

Survey on impact of ECRIN data centre certification on inspections by regulatory authorities

- Report -

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1. Background and objectives

The European Clinical Research Infrastructure Network (ECRIN) has implemented and applied a Data Centre Certification Programme for several years (Ohmann et al., 2017). After a pilot phase ending in 2011, the certification procedure was implemented for regular application. Following a yearly call dedicated to ECRIN member and observer countries, so far 23 data centres applied to the certification programme. From these centres, 13 were certified (+ 2 centres with expired certification) according to the open ECRIN standards (see: ZENODO; <https://zenodo.org/record/1240941#.W-6PLjhKi1s>): 6 (+1 expired) from Germany, 2 from France, 3 from Italy, 1 from Portugal, 1 from Norway and 1 from Sweden (expired).

A recent survey on the ECRIN data centre certification programme (Toneatti et al., April 2019) clearly demonstrates that the programme is well received by the National Scientific Networks. Most of the participating countries perceive the procedure as a benefit for CTUs in their network and are satisfied with the certification procedure. Program participation increases the data management services and provides rewards through the sharing of the latest technical developments and training on data management/IT. Apart from the overall positive feedback, some critical comments have been raised. In the majority of cases, data management in ECRIN-supported trials is not performed by certified data centres. So for some centres a direct benefit of the certification procedure has not been demonstrated and the return on the investment may be questionable. These points raised are relevant and it has been discussed within ECRIN on several occasions. During a common meeting of ECRIN Assembly of Members (AOM) and Network committee (NC) it was suggested to ask certified data centres whether inspections by regulatory authorities have been performed and whether the ECRIN certification procedure had an impact on the inspections. A positive feedback by inspectors could well be seen as another confirmation of the benefit of the programme.

Objective of the survey

To get feedback from ECRIN-certified data centres whether the certification procedure was appreciated by the inspectors and perceived as a benefit for the inspection.

2. Methodological approach

The survey was initiated during a common ECRIN AOM- and NC-meeting on 21 May in Paris. A questionnaire was developed and sent to all 13 ECRIN-certified data centres in June 2019. 11 out of 13 certified centres answered the survey between June and July 2019. The data were anonymised for this report.

3. Results

From Germany 6 certified centres participated in the survey, from France and Italy two and one from Portugal. Four of the participating centres had an inspection by a regulatory authority after certification. These inspections occurred 14, 16, 17 and 77 months after certification. The answers to the questions are summarised in the following table:

Question	A	B	C	D	E	F	G	H	I	J	K
Was an inspection by a regulatory authority performed after the certification?	No	Yes	Yes	Yes	No	No	No	No	No	No	Yes
Was the ECRIN certification programme a topic of discussion during the inspection?	NA	No	Yes	No	No	NA	NA	NA	NA	NA	No
When answering questions to the inspectors, did you refer to the ECRIN data centre certification programme and/or to the ECRIN IT/DM standards?	NA	No	Yes	No	No	NA	NA	NA	NA	NA	Yes
Did you show documents related to the ECRIN data centre certification programme to the inspectors (e.g. ECRIN standards, certification webpage, publications)?	NA	No	Yes	No	No	NA	NA	NA	NA	NA	Yes
Did the inspectors appreciate the ECRIN data centre certification procedure?	NA	No	Yes	No	No	NA	NA	NA	NA	NA	Yes
Was your certification as ECRIN data centre beneficial for the inspection?	NA	No	Yes	No	No	NA	NA	NA	NA	NA	Yes

NA = not applicable

In two centres, which had inspections, DM/IT was not the focus of the inspections and the ECRIN data centre certification programme was not discussed.

In one inspected centre the ECRIN certification programme was explained to the inspectors. It was referred to the ECRIN data centre certification programme and to the ECRIN IT/DM standards because all IT- and DM-SOPs of this centre are related to ECRIN standards. The ECRIN standards, were presented to the inspectors. The inspectors appreciated the ECRIN data centre certification procedure because the standards were checked by a formal process and audit. The certification procedure was perceived as beneficial because it was documented that the centre has defined requirements for DM and IT, which are implemented in SPOs.

In the other inspected centre, the ECRIN certification programme was explained in the context of a sponsor inspection. The CTU presented the ECRIN certification in order to show that the system and the data management processes work properly. The inspectors appreciated the certification and any criticism stopped immediately. The certification procedure was beneficial to the unit because they could demonstrate that the data management processes work adequately, and that staff is qualified.

One centre referred to audits (not inspections) by other entities. During such audits normally the ECRIN certification is discussed and presented and the ECRIN certificate is shown. It is seen as a strength aspect and differentiation factor in every audit process. ECRIN standards are naturally related with all activities of this centre. Normally, security and data management standards are always referred to auditors. Auditors normally appreciate the scope and the documentation of the ECRIN certification and the way the documents are organized is very important to the audit.

This was supported by another centre, also referring to audits by pharmaceutical companies. Here it was also referred to the ECRIN certification programme and the information was well received. The centre had the impression that the involvement in the certification programme contributed to the positive assessment of the auditors.

8 out of 11 centres used the possibility to answer the question “Is there anything else you want to say, which could be relevant for the ECRIN data centre certification programme?”

Is there anything else you want to say, which could be relevant for the ECRIN data centre certification programme?
ECRIN certification was an essential process of further development, improvement and efficiency. As part of the ISO certification, the processes in data management and IT were reviewed and positively evaluated.
Certificate was mentioned within preliminary discussion only but was not of further interest.
As far as we could assess it, the ECRIN certification was an asset to get in charge of the data-management in two projects.
The intensive preparation process before the 3-day audit was generally helpful in terms of discussion and definition respectively refinement of several processes and completion of our documentation. Although no inspections

<p>took place, we had several audits by pharmaceutical companies after the ECRIN audit. We mentioned the ECRIN certification in connection with questions to data management and IT, explained background and content of the programme if not known to the auditors, and at least once showed the certificate. The information was well received, and we had the impression it contributed to the positive assessment.</p>
<p>ECRIN should provide more information regarding to other centres certification and good practices implemented. Establish a link between the certified Data Centres so they can share probably an open blog, or a forum or a wiki page in the main ECRIN website could be a first step. ECRIN should recommend the national clinical research network to use the ECRIN certified data centres for the studies they are involved to promote them and make them known to the clinical research community as a resource that complies with the ICH-GCP Guidelines, Good practice for computerised systems in regulated GXP environments, PIC/S Inspectors Guide, FDA Guidance for Industry, Computerized Systems Used in clinical studies and 21 CFR Part 11, GAMP 5, ISO27000,etc to collect , transfer and secure clinical data.</p>
<p>ECRIN certification has been instrumental to boost compliance, quality and security. It has been extremely well considered by auditors during the ISO 2015 certification. It also represented a competitive advantage when offering services to third parties.</p>
<p>ECRIN data centre certification is considered as an important part of the quality system and an opportunity for continuous improvement of quality for DM and IT activities but also for internal quality standards</p>
<p>Not many ECRIN projects were acquired with the certificate. However, it helps to document the quality of data management. The preparation of the ECRIN audit helps to detect gaps and errors in processes.</p>

In summary, there were five positive statements in answering this question, considering the certification programme as important part of the quality system and as an opportunity for continuous improvement.

For two centres the ECRIN certification programme was helpful for ISO certification. As part of the ISO-certification DM- and IT processes have been reviewed and were positively evaluated.

For one centre the programme was an asset to get in charge of data management in two projects.

One centre made suggestions to improve the programme. It was proposed to establish a link between the certified data centres (to build up a forum and/or wiki page) and ECRIN should promote the programme stronger towards the national scientific networks to achieve better involvement of certified centres in ECRIN-supported trials.

One centre complained that they did not acquire many projects with the ECRIN certification.

4. Discussion

Participation of certified centres in this survey was good (11/13). Unfortunately, only four inspections were performed with only two relevant for DM and IT. So, the general applicability of the results of this survey is certainly limited.

Nevertheless, several positive statements were made:

- Beneficial for inspection (n=2)
- Beneficial for audits (n=2)
- Useful to support ISO-certification (n=2)
- Asset to be involved in studies (n =1)
- Important for quality system (n=5)

The statements related to audits are interesting and need further elaboration. Audits were not a specific target in this study so it could be an option to extend the survey to this area.

The suggestion to build up a community of ECRIN certified centres is a good one and should be followed. Furthermore, better promotion of the programme towards the national scientific networks is certainly of major relevance and here a strategic plan should be developed.

There was one negative statement about inadequate involvement of a certified centre in ECRIN-supported trials. This point was also raised by other certified centres at other occasions and measures have to be discussed and implemented to strengthen the role of certified centres in providing DM-services for ECRIN-supported trials.

5. References

Ohmann C, Canham S, Demotes J, Chêne G, Lauritsen J, Martins H, Mendes RV, Nicolis EB, Svobodnik A, Torres F. Raising standards in clinical research—The impact of the ECRIN data centre certification programme, 2011–2016. *Contemporary clinical trials communications*. 2017;5: 153-9.

Toneatti C, Ohmann C: Feedback of the National Scientific Networks of ECRIN regarding the Data Centre Certification Programme. Results of a survey, 18 April 2019

6. Appendix: Questionnaire for survey by ECRIN (June 2019)**ECRIN Data Centre Certification Programme: Impact on inspections**

Centre: _____

1. **When did you get your ECRIN certification?**
month/year (prefilled)
2. **Was an inspection by a regulatory authority performed after the certification?**
no
yes, when
3. **Was the ECRIN certification programme a topic of discussion during the inspection?**
no
yes, please specify
4. **When answering questions to the inspectors, did you refer to the ECRIN data centre certification programme and/or to the ECRIN IT/DM standards?**
no
yes, please specify, where you referred to and how
5. **Did you show documents related to the ECRIN data centre certification programme to the inspectors (e.g. ECRIN standards, certification webpage, publications)?**
no
yes, please specify
6. **Did the inspectors appreciate the ECRIN data centre certification procedure?**
no
yes, in which way
7. **Was your certification as ECRIN data centre beneficial for the inspection?**
no
yes, please describe in which way
8. **Is there anything else you want to say, which could be relevant for the ECRIN data centre certification programme?**
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