European Network for the Study of Adrenal Tumors Center of Excellence

DOCUMENT HISTORY

Version	Date	Description	Author(s)
0.1	19.12.2017 + 07.04.2018	1st draft	Felix Beuschlein Martin Fassnacht
0.2	12.04.2018 + 01.05.2018	Extensive revision during ExCo meeting	ENS@T ExCo Members
0.3	26.10.2018	Adaptation following feedback from WP scientific members	Martin Fassnacht, Felix Beuschlein
0.4	30.11.2018	Adaptation following feedback from members during the ENS@T meeting in Florence	Martin Fassnacht, Felix Beuschlein
1.0	17.12.2018	First version approved by the ExCo	ENS@T ExCo Members
2.0	XX.08.2019	Modified version following feedback from members and internal discussion in the ExCo	ENS@T ExCo Members

Definitions

"ENS@T" means the European Network for the Study of Adrenal Tumors established in 2002 as recalled in section 1.1 of the ENS@T Bye-Laws.

"ENS@T Center of Excellence" means either a clinical center with particular expertise in patient care for one or several adrenal tumor entities or a research center with strong expertise in adrenal tumors.

"ENS@T Centers of Excellence" are established interdisciplinary collaborative entities in one hospital / research institute with one unique ENSAT ID within the ENSAT Registry structure.

1. Aims and benefits

The overall aim is to improve care for patients with adrenal tumors.
By this official certification ENS@T also aims to achieve the following goals:

- Improve research and enrollment of patients in translational and/or clinical trials and pave the way for high-quality and personalized medicine
- Improve structural cooperation among clinical disciplines
- Improve patient follow-up and quality control
- Improve patient documentation and provide data for epidemiology and public health
- Improve recognition and visibility of centers
- Provide guidance to establish reference center standards

2. Application and accreditation

2.1 Application process

Centers apply through a representative researcher/clinician, who serves as the contact point throughout the accreditation process. Accreditation will be initiated only upon provision of all required documents and following transfer of associated costs (as specified in the attachment and in 2.3.). Accreditation is performed by an accreditation committee that is formed at the discretion of the ENS@T executive committee.
Documents are reviewed off-site. If requested by the accreditation committee, additional appropriate documents have to be provided and site visits by committee members have to be accepted by the clinical/research centers.

2.2 Timeline and documentation of accreditation

Applications can be put forward at any time. Accreditations are granted for a duration of three years. During this time no further applications are admitted.
Successful application for one or more of the clinical sub-specialties (i.e. ACC, PPGL, incidentaloma/NAPACA, APA) are documented with the title "ENS@T Clinical Center of Excellence).
Sub-specialties are mentioned individually in the subtitle and symbolized by one star each as part of the logo
Successful application as a research center is documented with the title "ENS@T Research Center of Excellence" and symbolized by one star as part of the logo.
Centers that have successfully applied for at least one clinical sub-specialty and as a research center are entitled as "ENS@T Clinical and Research Center of

Excellence". Stars (one for each clinical sub-specialty and one for the research centers) are summed up accordingly.

2.3. Costs

Applications are considered when payment has been received as specified below:
First application:

- Clinical centers:
  - Basic rate: € 2000.-
  - Rate for each sub-specialty (i.e. ACC, PPGL, NAPACA, APA, Research center): € 500.-
- Research center: basic rate. € 500.-

Renewal:

- Clinical centers
  - Basic rate: € 1000.-
  - Rate for each sub-specialty (i.e. ACC, PPGL, NAPACA, APA, Research center): € 250.-
  - New application for additional sub-specialties as part of a renewal process is considered as a new application with a charge of € 500,-
- Research centers: basic rate: € 250.-

In case of unsuccessful application, costs for the basic rate are not refundable.

The fee will be used to cover costs related with the application process and organization of the Centers of Excellence, but also to maintain and progress the ENS@T Registry.

3. Requirements for accreditation

3.1 General requirements

- ENS@T Centers of Excellence must be part of ENS@T, which indicates activity in the field.
- Documentation of a minimum of 150 patients in the ENS@T registry has to be provided.
- Infrastructure for biobanking must be established (freezer, informed consent …)
- A clinical nurse adrenal specialist is desirable but not mandatory as for a clinical psychologist / psychiatrist.

3.2 ENS@T Center of Excellence for Adrenocortical Carcinoma

3.2.1 Requirements regarding number of patients

- ≥ 10 patients (new and/or follow-up) per year (average of 3 years) with proven adrenocortical carcinoma (ACC) and documented in the ENS@T registry.
- Current survival status (within the last 12 months) of at least 80% of patients diagnosed in the last 3 years
- Mean clinical annotation (defined by the ENS@T registry) per patients: ≥5
- A minimum of 30 different biosamples (e.g. tumor, blood, urine…) of patients diagnosed in the last 3 years suitable and available for ENSAT research project

3.2.2 Required board-certified medical specialties

- Endocrinologist
- Oncologist / radiation oncologist
- Surgical team experienced in endocrine oncology / adrenal surgery
- Radiologist / nuclear medicine physician
- Pathologist with adrenal expertise (possible as established collaboration outside the center)

3.2.3 Structural and technical requirements

- Multidisciplinary team meetings, in all disciplines mentioned above, at least twice per month
- Center specific standard-operating procedures for the management of patients with ACC (adapting the most recent ESE-ENS@T guidelines)
- Facilities to review and manage patients in an in- and outpatient setting
- Access to a laboratory facility for relevant hormone measurements
- Access to an imaging facility (at least computed tomography, magnetic resonance imaging and PET scanning*)
- Dedicated website with key information (including contact data) for patients and referring doctors

3.3 ENS@T Center of Excellence for Pheochromocytoma/Paraganglioma

3.3.1 Requirements regarding number of patients

- ≥ 25 patients (new and/or follow-up) per year (average of 3 years) proven pheochromocytoma/paraganglioma (PPGL) and documented in the ENS@T registry.
- Current survival status (within the last 18 months) of at least 50% of patients diagnosed in the last 5 years
- Mean clinical annotation (defined by the ENS@T registry) per patients: ≥5
- Genetic status is available in at least 80% of patients diagnosed in the last 5 years (if genetic testing is not available in a given country, testing within ENSAT research projects should be aimed at.)
- A minimum of 50 different biosamples (e.g. tumor, blood, urine…) suitable and available for ENSAT research project

3.3.2 Required medical specialties

- Endocrinologist or hypertensiologist
- Surgical team experienced in endocrine oncology / adrenal surgery (access to surgeons with special expertise in head and neck surgery)
- Radiologist/nuclear medicine physician
- Oncologist/radiation oncologist (optional)
- Pathologist with PPGL expertise (possible as established collaboration outside the center)
- Human geneticist (possible as established collaboration outside the center)

3.3.3 Structural and technical requirements

- Multidisciplinary team meetings, in all disciplines mentioned above, at least twice per month
- Center-specific standard-operating procedures for the management of patients with PPGL (adapting the most recent ESE-ENS@T and Endocrine Society guidelines)
- Facilities to review and manage patients in an in- and outpatient setting

- Access to a laboratory facility for relevant hormone measurements facility (including measurement of plasma or urinary metanephrines)
- Access to an imaging facility (at least computed tomography, magnet resonance imaging, PET scanning, somatostatin-based and MIBG-based imaging*)
- Access to somatostatin-based and MIBG-based therapy*
- Dedicated website with key information (including contact data) for patients and referring doctors

3.4 ENS@T Center of Excellence for Adrenal Incidentaloma (Non-Aldosterone Producing Adrenocortical Adenoma)

3.4.1 Requirements regarding number of patients

- 15 new patients evaluated in the center per year (average of 3 years) with NAPACAs greater than 4 cm and documented in the ENS@T registry.
- or
  - 15 new patients with autonomous cortisol secretion evaluated in the center and documented in the ENS@T registry.
- or
  - 10 new patients with bilateral masses evaluated in the center and documented in the ENS@T registry.
- or
  - 50 new patients per year with adrenal incidentaloma (independent of tumor size) evaluated in the center and documented in the ENS@T registry.
- Current follow-up status# (within the last 18 months) of at least 50% of patients diagnosed in the last 5 years
  # defined by the ENS@T registry
- Results of dexamethasone suppression test are available in at least 80% of patients diagnosed in the last 3 years.
- Mean clinical annotation (defined by the ENS@T registry) per patients: ≥ 3
- A minimum of 50 different biosamples (e.g. blood, urine, tumor…) suitable and available for ENSAT research project

3.4.2 Required medical specialties

- Endocrinologist
- Radiologist
- Surgeon experienced in adrenal surgery

3.4.3 Structural and technical requirements

- Interdisciplinary team meetings to discuss patients considered for surgery at least once per month
- Center-specific standard-operating procedures for the management of patients with NAPACA (adapting the most recent ESE-ENS@T guidelines)
- Facilities to see patients in an in- and outpatient setting
- Access to a laboratory facility for relevant hormone measurements
- Access to an imaging facility (at least computed tomography, magnet resonance imaging, PET scanning*)

- Dedicated website with key information (including contact data) for patients and referring doctors

3.5 ENS@T Center of Excellence for Aldosterone Producing Adenoma / Primary Aldosteronism

3.5.1 Requirements regarding number of patients

- ≥15 new patients per year (average of 3 years) with proven primary aldosteronism and documented in the ENS@T registry
- Current follow-up status# (within the last 18 months) of at least 50% of patients diagnosed in the last 5 years
  # defined by the registry
- Mean clinical annotation* per patients: ≥ 5
- A minimum of 50 different biosamples (e.g. tumor, blood, urine…) suitable and available for ENSAT research project
- Adrenal vein sampling at least 5/year

3.5.2 Required medical specialties

- Endocrinologist or hypertensiologist
- Interventional specialist experienced in adrenal vein sampling
- Surgeon experienced in adrenal surgery

3.5.3 Structural and technical requirements

- Interdisciplinary team meetings to discuss patients that will undergo surgery at least once per month
- Standard-operating procedure for the management of patients with primary aldosteronism (adapting the most recent guidelines)
- Facilities to review and manage patients in an in- and outpatient setting
- Access to a laboratory facility for relevant hormone measurements facility (intra-procedural cortisol measurement desirable)
- Access to an imaging facility (at least computed tomography, magnet resonance imaging)
- Dedicated website with key information (including contact data) for patients and referring doctors

3.6 ENS@T Research Center of Excellence for adrenal tumors

Requirements

- At least one researcher that is a principle investigator on basic, translational or clinical studies on adrenal tumors who has acquired national or international funding (documented within the last 5 years).
- Within the last 5 years: ≥ 20 peer-reviewed, PubMed listed publications in the field with at least 10 out of those with a leading authorship (first, senior or corresponding author)
- Participation in ENS@T activities
  - Leading a basic/translational ENS@T studies
  or
  - Contributing with essential techniques to an ENSAT studies

or
  - Presenting at least one oral talk at one of the ENSAT meeting in the last 5 years
- or
  - Contributing in an ENSAT grant application
- Active participations in scientific meetings with communications (poster or orals) focused on adrenal tumors.
- Dedicated research facility (e.g. lab space, animal facility, or clinical study center)
- Involvement in education of the next generation of adrenal experts (e.g. MD and or PhD program with an adrenal focus, postgraduate courses), is desirable but not mandatory

* If certain diagnostic or therapeutic tools are not available in your country, waiver can be granted.

APPLICATION FORM FOR ENS@T CENTER OF EXCELLENCE

Name of the center:
ENS@T center identifier:

Center representative: Deputy representative
Title:
First name:
Last name:
Professional degree (e.g. MD, PhD):
Date of birth:
Address:
Telephone
e-mail:

Which sub-specialty would you like to apply for?
Clinical Center of Excellence:
☐ ACC ☐ Pheo/PGL ☐ APA ☐ NAPACA

☐ Research Center of Excellence:

As a member of ENS@T I agree to accept and respect the ENS@T Statutes and Bye-Laws

Signatures (as defined by the requirements of sub-specialties):

Center representatives:

Name	Place, Date	Signature

Name	Place, Date	Signature

List of contributors
See above list of persons that are required for the different entities:

Endocrinologist:

Name	Place, Date	Signature

Surgeon experienced in adrenal surgery:

Name	Place, Date	Signature

Head and neck surgeon:

Name	Place, Date	Signature

Oncologist / radiation oncologist:

Name	Place, Date	Signature

Nuclear Medicine Physician:

Name	Place, Date	Signature

Radiologist

Name	Place, Date	Signature

Interventional specialist experienced in adrenal vein sampling

Name	Place, Date	Signature

Hypertensiologist:

Name	Place, Date	Signature

Human geneticist:

Name	Place, Date	Signature

Pathologist:

Name	Place, Date	Signature

Specialist adrenal nurse::

Name	Place, Date	Signature

Psychologist/psychiatrist

Name	Place, Date	Signature

Principal investigators of basic, translational or clinical studies

Name	Place, Date	Signature

Name	Place, Date	Signature

Name	Place, Date	Signature

Name	Place, Date	Signature

Additional documents to be submitted:

- Short CV of all required medical specialties mentioned above (including date of board certification)
- Table with number of required patients (including a list of new patients of the last 3 years (ENS@T ID)
- Table with technical and structural requirements
- Table with peer-reviewed, PubMed listed publications in the field (please indicate those with leading authorship (first, senior or corresponding author)
- Table with acquired funding on adrenal research in the last 5 years (only required for Research Centers