# Data Centre Certification Programme

## Application document to become an ECRIN Data Centre

Please complete this questionnaire and email it, with any associated documents, to ECRIN (the address is provided at the end of this document) by the **September 27th, 2019 with an organisational chart, and an inventory of computerised systems that directly support clinical trials.**

Please note this is a protected document and you can only type into the boxes provided and / or select the check boxes. You may also need to 'enable active content' before editing is possible.

### 1 General Information

1.1. Name of centre or unit

1.2. ECRIN Scientific Partner Organisation *(e.g. national network)*

1.3. Centre web site

1.4a. Head of centre or unit

Name

Address

Telephone Fax

Email

1.4b. Please indicate the normal contact for the ECRIN Certification Board / Audit Team

Head of centre, as above ☐ *otherwise…*

Name and Function

Address

Telephone Fax

Email

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1.5. Type of centre or unit

- ☐ Clinical Research Centre (CRC)
- ☐ Clinical Trials Unit (CTU)
- ☐ Other *(please specify below)*

1.6. Affiliated with…

- ☐ University / Medical faculty
- ☐ University Hospital
- ☐ Other Hospital
- ☐ Other Institution (please specify below)
- ☐ Not affiliated

1.7. Centre/Unit established in (year)

1.8. Is your centre/unit responsible for all aspects of data management and IT for all your trials, or are some services (e.g. server management, treatment allocation) provided by other institutions?

- ☐ a) All aspects of IT and data management provided by the applicant centre
- ☐ b) Some aspects of IT and / or data management provided by other institutions

If you answered b could you provide details below of the service(s) and institution(s) involved…

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### 2 Trial Activity

2.1. Please indicate the total number of **ongoing** trials your centre is currently supporting with regards to data management activities

2.2. Please indicate the numbers of the following types of trials your centre has supported **over the last 12 months**,

(a) where you have provided data management (DM) for the trial and

(b) where you have provided data management and the trial has been multinational

| | (a) Total Number of Studies with DM | (b) Number of Multinational Studies with DM |
|---|---|---|
| Drug trial, 1 – 50 subjects | | |
| Drug trial, 51 – 200 subjects | | |
| Drug trial, 201 – 1000 subjects | | |
| Drug trial, >1000 subjects | | |
| Medical Device trials | | |
| Non-Drug treatment trial (e.g. surgery, radiotherapy, psychotherapy etc.) | | |
| Epidemiological studies | | |
| Diagnostic studies | | |
| Other (please specify below) | | |
| | | |
| | | |

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2.3. Please provide a list of up to 15 clinical trials where your unit is providing data management (**currently or within the last 12 months**) that illustrate your unit's involvement in investigator initiated trials (IITs), and multi-centre and multi-national trials.

| Short title | Indication / disease area | Number patients[2] | Num. of centres | Num. of countries | eCRF[1]? YES/NO | IIT? |
|---|---|---|---|---|---|---|
| | | | | | ☐ | ☐ |
| | | | | | ☐ | ☐ |
| | | | | | ☐ | ☐ |
| | | | | | ☐ | ☐ |
| | | | | | ☐ | ☐ |
| | | | | | ☐ | ☐ |
| | | | | | ☐ | ☐ |
| | | | | | ☐ | ☐ |

[1] Used for some or all centres

[2] The number of patients, centres or countries recruited so far, not the total expected

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | ☐ | ☐ | |
| | | | | ☐ | ☐ | |
| | | | | ☐ | ☐ | |
| | | | | ☐ | ☐ | |
| | | | | ☐ | ☐ | |
| | | | | ☐ | ☐ | |
| | | | | ☐ | ☐ | |

2.4. Please indicate up to five disease area(s) and/or therapeutic and / or methodological specialisms where you consider your centre to have particular experience and expertise

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### 3 Staff

Please give the number of staff (full time equivalents) of the following types. If applicable please include staff working for any service provider organisation, though only those directly involved in the centre's service provision should be included.

| Staff Type | Your own Organisation | Service provider (if applicable) |
|---|---|---|
| Statisticians | | |
| Trials managers | | |
| Monitors | | |
| Quality managers | | |
| Data Managers | | |
| Data entry staff | | |
| IT-staff | | |
| Others, please specify below | | |
| | | |
| | | |
| | | |
| | | |
| **Totals** | | |

## 4 IT and Data Management Systems

4.1. Please indicate the type of clinical data management system(s) you use for multicentre / multi-national trials

(i.e. the specialist software designed for holding, auditing and checking trial data, not the more generic database products referred to in 4.2)

☐ commercial *(if so please specify the system / version)*

☐ open source *(if so please specify the system / version)*

☐ proprietary, developed by software company *(if so please specify the company)*

☐ proprietary, developed by your own or a partner institution *(if so, please specify the age/version and institution)*

☐ other (please specify below)

4.2. Please indicate the generic database system(s) you use to support your data management (e.g. Oracle, MySQL, SQL Server)

4.3. Please provide a listing of *all* systems used, directly or indirectly, by the centre to directly support trial activity, and their validation status and history, **as a separate document**.

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### 5 Standards and corresponding quality documents

Up-to-date Standard Operating Procedures (SOPs) or equivalent controlled documents for IT and data management are *essential* for successful certification.

Please list below, for each of the lists of standards, the relevant codes and names of SOPs and related policy / procedural documents.

| | |
|---|---|
| GE01 Centre Staff training and support | |
| IT01 Management of IT Infrastructure | |
| IT02 Logical Security | |
| IT03 Logical Access | |
| IT04 Business Continuity | |
| IT05 General System Validation | |
| IT06 Local Software Development | |
| DM01 Data Management Planning | |
| DM02 CDMAs – Design, Development and Validation | |

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### 5 Standards and corresponding quality documents *(Continued)*

DM03 CDMAs - Change management

DM04 Site Management Training and Support

DM05 Data Entry and Processing

DM06 Managing Data Quality

DM07 Managing Data Transfers

DM08 Delivery and Coding of Data for Analysis

DM09 Long Term Data Storage

### 6 Optional Standards and corresponding quality documents

Please indicate whether you would like to apply for an assessment of the optional standards (related to Treatment Allocation) during the audit. When acting as a lead CTU, this option is highly recommended.

☐ YES (if so Please list below, for Treatment Allocation, the relevant codes and names of SOPs and related policy / procedural documents.)

☐ NO

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### 7 Quality Systems and Audit

7.1 Has your centre / unit gone through an inspection or audit related to IT/ data management activities in the last 5 years? ☐ Yes ☐ No

7.2 If yes, please specify the audit or inspection type ( e.g. regulatory authority, IT specific, study specific, etc.) and dates

| Audit / Inspection Type | Date |
|---|---|
| | |
| | |
| | |
| | |

### 8 Further Comments

Please add any further comments or explanation supporting your application for ECRIN certification that you would like the Certification Board and / or auditors to be aware of

## Application document to become an ECRIN Data Centre

**Completed applications should be e-mailed to** christian.ohmann@med.uni-duesseldorf.de,

cc: jacques.demotes@ecrin.org, Christine.toneatti@ecrin.org **by September 27th, 2019.**

Or alternatively print and post to

J. Demotes
Director General, ECRIN-ERIC
European Clinical Research Infrastructure Network
5-7 rue Watt, 75013 PARIS, France
Telephone +33 18005 8646

*For further information or clarification please contact:*

*Christian Ohmann (Chair of the Certification Board) at christian.ohmann@med.uni-duesseldorf.de*
*or*
*Christine Toneatti (ECRIN Head of Quality and Information Systems, Secretary to the Independent Certification Board) at christine.toneatti@ecrin.org*