

# ENETS CoE

## Specifications for the Certification of ENETS Centers of Excellence Version 10.0

*[Incl. specifications of an extended scope to Pulmonary NET]*

Within this specification, the term “NET” remains for historic reasons. It refers to “NEN” and implicates

- **Gastrointestinal (GEP) NEN** and
- **Gastrointestinal (GEP) NEC** as well as
- **Neuroendocrine CUP**

These entities are to be discussed in a NET MDT and ‘count’ for the ENETS CoE.

The extended scope for ENETS CoE comprises:

- **Pulmonary (PULM) NETs (typical and atypical carcinoid) and**
- **Borderline Pulmonary (PULM) NET/NEC cases**
- **DIPNECH**

These entities should be discussed in a NET MDT and ‘count’ for the ENETS CoE extended scope

### Definition of pulmonary NENs:

Pulmonary NENs comprise NETs (e.g. typical and atypical carcinoid) and NECs (small-cell and large-cell neuroendocrine carcinoma).

***Pulmonary NECs (small-cell and large-cell neuroendocrine carcinoma) are not part of the certification scope as they are usually treated by pulmonary oncologists.***

However, there might be borderline NEC/NET cases which require NET expertise and should be discussed in a NET MDT.

Examples of borderline NET /NEC cases: doubt about tumor morphology or presence of high KI-67 /mitosis index with a well differentiated morphology

In this version of the CoE specifications, all changes and/or additions are highlighted in blue.

Also, a number of requirements were identified as being dispensable during the revision process; these have been crossed out and are highlighted in yellow for easy visibility.

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## 1. Structure

### Rationale:

A center or network of excellence applying for certification needs a clear organisational structure. Responsibilities and decision-making conditions within the management and affiliated treatment partners are to be displayed / written down (e. g. cooperation treaties /by-laws / procedural rules / standing rules). These agreements provide the basis of structured, efficient, well-founded multidisciplinary medical treatment and patient management within the center / network. Regulations should be directed toward the improvement of patient care and patient satisfaction.

Kindly note: Chapter 1. of this requirements catalogue is part of the annual return data

<b>1.1. Organisational Chart/ Management Structure</b>		Guidance: Please fill in center information in this column Add further information as an appendix.	
1.1.1 Center administration / Steering committee	One person and a deputy should be nominated as “Head of the Center” (mandatory) Their tasks should be defined according to local conditions. (mandatory)	Please provide a task description as an appendix (For guidance there is a template available)	
1.1.2 Center coordination	A center coordinator should be nominated (mandatory) (could be vice to the head of center) A task description has to be provided (mandatory)		
1.1.3 Contact partner for all practitioners	A contact partner for all practitioners should be named, e.g. NET-specialist / organiser tumor board. (optional)		
1.1.4 Patient coordinator	A patient coordinator should be defined, including deputising this position. (e.g.NET-Specialist, e.g. dedicated nurse) (mandatory) A description of tasks, including responsibility for efficiency in patient management has to be provided. (mandatory)	Please provide a task description as an appendix (For guidance there is a template available)  One person might be named for several duties e.g. as “contact partner” and “patient coordinator”	
1.1.5 Quality management coordinator	A quality management coordinator (internal quality) has to be named (nomination / appointment of one person). (mandatory) A description of tasks has to be provided (mandatory)	Please provide a task description as an appendix (For guidance there is a template available)	

## 1.2. Main partners/core partners

Please fill in center information. If needed, add further information as an appendix.

The following specialisations are mandatory for the treatment of NET patients and are named main- or core partners. These partners can be decentralised liaison- or cooperation partners, if not available at the site of the center. All partners at the center of excellence should establish written cooperation agreements to determine general and subject-specific cooperation conditions. Due to local or country-related circumstances, expertise in one field might be covered by other disciplines – this should be explained in writing. It is essential to have the expertise available, not necessarily the discipline.

It is important that in addition to specific qualifications required for each given specialist within their national structure, the NET main partner expert should provide proof of expertise within the NET domain (e.g., duration of time devoted to NET

<p>expertise, proof of attending specific NET courses and meetings [either giving lectures or as part of CME] other particulars pertaining to NET expertise). If as a NET specialist you are replacing a recognised NET specialist colleague, then this should be stated and an <u>educational plan</u> should be provided by the specialist in conjunction with the NET leader in your centre.</p>		
1.2.1 Gastroenterology (expertise)	Please fill in names and addresses and up- date in your individual [GEP] NET Center account on the ENETS website	
1.2.2 Endocrinology (expertise)		
1.2.3 Oncology (expertise)		
1.2.4 Pathology		
1.2.5 Radiology		
1.2.6 Nuclear Medicine (expertise)		
1.2.7 Visceral Surgery (may be within endocrine surgery)		
1.2.8 Endocrine Surgery (may be within visceral surgery)		
1.2.9 Thoracic surgeon	The thoracic surgeon is a main partner, if the centre applies for certification of the 'extended scope on Pulmonary NET'	
1.2.10 Pulmonologist	The pulmonologist is a main partner, if the centre applies for certification of the 'extended scope on Pulmonary NET'	
1.2.11 Contract issues	<p>Please formulate your contracts according to local conditions and consider all issues mentioned. Please upload your contracts (new or updated) as part of the file of evidence to the document system of the certification company prior to the on-site audit (this is due for all centers either initial certification or re-certification (For guidance: there is a contract/agreement template available)</p> <p>The following issues must be addressed with the main partners:</p>	
	1. Assignment of responsibilities in the center	
	2. Determination of contact partners	
	3. Implementation of quality goals	
	4. Decision on obligatory attendance of tumor conference	
	5. Guarantee of availability	
	6. Definition of qualification (curriculum / CV) and continuing education requirements	
	7. Description of processes (diagnostics / treatment) that are relevant for the center, including description of interfaces and disclosure of information (with adherence to specific timeframes)	
	8. Requirement to implement ENETS Guidelines and SOPs	
	9. Description of cooperation regarding tumor documentation	
	10. Declaration of contract partners regarding the cooperation with respect to audit	
	11. Obligation for the contractors to implement legal requirements according to national health bodies (occupational health and safety requirements [Medical Device, Operator Ordinance], etc.)	
	12. Continuing education / CME	
	13. Participation on quality improvement measures (Quality circles, Management Review)	
<p><b>1.3. Secondary Partners</b></p> <p>Please fill in center information. If needed, add further information as an appendix.</p> <p>Defined access to the following specialities is mandatory for the treatment of NET patients. These specializations, named secondary partners, can be decentralised liaison partners.</p> <p>Please provide detailed information about your network of secondary partners and describe the pathways of collaboration and communication (no formal contracts and agreements required anymore) according to (at least local) best practice standards.</p>		
1.3.1 Laboratory (accredited)	Special diagnostics - tumor marker, CgA, 5-HIAA, insulin, pro-insulin, gastrin, somatostatin ,VIP etc.	
1.3.2 Genetics (accredited laboratory)	Genetic analysis of: MEN I /MEN II /Von Hippel Lindau. Genetic counseling.	

1.3.3	Cardiology		
1.3.4	Cardiac Surgery		
1.3.5	Thoracic Surgery	If the centre applies for the extended scope, thoracic surgery is a main partner of the centre → see 1.2.9	
1.3.6	Transplant Surgery	Transplant surgery is an optional partner of the NET centre. Please name this partner if transplantation is part of your therapy portfolio for NET	
1.3.7	Radiotherapy		
1.3.8	Palliative Care		
1.3.9	Pain Therapy		
<b>1.4. Supportive Care Partners</b>			
Please fill in center information. If needed, add further information as an appendix.			
Recent patients' surveys revealed that there is very little psychological support available for NET patients in general, although patients would appreciate and require this kind of counseling. The following specialities of supportive care are important for the treatment and psychosocial support of NET patients in a center. A description of collaboration and communication according to best practice standards is required for each of the mentioned supportive care partners.			
1.4.1	Psychosocial support offers		
1.4.2	Nutrition expert		
1.4.3	Self-help-group	Please provide an explanation on how you communicate with patient advocacy groups.	
<b>1.5. Referring Partners/ Affiliated Partners</b>			
Please fill in center information. If needed, add further information as an appendix			
A center should name its external referring partners and affiliated partners. Please provide an explanation how patients are referred and how the center communicates with the referral center(s). This may evolve in terms of quality and quantity after your institution has been recognised as an ENETS CoE.			
1.5.1	University hospitals		
1.5.2	Non-university hospitals		
1.5.3	Physicians in private practice		
<b>2. Interdisciplinary Cooperation and Communication structure</b>			
Rationale: A certified center needs structured interdisciplinary communication The forwarding of information in the center should be subject to timely minimal requirements. In a certified center, it is necessary to discuss results and interdisciplinary problems/issues in order to regularly update quality planning.			
<b>2.1. NET Tumor Board /Multidisciplinary Decision-Making Team (MDT)</b>			
Please fill in center information (and/or add further information as an appendix...) Minimum requirement: A dedicated NET Tumor Board has to be in place, this can be integrated into another MDT structure or held separately. <u>NET expertise is required for each expert in the NET MDT</u>			
Pulmonary NET patients are either to be discussed in the NET Tumor Board with thoracic surgeons and pulmonologist in attendance or in a Thoracic Tumor Board with NET specialists attending. The center is to guarantee that all tumor entities within the accreditation scope are discussed and documented consistently.			
A certified center needs structured interdisciplinary decision-making.			
2.1.1.	Participants	<b>Mandatory participants [GEP] NET MDT:</b> 1. Internist NET specialist 2. Surgeon 3. Radiologist 4. Pathologist 5. Nuclear Medicine Specialists – or Radiologist if they are experienced in nuclear medicine	Guidance: In the on-site audit the auditors expect to attend a Tumor Board meeting

	<p>6. Endocrinologist, if NET expertise is not covered by NET-Specialist</p> <p>7. Oncologist (or general internist experienced in oncology) if NET expertise is not covered by Internist NET Specialist</p> <p><b>Mandatory participants Pulmonary NET MDT: (1,3,4,5,6,7)</b></p> <p>8. Thoracic surgeon</p> <p>9. Pulmonologist, if NET expertise is not covered by Internist NET Specialist</p> <p><b>Optional participants:</b> All specialists needed ( at the request of tumor board organiser)</p>		
<b>2.1.2.</b> Organisation	There should be a description of the organization of the tumor board referring to local organization structures, including responsibilities and resources.	Guidance: templates of a SOP for tumor board organisation and MDT protocol are available	
2.1.2.1 Coordination of tumor board	The coordinator of the tumor board should be the internist NET specialist or the NET specialist surgeon. (optional)		
2.1.2.2 Preparation of tumor board	Information shall be provided to all participants prior to meeting. (mandatory)		
2.1.2.3 Meeting conditions	Physical presence of the participants is desirable (but video conferencing is also possible)		
2.1.2.4 Imaging	Images have to be made available, including external histology slides and imaging. (mandatory)		
2.1.2.5 Frequency	Minimum required frequency of the tumor board is every four weeks, (mandatory) but it should be appointed weekly. (Emergency therapies can be given prior)		
2.1.2.6 Patients to be presented in TU Board	<ol style="list-style-type: none"> <li>All new GEP NET/ PULM NET patients (mandatory)</li> <li>All GEP NET/PULM NET patients where a diagnostic or therapeutic decision needs multidisciplinary input (mandatory)</li> <li>All GEP NET/ PULM NET patients after surgery</li> </ol>	<p>If the center applies for the extended scope: PULM NET are mandatorily to be discussed in tumor board</p> <p>To be discussed during the pilot phase: Recommendation: please, read in 3. "All [GEP] NET/ pulmonary NET patients in follow-up" instead of "after surgery"</p>	
<b>2.1.3</b> Documentation 2.1.3.1 Tumor board protocol	<p>The-NET tumor board protocol should contain the following information:</p> <ol style="list-style-type: none"> <li>Date of tumor board meeting.</li> <li>Routine patient data.</li> <li>Brief overview of relevant clinical findings (e.g. imaging, functional tests, histological report).</li> <li>Tumor board decision: (including consideration of clinical trials)</li> <li>Names of all participants (physicians).</li> </ol>		

	6. Signature of at least one responsible participant.		
2.1.3.2 Patient information / Referrer information	Outcome of board will be distributed to: 1. Referring physician (mandatory) 2. Patient file (mandatory) 3. All members of the board (that have no electronic access to patient file) 4. General practitioner 5. Patients (on request)		
2.1.3.3 Time target	Two weeks		
2.1.4 Performance data of the tumor board	The center provides an annual statistics report on the tumor board. (mandatory)		
2.1.4.1 All GEP NET	No. of <u>all</u> GEP NET patients (individuals) discussed in tumor board (several presentations/ discussions in the tumor board per year count as 1 patient/ individual)  No. of tumor board discussions in [GEP] NET patients (each presentation/ discussion counts here – taking into account the workload of the center)	Mandatory – annual return data For onsite audit preparation please fill in chapter 14. Key figures: <u>15.2.1.</u>  Mandatory – annual return data	
2.1.4.2 NEW GEP NET	No. of <u>new</u> [GEP] NET patients (individuals) discussed in tumor board All new [GEP] NET patients have to be presented in the MDT. (at least to be mentioned e.g. small benignly behaving tumors)  This is not necessarily due for patients been referred to the center for specific therapies (like e.g. PRRT) who already had a MDT in their referring centre / home country	Mandatory – annual return data For onsite audit preparation please fill in chapter 15. Key figures 15.2.2.	
2.1.4.3 Second opinion GEP NET	No. of second opinions (GEP NET, individuals) discussed in tumor board  Clarification: A patient to be counted as “second opinion patient” for the center is to be seen by a NET expert of the CoE and to be presented in the MDT and gets a full MDT report with recommendation for diagnostics, treatment and follow-up, but treatment and F-U are carried out in other center.  “second opinions” are an intersection of “NEW [GEP] NET patients” Second opinions on radiology review or pathology review on their own don’t count for the CoE	Please fill in chapter 15. . Key figures 15.2.3.	
2.1.4.4 All PULM NET	No. of <u>all</u> PULM NET patients (individuals) discussed in tumor board (several presentations/discussions in the tumor board per year count as 1 patient)  No. of tumor board discussions in [PULM] NET patients (each presentation/	Mandatory annual return data for CoE applying for the extended scope on Pulmonary NET Please fill in chapter 15. Key figures: <u>15.2.4.</u>  Mandatory – annual return data	



	discussion counts here – reflecting the workload of the center)	For onsite audit preparation, please fill in chapter 14. Key figures: <u>15.2.4.</u>	
2.1.4.5 NEW PULM NET	No. of <u>all NEW</u> PULM NET patients (individuals) discussed in tumor board (several presentations/discussions in the tumor board per year = 1 patient)	Mandatory annual return data for CoE applying for the extended scope on Pulmonary NET For onsite audit preparation please fill in chapter 14. Key figures: <u>14.2.5.</u>	
2.1.4.6 Second opinion PULM NET	No. of second opinions (PULM NET, individuals) discussed in tumor board  Clarification: A patient to be counted as “second opinion patient” for the center is to be seen by a NET expert of the CoE and to be presented in the MDT and gets a full MDT report with recommendation for diagnostics, treatment and follow-up, but treatment and F-U are carried out in other center.  “second opinions” are an intersection of “NEW [PULM] NET patients” Second opinions on radiology review or pathology review don’t count for the CoE on their own.	Mandatory annual return data for CoE applying for the extended scope on Pulmonary NET For onsite audit preparation please fill in chapter 14. Key figures: <u>14.2.6.</u>	
2.1.4.7	Treatment decision-making /outcome of the tumor board <ul style="list-style-type: none"> <li>▪ surgery (n)</li> <li>▪ interventional radiology (n)</li> <li>▪ nuclear medicine (n)</li> <li>▪ medical therapies (n)</li> <li>▪ watch and wait</li> <li>▪ other (n)</li> </ul>	For onsite audit preparation please fill in chapter 15 Key figures 15.2.7.  The center must evaluate its adherence to ENETS guidelines in MDT decisions, e.g. based on random samples and local internal audits (documentation is part of the ‘file of evidence’ the auditors will require for the onsite audit)	
2.1.4.8	Implementation of tumour board decision-making (percentage)	Please fill in chapter 15. Key figures 15.2.8. The center must evaluate its adherence to MDT decisions e.g. based on random samples and local internal audits (documentation is part of the ‘file of evidence’ the auditors will require for the onsite audit)	

**2.2. Quality Management Meetings**

Please fill in center information. If needed, add further information as an appendix.

In a certified center it is necessary to maintain procedures of structured discussion of results and interdisciplinary problems in order to regularly update quality planning.

**2.2.1. Organisational meetings**

2.2.1.1 Frequency	Minimum every 6 months (mandatory) (conference calls and videoconferences are possible)	For onsite audit preparation: results will be discussed (this documentation is part of the ‘file of evidence’ the auditors will require for the onsite audit)	
2.2.1.2 Participants	Main partners (mandatory), others (constitution referring to selected topics)	For onsite audit preparation: results will be discussed (this documentation is part of the ‘file of evidence’ the auditors will require for the onsite audit)	

2.2.1.3 Documentation	Protocols and planned measures are to be retained as proof of documentation. (Mandatory)	For onsite audit preparation: protocols are required, and results will be discussed during onsite audit (this documentation is part of the 'file of evidence' the auditors will require for the onsite audit)	
<b>2.2.2. Internal audits</b>			
2.2.2.1. Frequency	Once a year (mandatory)	For onsite audit preparation: results of internal audits will be discussed during onsite audits (this documentation is part of the 'file of evidence' the auditors will require for the onsite audit)	
2.2.2.2. Participants	Main partners (mandatory)		
2.2.2.3 Documentation	Protocols and planned measures are to be retained as proof of documentation. (Mandatory)	For onsite audit preparation: protocols are required, and results will be discussed (documentation is part of the 'file of evidence' the auditors will require for the onsite audit)	
<b>2.2.3. Quality Multidisciplinary Review Meeting</b>			
Centers should define and review their strategic and operational plans including long-term and short-term goals and objectives for the organisation and its services. Review meetings are strategic meetings that should evaluate the results of your center of the last year and undertake service planning			
2.2.3.1. Frequency	A center review (review of procedures and results) is required at least once a year. (Mandatory)	For onsite audit preparation: protocols are required and results will be discussed (documentation is part of the 'file of evidence' the auditors will require for the onsite audit)For onsite audit preparation: protocols	
2.2.3.2. Participants	Main partners (mandatory)		
2.2.3.3 Documentation	Protocols and planned measures are to be retained as proof of documentation. (Mandatory)	For onsite audit preparation: protocols are required, and results will be discussed (documentation is part of the 'file of evidence' the auditors will require for the onsite audit)	
<b>2.3. Information Transfer to Interfaces</b>			
The forwarding of information in the center should be subject to timely minimal requirements.			
2.3.1 Time targets for reports	All reports (tumor board meeting reports / physician's letters / patient reports after consultation and or inpatient treatment) should be forwarded within two weeks	Guidance: A random sample will suffice as proof.	

<b>3. Specialist NET Consultation (Inpatient or Outpatient)</b>			
Rationale: In a center, a NET consultation should be carried out to coordinate necessary diagnostics and therapeutics.			
<b>3.1. Resources</b>			
3.1.1 Task of the specialist NET consultation	Diagnostics / confirmation and staging (including genetic testing if required)		
	Coordination of staging tests (according to center-specific clinical pathways in line with the ENETS Guidelines)		
	Differentiated personal patient information		

	Coordination of therapy planning (in the centre or affiliated institutions)		
	Carrying out of therapy (according to center-specific clinical pathways in line with ENETS Guidelines)		
	Coordination of specific tumor F / U		
	Coordination of tumor board		
3.1.2 . Frequency of special consultations	The special consultations should be held at least a once per week.		
3.1.3 Human Resources	Two NET specialists in a center must be permanently made available in order to guarantee a high quality of care. (mandatory)		
	Two nurses / assistants must be permanently made available in order to guarantee a high quality of care. (mandatory)		
3.1.4 Special qualifications for physicians	A NET specialist is defined as a <b>senior</b> endocrinologist, gastroenterologist, oncologist or specialist gastrointestinal or endocrine surgeon with extensive experience in diagnostics and therapeutics of NETs. Minimum length of time: 5 years (mandatory)		
	The NET specialist has access to all other specialist disciplines involved in NET patient care (main, secondary and supportive care partners). (mandatory)		
3.1.5 Keeping the qualification	CME, according to center-specific conditions for physicians and nursing staff, should be organised.	Guidance: please describe how further training of staff <b>referring to NET</b> is organised and keep proofs and certificates ready for the on-site audit.	
<b>3.2 Quality related processes</b>			
3.2.1 Description of procedures	The center should display its standards of applied diagnostics and therapeutics e.g. general therapy of NETs, MEN I patient management (algorithm).  The descriptions should refer to ENETS Guidelines and ENETS SOC (as far as currently published) including definition of responsibilities and resources	Guidance: please list and provide descriptions of your main procedures	
3.2.2 . Presentation of access to specialised consultation	Waiting times concerning the consultation appointment should be kept to a minimum, e.g. should not exceed 4 weeks.	Guidance: A random sample of. e.g. 4 to 6 weeks will suffice as proof (this documentation is part of the 'file of evidence' the auditors will require for the onsite audit)	
	Period during which staging is concluded (outpatient or inpatient) should be 4-6 weeks		
	The acceptable waiting period until the appointment at a center partner (main or secondary) should not exceed two weeks	Guidance: A random sample of. E.g., 4 to 6 weeks will suffice as proof. (this documentation is part of the 'file of evidence' the auditors will require for the onsite audit)	
3.2.3 Patient information	Informed consent is to be documented in patient's file		
<b>3.3 Performance Data</b>			

3.3.1 Number of NET patients			
3.3.1.1	No. of <b>new GEP NET</b> patients seen by NET specialists of the center in the last calendar year  [Clarification: “patients” are <b>individuals</b> , not patient contacts. One patient with several appointments in the center is counted once/ year as “patient”]	Mandatory – annual return data  For onsite audit preparation: please fill in chapter 14. Key figures: <u>15.1.1.</u>	
3.3.1.2	No. /percentage of these new [GEP] NET patients treated in the center	For onsite audit preparation: please fill in chapter 14. Key figures: <u>15.1.2</u>	
		Centers who are NOT applying for the scope [GEP] NET Center can additionally mention: no. of NEW PULM NET to underline their NET expertise, but these don't 'count' for the [GEP] NET center	
3.3.1.3	No. of <b>current</b> GEP NET patients seen annually by NET specialist [“current patients”: all GEP NET patients (individuals) seen in the center, including NEW GEP NET patients, patients seeking for SECOND OPINION as well as patients in Follow-Up]	Mandatory – annual return data For onsite audit preparation please fill in chapter 14. Key figures: <u>15.1.3.</u>	
3.3.1.4	<b>For centers applying for the extended scope</b> No. of <b>new PULM NET</b> patients seen by NET specialists of the center in the last calendar year  [Clarification: “patients” are <b>individuals</b> , not patient contacts. One patient with several appointments in the center is counted once/ year as “patient”]	Mandatory – annual return data  For onsite audit preparation: please fill in chapter 14. Key figures: <u>15.1.4.</u>	
3.3.1.5	No. /percentage of these new [PULM] NET patients treated in the center	For onsite audit preparation: please fill in chapter 14. Key figures: <u>15.1.5</u>	
3.3.1.6	No. of <b>current</b> [PULM]-NET patients seen annually by NET specialist [“current patients”: all PULM NET patients (individuals) seen in the center, including NEW PULM NET patients, patients seeking for SECOND OPINION as well as patients in Follow-Up]	Mandatory – annual return data For onsite audit preparation please fill in chapter 14. Key figures: <u>15.1.6.</u>	
3.3.2	Percentage of patients with waiting times concerning the consultation appointment less than 2-4 weeks. (sample possible)	A random sample of. e.g. 4 to 6 weeks will suffice as proof (documentation is part of the ‘file of evidence’ the auditors will require for the onsite audit)	
3.3.3	percentage of patients with concluded staging within 4/6 weeks	(documentation is part of the ‘file of evidence’ the auditors will require for the onsite audit)	
3.3.4	percentage of appointments at center partners within 2 weeks (sample possible)	(documentation is part of the ‘file of evidence’ the auditors will require for the onsite audit)	

## 4. Endocrinology

### 4.1.Resources

4.1.1 HR Resources	In a center/ network, one physician with special qualifications must be permanently available; a back-up has to be defined in order to guarantee a high quality of care.	NET main partner expert should provide <u>proof of expertise within the NET domain</u> (e.g., duration of time devoted to NET expertise, proof of attending specific NET courses and meetings [either giving lectures or as part of CME] other particulars pertaining to NET expertise).	
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		If as a NET specialist you are replacing a recognised NET specialist colleague, then this should be stated, and an <u>educational plan</u> should be provided by the specialist in conjunction with the NET leader in your center.	
4.1.2 Special qualifications for physicians	An endocrinologist must be available during office hours at the center. (liaison possible) A senior endocrinologist (or doctor with adequate expertise) is expected.		
	A physician with experience in endocrine functional tests (e.g., pituitary tumor, ectopic hormonal syndromes, and adrenal diseases) is expected.		
4.1.3 Keeping the qualification	CME - defined by national societies for physicians and nursing staff should be verified annually.	Guidance: please describe here how further training of staff <b>referring to-NET</b> is organised and keep proofs and certificates ready for on-site audit.	
<b>4.2. Quality-Related Processes</b>			
4.2.1 Description of procedures	The center needs to display its standards of applied diagnostics and therapeutics. <ul style="list-style-type: none"> <li>1. general therapy algorithm for NETs,</li> <li>2. MEN I patient management (algorithm),</li> </ul> The descriptions should refer to ENETS GL and ENETS SOC (as far as currently published), to national/ international protocols and include responsibilities and resources.	Guidance: please list and provide descriptions of your main procedures	
4.2.2. Patient information	Informed consent to be documented in patient's file (for experimental procedures)		
4.2.3. Tumor documentation	Data/results pertaining to endocrinology should be made available to the NET coordinator/ specialist		
<b>4.3. Performance data</b>			
No additional performance data for endocrinology required up to now			

<b>5. Gastroenterology – Expertise in Endoscopy</b>			
<b>5.1. Resources</b>			
5.1.1 HR Resources	In a center/ network, one physician with special qualifications must be permanently available. A back-up has to be defined in order to guarantee a high quality of care.		
5.1.2 Special qualifications for physicians	A specialist for internal medicine with special skills in gastroenterology (corresponding senior gastroenterologist) is expected.	NET main partner expert should provide <u>proof of expertise within the NET domain</u> (e.g., duration of time devoted to NET expertise, proof of attending specific NET courses and meetings [either giving lectures or as part of CME] other particulars pertaining to NET expertise). If as a NET specialist you are	

		replacing a recognised NET specialist colleague, then this should be stated and an <u>educational plan</u> should be provided by the specialist in conjunction with the NET leader in your centre.	
5.1.3 Endoscopy-special examiner qualifications	An expert with special skills in endoscopies (EGD / colonoscopy) including biopsies is expected.		
	An expert with special skills in pancreatic EUS is expected.		
	An expert with special skills in endosonography, including EUS-guided FNA (1 specialist mandatory) is expected.		
	An expert with special skills in abdominal sonography is expected (If abdominal sonography is done by radiologists or GI surgeons, identical skills are required).		
5.1.4 Keeping the qualification	CME-defined by national societies for physicians and nursing staff should be verified annually.	Guidance: please describe here how further training of staff <b>referring to NET</b> is organised and keep proofs and certificates ready for on-site audit.	
5.1.5 Specialist endoscopists	Please provide the no. of specialist endoscopists that perform the various endoscopies	For onsite audit preparation please fill in chapter 14. Key figures: 14.5.1.	
5.1.6 Equipment	Equipment is expected for: <ul style="list-style-type: none"> <li>▪ Specific EUS</li> <li>▪ Gastric EMR</li> <li>▪ Rectal EMR</li> <li>▪ Small bowel studies</li> </ul> Please provide a description of your equipment.		
<b>5.2. Quality-related Processes</b>			
5.2.1 Description of procedures	The center needs to display its standards of applied diagnostics and therapeutics. The descriptions should refer to ENETS GL and ENETS SOC (as far as currently published) and include responsibilities and resources	Guidance: please list and provide descriptions of your main procedures or applied standardised reporting on NET)	
5.2.2. Patient information	Informed consent is documented in patient's file. (Appropriate to individual countries.)		
5.2.3 Patient safety	The partner should confirm that the national requirements in reference to patient safety are adhered to.		
5.2.4 Tumor documentation	Data/results pertaining to gastroenterology should be made available to the NET coordinator/ specialist		
<b>5.3. Performance Data</b>			
Currently no additional data collection			

6. Oncology			
6.1. Resources			
6.1.1 HR Resources	In a center/network, one physician with special qualifications must be permanently available. A back-up has to be defined in order to guarantee a high quality of care.		
6.1.2 Special qualifications for physicians	A specialist for internal medicine with special skills in hematooncology (senior oncologist) is expected.	The NET main partner expert should provide <u>proof of expertise within the NET domain</u> (e.g., duration of time devoted to NET expertise, proof of attending specific NET courses and meetings [either giving lectures or as part of CME] other particulars pertaining to NET expertise). If as a NET specialist you are replacing a recognised NET specialist colleague, then this should be stated, and an <u>educational plan</u> should be provided by the specialist in conjunction with the NET leader in your centre.	
6.1.3 Keeping the qualification	CME-defined by national societies for physicians and nursing staff should be verified annually.	Guidance: please describe here how further training of staff <b>referring to NET</b> is organised and keep proofs and certificates ready for on-site audit.	
6.2. Quality Related Processes			
6.2.1. Description of procedures used	The center needs to display its standards of applied diagnostics and therapeutics. The descriptions should refer to ENETS G ENETS GL and ENETS SOC L (as far as currently published) and include responsibilities and resources.	Guidance: please list and provide descriptions of your main procedures	
6.2.2. Patient information	Informed consent is documented in patient's file.		
6.2.3 Patient safety	The partner should confirm that the national requirements in reference to patient safety are adhered to.		
6.2.4 Tumor documentation	Data/results pertaining to oncology should be made available to the NET coordinator/ specialist.		
6.3. Performance data			
6.3.1. NET patients with systemic and targeted therapy	<p>Number of [GEP] NETS [if extended scope applies: plus PULM NETS] with systemic and targeted therapy (somatostatin therapy is excluded)</p> <p>Numbers are required for</p> <ul style="list-style-type: none"> <li>• Interferon</li> <li>• Everolimus</li> <li>• Sunitinib</li> <li>• Other</li> </ul> <ul style="list-style-type: none"> <li>• Streptozocin/5-FU</li> <li>• Temozolomide/Capecitabine</li> <li>• Carbo- or Cisplatin/Etoposide</li> <li>• Other combinations</li> </ul>	<p>Mandatory – annual return data</p> <p>Please fill in chapter 15. . Key figures: <u>15.6.1.</u></p>	



<p>6.3.2 Systemic and targeted therapy - morbidity</p>	<p>Number of serious adverse events after targeted therapy in NET patients</p> <p>Number of serious adverse events after systemic therapy in NET patients</p> <p>Centers can set the time frame due to local and national circumstances and obligations.</p> <ul style="list-style-type: none"> <li>▪ In-house morbidity /mortality</li> <li>▪ 30 day morbidity /mortality</li> <li>▪ 90 day morbidity /mortality</li> <li>▪ Centers can collect full data or a random sample</li> </ul> <p>It is clear that the comparability will be limited, but please emphasise: that this data is important for the internal discussion within the centers and during the external audit.</p>	<p>Mandatory – annual return data: x out of y: serious adverse events</p> <p>For onsite audit preparation please fill in chapter 15. Key figures: 15.6.2</p> <p>FOR CLARIFICATION: Please report only “major AEs” e.g., sepsis after chemotherapy leading to new hospitalization, extended hospitalization, emergency room access...</p>	
<p>6.3.3 Systemic and targeted therapy- mortality</p>	<p>Number of deaths after targeted therapy in NET patients</p> <p>Number of deaths after systemic therapy in NET patients</p>	<p>Mandatory – annual return data x out of y: deaths</p> <p>Please fill in chapter 15. . Key figures: 14.5.3</p>	

## 7. Pathology

### 7.1. Resources

<p>7.1.1 HR Resources</p>	<p>In a center/network, one physician with special qualifications must be permanently available. A back-up has to be defined in order to guarantee a high quality of care.</p>		
<p>7.1.2</p>	<p>In a center, one technical medical assistant with qualifications in the applied methods must be permanently available. A back-up has to be defined in order to guarantee a high quality of care.</p>		
<p>7.1.3 Special qualifications for physicians</p>	<p>A senior pathologist with experience in diagnostics of NETs is expected: the NET expert holds a certificate of NET expertise by national institutions or from ENETS (Liaison is possible)</p>	<p>The NET main partner expert should provide <u>proof of expertise within the NET domain</u> (e.g., duration of time devoted to NET expertise, proof of attending specific NET courses and meetings [either giving lectures or as part of CME] other particulars pertaining to NET expertise). If as a NET specialist you are replacing a recognised NET specialist colleague, then this should be stated and an <u>educational plan</u> should be provided by the specialist in conjunction with the NET leader in your center.</p>	
<p>7.1.4 Expertise in PULM NET</p>	<p>If extended scope applies: A senior pathologist with experience in diagnostics of [PULM] NETs is expected. <del>The NET expert holds a certificate of NET expertise by national institutions or from ENETS (Liaison is possible)</del></p>	<p>The NET main partner expert should provide <u>proof of expertise within the NET domain</u> (e.g., duration of time devoted to NET expertise, proof of attending specific NET courses and meetings [either giving lectures or as part of CME] other particulars pertaining to NET expertise). If as a NET specialist you are replacing a recognised NET specialist colleague, then this should be</p>	



		stated and an <u>educational plan</u> should be provided by the specialist in conjunction with the NET leader in your center.	
7.1.5 Keeping the qualification	CME-defined by national societies for physicians and nursing staff.	Guidance: please describe here how further training of staff <b>referring to NET</b> is organised and keep proofs and certificates ready for on-site audit.	
7.1.6 External quality control	Participation in inter-laboratory comparisons	Guidance: Please provide evidence of participation in inter-laboratory comparisons as they are nationally applicable (e.g. KI67)	
<b>7.2. Quality-related Processes</b>			
7.2.1 Description of procedures used	The center needs to display its standards of applied diagnostics and therapeutics. The descriptions should refer to ENETS GL and ENETS SOC (as far as currently published) and include responsibilities and resources.	Guidance: please list and provide descriptions of your main procedures	
7.2.2 Complete pathology reports	The no. of complete pathology reports should be <b>100%</b>		
	A complete pathology report consists of: <ol style="list-style-type: none"> <li>1. Site</li> <li>2. Tumor type according to WHO and ENETS - TNM classification</li> <li>3. Tumor size</li> <li>4. Tumor invasion (depth)</li> <li>5. Assessment of neural-, (lymph), angio-invasion</li> <li>6. No. and status of lymph nodes</li> <li>7. R-Status</li> <li>8. Ki-67, Ki-67 labeling index, mitosis rate</li> <li>9. Grading</li> <li>10. Neuroendocrinological marker: chromogranin A, Synaptophysin</li> </ol> The following are optional: <ol style="list-style-type: none"> <li>11. Other markers (hormones: serotonin, gastrin, glucagon, pancreatic polypeptide)</li> <li>12. Optional: somatostatin receptors</li> </ol>		
7.2.3 Time target for pathology reports	The pathology report of biopsies (not surgical specimen) should be provided within 5 working days.	Please provide an overview about the turnaround times (random sample for NET)	
<b>7.3. Performance data</b>			
7.3.1 No. of pathologists	No. of pathologists who are experts in GEP NET	Please fill in chapter 15. . Key figures: 15.7.1.	
7.3.2 No. of pathology reports - biopsies	No. of pathology reports : NET biopsies GEP NET	Please fill in chapter 15. . Key figures: 15.7.2.	
7.3.3 No. of pathology reports - surgical specimen	No. of pathology reports : surgical specimen GEP NET	Please fill in chapter 15. . Key figures: 15.7.3.	
7.3.4 No. of immunohistological examinations		Please fill in chapter 15. . Key figures: 15.7.4.	
7.3.5 Percentage of complete pathology reports	Percentage of complete pathology reports (surgery and biopsy)	Please fill in chapter 15. Key figures: 15.7.5.	

7.3.6 No. of pathologists	No. of pathologists, who are experts on PULM NET	Please fill in chapter 15. . Key figures: 15.7.6.	
7.3.7 No. of pathology reports - biopsies	No. of pathology reports on PULM NET biopsies	Please fill in chapter 15. . Key figures: 15.7.7.	
7.3.8 No. of pathology reports - surgical specimen	No. of pathology reports : surgical specimen PULM NET	Please fill in chapter 15. . Key figures: 15.7.8.	
7.3.9 No. of immunohistological examinations		Please fill in chapter 15. . Key figures: 15.7.9.	
7.3.10 Percentage of complete pathology reports	Percentage of complete pathology reports (surgery and biopsy)	Please fill in chapter 15. . Key figures: 15.7.10.	

8. Radiology			
8.1. Resources			
8.1.1 HR Resources	In a center/network, one physician with special qualifications must be permanently available. A back-up has to be defined in order to guarantee a high quality of care.		
	One radiologist should be named as a contact person.		
8.1.2 Special qualifications for physicians	A senior radiologist with experience in diagnostics (CT/ MRI) of NETs is expected.	The NET main partner expert should provide proof of expertise within the NET domain (e.g., duration of time devoted to NET expertise, proof of attending specific NET courses and meetings [either giving lectures or as part of CME] other particulars pertaining to NET expertise). If as a NET specialist you are replacing a recognised NET specialist colleague, then this should be stated and an educational plan should be provided by the specialist in conjunction with the NET leader in your centre.	
	A senior radiologist with experience in interventional radiology in NETs is expected.		
8.1.3 Keeping the qualification	CME-defined by national societies for physicians and nursing staff should be annually verified.	Guidance: please describe here how further training of staff <b>referring to NET</b> is organised and keep proofs and certificates ready for on-site audit.	
8.1.4 Technical equipment	The following technical equipment should be available. <ul style="list-style-type: none"> <li>1. Magnetic Resonance Imaging of liver, pancreas and small bowel</li> <li>2. MR Cholangio pancreatography (MRCP).</li> <li>3. Computed tomography (CT):</li> <li>4. CT software for image reconstruction.</li> </ul> <p>Technical specifications according to ENETS Standard of Care.</p>	Guidance: please list and describe your equipment	

	The radiology unit should have timely access to interventional radiology, including chemoembolisation and radiofrequency ablation and/or laser therapies for hepatic metastases.		
<b>8.2. Quality-related Processes</b>			
8.2.1 Description of procedures used	The center needs to display its standards of applied diagnostics and therapeutics. The descriptions should refer to ENETS GL and SOC (as far as currently published) and include responsibilities and resources. SOPs in place for: CT, MRI, MRCP, US including biopsies, TACE and TAE, TAE with radio labeled spheres, PTC.	Guidance: please list and provide descriptions of your main procedures	
8.2.2 Patient information	Informed consent is documented in patient's file.		
8.2.3 Patient safety	The partner center should confirm that the national requirements in reference to patient safety should be adhered to.		
8.2.4 Time target for access	The appointments (diagnostics and therapy) should be made possible within two weeks.		
<b>8.3. Performance data</b>			
8.3.1	No of interventions	Please fill in chapter 15. . Key figures: 14.5.ff.	
8.3.2	<del>Total No. of TA(C)E</del>  No of TA(C)E in NET  No of ablation in NET (RFA , CRYO.. etc)	Mandatory annual return data	
8.3.3	<del>Total No. of SIRT/intra-arterial PRRT with (radio)pharmaceuticals</del>  No of SIRT/ intra-arterial PRRT with (radio)pharmaceuticals in NET	Mandatory annual return data	
8.3.4 Morbidity in (combined) interventional radiology	Number of serious adverse events after (combined) interventional radiology  Centers can set the time frame due to local and national circumstances and obligations. <ul style="list-style-type: none"> <li>▪ In-house morbidity /mortality</li> <li>▪ 30 day morbidity /mortality</li> <li>▪ 90 day morbidity /mortality</li> <li>▪ Centers can collect full data or a random sample</li> </ul> It is clear that the comparability will be limited, but please emphasise: that this data is important for the internal discussion within the centers and during the external audit.	Mandatory – annual return data: x out of y: serious adverse events  FOR CLARIFICATION: Please report only "major AEs" e.g., sepsis after chemotherapy leading to new hospitalization, extended hospitalization, emergency room access...  For onsite audit preparation please fill in chapter 15. Key figures: 15.8.4 Due to the omission of the previous items 8.3.4 - 8.3.6 as of requirements catalogue version 9.1, this item receives a new number in requirements catalogue version 10.0	
8.3.5. Mortality in (combined) interventional radiology	Number deaths after (combined) interventional radiology	Mandatory – annual return data: x out of y: deaths  For onsite audit preparation, please fill in chapter 14. Key figures: 15.8.5 Due to the omission of the previous items 8.3.4 - 8.3.6, as of requirements catalogue version 9.1, this item receives a new number in requirements catalogue version 10.0	

9. Nuclear Medicine			
9.1. Resources			
9.1.1 HR Resources	In a center/network, one physician with special qualifications must be permanently available. A back-up has to be defined in order to guarantee a high quality of care.		
9.1.2 Specialist qualifications for physicians	A senior physician with experience in diagnostics and therapeutics of NETs is expected. (Threshold under consideration: diagnostics 30 NET patients/doctor/ year and therapies - 10 NET patients/doctor/ year)	The NET main partner expert should provide <u>proof of expertise within the NET domain</u> (e.g., duration of time devoted to NET expertise, proof of attending specific NET courses and meetings [either giving lectures or as part of CME] other particulars pertaining to NET expertise). If as a NET specialist you are replacing a recognised NET specialist colleague, then this should be stated and an <u>educational plan</u> should be provided by the specialist in conjunction with the NET leader in your centre.	
9.1.3 Keeping the qualification	CME-defined by national societies for physicians and technical staff should be annually verified.	Guidance: please describe here how further training of NET staff is organised and keep proofs and certificates ready for on-site audit.	
9.1.4 Technical equipment	Please provide information about all available technical equipment <ul style="list-style-type: none"> <li>▪ SPECT/CT</li> <li>▪ PET/CT</li> </ul> NET relevant PET tracer please specify: <ul style="list-style-type: none"> <li>▪ FDG</li> <li>▪ DOPA</li> <li>▪ Gallium Peptide</li> <li>▪ Other</li> </ul>		
9.2. Quality-related Processes			
9.2.1 Description of procedures used	The center needs to display its standards of applied diagnostics and therapeutics. The descriptions should refer to ENETS Guidelines and include responsibilities and resources.	Guidance: please list and describe your main procedures	
9.2.2 Patient information	Informed consent is documented in patient's file.		
9.2.3 Patient safety	The partner center should confirm that the national requirements in reference to patient safety should be adhered to.		
9.2.4 Tumor documentation	Data/results pertaining to nuclear medicine tests or work up should be made available to the NET coordinator/ specialist.		
9.2.5 Time target for access	The appointments (diagnostics and therapy) should be made possible within two weeks. (Optional)		
9.3. Performance Data			
9.3.1 No. of nuclear medicine examinations in SSTR- PET	Please provide information on total No. of SSTR PET in NET (mandatory)	Mandatory – annual return data	

		<p>Please fill in chapter 15. Key figures: 15.9.1.</p> <p>Due to the omission of the previous items 9.3.1, as of requirements catalogue version 9.1, this item receives a new number in requirements catalogue version 10.0</p>	
9.3.2 No. of nuclear medicine examinations – FDG PET in NET	<p>Please provide information on total No. of FDG PET in NET (currently voluntary)</p>	<p>Please fill in chapter 15. Key figures: 15.9.2. Due to the omission of the previous items 9.3.1, as of requirements catalogue version 9.1, this item receives a new number in requirements catalogue version 10.0</p> <p>As it is likely that that each CoE will have to organise a method to monitor FDG-PETs performed for NET in the near future, CoE should try to collect these numbers.</p>	
9.3.3 No. of nuclear medicine interventions in NET (own center)	<p>Please provide information on where nuclear medicine interventions in NET are done</p> <p>→ in own center and add numbers</p> <ul style="list-style-type: none"> <li>▪ PRRT</li> <li>▪ MIBG</li> <li>▪ PRRT in combination with other treatments</li> </ul>	<p>Please fill in chapter 15. Key figures: 15.9.3.</p> <p>Due to the omission of the previous items 9.3.1, this item receives a new number</p> <p>Clarification: number of therapeutic interventions is to be interpreted as “number of administrations”</p>	
9.3.4 No. of Nuclear medicine interventions in NET (partner center)	<p>Please provide information on where nuclear medicine interventions in NET are done</p> <p>→ in partner center and add numbers</p> <ul style="list-style-type: none"> <li>▪ PRRT</li> <li>▪ MIBG</li> <li>▪ PRRT in combination with other treatments</li> </ul>	<p>Please fill in chapter 15. Key figures: 15.9.4. Due to the omission of the previous items 9.3.1, this item receives a new number</p>	
9.3.5 Interventions - Morbidity	<p>Number of serious adverse events after</p> <ul style="list-style-type: none"> <li>▪ PRRT</li> <li>▪ MIBG</li> <li>▪ PRRT in combination with other treatments</li> </ul> <p>Centers can set the time frame due to local and national circumstances and obligations.</p> <ul style="list-style-type: none"> <li>▪ In-house morbidity /mortality</li> <li>▪ 30 day morbidity /mortality</li> <li>▪ 90 day morbidity /mortality</li> <li>▪ Centers can collect full data or a random sample</li> </ul> <p>It is clear that the comparability will be limited, but please emphasise: that this data is important for the internal discussion within the centers and during the external audit.</p>	<p>Mandatory – annual return data: x out of y: serious adverse events</p> <p>Please fill in chapter 15. Key figures: 15.9.5. Due to the omission of the previous items 9.3.1, this item receives a new number</p> <p>CLARIFICATION: please report major AE of special interest (e.g. bone marrow damage or renal insufficiency after PRRT leading to new hospitalization, extended hospitalization, emergency room access)</p>	
9.6.6 Interventions - mortality	<p>Number of deaths after PRRT</p> <p>Number of deaths after MIBG</p>	<p>Mandatory – annual return data: x out of y: deaths</p> <p>Please fill in chapter 15. Key figures: 15.9.6 Due to the omission of the previous items 9.3.1, this item receives a new number</p>	

## 10. Surgery

### 10.1. Resources

10.1.1 HR Resources	In a center/network, one surgeon with special qualifications must be		
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	permanently available. A back-up has to be defined in order to guarantee a high quality of care.		
10.1.2 Special qualifications HBP Surgery	An endocrine surgeon and a HPB surgeon (or surgeon with comparable expertise according to national standards) is expected. (Liaison possible.)	The NET main partner expert should provide <u>proof of expertise within the NET domain</u> (e.g., duration of time devoted to NET expertise, proof of attending specific NET courses and meetings [either giving lectures or as part of CME] other particulars pertaining to NET expertise). If as a NET specialist you are replacing a recognised NET specialist colleague, then this should be stated and an <u>educational plan</u> should be provided by the specialist in conjunction with the NET leader in your center.	
10.1.3 Special qualifications Thoracic Surgery	For the extended Scope: A thoracic surgeon (or surgeon with comparable expertise according to national standards) is expected. (Liaison possible.)	NET main partner expert should provide <u>proof of expertise within the NET domain</u> (e.g., duration of time devoted to NET expertise, proof of attending specific NET courses and meetings [either giving lectures or as part of CME] other particulars pertaining to NET expertise). If as a NET specialist you are replacing a recognised NET specialist colleague, then this should be stated and an <u>educational plan</u> should be provided by the specialist in conjunction with the NET leader in your center	
<b>10.2. Quality-related Processes</b>			
10.2.1. Tumor board presentation	Every NET patient should be presented at the tumor board after surgery.		
10.2.2. Patient Information	Patient information according to standard practice. The minimum: Documentation in patient file, tumor board protocol.		
10.2.3. Patient safety	The partner should confirm that the national requirements in reference to patient safety are adhered to.		
<b>10.3. Performance Data Surgery</b>			
The items 10.3.1ff – have been rephrased in 2022. Focus is now on surgical interventions in NET			
10.3.1 No. of hepato-biliary surgery (HB-surgeries in NET and non-NET patients)	VOLUNTARY: Please provide information about: <ul style="list-style-type: none"> <li>▪ Partial hepatectomy</li> <li>▪ Radiofrequency assisted resection</li> <li>▪ Other (optional)</li> </ul>	Please fill in chapter 15. . Key figures: 15.10.1 This requirement has been reconsidered. The focus of reporting is now on NET interventions. It is recommended to provide these data on performance volume voluntarily	
10.3.2. No. of Hepato-biliary surgery in NET	Please provide information about NET: <ul style="list-style-type: none"> <li>▪ Partial hepatectomy</li> <li>▪ Radiofrequency assisted resection</li> <li>▪ Other(optional)</li> </ul>	Please fill in Key figures: 15.10.2 <b>Mandatory annual return data</b> <b>Mandatory annual return data</b>  This requirement has been reconsidered. The focus regarding performance volume is now on NET interventions.	
10.3.3 No. of pancreatic surgery (in NET and non-NET patients)	Please provide information about: <ul style="list-style-type: none"> <li>▪ Pancreaticoduodenectomy</li> <li>▪ Distal resection</li> </ul>	Please fill in chapter 15. . Key figures: 15.10.3 This requirement has been reconsidered. The focus of reporting is now on NET interventions. It	

	<ul style="list-style-type: none"> <li>▪ Enucleation</li> <li>▪ Other (optional)</li> </ul>	is recommended to provide these data on performance volume voluntarily	
10.3.4 No. of pancreatic surgery in NET	<p>Please provide information about [GEP] NET</p> <ul style="list-style-type: none"> <li>▪ Pancreaticoduodenectomy</li> <li>▪ Distal resection</li> <li>▪ Enucleation</li> <li>▪ other (optional)</li> </ul>	<p>Please fill in chapter 15. . Key figures: 15.10.4</p> <p>Mandatory annual return data Mandatory annual return data Mandatory annual return data</p>	
10.3.5 No. of bowel surgery in general (in NET and benign and malignant non NET patients)	<p>VOLUNTARY: Please provide information about:</p> <ul style="list-style-type: none"> <li>▪ Stomach</li> <li>▪ Ileum</li> <li>▪ Colon</li> <li>▪ Rectum</li> <li>▪ Peritoneal resections</li> <li>▪ other (optional)</li> </ul>	<p>For onsite audit preparation, please fill in chapter 14. Key figures: 14.10.5</p> <p>It is recommended to provide these data on performance volume voluntarily</p> <p>This requirement has been reconsidered. The focus of reporting regarding performance volume is now on NET interventions.</p>	
10.3.6 No of GI NET Surgery	<p>Please provide information about resections in NET</p> <ul style="list-style-type: none"> <li>▪ Stomach</li> <li>▪ Ileum</li> <li>▪ Colon</li> <li>▪ Rectum</li> <li>▪ Peritoneal resections</li> <li>▪ other (optional)</li> </ul>	<p>Mandatory – annual return data Please fill in chapter 15. Key figures: 15.10.6</p>	
10.3.7 Morbidity and mortality after hepato-biliary surgery  Index procedure “partial hepatectomy” in NET u  Clavien Dindo Classification	<p>Please provide information about morbidity and mortality on index procedure “partial hepatectomy” in NET using the Clavien Dindo Classification</p> <ol style="list-style-type: none"> <li>1. Grade 3 (n)</li> <li>2. Grade 4 (n)</li> <li>3. Grade 5 (n)</li> </ol> <p><b>Clavien Dindo Classification</b>  <b>Grade 3:</b> Requiring surgical, endoscopic or radiological intervention  <b>Grade 4:</b> Life-threatening complication (including CNS complications) requiring IC/ICU management  <b>Grade 5:</b> death  Dindo D., Demartines N., Clavien P.A.; Ann Surg. 2004; 244: 931-937</p> <p>Centers can set the time frame due to local and national circumstances and obligations.</p> <ul style="list-style-type: none"> <li>▪ In-house morbidity /mortality</li> <li>▪ 30 day morbidity /mortality</li> <li>▪ 90 day morbidity /mortality</li> <li>▪ Centers can collect full data or a random sample</li> </ul> <p>It is clear that the comparability will be limited, but please emphasise: that this data is important for the internal discussion within the centers and during the external audit.</p>	<p>Mandatory – annual return data x out of y</p> <ul style="list-style-type: none"> <li>▪ Grade 3</li> <li>▪ Grade 4</li> <li>▪ Grade 5</li> </ul> <p>Please fill in chapter 15. Key figures: 15.10.7</p>	
10.3.8 Morbidity and mortality after pancreatic surgery  Bassi Classification	<p>Please provide information about morbidity using the Bassi Classification for pancreatic fistula</p> <ol style="list-style-type: none"> <li>1. Grade A (n)</li> <li>2. Grade B (n)</li> <li>3. Grade C (n)</li> </ol> <p>Bassi C, Dervenis C, Butturini G et al. (2005) postoperative pancreatic fistula: an</p>	<p>Mandatory – annual return data x out of y</p> <ul style="list-style-type: none"> <li>▪ Grade A</li> <li>▪ Grade B</li> <li>▪ Grade C</li> <li>▪ death</li> </ul>	



	<p>international study group (ISGPF) definition Surgery 2005; 138: 8-13</p> <p>Please enumerate deaths after pancreatic surgery Death _____ (n)</p>	<p>Please fill in chapter 15. . Key figures: 15.10.8</p> <p>Bassi has been relaced by Clavien Dindo</p>	
<p>10.3.8 Morbidity and mortality after pancreatic surgery</p> <p>“index procedure” – Pancreaticoduodenectomy</p>	<p>NEW: Please provide information about morbidity and mortality on index procedure pancreaticoduodenectomy using the Clavien Dindo Classification</p> <p>Grade 3 (n) Grade 4 (n) Grade 5 (n)</p> <p>Centers can set the time frame due to local and national circumstances and obligations. In-house morbidity /mortality 30 day morbidity /mortality 90 day morbidity /mortality Centers can collect full data or a random sample It is clear that the comparability will be limited, but please emphasise: that this data is important for the internal discussion within the centers and during the external audit.</p>	<p>Mandatory – annual return data x out of y Grade 3 Grade 4 Grade 5</p> <p>Please fill in chapter 15. . Key figures: 15.10.8</p>	
<p>10.3.9 Morbidity and mortality after other GI surgery</p> <p>“index procedure SI NET surgery “</p>	<p>NEW: Please provide information about morbidity and mortality on the index procedure SI NET surgery using the Clavien Dindo Classification</p> <ul style="list-style-type: none"> <li>• Grade 3 (n)</li> <li>• Grade 4 (n)</li> <li>• Grade 5 (n)</li> </ul>	<p>Please fill in chapter 15. . Key figures: 15.10.9</p> <p>Mandatory annual return data Mandatory annual return data Mandatory annual return data</p>	
<p>If the center applies for certification of the extended scope -</p>			
<p>10.3.10 No. of thoracic surgery in NET and non-NET patients</p>	<p>VOLUNTARY: Please provide information about numbers of:</p> <ul style="list-style-type: none"> <li>▪ Anatomical lung resections</li> <li>▪ Atypical lung resections</li> <li>▪ Minimal invasive (video assisted) lung resections (VATS)</li> </ul>	<p>For centers with extended scope</p> <p><del>Mandatory annual return data</del> Please fill in chapter 15. . Key figures: 15.10.9</p> <p>This requirement has been reconsidered. The focus of reporting on performance volume is now on NET interventions. It is recommended to provide these data on performance volume voluntarily</p>	
<p>10.3.11 No. of thoracic surgery in NET patients</p>	<p>Please provide information about numbers of thoracic surgeries in [PULM] NET patients</p> <ul style="list-style-type: none"> <li>▪ Anatomical lung resections</li> <li>▪ Atypical lung resections</li> <li>▪ Minimal invasive (video assisted) lung resections (VATS)</li> </ul>	<p>For centers with extended scope</p> <p>Mandatory annual return data Please fill in chapter 15. Key figures: 15.10.10</p>	
<p>10.3.11 Morbidity and mortality after thoracic surgery in NET patients</p> <p>indicator procedure: “Anatomical lung resections</p>	<p>Please provide information about morbidity and mortality on the index procedure “anatomical lung resection” in [PULM] NET patients using the Clavien Dindo Classification</p> <ol style="list-style-type: none"> <li>1. Grade 3 (n)</li> <li>2. Grade 4 (n)</li> <li>3. Grade 5 (n)</li> </ol> <p>It is clear that the comparability will be limited, but please emphasise: that this data is important for the internal</p>	<p>Mandatory – annual return data x out of y</p> <ul style="list-style-type: none"> <li>▪ Grade 3</li> <li>▪ Grade 4</li> <li>▪ Grade 5</li> </ul> <p>Please fill in chapter 15. Key figures: 15.10.11</p>	



	discussion within the centers and during the external audit.		
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## 11. Pulmonology – Expertise in Endoscopy

### 11.1. Resources

11.1.1. HR Resources	In a center/ network, one physician with special qualifications must be made permanently available. A back-up has to be defined in order to guarantee a high quality of care.		
11.1.2 Special qualifications for physicians	A specialist for internal medicine with special skills in pulmonology (corresponding senior pulmonologist) is expected.	The NET main partner expert should provide <u>proof of expertise within the NET domain</u> (e.g., duration of time devoted to NET expertise, proof of attending specific NET courses and meetings [either giving lectures or as part of CME] other particulars pertaining to NET expertise). If as a NET specialist you are replacing a recognised NET specialist colleague, then this should be stated and an <u>educational plan</u> should be provided by the specialist in conjunction with the NET leader in your centre.	
11.1.3. Endoscopy- special examiner qualifications	An expert with special skills in endoscopies (bronchoscopy) including biopsies is expected.		
	An expert with special skills in endobronchial sonography, including EUS-guided FNA (1specialist is mandatory) is expected.		
11.1.4 Specialist endoscopists	Please provide the No. of specialist endoscopists which perform the various endoscopies	For onsite audit preparation please fill in chapter 15. Key figures: 15.11 ff.	
11.1.5 Keeping the qualification	CME-defined by national societies for physicians and nursing staff should be verified annually.	Guidance: please describe here how further training of NET staff is organised and keep proofs and certificates ready for on-site audit.	
11.1.6 Equipment	Equipment is expected for: <ul style="list-style-type: none"> <li>▪ Specific EUS</li> </ul> Please provide a description of your equipment.		

### 11.2. Quality-related Processes

11.2.1 Description of procedures	The center needs to display its standards of applied diagnostics and therapeutics. The descriptions should refer to ENETS GL and ENETS SOC (as far as currently published) and include responsibilities and resources	Guidance: please list and provide descriptions of your main procedures or applied standardised reporting on NET)	
11.2.2 Patient information	Informed consent is documented in patient's file. (Appropriate to individual countries.)		
11.2.3 Patient safety	The partner should confirm that the national requirements in reference to patient safety are adhered to.		

11.2.4 Tumor documentation	Data/results pertaining to pulmonology should be made available to the NET coordinator/ specialist.		
<b>11.3. Performance Data</b>			
Currently no additional data collection is required			

## 12. Scientific Activities

Rationale:  
A center of excellence on rare tumors should have ambitious research efforts in this field.

### 12.1. Clinical Trials

<b>12.1.1 Resources</b>	Study nurse (mandatory)		
	Study representative (mandatory)		
	Study sponsor (mandatory)		
	CRC locally (CRC = cancer research commission) (optional)	Guidance: please describe your NET research group and how it functions.	
<b>12.1.2 Documentation</b>	Individual documentation according to study protocol (mandatory). Active participation protocol should be featured on ENETS website (optional)		
<b>12.1.3 Patient information</b>	Comprehensive patient information regarding ongoing studies according to GCP - Guidelines and EC approval (mandatory)		
<b>12.1.4 Performance data scientific activities - to be discussed for extended scope</b>			
<b>12.1.4.1 Prospective trials</b>	Number of prospective specific diagnostic / therapeutic trials ([GEP] and [PULM]NET) within the last calendar year  Trials that “count” here: Any GI and Pulmonary NET- focused diagnostic or therapeutic prospective research according to international rules (approval by ethics committee) and intention to be published, either in an international, national setting or as a local initiative of the center.	Guidance: please fill in chapter 14. Key figures: 15.12.1.1.	
<b>12.1.4.2 Patients in clinical trials</b>	Number of [GEP] and [PULM] NET patients treated in clinical trials within the <b>last calendar year (treatment and F/U)</b> Trials that “count” here: any GI and pulmonary NET-focused diagnostic or therapeutic prospective research according to international rules (approval by ethics committee) and intention to be published, either in an international or national setting or as a local initiative of the center. Ideally 10% of current patients should be included/treated in trials following this definition.	Mandatory – annual return data  Please fill in chapter 15. . Key figures: 15.12.1.2	
<b>12.1.4.3 Patients newly enrolled into clinical trials</b>	Number of newly enrolled [GEP] and [PULM] NET patients in prospective trials during the <b>last calendar year</b>	Mandatory – annual return data Please fill in chapter 15. Key figures: 15.12.1.3.	

<b>12.2. Publications</b>			
12.2.1 Performance data	Annual research report is to be provided (mandatory)	Centers are to provide an updated publication list ([GEP] NET focus) together with annual return data	
12.2.2 No. of original articles	Number of peer reviewed publications (originals focusing on NET within last calendar year)	Mandatory – annual return data  Please fill in chapter 15. . Key figures: 15.12.2.1.	
12.2.3 No. of other peer-reviewed publications in NET	Number of review articles, case studies, letters or other peer reviewed works focusing on [GEP]-NET within the last calendar year	Mandatory – annual return data  Please fill in chapter 15. . Key figures: 15.12.2.2	
<b>12.3. Research Projects</b>			
12.3.1 International studies	International studies should be supported (optional)	For onsite audit preparation please fill in chapter 15 Key figures: 15.12.3.1.	
12.3.2 Retrospective analysis	No. of retrospective analysis (therapy/diagnostics ) within the last 5 years	Please fill in chapter 15. Key figures: 15.12.3.2.	
12.3.3 Current basic NET research	No. of active/current basic NET research within the last 5 years	For onsite audit preparation please fill in chapter 15. Key figures: 15.12.3.3.	
12.3.4 Current research students	No. of active /current specific research students, please differentiate into PhD Lower grade	For onsite audit preparation please fill in chapter 15. Key figures: 15.12.3.4.	
12.3.5 International exchange of experience	Participation at ENETS conferences is required: at least one member of tumor board (mandatory)	For onsite audit preparation please fill in chapter 15. Key figures: 15.12.3.5.	
12.3.6 Clinical trials announcement	Clinical trials should be published on the ENETS website		
<b>12.4. National / International NET Activity</b>			
12.4.1 National/international NET networking	Centers should be involved in national/international networking activities in NET	Please describe your activities	

<b>13. Patient Involvement</b>			
Rationale: Certified centers should focus on patient orientation. Patients require information pertaining to both general and individual aspects of their disease. Patient satisfaction should be determined at the center.			
<b>13.1. Patient Information</b>			
13.1.1. Informed consent	Documentation of Informed Consent should be provided in patient file. (mandatory) Letters and tumor board decisions should be given to patients (optional / upon request)		
13.1.2 Internet and / or flyer	Introduction of the center (mandatory) Information about Psychosocial services (mandatory) Treatment options for NETS (optional, dependent on national law)		

13.1.3 Patient conferences	Support of patient information conferences (optional)		
<b>13.2. Patient Questionnaire / feedback</b>			
13.2.1 Patient questionnaire	A patient questionnaire should be handed out. (Mandatory)		
13.2.2 Performance data	Percentage of questionnaire feedback	Mandatory – annual return data  For onsite audit preparation, please fill in chapter 14. Key figures: 14.12.2.1.	
13.2.3 Patient feedback	Please describe how patients provide feedback	Guidance: e.g. patient complaint system	
<b>14. Follow-up and Tumor Documentation</b>			
<b>14.1. Resources</b>			
14.1.1. HR Resources	A data manager should be available	Please name the data manager and describe tasks.	
14.1.2 Technical equipment	Software (in the future)		
<b>14.2. Quality-related Processes</b>			
14.2.1 Description of procedures used	The center will determine the mode that governs the feedback about results of the follow-up including responsibilities and resources.		
14.2.2 Registry	Centers must have a local database and have to show how this works during the audit. The CoE process has to be linked to a registry in some format (although it is recognised that this may be difficult for certain countries)	Please describe- how is your patient registry organised?	
14.2.3 ENETS registry	In case of availability of a national NET registry, centers should contribute to the national registry.  CoE in countries without a national NET registry are encouraged to directly contribute to the ENETS registry	Please describe how you participate in a national or supranational NET registry. (if applicable)	
14.3.4 Patient files		Please describe your use of electronic patient files-and how your patient documentation is organised?	
14.3.5 Dataset	A dataset must be defined		
<b>14.3. Performance Data</b>			
<b>Centers applying for re-certification fill in /or provide data from the last calendar year</b>			
<b>Centers applying for initial certification fill in data of the calendar year before application</b>			
14.3.1 GEP NET patients in follow-up	[GEP] NET patients in follow-up (n) and (%)  Target: >70%	Mandatory – annual return data  For onsite audit preparation, please fill in chapter 15. Key figures: 15.13.1.	
14.3.2 Percentage of GEP NET patients lost to follow up		Guidance: please fill in chapter 15. Key figures: 15.13.2.	
14.3.3 PULM NET patients in follow-up	[GEP] NET patients in follow-up (n) and (%)  Target: >70%	Mandatory – annual return data  For onsite audit preparation, please fill in chapter 15 Key figures: 15.14.3	

14.3.4 PULM NET percentage of patients lost to follow-up		Guidance: please fill in chapter 14. Key figures: 15.14.4	
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## 15. Key Figures

The center will determine the mode that governs the feedback about results of the follow-up including responsibilities and resources. A registry-associated follow-up procedure is recommended.

**Centers applying for initial certification should fill in data from previous the calendar year before application – If this data is not available – the starting point for data collection is the day of enrolment into the CoE programme.**

**Centers applying for re-certification fill in data from the last calendar year. (caveat: all key figures, not only annual return data)**

**Please note: This document can be filled in for internal audit and documentation purposes – the data must be provided digitally via the center account in MY ENETS. Each application /Re-application as well as annual return data submission will be provided to the CoE as a pdf report.**

15.1 NET Patients			
15.1.1. New GEP NET patients Referring item 3.3.1.1	No. of <b>new</b> ([GEP] NET) patients annually seen by NET specialists at the center [Clarification: “patients” are individuals, not patient contacts. One patient with several appointments in the center is counted once/ year as “patient”]	Mandatory – annual return data	
	Centers who are NOT applying for the scope [GEP] NET Center can additionally mention: no. of NEW PULM NET to underline their NET expertise	Optional for centers applying for certification as GEP NET CoE	
15.1.2 Percentage GEP NET patients treated in center Referring item 3.3.1.2	No. /percentage of these new GEP NET patients treated in the center	Mandatory – annual return data	
15.1.3 current GEP NET patients Referring item 3.3.1.3.	No. of <b>current</b> [GEP] NET patients seen annually by NET specialist [“current patients”: all [GEP] NET patients (individuals) seen in the center, including NEW [GEP] NET patients and patients seeking for SECOND OPINION]	Mandatory – annual return data	
	Pulmonary NET: Centers can mention: <b>current non-small cell NET and typical and atypical carcinoma</b> to display their NET expertise but these do not ‘count’ for the [GEP] NET center	Optional for centers applying for certification as <b>GEP NET</b> CoE (without scope on PULM NET)	
15.1.4 New PULM NET patients Referring item 3.3.1.4	For centers applying for the extended scope No. of <b>new PULM NET</b> patients seen by NET specialists of the center in the last calendar year  [Clarification: “patients” are <b>individuals</b> , not patient contacts. One patient with several appointments in the center is counted once/ year as “patient”]	For centers with extended scope Mandatory – annual return data	
15.1.5 Referring item 3.3.1.5	No. /percentage of these new [PULM] NET patients treated in the center		
15.1.6 Referring item 3.3.1.6	No. of <b>current</b> [PULM]-NET patients seen annually by NET specialist	For centers with extended scope Mandatory – annual return data	

	["current patients": all PULM NET patients (individuals) seen in the center, including NEW PULM NET patients, patients seeking for SECOND OPINION as well as patients in Follow-Up]		
15.1.7 Referring item 3.3.2	Percentage of patients with waiting times concerning the consultation appointment less than 2-4 weeks. (sample possible)	A random sample of. e.g. 4 to 6 weeks will suffice as proof (documentation is part of the 'file of evidence' the auditors will require for the onsite audit)	
15.1.8. Referring item 3.3.3.	Percentage of patients with concluded staging within 4-6 weeks	(documentation is part of the 'file of evidence' the auditors will require for the onsite audit)	
15.1.9 Referring item 3.3.4	Percentage of appointments at center partners within 2 weeks (sample possible)	(documentation is part of the 'file of evidence' the auditors will require for the onsite audit)	
<b>15. 2 NET Tumor Board / Multidisciplinary Decision Making Team (MDT)</b>			
15.2.1. [GEP] NET patients Referring item 2.1.4.1	No. of <u>all</u> [GEP] NET patients (individuals) discussed in tumor board.	Mandatory – annual return data	
	No. of tumor board discussions in [GEP] NET patients	Mandatory – annual return data	
15.2.2 New GEP NET patients Referring item 2.1.4.2	No. of <u>new</u> [GEP] NET patients (individuals) discussed in tumor board <b>All new [GEP] NET patients</b> have to be presented in the MDT. (at least to be mentioned e.g. small benignly behaving tumors) This is not required for patients referred to the center for specific therapies (like e.g. PRRT) from other centers with MDT or from other countries.	Mandatory – annual return data	
15.2.3 Second. opinions Referring item 2.1.4.3	No. of second opinions ([GEP] NET, individuals) discussed in tumor board  Clarification: A patient to be counted as "second opinion patient" for the center is to be seen by a NET expert of the CoE and to be presented in MDT with patient history, blood test results where appropriate, full imaging and pathology - both revised by the CoE experts - and gets a full MDT report with recommendation for diagnostics, treatment and follow- up, but treatment and F-U are carried out in other center. "Second opinions" are an intersection of "NEW [GEP] NET patients" Second opinions on radiology review or pathology review on their own should not be counted as a second opinion but only as an opinion from an individual NET specialist partner.		
15.2.4 Number of all PULM NETs discussed in TU Board Referring item 2.1.4.4	No. of <u>all</u> PULM NET patients (individuals) discussed in tumor board (several presentations/discussions in the tumor board per year = 1 patient)  No. of tumor board discussions in [PULM] NET patients (each presentation/discussion	Mandatory – annual return data For onsite audit preparation please fill in chapter 3. Key figures: <u>3.2.1.</u>  Mandatory – annual return data	

	counts here – reflecting the workload of the center)		
15.2.5. Number of all NEW PULM NET patients discussed in TU Board Referring item 2.1.4.5	No. of <u>all</u> NEW PULM NET patients (individuals) discussed in tumor board (several presentations/discussions in the tumor board per year = 1 patient)  No. of tumor board discussions in [PULM] NET patients (each presentation/discussion counts here – reflecting the workload of the center)	Mandatory – annual return data For onsite audit preparation please fill in chapter 14. Key figures: <u>14.2.1.</u>  Mandatory – annual return data	
15.2.6 Second opinion on PULM NET Referring item 2.1.4.6	No. of second opinions (PULM NET, individuals) discussed in tumor board		
15.2.7 Treatment decision making / outcome of the tumor board / adherence to ENETS guidelines  Referring item 2.1.4.7	Treatment decision making <ul style="list-style-type: none"> <li>▪ surgery (n)</li> <li>▪ interventional radiology (n)</li> <li>▪ nuclear medicine (n)</li> <li>▪ medical therapies (n)</li> <li>▪ watch and wait</li> <li>▪ other (n)</li> </ul>	Adherence to ENETS guidelines in MDT / evaluation based on internal audits (e.g. sample of 15-20 cases) (voluntary annual return data, results will be discussed during onsite audits)	
15.2.8 Adherence to MDT decision making Referring item 2.1.4.8	Implementation of tumour board decision making (percentage)	Adherence to MDT (evaluation based on internal audits, e.g. sample of 15-20 cases)	
<b>15.3 Specialist NET Consultation</b>			
15.3.1 Waiting times	Waiting times concerning the consultation appointment (days)	A random sample of. e.g. 4 to 6 weeks will suffice as proof	
	Period during which staging is concluded (days)	A random sample of. e.g. 4 to 6 weeks will suffice as proof	
<b>15.4 Endocrinology</b>			
<b>15.5 Gastroenterology</b>			
15.1.5.1 Endoscopists Referring item 5.1.5	No. of specialist endoscopists who perform the various endoscopies		
<b>15.6 Oncology</b>			
15.6.1 Systemic and targeted therapy Referring item 6.3.1.	Number of NETS with systemic and targeted therapy (somatostatin therapy is excluded) Numbers are required for <ul style="list-style-type: none"> <li>• Interferon</li> <li>• Everolimus</li> <li>• Sunitinib</li> <li>• Other</li> </ul> <ul style="list-style-type: none"> <li>• Streptozocin/5-FU</li> <li>• Temozolomide/Capecitabine</li> <li>• Carbo- or Cisplatin/Etoposide</li> <li>• Other combinations</li> </ul>	Mandatory – annual return data	
15.6.2 Systemic and targeted therapy morbidity Referring item 6.3.2.-	Number of serious adverse events after targeted therapy <b>NET patients</b>	Mandatory – annual return data: x out of y: serious adverse events	



	<p>Number of serious adverse events after systemic therapy <b>NET patients</b></p> <p>Number of serious adverse events after interferon therapy <b>NET patients</b></p>	<p>FOR CLARIFICATION: Please report only "major AEs" e.g., sepsis after chemotherapy leading to new hospitalization, extended hospitalization, emergency room access...</p>	
<p>15.6.3 Systemic and targeted therapy mortality Referring item 6.3.3.</p>	<p>Number of deaths after targeted therapy in <b>NET patients</b></p> <p>Number of deaths after systemic therapy in <b>NET patients</b></p> <p>Number of deaths after interferon therapy in <b>NET patients</b></p>	<p>Mandatory – annual return data x out of y: deaths</p> <p>FOR CLARIFICATION: Please report only "major AEs" e.g., sepsis after chemotherapy leading to new hospitalization, extended hospitalization, emergency room access...</p>	
<p><b>15.7. Pathology</b></p>			
<p>15.7.1 Pathologists Referring item 7.3.1</p>	<p>No. of pathologists who are experts in [GEP] NET</p>	<p>NET expertise in Pathology: the NET expert holds a certificate of NET expertise from national institutions or from ENETS</p>	
<p>15.7.2. Biopsies Referring item 7.3.2</p>	<p>No. of pathology reports on bioptic specimen in [GEP] NET</p>	<p>This information is required prior to certification audits</p>	
<p>15.7.3 Surgical spec. Referring item 7.3.3</p>	<p>No. of pathology reports on surgical specimen in [GEP] NET</p>	<p>This information is required prior to certification audits</p>	
<p>15.7.4. Immunohistology Referring item 7.3.4</p>	<p>No. of immuno-histochemical examinations in [GEP] NET</p>	<p>This information is required prior to certification audits</p>	
<p>15.7.5 Complete reports Referring item 7.3.5</p>	<p>percentage of complete pathology reports on [GEP] NET (surgery and biopsy)</p>	<p>This information is required prior to certification audits</p>	
<p>15.7.6 Pathologists Referring item 7.3.6</p>	<p>No. of pathologists who are experts in PULM NET</p>	<p>This information is required prior to certification audits</p>	
<p>15.7.7 Biopsies Referring item 7.3.7</p>	<p>No. of pathology reports on bioptic specimen in [PULM] NET</p>	<p>This information is required prior to certification audits</p>	
<p>15.7.8 Surgical specimens Referring item 7.3.8</p>	<p>No. of pathology reports on surgical specimens in [PULM] NET</p>	<p>This information is required prior to certification audits</p>	
<p>15.7.9 Immunohistology Referring item 7.3.9</p>	<p>No. of immuno-histochemical examinations on [PULM] NET</p>	<p>This information is required prior to certification audits</p>	
<p>15.7.10 Complete reports Referring item 7.3.10</p>	<p>Percentage of complete pathology reports on [PULM] NET (surgery and biopsy)</p>	<p>This information is required prior to certification audits</p>	
<p><b>15.8 Radiology</b></p>			
<p>15.8.1 No. of interventions</p>			
<p>15.8.2 TA(C)E Referring item 8.3.2</p>	<p>Total No. of TA(C)E</p> <p>No of TA(C)E in NET NEW: No of ablation in NET (RFA , CRYO.. etc)</p>	<p>Mandatory annual return data Mandatory annual return data</p>	
<p>15.8.3 SIRT/ intra-arterial PRRT with (radio) pharmaceuticals Referring item 8.3.3</p>	<p>No of SIRT in NET/ intra-arterial PRRT with (radio)pharmaceuticals</p>	<p>Mandatory annual return data</p>	
<p>15.8.4 Morbidity in (combined) interventional radiology Referring item 8.3.4</p>	<p>Number of serious adverse events after (combined) interventional radiology Morbidity and mortality have to be collected for the <b>Procedures (TA[C]E and SIRT) in general</b>, not only related to these procedures used in [GEP] NET patients (this is different to oncology) Centers can set the time frame</p>	<p>Mandatory – annual return data: x out of y: serious adverse events</p> <p>FOR CLARIFICATION: Please report only "major AEs" e.g., sepsis after chemotherapy leading to new hospitalization, extended hospitalization, emergency room access...</p>	



	<p>due to local and national circumstances and obligations.</p> <ul style="list-style-type: none"> <li>In-house morbidity /mortality</li> <li>30 day morbidity /mortality</li> <li>90 day morbidity /mortality</li> </ul> <p>Centers can collect full data or a random sample</p>		
15.8.5 Mortality in (combined) interventional radiology Referring item 8.3.5	Number of deaths after (combined) interventional radiology	Mandatory – annual return data: x out of y: deaths	
<b>15.9 Nuclear Medicine</b>			
15.9.1. SSTR PET in NET Referring item 9.3.1.	Total <u>No. of SSTR PET in NET</u>	Mandatory annual return data	
15.9.2 FDG PET in NET Referring item 9.3.2.	No. of <u>FDG PET in NET</u>	<u>Currently voluntary</u> annual return data	
15.9.3 Therapeutic interventions in own center Referring item 9.3.3. Number of therapeutic interventions is to be interpreted as <b>“number of administrations”</b>	<p>No. of therapeutic interventions (administrations) in own center</p> <ul style="list-style-type: none"> <li>PRRT</li> <li>MIBG</li> <li>PRRT in combination with other treatments</li> </ul>	<p>Mandatory annual return data</p> <p>Mandatory annual return data</p> <p>Mandatory annual return data</p>	
15.9.4. Therapeutic interventions in partner (referral) center Referring item 9.3.4. Number of therapeutic interventions should be interpreted as <b>“number of administrations”</b>	<p>No. of therapeutic interventions in partner center (referrals to this partner center )</p> <ul style="list-style-type: none"> <li>PRRT</li> <li>MIBG</li> <li>PRRT in combination with other treatments</li> </ul>	<p>Mandatory annual return data</p> <p>Mandatory annual return data</p> <p>Mandatory annual return data</p>	
15.9.5 Therapeutic interventions –morbidity referring item 9.3.5 Number of therapeutic interventions should be interpreted as <b>“number of administrations”</b>	<p>Number of serious adverse events after</p> <ul style="list-style-type: none"> <li>PRRT</li> <li>MIBG</li> <li>PRRT in combination with other treatments</li> </ul> <p>Centers can set the time frame due to local and national circumstances and obligations.</p> <ul style="list-style-type: none"> <li>In-house morbidity /mortality</li> <li>30-day morbidity /mortality</li> <li>90-day morbidity /mortality</li> </ul> <p>Centers can collect full data or a random sample</p>	<p>Mandatory annual return data</p> <p>Mandatory annual return data</p> <p>Mandatory annual return data</p> <p>CLARIFICATION: please report major AE of special interest (e.g. bone marrow damage or renal insufficiency after PRRT leading to new hospitalization, extended hospitalization, emergency room access)</p>	
15.9.6 Therapeutic interventions –mortality referring item 9.3.6 Number of therapeutic interventions is to be interpreted as <b>“number of administrations”</b>	<p>Number of deaths after</p> <ul style="list-style-type: none"> <li>PRRT</li> <li>MIBG</li> <li>PRRT in combination with other treatments</li> </ul>	<p>Mandatory annual return data</p> <p>Mandatory annual return data</p> <p>Mandatory annual return data</p>	
<b>15.10 Surgery</b>			
15.10.1 No. of hepato-biliary surgery in NET non-NET patients Referring item 10.3.1.	<p>Voluntary: Please provide information about numbers</p> <ul style="list-style-type: none"> <li>Partial hepatectomies</li> <li>Radiofrequency assisted resection</li> <li>Other</li> </ul>	<p>This requirement has been reconsidered. The focus of reporting is now on NET interventions. However, it is recommended to provide these data on performance volume voluntarily.</p>	
15.10.2 No. of hepato-biliary surgery in NET Referring item 10.3.1	<p>Please give information about NET</p> <ul style="list-style-type: none"> <li>Partial hepatectomies</li> <li>Radiofrequency assisted resection</li> <li>Other</li> </ul>	<p>Mandatory annual return data</p> <p>Mandatory annual return data.</p>	

		This requirement has been reconsidered and rephrased. The focus is now on performance volume in NET interventions	
15.10.3 No. of pancreatic surgery in NET and non-NET patients Referring item 10.3.3.	Voluntary: Please provide information about numbers <ul style="list-style-type: none"> <li>▪ Pancreaticoduodenectomy</li> <li>▪ Distal resection</li> <li>▪ Enucleation</li> <li>▪ other</li> </ul>	This requirement has been reconsidered. The focus of reporting is now on NET interventions. However, it is recommended to provide these data on performance volume voluntarily.	
15.10.4 No. of pancreatic surgery in NET patients Referring item 10.3.2.	Please provide information about pancreatic surgery in NET <ul style="list-style-type: none"> <li>▪ Pancreaticoduodenectomy</li> <li>▪ Distal resection</li> <li>▪ Enucleation</li> <li>▪ Other</li> </ul>	Mandatory annual return data Mandatory annual return data.  This requirement has been reconsidered and rephrased. The focus is now on performance volume in NET interventions	
15.10.5 No. of bowel surgery in general (in NET and benign and malignant non-NET patients) Referring item: 10.3.5	Please provide information about: <ul style="list-style-type: none"> <li>▪ Stomach</li> <li>▪ Ileum</li> <li>▪ Colon</li> <li>▪ Rectum</li> <li>▪ Peritoneal resections</li> <li>▪ other (optional)</li> </ul>	This requirement has been reconsidered. The focus of reporting is now on NET interventions. However, it is recommended to provide these data on performance volume voluntarily.	
10.3.6 No of bowel surgery in NET patients Referring item: 10.3.6	Please provide information about resections in NET <ul style="list-style-type: none"> <li>▪ Stomach</li> <li>▪ Ileum</li> <li>▪ Colon</li> <li>▪ Rectum</li> <li>▪ Peritoneal resections</li> <li>▪ other (optional)</li> </ul>	Mandatory annual return data This requirement has been reconsidered and rephrased. The focus is now on performance volume in NET interventions	
15.10.7 Morbidity and mortality after hepato-biliary surgery (in NET patients)  Index procedure : partial hepatectomy in NET Referring item 10.3.7	Please provide information about the morbidity rate for the index procedure “partial hepatectomies in NET” using the Clavien Dindo Classification <ul style="list-style-type: none"> <li>▪ Grade 3 (n)</li> <li>▪ Grade 4 (n)</li> <li>▪ Grade 5 (n)</li> </ul> Centers can set the time frame due to local and national circumstances and obligations. <ul style="list-style-type: none"> <li>▪ In-house morbidity /mortality</li> <li>▪ 30 day morbidity /mortality</li> <li>▪ 90 day morbidity /mortality</li> </ul> Centers can collect full data or a random sample	Mandatory annual return data  <b>Clavien Dindo Classification</b> Grade 3: Requiring surgical, endoscopic or radiological intervention Grade 4: Life-threatening complication (including CNS complications) requiring IC/ICU management Grade 5: death Dindo D., Demartines N., Clavien P.A.; Ann Surg. 2004; 244: 931-937	
15.10.8 Morbidity and mortality after pancreatic surgery ( in NET patients)  Index procedure: pancreaticoduodenectomy in NET  Referring item 10.3.8	NEW: Please provide information about morbidity and mortality on the index procedure pancreaticoduodenectomy in NET ) using the Clavien Dindo Classification Grade 3 (n) Grade 4 (n) Grade 5 (n) Centers can set the time frame due to local and national circumstances and obligations. <ul style="list-style-type: none"> <li>▪ In-house morbidity /mortality</li> <li>▪ 30 day morbidity /mortality</li> <li>▪ 90 day morbidity /mortality</li> </ul> Centers can collect full data or a random sample	Mandatory annual return data  <b>Explanation:</b> Bassi classification has been replaced by <b>Clavien Dindo</b> which is widely used	

<p>15.10.6 Morbidity and mortality after bowel surgery in NET</p> <p>Index procedure: SI NET SURGERY</p>	<p><b>NEW:</b> Please provide information about morbidity and mortality in SI NET Surgery using the Clavien Dindo Classification</p> <ul style="list-style-type: none"> <li>• Grade 3 (n)</li> <li>• Grade 4 (n)</li> <li>• Grade 5 (n)</li> </ul>	<p>Mandatory annual return data</p> <p>This requirement on reporting morbidity and mortality data have been reduced. The focus is now on one index procedure .</p>	
<p>15.10.10 No. of thoracic surgery in NET and non-NET patients Referring item 10.3.10</p>	<p><b>VOLUNTARY:</b> Please provide information about numbers</p> <ul style="list-style-type: none"> <li>▪ Anatomical lung resections</li> <li>▪ Atypical lung resections</li> <li>▪ Minimal invasive (video assisted) lung resections (VATS)</li> </ul>	<p><b>For centers with extended scope</b> <del>Mandatory annual return data</del></p> <p>This requirement has been reconsidered. The focus of reporting is now on NET interventions. However, it is recommended to provide these data on performance volume voluntarily.</p>	
<p>15.10.11 No. of thoracic surgery in NET patients Referring item 10.3.11</p>	<p>Please provide information about numbers in [PULM] NET patients</p> <ul style="list-style-type: none"> <li>▪ Anatomical lung resections</li> <li>▪ Atypical lung resections</li> <li>▪ Minimal invasive (video assisted) lung resections (VATS)</li> </ul>	<p><b>For centers with extended scope</b> Mandatory annual return data Mandatory annual return data Mandatory annual return data</p> <p><b>Explanation:</b> This requirement has been reconsidered and rephrased. The focus is now on performance volume in NET interventions</p>	
<p>15.10.8 Morbidity and mortality after thoracic surgery in NET patients</p> <p>index invention: “Anatomical lung resections”</p> <p>Referring item 10.3.8</p>	<p>Please provide information about morbidity and mortality on the index procedure anatomical lung resection in NET using the Clavien Dindo Classification</p> <ul style="list-style-type: none"> <li>▪ Grade 3 (n)</li> <li>▪ Grade 4 (n)</li> <li>▪ Grade 5 (n)</li> </ul> <p>Centers can set the time frame due to local and national circumstances and obligations.</p> <ul style="list-style-type: none"> <li>▪ In-house morbidity /mortality</li> <li>▪ 30 day morbidity /mortality</li> <li>▪ 90 day morbidity /mortality</li> </ul> <p>Centers can collect full data or a random sample</p>	<p>Mandatory annual return data Mandatory annual return data Mandatory annual return data</p> <p>This requirement on reporting morbidity and mortality data have been reduced. The focus is now on one index procedure .</p>	
<p><b>15.11. Pulmonology - Expertise in Endoscopy</b></p>			
<p>15.11.1 Pulmonologists Referring item 15.11.3</p>	<p>No. of specialist endoscopists that perform the various endoscopies</p>		
<p><b>15.12 Scientific Activities</b></p>			
<p>15.12.1 Clinical trials</p>	<p>Clinical trials that “count” here: GI and pulmonary NET-focused diagnostic or therapeutic prospective research according to international rules (approval by ethics committee) and intention to be published, either international or national setting or on local initiative of the center.</p>		
<p>15.12.1.1 Prospective trials Referring item 12.1.4.1.</p>	<p>No. of prospective specific diagnostic / therapeutic trials ([GEP] and [PULM] NET) within the last calendar year</p>	<p>Mandatory annual return data</p>	
<p>15.12.1.2 NET patients in clinical trials Referring item 12.1.4.2.</p>	<p>percentage of patients included /treated in trials ([GEP] NET and [PULM] NET) within the last calendar year (treatment and F/U)</p> <p>Target: No. of patients in studies should be &gt;10 %</p>	<p>Mandatory annual return data</p>	
<p>15.12.1.3 NEW NET patients in clinical trials referring item 12.1.4.3</p>	<p>No of newly enrolled [GEP] NET and [PULM] NET patients into prospective clinical trials during the last calendar year</p>	<p>Mandatory annual return data</p>	

<b>15.12.2 Publications</b>			
No. of original articles Referring item 12.2.2.	Number of peer reviewed publications (original articles focusing on NET within last calendar year)	Mandatory annual return data	
No. of other peer reviewed publications Referring item 12.2.3	Number of review articles, case studies, letters or other peer-reviewed works focusing on [GEP] NET within the last calendar year	Mandatory annual return data	
<b>15.12.3 Research Projects</b>			
15.12.3.1 International studies Referring item 12.3.1.	International studies should be supported (optional)		
15.12.3.1 Retrospective analysis Referring item 12.3.2.	No. of retrospective analysis (therapy/diagnostics ) within the last 5 years	This information is required prior to certification audits	
15.12.3.3 Current basic NET research Referring item 12.3.3.	No. of active /current basic NET research within the last 5 years	This information is required prior to certification audits	
	ENETS CoE provide an annual update of their publications regarding their [GEP] NET /NET-related research	Mandatory annual return data: updated publication list is to be uploaded [background: research and clinical trials driven by pharmaceutical industry are diminishing. The number of “patients in clinical trials” decreasingly reflects the research efforts of a CoE.]	
15.12.3.4 Research students Referring item 11.3.4.	No. of active /current specific research students, please differentiate into <ul style="list-style-type: none"> <li>▪ PhD</li> <li>▪ Lower grade</li> </ul>	This information is required prior to certification audits	
15.12.3.5 International exchange of experience Referring item 11.3.5.	Participation at ENETS conferences is required: at least one member of tumor board (mandatory)	This information is required prior to certification audits	
<b>15.13 Patient Questionnaire</b>			
15.13.1 Percentage of questionnaire feedback Referring item 13.2.2	Percentage of questionnaire feedback Target >50%	Mandatory annual return data	
<b>15.14. F / U data</b>			
15.14.1 GEP NET Patients in follow up Referring item 14.3.1.	[GEP] NET patients in follow up Target: >70% (n) and (%)	Mandatory annual return data	
15.1.4.2. Percentage of GEP NET patients lost to follow up Referring item 14.3.2.	percentage of [GEP] NET patients lost to follow up Target: <30%		
15.14.3 PULM NET Patients in follow up Referring item 14.3.3.	[PULM] NET patients in follow up Target: >70% (n) and (%)	Mandatory annual return data for centers applying for the extended scope on pulmonary NET	
15.1.4.2. Percentage of PULM NET patients lost to follow up Referring item 14.3.4.	percentage of [PULM] NET patients lost to follow up Target: <30%		