04/03/2019
EMA/46269/2017 Rev.1
Human Medicines Research and Development Support Division

Guidance to fill in Enpr-EMA self-assessment form

Section 1

1.1, 1.4, and 1.10: Number of ongoing/completed clinical trials whether academic, industry-sponsored or commercial:

Please state in these fields only the trials or studies which have been/or are being conducted by the <xxx name of network> itself, as opposed to trials or studies conducted by individual investigators or collaborating centres. Only trials that mention that they have been conducted/organised by <xxx name of network> and have a reference to <xxx name of the network> can be accepted. Trials from individual members or partners of <xxx name of network> cannot be considered as trials conducted by this network. The purpose is to encourage and drive the members involved in your network to act and publish as a well-established network and not as a conglomeration of individual centres/investigators. This will also increase visibility of your network for industry. You still have the possibility to attach all research experience of individual collaborating centres as either a link or attached document to the information provided in the section "description, number of collaborating centres".

Therefore, please attach a list of all completed or ongoing studies that have been conducted by <xxx name of network> (as above) and provide the exact references regarding these trials. (EudraCT reference or link to CT publications).

1.5 - 1.7: Number of paediatric specialities/conditions/research studies:

What are the paediatric specialities covered, as well as the conditions, and what are the ongoing studies.

Number of other research studies/programs: please state the number of studies or translational research studies here. If none has been conducted by the <xxx name of network> so far, please state 0.

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Section 2

2.2 - 2.3: Existence of an internal/external Advisory/Steering Committee directing the reporting party:

Please provide an update on this field with regards to the members of the internal steering/external Advisory Committee and how this is made publicly available (on network's website, other?).

<The requirement of an external advisory committee is related to an external body able to provide advice, e.g. on quality or performance control.>

2.5 Existence of a newsletter:

Please clarify how the newsletter is made available and to whom.

2.6: Existence of an internal database for disease, condition, treatment and outcome:

Please update this field and describe the type of information which is stored in your internal database. (Please also refer to comment re 1.2)

Please clarify whether the internal database mentioned is a database of the <xxx name of network> or of the individual collaborating centres and whether the database also includes information on eligible patients pool(s) in addition to contact details of participating centres/investigators.

2.7: Provisions to ascertain data protection and data security:

If available, please describe here the provisions to ascertain data protection and data security and/or indicate whether it is/will be publicly available, e.g. on your website to allow public scrutiny of your claims.

Please clarify whether data protection and data security do constitute a requirement within the network's rules/operations and if so, whether it is included or described in any document of the organisation such as its mission statement/statute and publicly available.

2.8 Procedures to access the database:

Please clarify what are the procedures to access the database by third parties.

Section 3

3.1 Number of peer-reviewed publications:

Please provide a list of publications or a link to the publications)

3.2 Number of competitive grants obtained in the last 5 years:

Please provide a list of grants obtained. Should you wish the information not to be in the public domain, please inform us and Enpr-EMA secretariat will keep the information provided confidential.

3.3: Access to expert groups:

"Yes". Please describe how access to the various expert groups is made.

3.4: Capacity to answer external scientific questions

Please describe how the information is captured in the network website and provide name and contact details, if there is a coordinated capacity. Please clarify if any process is in place and is described on the website.

This information will be valuable for industry sponsors.

3.5 - 3.7 Standardized procedures for assessment of Site feasibility, Participant recruitment, Budget calculation for studies:

Please clarify if the SOP(s) for 3.5, 3.6, 3.7 are in place and are publicly accessible and if yes provide a link. If not please send us these documents.

3.7 Standardized procedures for budget calculation for studies:

Please clarify if SOP(s) are available on how to calculate costs for clinical studies which may be requested by sponsors and whether they are publicly accessible; if yes provide a link. If not please send us these documents.

Section 4

4.1 Documented adherence to GCP Guideline:

Please clarify if adherence to GCP and especially to ethical consideration for clinical trials in children are included or described in any document of the organisation such as its mission statement/statute. Please specify how frequently the clinical research staff is trained/refreshed on ICH GCP.

4.2 Documented adherence to the ethical considerations for clinical trials in children:

Please provide the appropriate SOPs to and/or explain the EC review process and/or indicate whether they will be publicly available, e.g. on your website to allow public scrutiny of your claims

4.3 Documented adherence to ethical considerations:

Please clarify whether paediatric experts are involved in the Ethics Committees approached for approval of studies conducted by the <xxx name of the network>.

4.4 Availability of Standard Operation Procedures (SOP):

Please indicate whether available SOPs are publicly accessible or whether it is planned in the future to make the available SOPs (or some of them) publically available on your website.

4.5 Capacity to monitor studies (academic trials, industry sponsored trials):

Please clarify if the network is actually responsible for trial monitoring or whether monitoring is delegated to external bodies, e.g. CROs.

4.6 Capacity to monitor performance of collaborating centres:

Please clarify how performance of collaborating centres is evaluated and whether it is publicly described. Please clarify whether an SOP for sites' performance monitoring is available, publicly accessible and/or provide a link to <xxx, e.g. national law, etc.>

4.7 QC and QA, traceability and data safety:

Please state here that these processes are fully described in SOPs which are currently not publically accessible. Would there be any plan to make these available on your website, in the future, to allow public scrutiny of your claims?

<Please clarify whether Quality control, quality assurance, traceability and data safety according to national law is included or described in any document of <xxx name of network> such as its mission statement/statute and publicly available.>

Section 5

5.1 Evidence of collaboration with regulatory authorities:

Please clarify what type of collaboration is established and provide supporting evidence to allow public scrutiny.

5.2 Capacity to provide competent consultation to regulatory authorities:

Please clarify what type of collaboration is established and provide supporting evidence to allow public scrutiny.

5.3 Formal meetings for clinical trials:

Please provide the number of meetings as requested.

5.4 Training courses given:

It is understood that the network actively participates in organising training courses for various healthcare professionals. Please substantiate this claim with available examples to allow public scrutiny.

5.5 Training courses received:

Please clarify which training specifically aimed at the members of <xxx name of network> have received and whether the trainings organisations/attendance do constitute a requirement within the network's rules/operations and if so, whether it is included or described in any document of the organisation such as its mission statement/statute and publicly available.

Section 6

6.3 Involvement of patients, parents and their organisations in prioritising needs for clinical trials:

Please indicate in which ways your network involves patients/parents groups (e.g. organisation of specific meetings?) Please provide specific examples of clinical studies in which parent/patient groups/Young people advisory groups have been consulted and please describe their input. Is this information available on your website?