2019 Call for Applications - Guideline
ECRIN Data Centre Certification programme

As part of the further development of the European Clinical Research Infrastructure Network (ECRIN) Data Centre Certification programme, applications are invited from clinical trials units (CTUs) within ECRIN countries to become certified as ECRIN data centres.

Successful certification will indicate to both sponsors and researchers that a CTU is operating as a data centre to known quality standards and can fully support the conduct of multi-national clinical trials within ECRIN. Successful certification will also allow a framework agreement to be put in place between the CTU and ECRIN, facilitating the future involvement of the unit within ECRIN programmes.

Application Process:

- Applicant units should complete the [application form](), which asks for details on unit activity, staff and systems, and an indication of how the unit's own quality management documents (e.g. SOPs) compare to ECRIN standards. A summary of all the systems supporting data management and their validation status is also required.

- This audit will be performed against the current version of the ECRIN DM standards, ([version 4.0 dated of April 2018]()). It is important to emphasise that, at time of the audit, **the application of DM standards will normally be required to be demonstrated in the context of at least two recent studies (where the CTU was responsible for the data management)**. In other words, it is not enough simply to have a quality system in place - it must be clearly demonstrated in practice. This requirement may guide the choice for the most suitable audit period.

- The final deadline for applications is **27 September 2019**. Applicants should return the completed application form to: [christian.ohmann@med.uni-duesseldorf.de](), cc: [jacques.demotes@ecrin.org, Christine.toneatti@ecrin.org]().

Centres will be **selected for audit within National Clinical Research Networks (scientific partner of ECRIN) and after assessment of their application by the ECRIN Independent Certification Board (ICB)**. The main criterion will be the ability of units to meet the quality standards demanded by ECRIN, as indicated by the application form and supporting documents.

Please note that application documents must be provided and will be assessed in English.

Fee Structure:
There will be no fees for units in countries that are ECRIN members. Units from ECRIN observer countries will be asked to pay a fee to cover the cost of the audit itself (direct expense cost, expected at around €6000), though not the associated administrative costs (preparation and travel expenses).

The ECRIN Standards:
Certification will be based on evidence gathered by an on-site audit team testing compliance with the ECRIN standards. The current standards are [here](#).

The Certification Process:
The audit team will consist of up to three senior trial unit staff members familiar with the standards and their interpretation. Audits will last up to three days and be conducted in English, though usually at least one of the team members will be fluent in the native language of the centre being audited so that local documents can be examined.

Please note that if a centre uses an external supplier for some of its IT or data management systems, for example if it uses IT services provided by its parent university, the centre will still be expected to have all the relevant evidence available during the audit and arrange, where necessary, for the relevant staff to be available.

The results of the audit will be relayed informally to the centre before being presented to the ICB, which will make the final decision regarding certification. The ICB has four main options:

a) If it feels all standards have been met, the ICB can award ECRIN certification;

b) If almost all standards have been met, the ICB can recommend that the centre provide written evidence, usually within four months, indicating how it has complied with the remaining standards, after which the certification decision will be reconsidered;

c) If most standards have been met, the ICB can recommend that the centre have a short re-audit after a mutually agreed time to examine compliance with the remaining standards, after which the certification decision will be reconsidered;

d) If the ICB feels that the level of non-compliance is such that options b) or c) are unrealistic, it can withhold certification. In this case the centre will need to re-apply for certification in the future.

The details of the audit will be confidential and auditors will sign confidentiality agreements with centres. ECRIN reserves the right, however, to publicise the names of the centres selected for audit and the overall result (name and location of certified units, units with audit pending, units with certification in progress). Where certification is successful, it will be granted for 4 years.

For any questions concerning this call or the certification process, please contact:
Christian Ohmann, (Chair of the Independent Certification Board) at christian.ohmann@med.uni-duesseldorf.de, or Christine Toneatti (Independent Certification Board Secretary, ECRIN Quality Manager), Christine.TONEATTI@ecrin.org.