2016 Call for Applications for Certification as an ECRIN Data Centre

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 within the ECRIN-ERIC countries to become certified as ECRIN data centres.

Successful certification will indicate to both sponsors and researchers that a clinical trials unit 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 trials unit and ECRIN-ERIC, facilitating the future involvement of the unit within ECRIN programmes.

Application Mechanism:
It is the intention in 2016 to certify up to seven clinical trials units in ECRIN-ERIC member countries (France, Germany, Italy, Portugal, Spain, Hungary, Norway). If possible, one applicant from each ECRIN-ERIC country will be sought. However, if a suitable candidate unit is not available, it may be possible to redistribute some of the audits among the remaining countries.

Applicant units should download and complete the application form available for download here, which asks for details of unit activity, staff and systems, and an indication of how the unit's own quality management documents (SOPs etc.) map to the lists of ECRIN standards. A summary listing of all the systems supporting data management and their validation status is also required.

The final deadline for applications is **31 August 2016**. Applicants should return the application form to jacques.demotes@ecrin.org by that date.

Centres will be selected for audit from the applicants by an 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. The ICB takes into consideration any prioritisation of units for certification expressed by national networks.

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-ERIC members.

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 available here.

The Certification Mechanism

The audit team will consist of three senior trials unit staff 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 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 their IT or data management systems, for example if it uses IT services provided by their 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 trials unit before being presented to the Independent Certification Board who will make the final decision regarding certification. The Independent Certification Board has four main options:

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

b) If almost all standards have been met, the Board 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 Board 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 Board 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:
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