

INTRODUCTION TO EAACI CERTIFIED CLINICAL CENTRE (ECCC) ON IMMUNOTHERAPY

EAACI aims to improve quality of health care, research and education in the area of allergy and clinical immunology. Targeting this aim, as one of its activities, EAACI intends to establish “**EAACI Quality Centres**”. Different type of centres are categorised under Quality Centres, including the “Centre of Excellence” (ECE), EAACI Advanced Research Centre (EARC); and EAACI Certified Clinical Centre (plus Research) in certain fields of Allergy and Immunology.

EAACI Certified Clinical Centre (ECCC) defines the centres that fulfill the essential standards for delivering high-quality patient care in a specific area of Allergy and Immunology. As one level up category, **EAACI Certified Clinical and Research Centre (ECCRC)** defines the centres meeting both clinical standards but also some advanced standards particularly in research in that specific area. These centres are considered as conducting impactful research on that specific area.

EAACI guarantees that all processes related to the Quality Centres will be managed under quality standards by covering planning, doing, checking and revising parts. This instruction provides information about the process AND standards for application for **EAACI Certified Clinical Centre** and **EAACI Certified Clinical and Research Centres**. All standards were prepared based on this quality approach. Two different types of standards are being asked:

Essential (Basic) standards: All programmes ask for the existence of specific standards based on recommendations on current guidelines and task force reports/position papers. The applicant centres should fulfill all essential standards. The rationale behind essential standards is to certify the centres who provide standardized and evidence-based care in that specific area.

Area for Improvement: These standards are not necessarily covered in the first application, but the centres will also be asked about their studies on providing the standards for “area for improvement” in the third year evaluation. Moreover, if the centres agree to apply for recertification after 5 years later, then, they should fulfill both basic requirements and areas for improvement. The rationale behind “Area for Improvement” is to increase the extent and impact of the activities as well as scientific and educational collaboration and network of the centres throughout Europe.

Please read the standards and check whether your centre fulfills all the basic requirements. If you fulfill the basic criteria, we kindly ask you to prepare a report on how you provide the basic standards and also attach the evidence related to these standards in digital format (please see the specific checklist for further details), fill the application form and submit your application electronically to the Quality Committee.

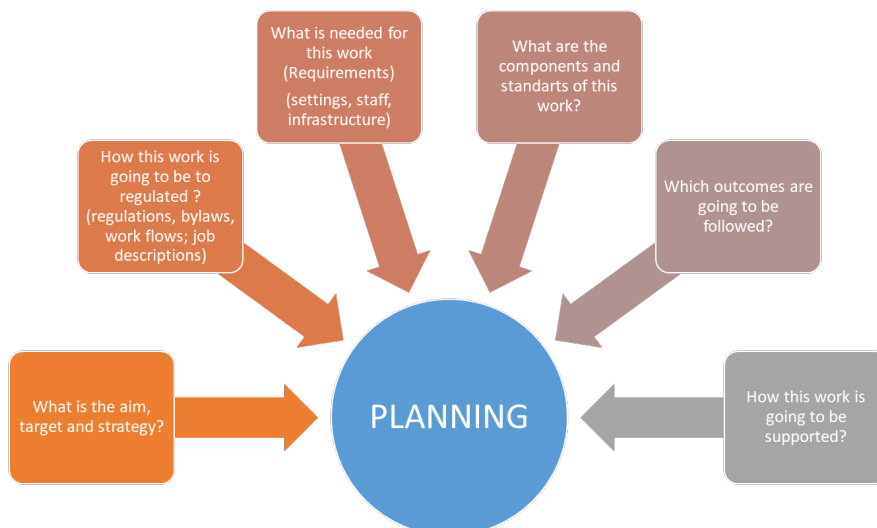
EAACI is aware of the diversity in regulations across countries, which may lead to a limitation for covering some of the basic standards. So, if any of the standards are not covered due to local regulations or data protection policy, please first contact the Quality Committee to evaluate the eligibility of your application.

Contact information: info@eaaci.org

We, as EAACI family, are very happy to introduce this great initiative which will increase the impact of patient care, and research as well as our collaborations and network throughout Europe.

**PART 1:
STANDARDS FOR
EAACI CERTIFIED CLINICAL CENTRE (ECCC) ON IMMUNOTHERAPY**

QUALITY STANDARD 1: PLANNING



1.1. AIM AND STRATEGY

1. The centre should have a strategy/strategic plan compatible with this aim/vision and mission for Immunotherapy indication and management.

EVIDENCES FOR BASIC STANDARDS

1. The statement of the centre about their aim, mission and vision.
2. Strategic plan of the centre for Immunotherapy indication and management.

1.2 REGULATION

1. The centre should have relevant bylaws, instructions and Standard Operation Procedures (SOP) related to management Immunotherapy.
2. Job descriptions should be available for each physician and staff working in the centre for the management of Immunotherapy.
3. The centre should follow national or international Immunotherapy guidelines, position papers and practice parameters of EAACI.
4. The centre should have the definition of the works and related workflows based on these sources.

EVIDENCES FOR BASIC STANDARDS

1. Relevant bylaws, instructions/protocols or SOPs related to Immunotherapy management
2. Descriptions of works and workflows
3. Job descriptions of the staff working in the outpatient clinic
4. Statement of the centre about their clinical practice sources (which guidelines or other sources are used)

AREA FOR IMPROVEMENT

1. The centre should have an active quality management protocol including planning, doing, reviewing and revising of the works of the outpatient clinic. This circle should be done on a regular basis.

1.3. PATIENT CARE

1.3.1. Faculty and Staff

1. At least two of the members of the centre should have EAACI membership.
2. The centre should have at least two allergy&immunology (adult and/or pediatric) specialists with evidence of expertise* in immunotherapy.
3. It would be advisable to have one nurse for immunotherapy procedures.
4. The centres should have a multi-disciplinary approach to the patient with relevant specialists (anesthesiology, pharmacology, gastro-enterologist etc). When needed, the patients should be evaluated by this team and discussed for appropriate testing with the referring specialist.

**Immunotherapy experts: All experts should have documented professional activity in management of Immunotherapy for ≥5 years. Manuscripts and/or congress abstracts or authorship in guidelines, in review articles, position papers, members of working groups of Immunotherapy of national/international societies are valid as proof of expertise.*

The expert will be evaluated based on publications/abstracts and participation in immunotherapy related working groups in international or national societies in the past 5 years following this scoring system: 2 points for participating in guidelines, 1-4 points for publications, 1-2 for abstracts, 2 points for participating in immunotherapy related working groups in international or national societies. The experts need to obtain at least 5 points in evaluation.

EVIDENCES FOR BASIC STANDARDS

1. Lists of the physicians, assigned physicians; nurses and technicians working in the Immunotherapy Outpatient Clinic, provided by the Hospital Administration or local departmental leadership.
2. CV of the experts (certificates of the allergy & immunology specialist/pediatrics with expertise in allergy, list of publications, talks, projects courses and/or training in general and related to Immunotherapy). A statement should also be included about providing the criteria for being considered as an expert in the field.
3. Workflow and documents (reports, consultation notes etc) related to multidisciplinary approaches
4. List of the physicians in multidisciplinary team

AREA FOR IMPROVEMENT

1. **Ongoing Staff Training:** Ensure that all staff regularly participate in training on updated Immunotherapy management protocols, new treatment approaches, and technological advancements.
2. **Dedicated Immunotherapy Care Coordinator:** Appointment of an "Immunotherapy care coordinator" to oversee patient follow-ups, manage comorbidities, and organize multidisciplinary approaches effectively.
3. **Enhanced Proof of Expertise:** Ensure Immunotherapy specialists actively participate in national and international conferences, with regular documentation of their contribution

1.3.2. Settings and infrastructure

1. There should be an Immunotherapy outpatient clinic working for at least one year.
2. Hospital administration or Local Departmental Leadership should approve this outpatient clinic officially.
3. There should be a dedicated setting with emergency equipment necessary for Immunotherapy adverse events, with access to the ICU.
4. The centre should have necessary diagnostic tools for Immunotherapy indication, including skin prick test, specific IgE and components and functional respiratory tests with a dedicated room, having a specific place, when needed.
5. The information on clinical history and physical examination as well as laboratory tests such as serological tests, SPTs, and advisably administration of other medications should exist in case files.

EVIDENCES FOR BASIC STANDARDS

1. An official document provided by the hospital administration on the existence of the Immunotherapy Outpatient Clinic, location of the clinic and staff list and support statement for application.
2. List of the equipment available in the outpatient clinic.
3. Pictures from the outpatient clinic.
4. Documentation of the facilities of the clinic

AREA FOR IMPROVEMENT

1. There should be a standardized form to evaluate the patients. The form should include detailed Immunotherapy procedures, follow up of the patients in addition to general allergy work up.
2. Risk evaluation and stratification should be assessed.

1.4. PATIENT CENTREED APPROACH

1. A patients' centreed approach should be followed up in the centre. The patients should be a part of the decision on management strategy related to themselves.

EVIDENCES FOR BASIC STANDARDS

1. The statement of the centre of their policy on patient centreed approach with examples.

AREA FOR IMPROVEMENT

1. Organize regular feedback sessions to actively involve patients in shared decision-making regarding their treatment and management.
2. Develop structured systems to collect and analyze patient feedback.
3. Act on patient feedback, implement necessary improvements, and communicate these enhancements to the patients.
4. Implement patient support networks and direct them to community-based resources for additional assistance and self-management strategies.

1.5. IMPACT ON PUBLIC HEALTH AND HEALTH ADVOCACY

1. The centre should have released information to the public on Immunotherapy.

EVIDENCES FOR BASIC STANDARDS

1. Public releases on Immunotherapy of the centre (tv talks, newspapers, radio talks, social media posts, web page posts).

AREA FOR IMPROVEMENT

1. The centre is encouraged to have an active webpage. In the clinical department webpage, the existence of the Immunotherapy clinic should be highlighted. The patients may apply for an appointment from the web page.
2. The webpage includes relevant information on referral paths, available testing and therapeutic options.
3. The centres are encouraged to have an active social media account on Immunotherapy
4. The centres are encouraged to act as a health advocate in the immunotherapy area.

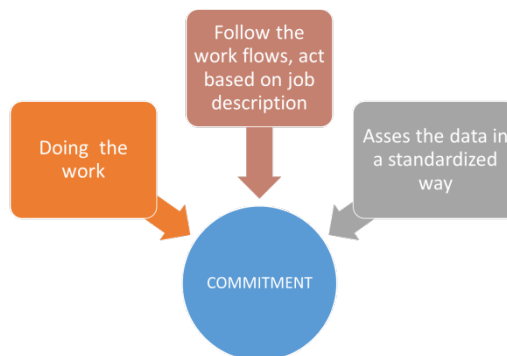
1.6. ARCHIVING AND DATA PROTECTION

1. The Immunotherapy outpatient clinic should have an electronic or physical data storage system that complies with local and national regulations.
2. Patient data should be securely stored and managed according to applicable legal and institutional data protection policies.

EVIDENCES FOR BASIC STANDARDS

- Document on data management and security overview, privacy and confidentiality policies

QUALITY STANDARD 2: DOING



2.1. PATIENT CARE

2.1.1. Clinical practice

1. The centre should perform necessary immunotherapy practice on a regular basis.
2. Information on respiratory allergy history and management and test results should be recorded in case files.
3. Each centre should be able to perform food skin test and blood tests for indicating the best Immunotherapy.
4. A standardized protocol based on Immunotherapy guidelines/task force reports (and specific protocols, when available) should be used.

EVIDENCES FOR BASIC STANDARDS

1. Documents on management algorithms
2. Consent form of the Immunotherapy
3. Examples of test forms of the cases (if it is permitted by local regulations)
4. Written specific immunotherapy procedures, including technical details Examples from Immunotherapy forms (case files) (if it is permitted by local regulations)

2.1.2 Long Term Management

1. Each patient should be given a written “Immunotherapy” plan.

EVIDENCES FOR BASIC STANDARDS

1. Examples from written plans for the patients

2.2. PATIENT CENTREED APPROACH

1. The centre should provide necessary information on immunotherapy and its management to the patients and their relatives.
2. This information could be provided in person, or in seminars or as written documents related to their respiratory allergy and Immunotherapy.

EVIDENCES FOR BASIC STANDARDS

1. Documents, brochures, information sheets on Immunotherapy provided to the patients and their relatives.
2. Agenda for seminars for the patients with respiratory allergy under the use of Immunotherapy.

2.3. FACULTY AND STAFF DEVELOPMENT PROGRAMME

1. A regular seminar/literature/case discussion time on Immunotherapy should be done at least once a month.

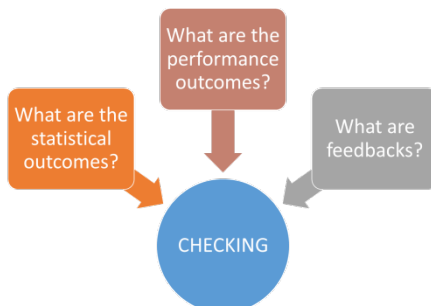
EVIDENCES FOR BASIC STANDARDS

1. Agenda and the programme of this educational sessions (yearly)

AREA FOR IMPROVEMENT

1. A standardized training programme on Immunotherapy for working staff should be available in the centre.
2. The physicians and other staff working in the outpatient clinic should have training on Communication Skills.
3. Staff/faculty should have CME for the activities related to Immunotherapy.
4. Staff/faculty are encouraged to join national and international courses on Immunotherapy.

QUALITY STANDARD 3: REVIEWING



3.1. EVALUATION OF THE OUTCOMES

1. The centre should have assessment tools to follow up the performance of the clinic.
2. The centre should collect all the relevant data for assessment of these predetermined outcomes.

EVIDENCES FOR BASIC STANDARDS

1. Statistical reports related to outcomes and safety (e.g. number of the patients applying the outpatient clinic/year, number of Immunotherapies/year, number of adverse events/year)
2. Patients feedbacks (if exists)
3. Staff feedbacks (if exists)

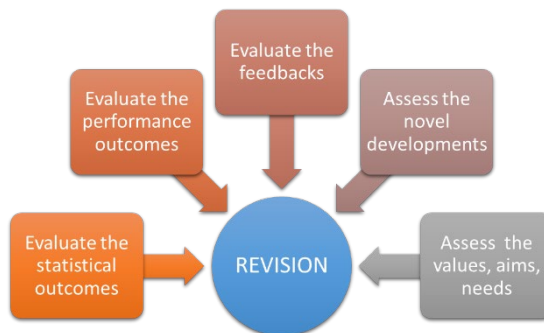
**basic information is necessary, however, providing more specific data could be helpful.*

AREA FOR IMPROVEMENT

1. *The patients should be evaluated at least once a year about the long term outcomes of the skin tests, laboratory tests or immunotherapy procedure.*
1. The centre should have detailed/specific predetermined outcomes on activities of the outpatient clinic (statistical outcomes; performance data/safety data) and provide these outcomes at least annually.
2. Patient feedback as well as satisfaction should be obtained by using questionnaires.
3. Feedback of the physicians, nurses and allied healthcare workers should be obtained.
4. The centre should also define strategic targets* in addition to descriptive analysis: these targets could be related to patient care; education and research as well as all activities under the umbrella of this outpatient clinic. Examples: increase the number of outpatient clinic days/increase the number of publication on immunotherapy.

**please define yours*

QUALITY STANDARD 4: REVISION OF THE PROGRAMME



4.1 REVISION OF THE PROGRAMME

1. All the outcomes of the centre should be reviewed..
2. These outcomes should be evaluated in regular time intervals (at least annually).
3. The centre should revise all the work of the outpatient clinic based on these outcomes and novel development and other requirements.

EVIDENCES FOR BASIC STANDARDS

1. The reports on follow up criteria (based on data in part: Quality Standards #3)
2. The documents on how the centre evaluates the outputs.
3. Meeting reports on evaluation of the centre.
4. The documents on the decision on revision of the management of the outpatient clinic.

PART 2: STANDARDS FOR EAACI CERTIFIED CLINICAL and RESEARCH CENTRE (ECCC) ON IMMUNOTHERAPY

The centres having advanced research and educational activity in Immunotherapy are candidates for EAACI Clinic and Research Centre on Immunotherapy.

In addition to basic standards for being a EAACI Certified Clinic Centre for immunotherapy, the centres should fulfill the criteria below:

Obligatory standards:

1. Having at least 3 research articles published on Immunotherapy in peer reviewed journals in the last 5 years (being 1st, last or corresponding author in at least 2 of them).
2. Having either their own research laboratory or access to a research laboratory.

AND at least 4* of below (Optional Standards):

1. Having at least one member of the unit with a H-index ≥ 20 (Scopus or Web of Science).
2. Having participated in at least 3 reviews, task force reports or guidelines on Immunotherapy in the last 5 years in peer reviewed journals.

3. Having at least 2 ongoing research activities (both clinical and translational) on Immunotherapy.
4. Having participated in clinical trials or registries or multicentred study (at least 1 in the last 5 years) on Immunotherapy.
5. Having at least 2 original manuscripts on immunotherapy published in Q1 or Q2 journals.
6. Having at least 1 translational studies on Immunotherapy published in peer reviewed journals.
7. Having at least 5 abstract presentations on Immunotherapy in the last 5 years, including at least 1 in EAACI annual congress.
8. Having a patent on Immunotherapy in the last 10 years.
9. Offering or being affiliated with a MSc or PhD programmes on Immunotherapy.
10. Providing theoretical and practical lectures/courses specifically focused on Immunotherapy for both undergraduate students and allergy/immunology fellows.
11. Providing public information on Immunotherapy on a regular basis.
12. Performing health advocacy activities on Immunotherapy.

EVIDENCES (* provide only those related to the selected criteria above)

1. List of the active ongoing projects of the centre and their outcomes
2. List of the peer reviewed published articles on Immunotherapy of the centre with the link to full text or pubmed (the last 5 year)
3. List of the abstracts presented in congress (national and international) (the last 5 year)
4. Educational programme of the centre
5. Evidence on health advocacy of the centre
6. Documentation on patent
7. Data on involving multicentre studies or registries
8. Data on public impact and health advocacy.

AREA FOR IMPROVEMENT

1. The centres are encouraged to be involved in multicentred studies.
2. The centres are encouraged to have master of science or PhD programmes on Immunotherapy
3. The centres are encouraged to be involved in allergy&immunology fellowship programmes or in graduate education.
4. The centres are encouraged to participate in advocacy studies and public information.
5. The centres are encouraged to present an abstract on Immunotherapy in EAACI congress.