CONTENT: SOP ENETS CoE CERTIFICATION

1. **Centre of Excellence Certification: aims and benefits**

ENETS with DQS - the Audit Company aim to analyze overall certification benefits prospectively and the process of recertification allows a degree of comparative.
Benefits reported by certified centers include:

- Improved recognition (in-house and external)

- More NET patients

- Improved structured cooperation

- Improved MDT Meetings (more in-depth discussions and consistent specialist participation)

- Improved patient documentation

- Improved patient follow-up, quality control and statistics

- Improved research and more patients in clinical trials

- Fruitful discussions with external peers during the audit

- Possibility of recognizing affiliated referral partners

The most important open question at the moment:

- Is there a benefit for patients?

It is likely that patients will benefit from implementation of this rigorous process applied to NET healthcare management, as well as the additional education and research. Tangible benefits are difficult to assess, but accumulated data during recertification, coupled with data from the ENETS European Registry should provide important information.

2. Scopes
   ENETS CoE certification is subsequent to available ENETS guidelines as there are primarily for GEP NET and also for Pulmonary NET.
   - Basic scope: GEP NET
   - ADD ON scope: Pulmonary NET
   Any first visit (either for GEP NEN scope and for PULM NEN scope) must be an -onsite audit.

3. **Who is eligible to apply?**

The applicant has to be an ENETS member and applying centers should consider whether they fulfil the requirements.
The overall accreditation process requires dedication, work and time. Centers should take this into account prior to embarking on this process.

Please note the **general threshold** for application is **80 NEW GEP NEN** patients per year. The threshold for pulmonary NEN is **20 NEW PULM NEN** per year.

The application contains information on quantitative and qualitative issues pertaining to the individual centers and the assessment is done independently of ENETS.

In general, a GEP NET center/ network should consist of one or not more than three clinically collaborating hospitals/ locations. The physical distance between the sites should should still allow for meaningful collaboration and clinical management.

Centers not falling under the criteria outlined above could be considered as "affiliated" partners and not as part of a certified multi-site center. Some limited exceptions can perhaps be made for a very specific indication such as a specific therapy/test and at the discretion of the ENETS Certification Commission / ENETS Executive Committee. In general, a CoE could evolve over time, become a local HUB and develop a network of affiliated centers, they relate to.

If a network or group of centres are applying, the overall structure requires detailed explanation at the outset and should be clarified during the application process. A clear and proven daily- work practice/collaboration and structure within groups has to be in place. Collaboration simply to increase patient numbers is not acceptable; the structure has to be a functioning unit.

Clarification on protection of status quo: Existing multisite CoE are subject to the rules as they were at the time of their initial certification.

4. Center Training

For applying centers and centers considering application in the following years a training day is held in connection with the ENETS Annual Conference.
The training is held by one member of the ENETS CoE task force and a representative of DQS.

Please note that passing the center training is **mandatory for applying centers.**

5. Certification Period

A certification period lasts five years, starting at the date of the awarding of the certificate (e.g., awarding date 03.03.2022 – elapse date: 02.03.2027)

Following successful initial audit (no major or minor deviations) then repeat on-site auditing will be after 5 years.

However, the auditors on- site might decide on a shortened certification validity, Aim of an earlier re-audit is to evaluate the centers measures on overcoming shortcomings identified during the on-site audit.

- All certified centres must return the annual benchmark data.
- The auditing commission will review annual returns to ensure data is adequate and the center maintained adequate standard

Notes:

Centres with deviations may be asked to provide proof of amendments in addition to annual benchmark returns; the auditors and auditing commission retains the right to demand an on- site visit if deemed necessary to verify amendments as requested; on-site visits may also be made in the event on non-return of annual benchmark data.

6. Costs

Applying centers must be willing to sign a contract with the certification company appointed by ENETS. This is currently **DQS GmbH-The Audit Company** https://www.dqs.de.

Applying centers situated in Europe pay DQS a fee of 7715, 00 EUR, plus applying travel costs for the Auditors.

The certification fee covers a regular 5-year-period. The costs are split into tranches for the organization of the onsite audit (4343, 00 €) and recurring annual tranches for annual return data evaluation which is part of the certification process and is called the maintenance audit of the certificate.
DQS-invoices will be issued after the respective service (Year 1: ENETS CoE on-site audit / Years 2-5: ENETS CoE annual return data evaluation report)

Additional costs:

Additional costs for a multi-site audit can occur, depending on the time needed for the on-site audits of the various collaborating network partners (rough estimation: additional 3-4 hours per site)

Additional costs also occur at any early re-audit.

For overseas audits different cost models will apply.

7. Application/Contracting

Applying centers are required to submit their application via ENETS on-line application tool which is available on the member protected part of the website from March to 30 April. DEADLINE: 30 April

Centers receive an automated acknowledgement of receipt via the ENETS backend.

ENETS will submit the application to DQS who pre-evaluates the application with regards to completeness.

In any doubt about the eligibility of a center to become certified, all application data is forwarded to the ENETS Certification Commission.

The Certification Commission decides in coordination with DQS about enrolment.
After positive decision about enrolment DQS will forward an offer for the certification of your management system according to ENETS Center of Excellence standard. This offer is based on the audit requirements defined by ENETS [requirements catalogue, and procedural instructions can be viewed at https://www.enets.org/coe-programme.html CoE Download center] and DQS. Acceptance of such offer comprises entering into of a contract and accepting the enclosed documents [General Terms and Conditions, Conditions & Prices and the DQS Audit and Certification Regulations] – each are an integral part of the contract concluded between the CoE and DQS.

DQS-invoices will be issued after the respective service (Year 1: ENETS CoE on-site audit / Years 2-5: ENETS CoE annual return data evaluation report)

8. Audit Organization

8.1. Independent auditors

Each on-site audit is conducted by at least two auditors, one ENETS expert auditor and one DQS auditor. The ENETS CoE Certification Commission may decide to delegate more expert auditors, this applies e.g. for multi-site centers.

Qualification of ENETS expert auditors
- Leading function in the health sector
- Experience and substantial skills in at least one area of NET
- Experience in research
- International reputation
- Personal attributes, including the ability to communicate effectively ENETS expert auditors will not conduct audits in countries of their own origin.

ENETS expert auditors conduct at least two consecutive audits in one center (e.g initial audit and one re-certification audit). For the following re-certification audits the expert auditor has to change.

Qualification of DQS auditors
- Occupation/degree in the health sector
- Qualification as an auditor (e.g., for ISO 9001 or other standards)

8.2. Information about Audit Date

Centers receive their audit date within 3 weeks after contracting. In order to keep travel expenses at a minimum by early booking it is necessary that the centers confirm the audit date within another 3 weeks.

8.3. Deadlines

The centers selected for the accreditation process (initial as well as re-certification) are obliged to send in the **completed CoE** documentation 9 weeks prior to the scheduled audit date.

Meeting the deadlines is the Center's responsibility. **Missing the deadlines means in effect quitting the procedure.** Fees will not be refunded, and disbursed travel expenses must be borne by the individual Center.

8.4. What has to be sent in?

- The requirements catalogue, filled in with individual center information in the right column or equivalent documentation.
- Contracts/ agreements as PDFs
- Certificates of expertise, i.e., PDFs of CV, with the **focus on GEP NET and /or Pulmonary NEN respectively**
  (E.g. for pathologists: Senior pathologist (5 year experience); participation in a course in NET pathology (or the like) as proof of expertise, proof of participation in ENETS meetings.
- Task descriptions (data manager/quality manager/head of the center and all others mentioned in the catalogue)
- Detailed information on patient flow (who sees the patient first, who coordinates diagnostics and treatment, who collects F-U data?)
- Detailed information about the tumor board including proof of attendance of the required NET experts from the main partner disciplines (2.1.1 requirements catalogue) and information about treatment decision (2.1.8.4 requirements catalogue)
- SOP as defined as mandatory in the requirements (Pathology reporting/PRRT/interventional radiology)
- Updated data (chapter 14 requirements catalogue)
  - Updated anonymized patient list
  - Updated list of patients in clinical trials
  - Updated publication list
- Analysis of waiting times (mandatory for re-cert audits)
- Analysis of patient feedback (mandatory for re-cert audits)

8.5. Audit Plan

The audit plan will be drafted accordingly to the provided documentation and anticipated need of discussion time - this means that the timeslots for the visits of departments can vary.

Final audit plans are sent to the individual center four weeks prior to the scheduled audit date.

8.6. On site Audit

Each audit is conducted by at least two auditors, one ENETS expert auditor and one GSG auditor.

For a single site center each audit lasts 7-8 hours. At Multi-site centers all sites need to be visited. The audit schedule will be adapted accordingly.

The audit allows some flexibility and the audit plan, if necessary, will be arranged either in accordance with the center's preference or with the auditors once they are on-site.

The standard audit is an -onsite physical audit. In exception (e.g. this was due for the Covid pandemic) a re-certification audit can also be conducted as a remote audit (both auditors participate virtually) or a hybrid audit (one auditor on-site, one auditor participates remotely)

Standard audit schedule:
- Opening session (Head of center/network and at least one specialist from each core discipline, including data manager and patient coordinator) must be present.
  For multi-site centers: representatives of the other sites should participate via video connection.

- Random sample of ten patient files (selected out of the list of anonymous NEW GEP NET patients)

- Presentation of the center (e.g. power point)
  - Structure and management of the network
  - Introduction of the specialist team in each discipline,
  - Case-flow / workflow: who sees the patient first, who decides about diagnostics, therapeutics, when and where as well as follow–up? How is the F- U organized?
  - Workflow, data collection and analysis of multidisciplinary team meetings
  - Multi-site centers also demonstrate access to the joint SOP of the center from all sites (e.g. via video connections /screen sharing/other)
  - Data of main partner departments

- Patient satisfaction and patient involvement
- Research projects
- Improvements since last audit (for re-certification audits)
- Results of internal audits (for re-certification audits)
- Results of the annual management review meeting (for re-certification audits)

- Multidisciplinary Tumor Board Meeting (MDT) (centers/ networks arrange for one of their regular multidisciplinary tumor board meetings) If MDTs are held via video connection in multi-site centers, this should also be the MDT setting during the audit. A mock-MDT is not accepted.
  If the MDT cannot be held in the audit language (English), an interpreter, a person commanding a proper level of English must be in place.

- Inspection of the initially selected patient files

- Visitation of selected departments
  The auditors meet NET specialized experts and their staff; they inspect the department location, the designated rooms and equipment and discuss the SOPs

- Patient registry and follow-up: The auditors meet the data manager and the center coordinator to discuss technical equipment, the registry organization, procedures of follow-up and outcome measurement.
  For multi-site centers: access from all sites to the database must be demonstrated

- Consideration of the auditors
- Feedback about major deviations , minor deviations, recommendations . In case of deviations, a deviation protocol, stating shortcomings and measures to overcome these has to be signed by both auditees and auditors.
- Closing of the meeting.

8.7. Major and minor deviations

There are definitions of major and minor deviations for initial certification and re-certification. These will be stated in a deviation protocol, signed by the center lead and the system- auditor on-site.

If there are

≥ 2 major deviations no certificate, new initial certification necessary. The center will re-apply when ready for.

1 major deviation **two scenarios are in place,**
A re-audit can be scheduled after 12-15 weeks, the center keeps the certificate and stays on the ENETS CoE map; a new fee for the onsite audit is due.

The certificate can be issued at a shortened certification period (1, 2, 3 year, , if declaration of commitment or proven solution of the identified problem is given by the center within defined timeframe after the audit date. (as per deviation protocol)

All minor deviations the center provides a declaration of commitment and next audit is due after 3 years

Annual benchmark data is required. Identified minor deviations are object of special attention in the re-certification audit.

8.8. Audit Report

The center will receive the audit report within four weeks and has the opportunity to formulate consent, clarifications, or an appeal, if necessary.

9. Decision

ENETS Certification Commission discusses the audit findings and clarifications of the individual centers and finally decides on the awarding/re-awarding of the certificate. Centers will be informed via e-mail about the final decision by DQS.

10. Appeal

If the center cannot accept the decision of the ENETS Certification Commission, the center has to formulate an appeal. This will be finally discussed by the ENETS Certification Commission and the ENETS Executive Board.

11. Preparation of Certificates

The individual center will be asked to send its logo and official name and address of the Center in order to accurately prepare the center's official certificate.

12. Awarding Ceremony

Certificates are sent by e-mail.

New ENETS CoE will be acknowledged during the ENETS Annual Conference following the onsite audit.

13. ENETS CoE certification procedure - further improvement

Audited centers receive a questionnaire in order to assess the procedure.

The results are evaluated by the CoE Certification Commission in their annual review meeting which is associated with ENETS annual conference. Amendments and further improvement of the certification and benchmark procedures are defined during this meeting.

14. Key figures and Benchmark - ANNUAL RETURN DATA

Chapter 15 of the requirements catalogue includes all key data to be collected by each center. An online tool covering this data set has been implemented on the member protected part of the ENETS website.

Recognized CoE's are provided with individual login data. This login data is only connected to the annual return data tool, no other contents of the protected member part of the website can be looked into.

Results of the previous calendar year (at least the mandatory minimal data set) are to be filled in **annually** by each individual CoE.

Additional to minimal return data set an updated publication list and an anonymised list of NEW patients is annually required.

Deadline: 31. July

These data will be submitted to DQS (in pdf format) where an evaluation about completeness and plausibility of main key figures is made.

The center receives a structured feedback from DQS within 6 weeks.

Anonymized results of the annual return data will be periodically basis for the discussion within the group of CoE's, auditors, DQS and ENETS.

15. Re-Certification

Re-certification is programmed 5 years after initial certification or earlier (see also conditions mentioned in paragraph 8.6 and 8.7)

Centers receive a reminder and additional information about the upcoming re-certification audit 8 month prior to the expiry date of the certificate.

Audit organization for re-certification will follow the same timelines as for initial certification.

ENETS expert auditors conduct at least two consecutive audits in one center (e.g., initial audit and one

re-certification audit). For the following re-certification audits the expert auditor has to change.