

ABOUT EAACI CERTIFIED CLINICAL CENTRE (E-CCC) and CERTIFIED CLINICAL AND RESEARCH CENTRE (E-CCRC)

EAACI has established **two categories** under its Clinical Certification Programme:

1. Certified Clinical Centre

This designation is for centres that provide **high-quality patient care** in a specific area (e.g., asthma, drug allergy). Centres applying for this level must meet the **basic standards outlined in Part 1** of this document.

2. Certified Clinical and Research Centre

Centres that not only provide excellent clinical care but also demonstrate **advanced research and educational activities** in the same area are eligible for this designation. To qualify, they must meet **both the standards in Part 1** (Certified Clinical Centre) **and the additional standards in Part 2** (Research Centre criteria).

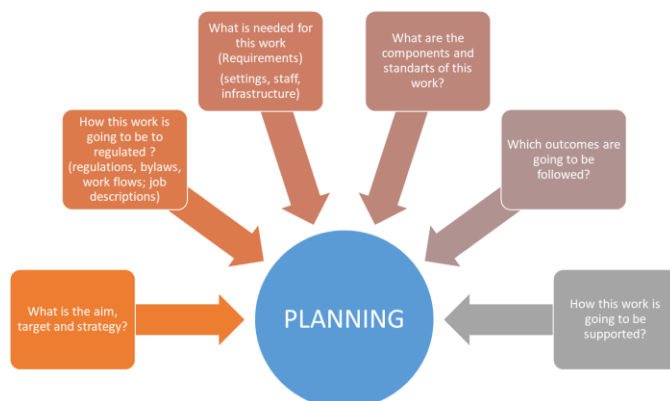
Centres that do **not** meet the requirements for advanced research activities are only eligible to apply as a **Certified Clinical Centre** and need to comply **only with the standards in Part 1**. There is **no need to fulfil the research criteria in Part 2** for this level.

Please first read the document “Questions and Answers for the Quality Centres” and follow the necessary steps to prepare your application.

This document provides standards for EAACI Certified Clinical Centre and Clinical and Research Centre.

PART 1: STANDARDS FOR EAACI CERTIFIED CLINICAL CENTRE (ECCC) ON DRUG ALLERGY

QUALITY STANDARD 1: PLANNING



1.1. AIM AND STRATEGY

1. The centre should have an aim, vision and mission for drug allergy diagnosis, and management
2. The centre should have a strategy/strategic plan compatible with this aim/vision and mission for drug allergy diagnosis, and management

EVIDENCE FOR BASIC STANDARDS

1. The statement of the centre about their aim, mission and vision
2. Strategic plan of the centre for drug allergy diagnosis, and management

1.2 REGULATIONS

1. The centre should have relevant bylaws, instructions and Standard Operation Procedures (SOP) related to management of drug allergy
2. Job descriptions should be available for each physician and staff working in the centre for the management of drug allergy
3. The centre should follow national or international drug allergy 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

EVIDENCE FOR BASIC STANDARDS

1. Relevant instructions, SOP
2. Descriptions of works and workflows
3. Job descriptions of the staff working in the outpatient clinic
4. Statement of the centre about their sources (which guidelines or other sources are used)
5. Algorithms related to management of drug allergy

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 an EAACI membership
2. The centre should have at least two allergy and immunology specialists (adult and/or paediatric) with evidence of expertise* in drug allergy diagnosis/management
3. It would be advisable to have one nurse for Drug Allergy diagnostic and eventually desensitization procedures
4. The centres should have a “multidisciplinary approach” to the patient with relevant specialists (Anaesthesiology, Pharmacology, ENT etc). When needed, the patients should be evaluated by this team and discussed for appropriate testing with the referring specialist

***Drug Allergy experts:** All experts should have documented professional activity in management of drug allergy for ≥ 5 years. Manuscripts and/or congress abstracts or authorship in guidelines, in review articles, position papers, members of working groups of drug hypersensitivity of national/international societies are valid as proof of expertise. The expert will be evaluated based on publications/abstracts and participation in drug allergy 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 drug allergy related working groups in international or national societies. The experts need to obtain at least 5 points in evaluation

EVIDENCE FOR BASIC STANDARDS

1. Lists of the physicians, assigned physicians; nurses and technicians working in the Drug Allergy Outpatient Clinic, provided by the Hospital Administration or Local Departmental Leadership
2. CV of the experts (certificates of the allergy & immunology specialist, list of publications, talks, projects courses and/or training in general and related to drug allergy). 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
5. Patient's notes (when available) or meeting reports showing the multidisciplinary approach

AREA FOR IMPROVEMENT

1. **Ongoing Staff Training:** Ensure that all staff regularly participate in training on updated drug allergy management protocols, new treatment approaches, and technological advancements
2. **Dedicated Drug Allergy Care Coordinator:** Appointment of a "Drug allergy care coordinator" to oversee patient follow-ups, manage comorbidities, and organize multidisciplinary approaches effectively
3. **Enhanced Proof of Expertise:** Ensure drug allergy specialists actively participate in national and international conferences, with regular documentation of their contributions
4. There should be at least one Pharmacist or technician assigned for Drug Allergy diagnostic and desensitization procedures for those drugs requiring dilution under safe conditions (e.g. chemotherapy, biologics)

1.3.2. Settings and infrastructure

1. There should be a drug allergy outpatient clinic working for at least one year AND with a minimum frequency of once a week and a day-hospital
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 drug tests and desensitization in the outpatient clinic/day hospital, with access to the ICU

4. The centre should have necessary diagnostic tools for drug allergy including skin prick test and intradermal tests with drugs, patch test with drugs, drug provocation, and desensitization with a dedicated room having a chemical hood for drug preparation, when needed (or a centralized procedure involving the hospital pharmacy)
5. The information on clinical history and physical examination as well as drug tests performed, and desensitization should exist in case files

EVIDENCE FOR BASIC STANDARDS

1. An official document provided by the hospital administration or local departmental leadership on the existence of the Drug Allergy 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 (skin prick test, intradermal tests, patch test, drug provocation test, advanced tests when available, statement and pictures of the laboratories)
5. Drug provocation and skin test forms
6. Drug desensitization form

AREA FOR IMPROVEMENT

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

1.4. PATIENT CENTERED APPROACH

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

EVIDENCE FOR BASIC STANDARDS

1. The statement of the centre of their policy on patient centred 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 analyse 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 drug allergy

EVIDENCE FOR BASIC STANDARD

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

AREA FOR IMPROVEMENT

1. The centre is encouraged to have an active webpage. In the clinical department webpage, the existence of the drug allergy 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 drug allergy
4. The centres are encouraged to act as a health advocate in the drug allergy area

1.6. ARCHIVING AND DATA PROTECTION

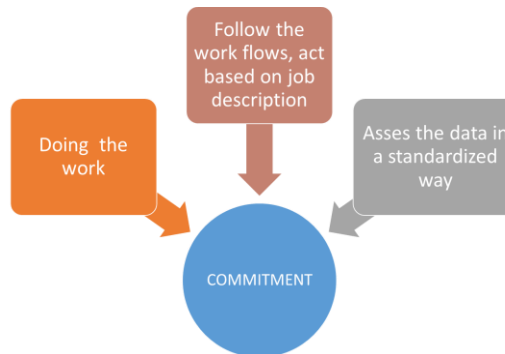
1. The drug allergy outpatient clinic should have an electronic or physical data storage system that complies with local and national regulations
2. Patient data should be securely stored and managed according to applicable legal and institutional data protection policies

EVIDENCE 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 drug allergy testing on a regular basis in the management of drug allergy
2. Information on drug allergy history and management and test results should be recorded in case files
3. Each centre should perform drug skin testing and/or DPTs for confirming or disproving allergy and finding safe alternative drugs
4. The centre should perform drug desensitization
5. A standardized protocol based on drug allergy guidelines/task force reports (and specific drug protocols, when available) should be used

EVIDENCE FOR BASIC STANDARDS

1. Documents on management algorithms
2. Consent form of the tests and desensitization
3. Examples of test forms of the cases (if it is permitted by local regulations)
4. List of drugs for which a desensitization procedure is available and written drug-specific desensitization procedures, including technical details for dilution preparation and administration and references
5. Examples from drug desensitization forms (case files) (if permitted by local regulations)

2.1.2 Long Term Management

1. Avoidance from culprit drugs also considering cross-reactivity should be recommended, each patient should be given a written "permission and avoidance" plan
2. A drug allergy passport should be provided

EVIDENCES FOR BASIC STANDARDS

1. Examples from written plans for the patients
2. Examples from Drug Allergy Passports

2.2. PATIENT CENTERED APPROACH

1. The centre should provide necessary information on drug allergy 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 drug allergy

EVIDENCE FOR BASIC STANDARDS

1. Documents, brochures, information sheets on drug allergy provided to the patients and their relatives
2. Agenda for seminars for the patients with drug allergy

2.3. FACULTY AND STAFF DEVELOPMENT PROGRAM

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

EVIDENCE FOR BASIC STANDARD

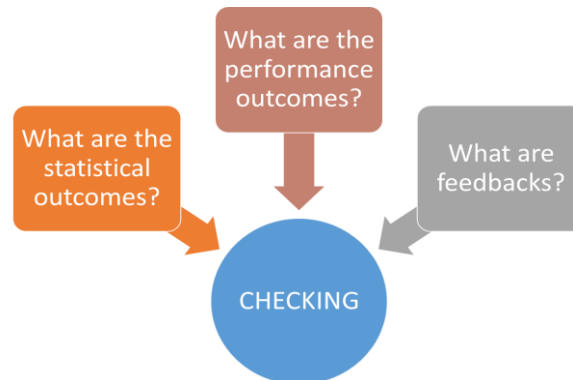
1. Agenda and the program of this educational sessions (yearly)

AREA FOR IMPROVEMENT

1. A standardized training program on drug allergy 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 drug allergy and anaphylaxis
4. Staff/faculty are encouraged to join national and international courses on drug allergies.

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

EVIDENCE FOR BASIC STANDARDS

1. Statistical reports related to outcomes and safety* (e.g. number of the patients applying the outpatient clinic/year, number of the tests applied/year, number of desensitization procedures/year, number of adverse events in the tests/year)
2. Patients feedback (if any)
3. Staff feedback (if any)

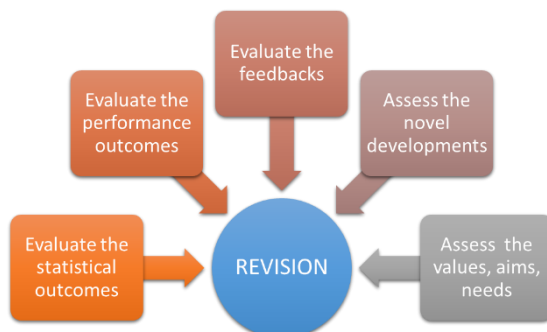
***basic information is necessary, however, providing more specific data could be helpful*

AREA FOR IMPROVEMENT

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 (like: increase the number of outpatient clinic days; increase the number of the patients without adverse drug reactions during tests/desensitization; increase the number of seminars organized for the patients; increase the number of publications; increase the patients' satisfaction)

*Please define yours

QUALITY STANDARD 4: REVISION OF THE PROGRAM



4.1 REVISION OF THE PROGRAM

1. The centre should review all the outcomes of the centre
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

EVIDENCE 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: ADDITIONAL STANDARDS FOR EAACI CERTIFIED CLINICAL and RESEARCH CENTRE (E-CCRC) ON DRUG ALLERGY

Centres that demonstrate **advanced research and educational activity in Drug Allergy** may apply for the designation of **EAACI Certified Clinical and Research Centre in Drug Allergy**.

In addition to meeting the **basic standards outlined in Part 1** (Certified Clinical Centre in Drug Allergy), these centres must also **fulfil the following additional criteria**:

Obligatory standards:

1. Having at least 3 research articles published on drug allergy in peer reviewed journals in the last 5 years (being a group member 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 drug allergy in the last 5 years in peer reviewed journals
3. Having at least 2 ongoing research activities (both clinical and translational) on drug allergy

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

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 drug allergy 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 program of the centre
5. Evidence on health advocacy of the centre
6. Patents
7. Data on involvement in 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 on drug allergy
2. The centres are encouraged to have Master of Science or PhD programs on drug allergy
3. The centres are encouraged to be involved in allergy and immunology fellowship programs 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 drug allergy in EAACI congress