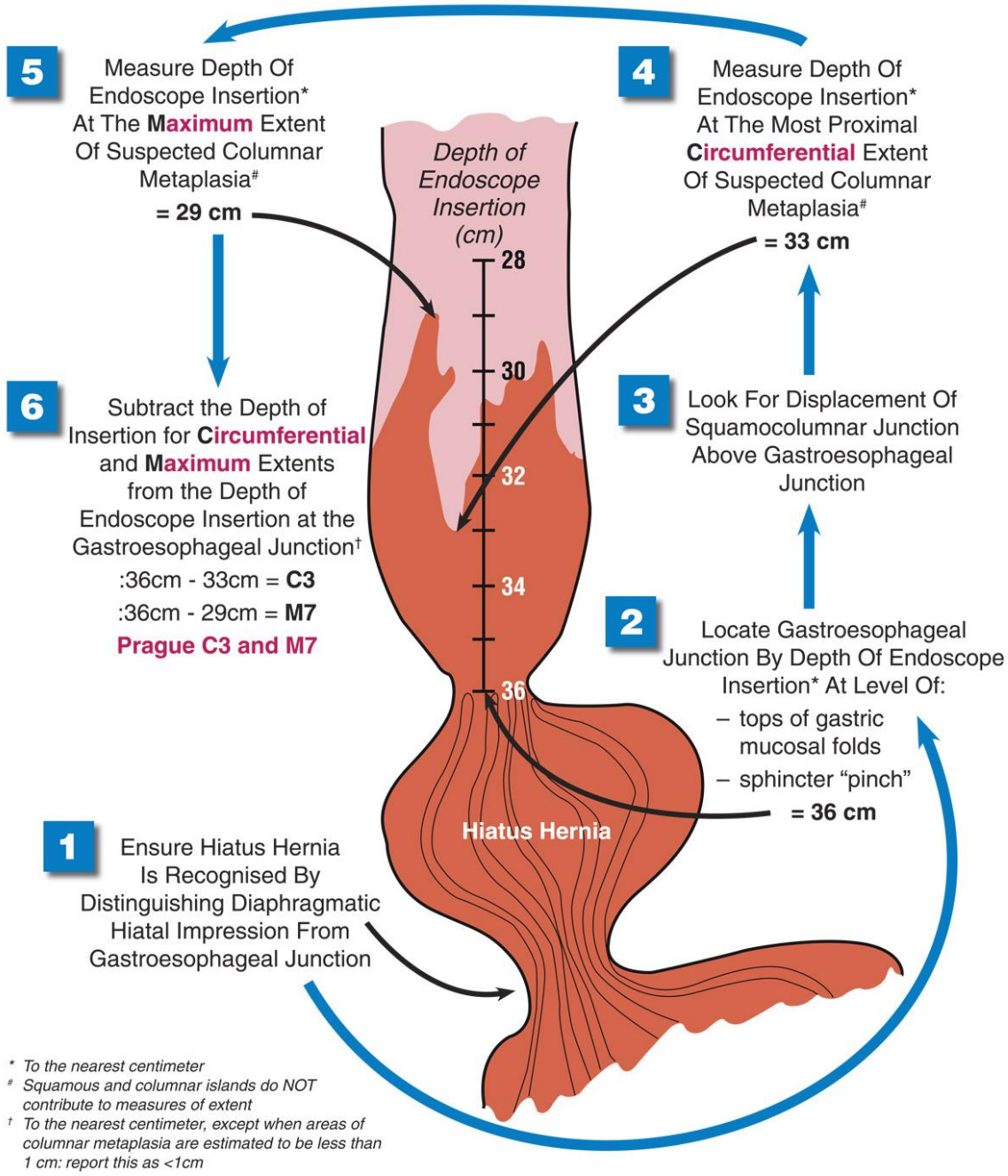

Figure 1: Prague criteria for endoscopically suspected esophageal columnar metaplasia/Barrett esophagus, developed by the Barrett's Oesophagus Subgroup of the International Working Group for the Classification of Reflux Oesophagitis (IWGCO).

Furthermore, it should be indicated whether the first RFA was preceded by a **pre-RFA treatment** such as an endoscopic mucosal resection (EMR), an endoscopic submucosal dissection (ESD) or ablation other than RFA. If not, it should be indicated whether a **biopsy** was performed prior to the first RFA and the **worst histology on biopsy** should be registered, as determined by the pathologist. If a pre-RFA treatment was not performed, you may turn to section 2.3.
Note: When multiple biopsies were analyzed, only the worst diagnosis should be registered.

If a **pre-RFA treatment** was performed prior to the first RFA, the **date** of the latest pre-RFA treatment and the **Prague classification** (Figure 1) on that date should be indicated, together with the **type(s) of pre-RFA treatment(s)** that were performed. For EMR the lesion can be removed in one part (en bloc) or in different parts (piecemeal). Lesion capture during EMR can be performed using a suction cap and closing of a snare (cap EMR) or using a banding cap to create a pseudopolyp and deploying of a band (band/multiband EMR).
In case EMR or ESD was performed, the **worst histology on the EMR/ESD-specimen** should be registered. In addition, the status of the deep and lateral margins of the resected specimen should be indicated, as determined by the pathologist (Figure 2). For the **deep margin** the pathologist will determine if it is positive or negative for carcinoma. If the margin itself is negative, it is important to state the extent of the tumor-free deep margin (e.g. smaller or larger or equal to 1 mm). At the **lateral margins** the pathologist will not only look for the presence of carcinoma, but also for the presence of intestinal metaplasia or dysplasia (with specification of LGIN or HGIN), which should be registered.

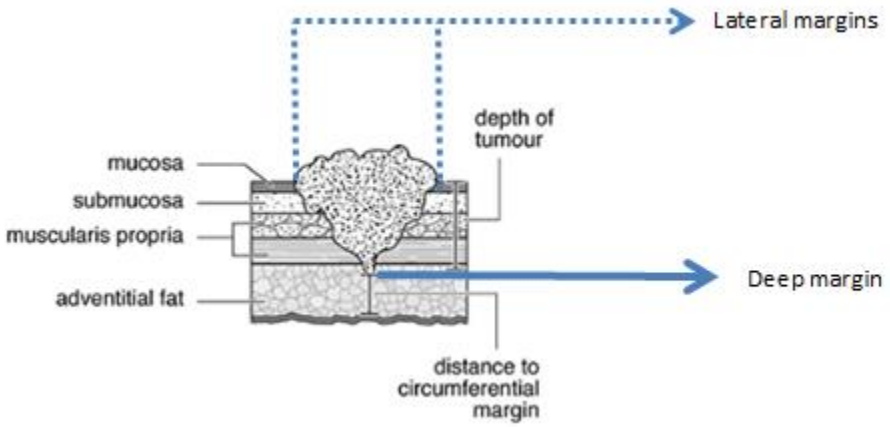

Figure 2: Location of the lateral and deep margins.

Furthermore, when the worst histology on EMR/ESD was an "invasive adenocarcinoma", the following variables should be registered:

- **Depth of tumor invasion**. The tumor depth options are depicted in Figure 3 and can be fitted into the TNM system. The T1a category (mucosa) can be subclassified into T1a m1 (tumor invades lamina propria) and T1a m2-4 (tumor invades muscularis mucosae). The T1b category (submucosa) can be subclassified into T1b sm1-3. Higher numbers of subcategories indicate a higher depth of tumor invasion.

- **Differentiation grade**. If more than one differentiation grade is mentioned by the pathologist, only register the highest grade (e.g. 4>3).
- **Lymphovascular invasion**. Please indicate the presence or absence of lymphovascular invasion.

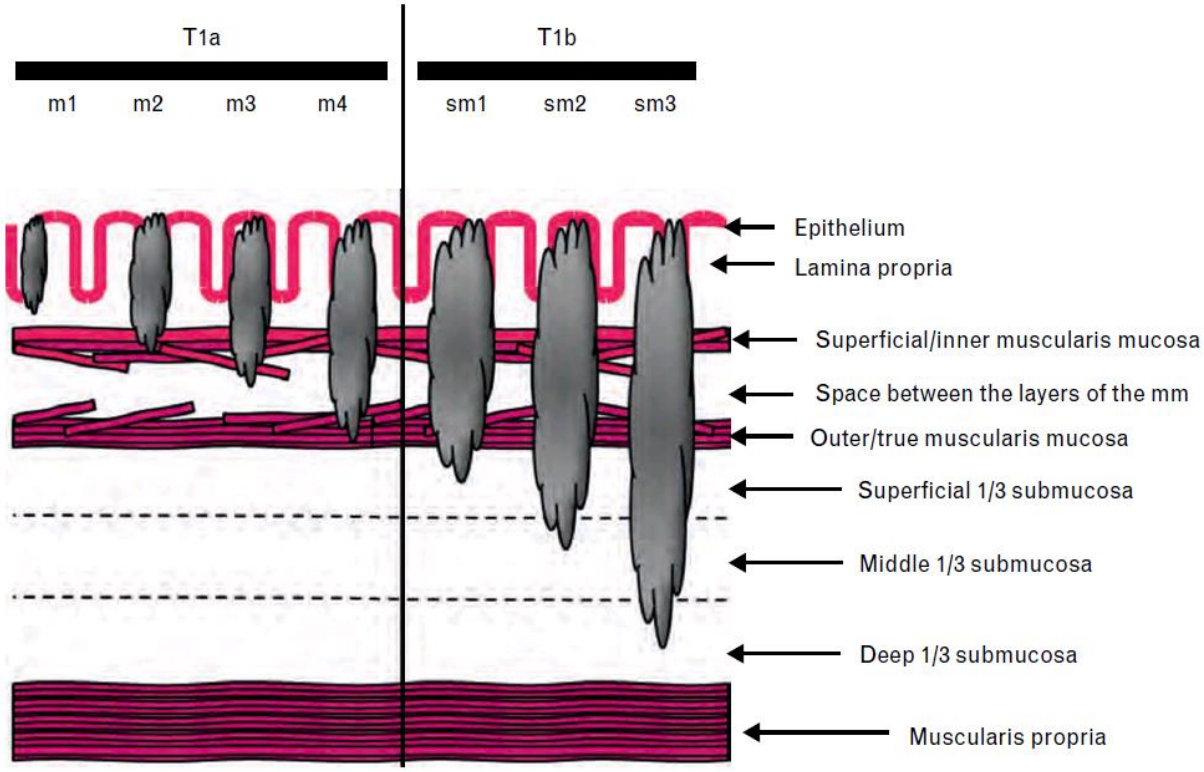

Figure 3: Schematic presentation of the subdivision of tumor depth according to the Vieth and Stolte system.

Lastly, when a pre-RFA treatment was performed prior to the first RFA, the presence of **early complications** during or shortly after the pre-RFA treatment(s) should be specified together with the type of complication. When an **endoscopic evaluation** of the (latest) pre-RFA treatment prior to the date of RFA was performed, please indicate this together with the **date** of this endoscopic evaluation. When a **biopsy** was performed prior to RFA **which had a more advanced histology** as compared to the worst histology on EMR/ESD, that **worst histology** on biopsy should be specified.

Name variable	Type	Answer options	
Date of diagnosis of the current dysplasia/neoplasia:	date	dd/mm/yyyy	
Prague classification at this endoscopy, if possible (cm):	decimal (1)	C:	(min-max = 0-20 or -99)
		M:	(min-max = 0-20 or -99)
Was the first RFA preceded by a pre-RFA treatment (e.g. EMR/ESD, non-RFA ablation)?	SS	No†	
		Yes*	

†Was a biopsy performed prior to RFA?	SS	No (turn to section 2.3)	
		Yes‡	

Name variable	Type	Answer options
‡Please specify the worst histology on biopsy:	SS	Barrett esophagus with intestinal metaplasia
		Barrett esophagus with low grade dysplasia (LGIN)
		Barrett esophagus with high grade dysplasia (HGIN) /Carcinoma *in situ*
		Invasive adenocarcinoma

*Date of the latest pre-RFA treatment:	date	dd/mm/yyyy		
*Prague classification, if possible (cm):	decimal (1)	C:	(min-max = 0-20 or -99)	
		M:	(min-max = 0-20 or -99)	
*Type of pre-RFA treatment(s) performed:	MS (+text)	Endoscopic (sub)mucosal resection (EMR/ESD)°	EMR, please specify if possible	En bloc EMR by means of cap EMR
				En bloc EMR by means of band EMR
				Piecemeal EMR by means of cap EMR
				Piecemeal EMR by means of multiband EMR
				Unknown
			ESD	
			Other: …	
		Ablation techniques (other than RFA)	Argon plasma coagulation (APC)	
			Cryoablation	
			Other: …	

°Please specify the worst histology on EMR/ESD:	SS	Barrett esophagus with intestinal metaplasia
		Barrett esophagus with low grade dysplasia (LGIN)
		Barrett esophagus with high grade dysplasia (HGIN) /Carcinoma *in situ*
		Invasive adenocarcinoma**
**Depth of tumor invasion:	SS	T1a
		T1a m1 (into the lamina propria)
		T1a m2 (into the superficial muscularis mucosae)
		T1a m3 (in between the muscularis mucosae layers)
		T1a m4 (into the deep muscularis mucosae)
		T1b
		T1b sm1
		T1b sm2
		T1b sm3
		Not applicable
		Unknown

Name variable	Type	Answer options
**Differentiation grade (if possible):	SS	1 = Well differentiated
		2 = Moderately differentiated
		3 = Poorly differentiated
		4 = Undifferentiated (anaplastic)
		9 = Unknown
**Lymphovascular invasion (if possible):	SS	No
		Yes
		Cannot be determined
		Not reported
°Deep margin of the resected specimen (if possible):	SS	Negative for carcinoma (margin < 1 mm)
		Negative for carcinoma (margin ≥ 1 mm)
		Negative for carcinoma (margin not reported)
		Positive for carcinoma
		Cannot be determined
		Unknown
°Lateral margin of the resected specimen (if possible; only the most advanced histology):	SS	Negative for metaplasia / dysplasia / carcinoma
		Positive for intestinal metaplasia
		Positive for LGIN
		Positive for HGIN or carcinoma
		Cannot be determined (i.e. piecemeal resection)
		Unknown

*Early complications during or shortly after pre-RFA treatment(s):	SS	No
		Yes$
$Specify:	MS (+text)	Bleeding
		Perforation
		Other: …
*Endoscopic evaluation of the latest pre-RFA treatment (prior to date of RFA), if possible:	SS	No
		Yes¥
¥Date (if possible):	date	dd/mm/yyyy
*Was a biopsy performed prior to RFA for which a more advanced histology was found compared to the worst histology on EMR/ESD?	SS	No
		Yesϕ
ϕPlease specify the worst histology on biopsy:	SS	Barrett esophagus with intestinal metaplasia
		Barrett esophagus with low grade dysplasia (LGIN)
		Barrett esophagus with high grade dysplasia (HGIN) /Carcinoma *in situ*
		Invasive adenocarcinoma

2.2.3 Second opinion of histological diagnosis

Please indicate what the worst histology was prior to the first RFA session and whether the worst histology was confirmed by a separate, second opinion, either on biopsy or on EMR/ESD-specimen, and whether this was performed by a doctor-specialist that belongs to another or the same hospital or partnership.

Name variable	Type	Answer options
Worst histology prior to first RFA session:	SS	Barrett esophagus with intestinal metaplasia
		Barrett esophagus with low grade dysplasia (LGIN)
		Barrett esophagus with high grade dysplasia (HGIN) /Carcinoma *in situ*
		Invasive adenocarcinoma
Was the worst histology confirmed by a separate, second opinion?	SS	No
		Yes (i.e. the second opinion was performed by another doctor-specialist that belongs to another hospital or partnership)
		The second opinion was performed by a doctor-specialist that belongs to the same hospital or partnership

2.2.4 MOC/COM discussion

During a multidisciplinary oncology consult (MOC), a decision will be made as to whether or not RFA will be performed for a new lesion. Please register whether such a MOC discussion has taken place and specify if this was done in the center that performed the RFA or the center that referred the patient. If a MOC discussion was not done in the performing RFA center and it is unclear whether it was done in the referring center, the fourth option should be indicated.

Name variable	Type	Answer options
Has a MOC/COM discussion been done before starting the RFA treatment for the new lesion?	SS	No
		Yes, by the center that performed the RFA
		Yes, by the center that referred the patient to a RFA center
		Unclear whether a MOC/COM discussion was done in the referring center

2.2.5 First RFA treatment session

Please indicate the **date of the first RFA** and the **Prague classification** that was determined on that date during the endoscopic assessment preceding RFA (Figure 1).

The **endoscopic (macroscopic) diagnosis** at the first RFA should also be registered. Barrett esophagus endoscopically presents as tongues or circular metaplastic mucosa with a minimum length of 1 cm above the upper end of the gastric folds. When islands of intestinal metaplasia are present, please indicate the **number of islands** and the **smallest and largest diameter of the islands**. If one or more of these numbers are unknown, '-99' can be registered.

Please indicate whether a **biopsy** was performed on the day of the first RFA and if yes, specify the **worst histology on biopsy**.

Different **catheters** can be used depending on the size and extent of the diseased tissue (e.g. circumferential devices, focal devices). Please register whether **1 or 2 catheters** were used during the first RFA treatment session and indicate the **type**(s) of catheter used. For each catheter it should be indicated whether the catheter is attested to the authorities for compensation (reimbursement), including the pseudo-nomenclature code used.

- Code **172616-172620** refers to treatment of circular lesion of 30 mm or more of length with a circumferential device.
- Code **172631-172642** refers to the use of a focal RFA device for a lesion of ≤ 20 mm of length.
- Code **172653-172664** refers to usage of a focal RFA device for a lesion of > 20 mm.

In addition, please specify for each catheter which **associated protocol** was used (including the energy level, number of electrode activations and presence or absence of a cleaning step).

Furthermore, it should be indicated whether the **z-line** was treated or not during the first RFA treatment session. This demarcation line, the squamocolumnar junction or z-line, represents the normal esophagogastric junction where the squamous mucosa of the esophagus and columnar mucosa of the stomach meet.

After the RFA treatment it is possible that patients experience complications. When these complications occur during RFA or within 24 hours after the RFA treatment, they can be registered as **acute complications** (e.g. bleeding, fever, perforation). Complications that occur more than 24 hours after RFA and before a subsequent EMR/ESD and/or RFA session can be registered as **late complications** (e.g. severe bleeding, symptomatic stenosis/strictures, poor healing, severe esophageal pain). The late complication 'poor healing' is defined as significant inflammation which is still present ≥ 3 months after the RFA treatment.

When the late complication 'Symptomatic stenosis/strictures with need for dilatation' is indicated, please also specify:

- The **number of dilatations needed** before the start of a subsequent RFA session or, if this was the final RFA session, at the end of this registration. If this number is unknown, '-99' can be filled out.
- Whether this **complication was resolved** before the start of a subsequent RFA session or, if this was the final RFA session, at the end of this registration.

Name variable	Type	Answer options	
Date of first RFA:	date	dd/mm/yyyy	
Prague classification (cm):	decimal (1)	C:	(min-max = 0-20)
		M:	(min-max = 0-20)
Endoscopic (macroscopic) diagnosis at first RFA:	MS (+text)	Islands of intestinal metaplasia†	
		Barrett esophagus without visible focal lesion (flat Barrett)	
		Barrett esophagus with visible focal, suspicious lesion	
		Other: …	
†Number of islands, if possible:	number	(min-max = 1-100 or -99)	
†Smallest diameter of islands, if possible (mm):	decimal (1)	(min-max = 0.1-100 or -99)	
†Largest diameter of islands, if possible (mm):	decimal (1)	(min-max = 0.1-100 or -99)	
Was a biopsy performed on the day of the first RFA?	SS	No	
		Yes‡	
‡Please specify the worst histology on biopsy:	SS	Barrett esophagus with intestinal metaplasia	
		Barrett esophagus with low grade dysplasia (LGIN)	
		Barrett esophagus with high grade dysplasia (HGIN) /Carcinoma *in situ*	
		Invasive adenocarcinoma	
Number of RFA catheters used during the first RFA treatment session:	SS	1 catheter*	
		2 catheters**	
*Type of first RFA catheter used:	SS (+ text)	Circumferential device: HALO/BARRX 360 Express RFA catheter	
		Focal device: HALO/BARRX 90 catheter	
		Focal device: HALO/BARRX 60 catheter	
		Focal device: HALO/BARRX Ultra long catheter	
		Focal device: HALO/BARRX Channel TTS RFA catheter	
		Other: …	
*Was the first RFA catheter attested to the authorities for compensation?	SS	No	
		Yes°	
°Please specify the attested pseudo-nomenclature code	SS	172616-172620	
		172631-172642	
		172653-172664	

Name variable	Type	Answer options
*Associated protocol used:	SS (+text)	2 x 10 J
		2 x 12 J
		3 x 12 J
		3 x 15 J
		10 J - clean - 10 J
		12 J - clean - 12 J
		2 x 12 J - clean - 2 x 12 J
		2 x 15 J - clean - 2 x 15 J
		Other: …
*,**Type of second RFA catheter used:	SS (+ text)	Circumferential device: HALO/BARRX 360 Express RFA catheter
		Focal device: HALO/BARRX 90 catheter
		Focal device: HALO/BARRX 60 catheter
		Focal device: HALO/BARRX Ultra long catheter
		Focal device: HALO/BARRX Channel TTS RFA catheter
		Other: …
*,**Was the second RFA catheter attested to the authorities for compensation?	SS	No
		Yes°
°Please specify the attested pseudo-nomenclature code	SS	172616-172620
		172631-172642
		172653-172664
*,**Associated protocol used:	SS (+text)	2 x 10 J
		2 x 12 J
		3 x 12 J
		3 x 15 J
		10 J - clean - 10 J
		12 J - clean - 12 J
		2 x 12 J - clean - 2 x 12 J
		2 x 15 J - clean - 2 x 15 J
		Other: …
Was the z-line treated?	SS	No
		Yes
Acute complications (during RFA and/or within 24 hours):	SS	No
		Unknown
		Yes°
°Specify acute complications:	MS (+text)	Bleeding
		Fever
		Perforation
		Other: …

2.3 Part II

If more than 1 RFA session is performed in a patient's treatment, a new primary registration form in which Part II should be started. This primary Part II registration can only be completed 1 year after the last RFA session in this treatment (i.e. the patient should be 1 year RFA-free).

2.3.1 Subsequent RFA treatment session(s) (RFA 2-8)

During RFA therapy radiofrequency energy is delivered via a catheter to remove a thin layer of diseased tissue. This ablation is repeated until all the diseased tissue has been removed. Please indicate **how many RFA treatment sessions** were performed (i.e. on different time points), including RFA1, which has been registered previously.

If part of the treatment session was performed in another center, this should be indicated for each session and the name of the other center performing the RFA treatment session(s).
If the RFA treatment was prematurely discontinued this can be indicated, including the reason for discontinuation.

Name variable	Type	Answer options	
How many RFA treatments were performed in total (including RFA1, which has been registered previously)?	SS	2	6
		3	7
		4	8
		5	
If certain RFA session(s) was/were performed in another center, please specify which RFA session(s): (*only fill out if RFA sessions within the current RFA treatment were performed in another center*)	MS	RFA1	RFA5
		RFA2	RFA6
		RFA3	RFA7
		RFA4	RFA8
In which other center was/were this/these RFA sessions performed	Text		
If the RFA treatment was prematurely discontinued, please specify the reason	MS (+ text)	Patient's request	
		Comorbidities	
		Patient died due to complications of the RFA treatment	
		Patient died due to other reasons	
		Other:……	

Information regarding late complications after the first RFA treatment session can be completed here.

Name variable	Type	Answer options
Late complications (more than 24 hours after RFA and before a subsequent EMR/ESD and/or RFA session):	SS	No
		Unknown
		Yes°°
°°Specify late complications:	MS (+text)	Severe bleeding
		Symptomatic stenosis/strictures with need for dilatation¥
		Poor healing (significant inflammation still present >= 3 months post-RFA)
		Severe esophageal pain
		Other: …
¥Number of dilatations needed before the start of a subsequent RFA session or, if this was the final RFA session, at the end of this registration, if possible:	number	(min-max = 1-20 or -99)
¥Was this complication resolved before the start of a subsequent RFA session or, if this was the final RFA session, at the end of this registration (if possible)?	SS	No
		Unknown
		Yes

During the endoscopy after the first RFA, it can be determined that a new RFA session is necessary to remove residual diseased tissue. If multiple RFA sessions are necessary, please fill out the following questions for each of the RFA treatment sessions (i.e. treatments that happened on different time points).

Note that when the decision to perform an additional RFA session is made within a year from the previous RFA session, this should be included in the same primary registration. Otherwise, the primary registration form should be completed 1 year after the last RFA session, at which time also the first follow-up registration form should be filled out.

The questioned variables are the same or very similar to those that were asked earlier on in the primary registration form (see sections 2.2 and 2.2.5 for more information). For the first question (RFA preceded by a separate endoscopy), please note that endoscopies that were solely performed to evaluate remaining lesions after a pre-RFA treatment or to evaluate late complications of a previous RFA session, are not included and should not be registered here.

Name variable	Type	Answer options
Was the (second - eighth) RFA preceded by a separate endoscopy (without pre-RFA treatment)?	SS	No
		Yes†

Name variable	Type	Answer options		
†Date of the latest endoscopy:	date	dd/mm/yyyy		
†Prague classification, if possible (cm):	decimal (1)	C:	(min-max = 0-20 or -99)	
		M:	(min-max = 0-20 or -99)	
†Was a biopsy performed during this/these endoscop(y)(ies)?	SS	No		
		Yes‡		
‡Please specify the worst histology on biopsy:	SS	Barrett esophagus with intestinal metaplasia		
		Barrett esophagus with low grade dysplasia (LGIN)		
		Barrett esophagus with high grade dysplasia (HGIN) /Carcinoma *in situ*		
		Invasive adenocarcinoma		
Was the (second - eighth) RFA preceded by a pre-RFA treatment (e.g. EMR/ESD, non-RFA ablation)?	SS	No		
		Yes*		
*Date of the latest pre-RFA treatment:	date	dd/mm/yyyy		
*Prague classification, if possible (cm):	decimal (1)	C:	(min-max = 0-20 or -99)	
		M:	(min-max = 0-20 or -99)	
*Type of pre-RFA treatment(s) performed:	MS (+text)	Endoscopic (sub)mucosal resection (EMR/ESD)°	EMR, please specify if possible	En bloc EMR by means of cap EMR
				En bloc EMR by means of band EMR
				Piecemeal EMR by means of cap EMR
				Piecemeal EMR by means of multiband EMR
				Unknown
			ESD	
			Other: …	
		Ablation techniques (other than RFA)	Argon plasma coagulation (APC)	
			Cryoablation	
			Other: …	
°Please specify the worst histology on EMR/ESD:	SS	Barrett esophagus with intestinal metaplasia		
		Barrett esophagus with low grade dysplasia (LGIN)		
		Barrett esophagus with high grade dysplasia (HGIN) /Carcinoma *in situ*		
		Invasive adenocarcinoma**		

Name variable	Type	Answer options
**Depth of tumor invasion:	SS	T1a
		T1a m1 (into the lamina propria)
		T1a m2 (into the superficial muscularis mucosae)
		T1a m3 (in between the muscularis mucosae layers)
		T1a m4 (into the deep muscularis mucosae)
		T1b
		T1b sm1
		T1b sm2
		T1b sm3
		Not applicable
		Unknown
**Differentiation grade (if possible):	SS	1 = Well differentiated
		2 = Moderately differentiated
		3 = Poorly differentiated
		4 = Undifferentiated (anaplastic)
		9 = Unknown
**Lymphovascular invasion (if possible):	SS	No
		Yes
		Cannot be determined
		Not reported
°Deep margin of the resected specimen (if possible):	SS	Negative for carcinoma (margin < 1 mm)
		Negative for carcinoma (margin ≥ 1 mm)
		Negative for carcinoma (margin not reported)
		Positive for carcinoma
		Cannot be determined
		Unknown
°Lateral margin of the resected specimen (if possible; only the most advanced histology):	SS	Negative for metaplasia / dysplasia / carcinoma
		Positive for intestinal metaplasia
		Positive for LGIN
		Positive for HGIN or carcinoma
		Cannot be determined (i.e. piecemeal resection)
		Unknown
*Early complications during or shortly after pre-RFA treatment(s):	SS	No
		Yes$
$Specify:	MS (+text)	Bleeding
		Perforation
		Other: …
*Endoscopic evaluation of the latest pre-RFA treatment (prior to date of RFA; if possible):	SS	No
		Yes¥
¥Date (if possible):	date	dd/mm/yyyy

Name variable	Type	Answer options	
Date of second-eighth RFA:	date	dd/mm/yyyy	
Prague classification (cm):	decimal (1)	C:	(min-max = 0-20)
		M:	(min-max = 0-20)
Endoscopic (macroscopic) diagnosis at second-eighth RFA:	MS (+text)	Remaining islands of intestinal metaplasia†	
		Barrett esophagus without visible focal lesion (flat Barrett)	
		Barrett esophagus with visible focal, suspicious lesion	
		Other: …	
†Number of islands, if possible:	number	(min-max = 1-100 or -99)	
†Smallest diameter of islands, if possible (mm):	decimal (1)	(min-max = 0.1-100 or -99)	
†Largest diameter of islands, if possible (mm):	decimal (1)	(min-max = 0.1-100 or -99)	
Was a biopsy performed on the day of the second-eighth RFA?	SS	No	
		Yes‡	
‡Please specify the worst histology on biopsy:	SS	Barrett esophagus with intestinal metaplasia	
		Barrett esophagus with low grade dysplasia (LGIN)	
		Barrett esophagus with high grade dysplasia (HGIN) /Carcinoma *in situ*	
		Invasive adenocarcinoma	
Number of RFA catheters used during the second-eighth RFA treatment session:	SS	1 catheter*	
		2 catheters**	
*Type of first RFA catheter used:	SS (+ text)	Circumferential device: HALO/BARRX 360 Express RFA catheter	
		Focal device: HALO/BARRX 90 catheter	
		Focal device: HALO/BARRX 60 catheter	
		Focal device: HALO/BARRX Ultra long catheter	
		Focal device: HALO/BARRX Channel TTS RFA catheter	
		Other: …	
*Was the first RFA catheter attested to the authorities for compensation?	SS	No	
		Yes°	
°Please specify the attested pseudo-nomenclature code	SS	172616-172620	
		172631-172642	
		172653-172664	

*Associated protocol used:	SS (+text)	2 x 10 J
		2 x 12 J
		3 x 12 J
		3 x 15 J
		10 J - clean - 10 J
		12 J - clean - 12 J
		2 x 12 J - clean - 2 x 12 J
		2 x 15 J - clean - 2 x 15 J
		Other: …
*,**Type of second RFA catheter used:	SS (+ text)	Circumferential device: HALO/BARRX 360 Express RFA catheter
		Focal device: HALO/BARRX 90 catheter
		Focal device: HALO/BARRX 60 catheter
		Focal device: HALO/BARRX Ultra long catheter
		Focal device: HALO/BARRX Channel TTS RFA catheter
		Other: …
*,**Was the second RFA catheter attested to the authorities for compensation?	SS	No
		Yes°
°Please specify the attested pseudo-nomenclature code	SS	172616-172620
		172631-172642
		172653-172664
*,**Associated protocol used:	SS (+text)	2 x 10 J
		2 x 12 J
		3 x 12 J
		3 x 15 J
		10 J - clean - 10 J
		12 J - clean - 12 J
		2 x 12 J - clean - 2 x 12 J
		2 x 15 J - clean - 2 x 15 J
		Other: …
Was the z-line treated?	SS	No
		Yes
Acute complications (during RFA and/or within 24 hours)	SS	No
		Unknown
		Yes°
°Specify acute complications:	MS (+text)	Bleeding
		Fever
		Perforation
		Other: …

Late complications (more than 24 hours after RFA and before a subsequent EMR/ESD and/or RFA session):	SS	No
		Unknown
		Yes°°
°°Specify late complications:	MS (+text)	Severe bleeding
		Symptomatic stenosis/strictures with need for dilatation¥
		Poor healing (significant inflammation still present >= 3 months post-RFA)
		Severe esophageal pain
¥Number of dilatations needed before the start of a subsequent RFA session or, if this was the final RFA session, at the end of this registration, if possible:	number	(min-max = 1-20 or -99)
¥Was this complication resolved before the start of a subsequent RFA session or, if this was the final RFA session, at the end of this registration (if possible)?	SS	No
		Unknown
		Yes

3 Follow-up registration

For each new registration the administrative patient data need to be provided. When the national number for social security (INSZ/NISS) is filled out in the online application, the rest of the administrative patient data will be automatically completed. When going to the next page, the actual follow-up registration form begins.

3.1 General follow-up data

The follow-up registration form should be filled out on regular follow-up time points, namely yearly for the first two years and every two years afterwards (i.e. 1, 2, 4, 6, 8, … years after the last RFA session).

Please register the **date of the last RFA treatment session** prior to this follow-up period. Note that this date does include RFA that was performed during this follow-up period. It should be specified for which **follow-up time point** this registration form is being filled out. If it concerns a first year follow-up registration and if the patient received only 1 RFA treatment session, information regarding possible late complications should be completed.

Name variable	Type	Answer options	
Date of last RFA treatment session prior to this follow-up period:	date	dd/mm/yyyy	
Follow-up time point (number of years after the last RFA treatment session):	SS	1 year*	12 years
		2 years	14 years
		4 years	16 years
		6 years	18 years
		8 years	20 years
		10 years	
*Was the patient treated with only 1 RFA treatment session	SS	No	
		Yes**	
**Late complications (more than 24 hours after RFA and before a subsequent EMR/ESD and/or RFA session):	SS	No	
		Unknown	
		Yes°	
°Specify late complications:	MS (+text)	Severe bleeding	
		Symptomatic stenosis/strictures with need for dilatation¥	
		Poor healing (significant inflammation still present >= 3 months post-RFA)	
		Severe esophageal pain	
¥Number of dilatations needed before the start of a subsequent RFA session or, if this was the final RFA session, at the end of this registration, if possible:	number	(min-max = 1-20 or -99)	

¥Was this complication resolved before the start of a subsequent RFA session or, if this was the final RFA session, at the end of this registration (if possible)?	SS	No
		Unknown
		Yes

It should be specified whether the **follow-up information** of this follow-up period is fully, partially or not **available**. The **reason** for no or incomplete follow-up information should be specified. When no follow-up information is available (completely lost to follow-up or death), the registration form ends here. Subsequent follow-up forms do not need to be completed until new information is again available.

The **number of endoscopies** performed during this follow-up period for which information is available should be indicated. For each of these endoscopies, the variables under section 3.2 should be completed.

Name variable	**Type**	**Answer options**	
Is the follow-up information of this follow-up period available?	SS (+text)	No†	Patient is completely lost to follow-up:……
			Patient died in the beginning of this follow-up period
		Partially*	Patient is lost to follow-up
			Patient died
			Other:……
		Yes*	
*Number of endoscopies performed during this follow-up period for which information is available:	SS	1	5
		2	6
		3	7
		4	8

Please fill out the following variables for each of the follow-up endoscopies for which information is available (1-8)!

3.2 First until eighth follow-up endoscopy

The **date of the follow-up endoscopy** should be indicated, together with the **Prague classification** at this endoscopy (Figure 1).

The **endoscopic (macroscopic) diagnosis** determined during the current endoscopy should be registered. When remaining islands of intestinal metaplasia were present, please indicate the **number of islands** and the **smallest and largest diameter of the islands**. If one or more of these numbers are unknown, '-99' can be registered. When esophagitis was present, please indicate the Los Angeles classification, which describes the endoscopic appearance of reflux esophagitis and grades its severity (Table 1).

Table 1: Los Angeles classification of esophagitis

Grade A	≥ 1 mucosal breaks (erosions) confined to the mucosal folds, each ≤ 5 mm in maximal length
Grade B	≥ 1 mucosal breaks > 5mm in maximal length, but without continuity across mucosal folds
Grade C	Mucosal breaks continuous between ≥ 2 mucosal folds, but involving less than 75% of the esophageal circumference
Grade D	Mucosal breaks involving more than 75% of esophageal circumference

It should be indicated what was performed during this follow-up period: biopsy, ablation technqiues, new EMR/ESD, esophagectomy or other.

When a **biopsy** was performed during this follow-up endoscopy, please specify the **worst histology** on biopsy. When an *in situ* cancer other than HGIN or an invasive cancer has been diagnosed, the specific **histological diagnosis** should be indicated.
When a free text field needs to be filled out, please include herein the histological code of the format XXXX/X, in which the first 4 numbers give information about the cell type of the tumor while the last number describes the behavior of the tumor (*in situ* cancers have behavior 2, invasive cancers have behavior 3). To code the histological diagnosis the 'International Classification of Diseases for Oncology' (ICD-O), 3rd edition, is used. When a biopsy or surgery is performed, await the results of the microscopic examination. NOS means 'Not otherwise specified".
Example: 8144/3 is the code for 'Adenocarcinoma, intestinal type'.

Please indicate whether buried Barrett's esophagus glands were found beneath regenerative neosquamous epithelium. **Buried glands** are also called buried (Barrett's) metaplasia, buried intestinal metaplasia or subsquamous intestinal metaplasia and they may have potential for dysplastic progression.

When a **new EMR or ESD** is performed, the **worst histology** on the EMR/ESD-specimen should be indicated and the **histological diagnosis** for *in situ* or invasive cancers specified (in the same way as for the histology on biopsy). Also, the status of the **deep and lateral margins** of the resected specimen should be indicated, as determined by the pathologist (Figure 2). Lastly, when the worst histology on EMR/ESD was 'invasive adenocarcinoma', please specify the **depth of tumor invasion** (Figure 3), the **differentiation grade** and the **lymphovascular invasion**. More information about these variables can be found in section 2.2 of this manual.

When an esophagectomy was performed, no new follow-up registration forms need be completed for this patient anymore.

The decision that was made during this follow-up endoscopy with regard to the **long-term follow-up** of the patient or the **next treatment steps** should be registered.

Note: In case of recurrence of Barrett's esophagus for which it is decided to perform a **new RFA** treatment, the follow-up registration form should be closed (including the data from the endoscopy after which the decision was made to start the new RFA treatment). Then a new primary registration form should be initiated in which the data of the new RFA treatment session(s) can be registered.

Name variable	Type	Answer options	
Date of first-eighth follow-up endoscopy:	date	dd/mm/yyyy	
Prague classification (cm):	decimal (1)	C:	(min-max = 0-20)
		M:	(min-max = 0-20)
Endoscopic (macroscopic) diagnosis:	MS (+text)	No Barrett esophagus	
		Remaining islands of intestinal metaplasia°	
		Barrett esophagus without visible focal lesion (flat Barrett)	
		Barrett esophagus with visible focal, suspicious lesion	
		Esophagitis°°	
		Other: …	
°Number of islands, if possible:	number	(min-max = 1-100 or -99)	
°Smallest diameter of islands, if possible (mm):	decimal (1)	(min-max = 0.1-100 or -99)	
°Largest diameter of islands, if possible (mm):	decimal (1)	(min-max = 0.1-100 or -99)	
°°Los Angeles classification:	SS	A	
		B	
		C	
		D	
		Unknown	
What was performed during the follow-up endoscopy of this follow-up period?	MS (+text)	Biopsy*	
		Ablation techniques (other than RFA)	Argon plasma coagulation (APC)
			Cryoablation
			Other: …
		New EMR/ESD°	
		Esophagectomy	
		Other: …	
*Please specify the worst histology on biopsy:	SS	No Barrett esophagus / no intestinal metaplasia	
		Intestinal metaplasia at cardia with or without dysplasia	
		Barrett esophagus with intestinal metaplasia	
		Barrett esophagus with low grade dysplasia (LGIN)	
		Barrett esophagus with high grade dysplasia (HGIN, 8148/2)	
		In situ cancer (other than HGIN)**	
		Invasive cancer***	
**Please specify the histological diagnosis:	SS (+text)	Adenocarcinoma in situ, NOS (8140/2)	
		Squamous cell carcinoma in situ, NOS (8070/2)	
		Other: ...	

Name variable	Type	Answer options
***Please specify the histological diagnosis:	SS (+text)	Adenocarcinoma, NOS (8140/3)
		Squamous cell carcinoma, NOS (8070/3)
		Other: ...
*Were there buried Barrett glands?	SS	No
		Yes
°Please specify the worst histology on EMR/ESD:	SS	No Barrett esophagus / no intestinal metaplasia
		Intestinal metaplasia at cardia with or without metaplasia
		Barrett esophagus with intestinal metaplasia
		Barrett esophagus with low grade dysplasia (LGIN)
		Barrett esophagus with high grade dysplasia (HGIN, 8148/2)
		In situ cancer (other than HGIN)°°
		Invasive cancer°°°
°°Please specify the histological diagnosis:	SS (+text)	Adenocarcinoma in situ, NOS (8140/2)
		Squamous cell carcinoma in situ, NOS (8070/2)
		Other: ...
°°°Please specify the histological diagnosis:	SS (+text)	Adenocarcinoma, NOS (8140/3)
		Squamous cell carcinoma, NOS (8070/3)
		Other: ...
°°°Depth of tumor invasion:	SS	T1a
		T1a m1 (into the lamina propria)
		T1a m2 (into the superficial muscularis mucosae)
		T1a m3 (in between the muscularis mucosae layers)
		T1a m4 (into the deep muscularis mucosae)
		T1b
		T1b sm1
		T1b sm2
		T1b sm3
		Not applicable
		Unknown
°°°Differentiation grade (if possible):	SS	1 = Well differentiated
		2 = Moderately differentiated
		3 = Poorly differentiated
		4 = Undifferentiated (anaplastic)
		9 = Unknown
°°°Lymphovascular invasion (if possible):	SS	No
		Yes
		Cannot be determined
		Not reported

Name variable	Type	Answer options
°Deep margin of the resected specimen (if possible):	SS	Negative for carcinoma (margin < 1 mm)
		Negative for carcinoma (margin ≥ 1 mm)
		Negative for carcinoma (margin not reported)
		Positive for carcinoma
		Cannot be determined
		Unknown
°Lateral margin of the resected specimen (if possible; only the most advanced histology):	SS	Negative for metaplasia / dysplasia / carcinoma
		Positive for intestinal metaplasia
		Positive for LGIN
		Positive for HGIN or carcinoma
		Cannot be determined (i.e. piecemeal resection)
		Unknown
Next treatment steps/Long-term follow-up decision:	MS (+text)	Endoscopic surveillance
		New RFA
		New EMR/ESD
		Ablation techniques (other than RFA)
		Esophagectomy
		Other: …

4 Frequently asked questions (FAQ)

4.1 Registration in general

4.1.1 At what time should a registration form be completed and sent?

Registrations can be **completed** year-round. However, **delivery** of these completed registrations to the BCR will be restricted to 1 mandatory delivery time point per year, i.e. October 1st. Which registrations need to be delivered to the BCR is summarized in the table below:

Which registrations should be sent?	Deadline 1/10/20xx	Example: Deadline 1/10/2021
Primary Part I	All patients with RFA1 until 30/06/20xx	All patients with RFA1 until 30/06/2021
Primary Part II	All patients with last RFA until 30/06/20xx-1	All patients with last RFA until 30/06/2020
FU 1 year	All patients with last RFA until 30/06/20xx-1	All patients with last RFA until 30/06/2020
FU 2 years	All patients with last RFA until 30/06/20xx-2	All patients with last RFA until 30/06/2019
FU 4 years	All patients with last RFA until 30/06/20xx-4	All patients with last RFA until 30/06/2017
FU 6 years	All patients with last RFA until 30/06/20xx-6	NA (because project only started 1/04/2016)
FU Y years	All patients with last RFA until 30/06/20xx-Y	

As a support BCR will provide yearly each center a list of which primary PART II and FU registrations should be registered by the next deadline.

Primary registration form

All RFA treatment sessions for one lesion should be registered within two separate primary registration forms (Part I and Part II).

Information regarding the medical history of the patient and first RFA treatment session can be completed in Part I primary registration form and can be sent to the Belgian Cancer Registry as soon as possible (preferably within 3 months after RFA1).

If more than 1 RFA session is performed in a patient's treatment, a new primary registration form in which Part II should be started. When the decision to perform an additional RFA session is made within a year from the previous RFA session, this should be included in the same primary registration (Part II). Otherwise, the primary registration form (Part II) should be completed 1 year after the last RFA session and sent to the Belgian Cancer Registry (i.e. the patient should be 1 year RFA-free).

One year after the last RFA session also the first follow-up registration form can be filled out and completed (follow-up time point "1 year").

Follow-up registration form

This should be filled out on regular time points, namely yearly for the first two years and every two years afterwards (i.e. 1, 2, 4, 6, 8, … years after the last RFA session). It should include information about all endoscopies that were performed in the prior follow-up period.

Example: On time point "2 years", all information about endoscopies performed since 1 year and 1 day until 2 years after the last RFA session should be included.

Note: The registration forms can be filled out and saved multiple times before submission. After staying on the same WBCR page for more than 1 hour, you will automatically be logged off and unsaved data will be lost! Please keep in mind to save the registration within the hour.

4.1.2 RFA was restarted after an initial successful RFA treatment. How should I register this?

The decision to restart RFA treatment was made within a year from the previous RFA session
If there is less than one year between the RFA treatment sessions, all these RFA sessions should be registered in the same primary registration form.

The decision to restart RFA treatment was made more than a year after the previous RFA session
A new primary registration form should be initiated for the newly started RFA treatment. The follow-up endoscopy after which the decision was made to start the new RFA treatment, should be included in the follow-up registration form. After the second RFA treatment of the patient, a new FU-1y should be completed.

Example: A patient receives 1 RFA treatment on 10th June 2021. During follow-up endoscopy 1,5 years later, the decision is taken to perform a new RFA treatment with several RFA sessions. What should be registered?

- RFA 1 on 10/06/2021
- Registration primary PART I can be completed from 11/06/2021 onwards, because then the acute complications within 24 hours from RFA1 are known (delivery deadline: 1/10/2021)
- ENDO1 (10/09/2021), ENDO 2 (10/05/2022), ENDO 3 (11/09/2022) with decision to perform new RFA treatment
- FU year one can be completed from 10/06/2022 (including ENDO 1 and ENDO 2)
- FU year 2 can be completed from 12/09/2022
- RFA 1 of new treatment on 10/10/2022
- Registration primary PART I can be completed from 11/10/2022 onwards (delivery deadline 1/02/2023)
- RFA 2 of new treatment on 10/02/2023
- Registration primary PART II can be started but not yet completed (only after the patient is 1 full year RFA-free)
- RFA 3 on 10/05/2023
- Registration primary PART II can be filled out further but not yet completed (only after the patient is 1 full year RFA-free)
- Registration primary PART II and FU year 1 can be completed from 10/05/2024 onwards, because then the patient is 1 full year RFA-free (delivery deadline: 1/10/2024)
- Registration FU year 2 can be completed from 10/05/2024 onwards, because then it is 2 years after the last RFA (delivery deadline: 1/10/2025)

4.1.3 What if a patient is lost to follow-up?

If a patient is lost to follow-up, the follow-up information that still is available should be registered for the correct follow-up time point (i.e. 1, 2, 4, 6, 8, … years after the last RFA session). When at the next follow-up time point no information is available, one last follow-up registration form should be filled out, in which the option 'No, the patient is completely lost to follow-up' is indicated. Subsequent follow-up forms do not need to be completed until new information is again available.

Note: Follow-up endoscopies can be performed by the center that performed the RFA treatment or by another hospital (e.g. that referred the patient to the RFA center). It is the responsibility of the hospital where the RFA was performed to collect the follow-up data of patients that are followed-up by the referring hospital.

Example: A patient received his last RFA treatment session in May 2016. Follow-up endoscopies were performed until December 2017, after which the patient was completely lost to follow-up. Three follow-up registration forms should be completed, with the answer to the question 'Is the follow-up information of this follow-up period available?' between brackets:

- Time point "1 year" with all information of the period May 2016 – May 2017 (Yes)
- Time point "2 years" with all information of the period May 2017 – May 2018 (Partially)
- Time point "4 years" (No, the patient is completely lost to follow-up)

4.1.4 What if a patient died?

If a patient died, all information about RFA treatments (primary form) or follow-up endoscopies (follow-up form) that is still available, should be registered. Afterwards, one last follow-up registration form should be filled out for the next follow-up time point, in which the option 'No, the patient died' is indicated.

Example 1: A patient received his last RFA treatment session in May 2016. Follow-up endoscopies were performed until December 2017, after which the patient died.
Three follow-up registration forms should be completed (with the answer to the question 'Is the follow-up information of this follow-up period available?' between brackets):

- Time point "1 year" with all information of the period May 2016 – May 2017 (Yes)
- Time point "2 years" with all information of the period May 2017 – May 2018 (Partially; patient died))
- Time point "4 years" (No, the patient died in the beginning of this follow-up period)

Example 2: A patient received a RFA treatment session in May 2016, after which the patient died.
A primary registration form should be completed with all information about the first RFA treatment session. In addition, also a follow-up registration should be completed (with the answer to the question 'Is the follow-up information of this follow-up period available?' between brackets):

- Time point "1 year" (No, the patient died in the beginning of this follow-up period)

4.1.5 Do I still need to register a patient who underwent an esophagectomy?

If a patient underwent an esophagectomy, all information preceding the surgery and including the esophagectomy itself should still be registered in the applicable follow-up registration forms. The option "esophagectomy" can be indicated for the variables "What was performed during the follow-up endoscopy of this follow-up period" and "Next treatment steps/Long-term follow-up decision". Afterwards, no new follow-up registration forms need be completed for this patient anymore.

4.1.6 In what language should I register?

Please fill out all variables in English, as well as the comment box at the bottom of the online registration form.

4.1.7 What if a patient is partially treated in another hospital?

1) If the RFA treatment is not completely finished (if RFA sessions are administered in 2 different centers) :

- Each institution registers the RFA sessions that are performed at their own center (this can be indicated at section 7 in the primary registration document). If certain RFA sessions were performed at another center this can be indicated, together with the name of the center.
- Concerning the follow-up the centers need to agree which institution will complete the follow-up registration. It seems logical that the center where the follow-up of the patient is performed also completes the follow-up. This can be indicated structurally at the section "General remarks" of the primary registration document: "*Follow-up will be registered by hospital x*".

2) If the RFA treatment is completed (follow-up in two hospitals or in another hospital different from the one performing the RFA treatment)

- At 1.2 of the manual is mentioned:
  Note: Follow-up endoscopies can be performed by the center that performed the RFA treatment or by another hospital (e.g. that referred the patient to the RFA center). It is the responsibility of the hospital where the RFA was performed to collect the follow-up data of patients that are followed-up by the referring hospital.
- If the hospital performing the follow-up also has an agreement with RIZIV, we recommend that both centers agree who will fill out the follow-up registrations, as long as all information is completely registered.

4.1.8 What several endoscopies are performed during the patients' treatment?

If a patient underwent multiple endoscopies during the RFA treatment before the decision was taken to perform another RFA session (within one year after the previous RFA session), only the endoscopy where the decision to perform a new RFA treatment session should be mentioned in the primary registration form.

4.2 Registration form variables

4.2.1 Only islands of intestinal metaplasia remain. Which Prague classification should I register?

In the case of islands of intestinal metaplasia, ‘0 cm’ can be filled out for both the C- and M-value of the Prague classification.