EMA/303300/2012, Rev 3
Human Medicines Development and Evaluation

# European network of paediatric research (Enpr-EMA)

## Recognition criteria for self-assessment

Recognition criteria which have to be fulfilled by any network seeking to become a member of Enpr-EMA were set up through a public process and finalised in March 2010. All networks wishing to become a member of Enpr-EMA are invited to complete this self-assessment form and send it to the European Medicines Agency.

The completed form should be sent to: enprema@ema.europa.eu

# European network of paediatric research at the European Medicines Agency (Enpr-EMA)

The European Paediatric Regulation (EC) No 1901/2006, as amended, calls for the fostering of high-quality ethical research on medicinal products for use in children. This should be achieved through efficient inter-network and stakeholder collaboration. To meet this objective, a European paediatric research network of national and European networks, investigators, and centres with specific expertise in performing drug trials in the paediatric population has been created.

## *Recognition criteria to become a member of Enpr-EMA (self-assessment)*

This document defines 6 criteria with several subcategories (items) for self-assessment. The minimum criteria/items which have to be fulfilled by any network to become a member of Enpr-EMA are marked with a superscript "M". Irrespective of whether or not only minimum criteria/items are fulfilled, the full list of criteria and items as well as the network identification should be completed to the extent possible.

The criteria should be reported for the highest level that the network currently attains. Networks should report on the status of the network, not on individual investigators or sites. For the purpose of this form, the highest level is called the reporting party.

The form should be filled in by the reporting party (once only per network), taking into account the guidance text provided. For transparency and to permit public scrutiny, the completed self-assessment form should be made public by the reporting party, for example on their website.

The reporting party should also make publicly accessible the actual data on which the statements are based (e.g. clinical trial registration numbers). The self-assessment should be updated every other year.

The completed form should be sent to: Enprema@ema.europa.eu. It will be published via the Enpr-EMA database at http://enprema.ema.europa.eu/enprema/.

## *Criteria for the recognition of a network as a member of Enpr-EMA*

## *Identification* [M]

| | | |
|---|---|---|
| Name | | Include acronyms |
| Network type and information on funding | | Indicate type of reporting party, e.g. national or specialty network. May include short mission statement. Provide web link to information on funding or a completed Enpr-EMA networks funding sources form. |
| Street | | |
| Postal code | | |
| Town | | |
| Country | | |
| Telephone 1 | | Contact for public enquires |
| Telephone 2 | | Contact for public enquires |
| Mobile phone | | Contact for public enquires |
| Fax | | Contact for public enquires |
| Website URL | | Contact for public enquires |
| E-mail for general enquiries | | Contact for public enquires |
| **Representative (main) contact**<br>Please enter information in the fields below, as far as available. | | |
| First name | | |
| Surname | | |
| Telephone | | EMA internal database |
| Mobile phone | | EMA internal database |
| E-mail | | EMA internal database |
| **Further contact(s)**<br>Please enter information in the fields below, as far as available. | | |
| First name | | |
| Surname | | |
| Telephone | | EMA internal database |
| Mobile phone | | EMA internal database |
| E-mail | | EMA internal database |
| The data in this document are 'current' as of | | Provide the date when the criteria were last updated. |
| State how this document can be accessed by the public | | This should be a link to a webpage, but other means and formats to make public are possible. |

## *Description* M

| | | |
|---|---|---|
| Year of foundation | | State year of foundation of the network, or year of start of the investigator's or site's specific paediatric research activities |
| Paediatric age ranges of study participants covered by the network | | |
| Preterm and/or term newborns from birth to less than 28 days of age | ☐ Yes ☐ No | |
| Infants and toddlers from 28 days to less than 2 years of age | ☐ Yes ☐ No | |
| Children from 2 years to less than 12 years of age | ☐ Yes ☐ No | |
| Adolescents from 12 years to less than 18 years of age | ☐ Yes ☐ No | |
| Specialties/conditions covered | | State specialties covered. Please use only terminology as per the glossary (http://enprema.ema.europa.eu/enprema/images/Glossary.pdf) to ensure search functionality in the Enpr-EMA database. If the network covers more than one specialty also state the term "multispecialty". If not all areas within one specialty are covered, specify conditions. |
| Multispecialty? Specify | | For example, oncology or infectious diseases |
| Specialty or disease specific? Specify | | For example, cardiology only |
| Conditions covered? Specify | | E.g. hypertension (within cardiology) or asthma (within respiratory diseases) |
| Procedure/intervention specific? Specify | | For example, surgery, organ or stem cell transplantation |

| | | |
|---|---|---|
| Number of collaborating countries | List all collaborating countries: | State the number of collaborating countries. Indicate '1' if national. Indicate if network is limited to Europe, includes regions outside of Europe, etc. |
| Number of collaborating centres | List all collaborating centres: | State the number of collaborating centres and provide a list of all collaborating centres (attachment or link possible) |
| **Type of activity/studies** | | |
| Clinical studies | ☐ Yes ☐ No | |
| Experimental research | ☐ Yes ☐ No | |
| Other activity | | Describe type of activities other than clinical and/or non-clinical studies |

## *Evidence for each criterion*



## *How to provide evidence*

1. The evidence for this self-assessment document should be based only on the activity of the network during the last 5 years.
2. Evidence used in this document should be supported by references (e.g. publication, annual or periodic report or internal network document).
3. The self-assessment form is to cover a range of different network types. It is recognised that some networks may not be able to complete every item. In such cases it should be stated why the item cannot be completed.The network is referred to as the "reporting party".

## Criterion 1: Research experience and ability

Do not include planned trials, but only ongoing and completed trials.

| | | |
|---|---|---|
| 1.1<br><br>Number of completed paediatric[1] trials [M]<br><br>Number of ongoing paediatric trials [M] | | Any (interventional or observational) paediatric clinical trials, whether non-commercial, investigator-initiated, industry-sponsored or commercial, which have been conducted by the reporting party (as opposed to trials conducted by individual investigators or collaborating centres). Listed trials must have a reference/mention of the reporting party in the public trial record. Please provide references as links or attachments (e.g. to EU-CTR, publications). Minimum requirement ([M]): one ongoing or one completed trial. |
| 1.2<br>Total number of paediatric participants screened per year<br><br>Total number of paediatric participants eligible per year<br><br>Describe methods of screening and participant recruitment | | State, as far as possible, average yearly enrolment numbers for trials listed in item 1.1. Which strategies or pathways are used to screen and recruit participants? |
| 1.3<br>Total number of collaborating centres which enrolled paediatric participants | | Provide the number of centres which enrolled participants into completed or ongoing trials listed in item 1.1. |
| **Academic (investigator) initiated studies**<br>Studies conducted independently from pharmaceutical companies. There is a separate category (below) for industry-funded studies. | | |

[1] A paediatric trial is a trial that includes at least one participant below 18 years of age.

| | | |
|---|---|---|
| 1.4<br>Number of ongoing and completed paediatric trials | Absolute number:<br><br>Proportion of all paediatric trials: | Paediatric interventional trials of any phase of the pharmaceutical development (phase I to IV, including therapy optimising trials if requiring authorisation by regulatory authority)<br>(for other paediatric trials unrelated to drug development see below)<br>Please provide references as links or attachments (e.g. to EU-CTR, publications). |
| 1.5<br>Number of paediatric specialties covered by paediatric trials | | Count specialties, without repetition, across all ongoing or completed paediatric trials. Please list the specialties covered. |
| 1.6<br>Number of paediatric conditions covered by paediatric trials | | If not all areas within one specialty covered count conditions, without repetition, across all ongoing or completed paediatric trials. Please list the conditions covered. |
| 1.7<br>Number of other ongoing research studies/programmes | | For example, epidemiological studies, outcome studies, translational research in which the reporting party is participating. Include cohort studies but not audits. Research is defined as a project with a specific research question in which the participant/family provides formal consent. Please attach a list of ongoing research studies/programmes, if available. |
| 1.8<br>Proportion of budget for academic (investigator) initiated studies deriving from public funding | Proportion of budget: | Indicate the proportion of the budget for completed and ongoing paediatric trials that is derived from public funding sources such as governmental programmes, competitive public grants, university contributions |

| | | |
|---|---|---|
| 1.9<br>Number of enrolled participants (all academic paediatric trials) | | |
| **Industry-sponsored trials** | | |
| 1.10<br>Number of ongoing and completed paediatric trials | | Paediatric (interventional or observational) trials of any phase of the pharmaceutical development (phase I to IV, including therapy optimising trials if requiring authorisation by regulatory authority) (for other paediatric trials unrelated to drug development see above)<br>Please provide references as links or attachments (e.g. to EU-CTR, publications). |
| 1.11<br>Number of paediatric specialties covered by paediatric trials | | Count specialties, without repetition, across all ongoing or completed paediatric trials |
| 1.12<br>Number of paediatric conditions covered by paediatric trials | | If not all areas within one specialty covered count conditions, without repetition, across all ongoing or completed paediatric trials. |
| 1.13<br>Number of enrolled participants (all industry-sponsored paediatric trials) | | |

## Criterion 2: Network organisation and processes

| | | |
|---|---|---|
| 2.1<br>Existence of an identified contact person for external enquiries [M] | ☐ Yes ☐ No<br>Comments: | Enquiries from patients, parents, organisations, researchers, pharma-ceutical companies or regulatory authorities are co-ordinated or answered by a nominated contact person. Provide contact details in section "Identification" above. |
| 2.2<br>Existence of an internal steering committee [M] | ☐ Yes ☐ No<br>Comments: | Minimum requirement ([M]): either an internal steering committee (2.2) or an external advisory/steering committee (2.3). Describe selection of the members, and how this information is made publicly available. |
| 2.3<br>Existence of an external advisory/steering committee directing the reporting party [M] | ☐ Yes ☐ No<br>Comments: | Minimum requirement ([M]): either an internal steering committee (2.2) or an external advisory/steering committee (2.3). Describe selection of the members, and how this information is made publicly available. |
| 2.4<br>Existence of a website | ☐ Yes ☐ No<br>Comments: | If available, mention in "identification" above |
| 2.5<br>Existence of newsletter | ☐ Yes ☐ No<br>Comments: | Newsletter of any format (electronic, surface mail), distributed actively to selected recipients. Clarify how the newsletter is made available and to whom. |

| | | |
|---|---|---|
| 2.6<br>Existence of an internal database(s) for disease, condition, treatment and/or outcome [M] | ☐ Yes ☐ No<br><br>Comments/description: | For example, database or disease registry to facilitate planning or conducting future trials (may or may not contain individual patient data). Describe the type of information stored in the database. Clarify if it is managed by the reporting party or by the individual collaborating centres, and whether it includes information on eligible patient pool(s) in addition to contact details of participating centres/investigators. |
| 2.7<br>Provisions to ascertain data protection and data security [M] | ☐ Yes ☐ No<br>Comments: | Are provisions in place to ascertain patients'/study participants' data protection and data safety within the network? Describe the provisions, clarify if they are described in any document of the reporting party (e.g. mission statement/statute) in SOPs, and whether they are publicly accessible. |
| 2.8<br>Procedure(s) to access the database by third parties | ☐ Yes ☐ No<br>Comments: | Describe the procedure for third parties to access the database, for planning, conducting or analysing clinical trials. |
| 2.9<br>Access to external databases/registries | ☐ Yes ☐ No<br>Comments: | Describe the access of the reporting party to relevant external databases, e.g. national databases that are not publicly accessible. |
| 2.10<br>Standardised process to access an external database(s) | ☐ Yes ☐ No<br>Comments: | Describe the standardisation (e.g. SOPs) |

## Criterion 3: Scientific competencies and capacity to provide expert advice

| | | |
|---|---|---|
| 3.1<br>Number of peer-reviewed publications in the last 5 years<br>Provide reference(s)<br>Describe the network's contribution to each publication | | The publications should include a reference to the reporting party (network). |
| 3.2<br>Number of competitive grants obtained in the last 5 years | | Grants obtained by the network,exclusively or not (as opposed to grants obtained by individual investigators or collaborating centres). Please provide a list of the grants obtained. (If you wish the information not to be in the public domain, please inform Enpr-EMA secretariat. |
| 3.3<br>Access to expert groups M | ☐ Yes ☐ No<br>Comments: | Describe how the reporting party has specific access to established expert groups, such as learned societies. |
| 3.4<br>Capacity to answer external scientific questions M | ☐ Yes ☐ No<br>Comments: | Describe if a coordinated capacity (staff, process) is available to answer external scientific queries in relation to clinical trials, and how it can be contacted (contact point, e.g. via network website). |
| **Existence of Standard Operating Procedures (SOP) for assessment of:**<br>Please enter information in the fields below.<br>Clarify if SOPs are publicly accessible. Provide links or attach documents. | | |
| 3.5<br>Site feasibility | ☐ Yes ☐ No<br>Comments: | This concerns the suitability of a site for conducting a given trial. |
| 3.6<br>Participant recruitment | ☐ Yes ☐ No<br>Comments: | This concerns provisions to regularly monitor recruitment progress for a trial. |
| 3.7<br>Budget calculation for studies | ☐ Yes ☐ No<br>Comments: | This concerns, for example, quotes and prospective financial planning for a trial. |

## Criterion 4: Quality management

| | | |
|---|---|---|
| 4.1<br><br>Documented adherence to Good Clinical Practice (GCP) guideline [M] | ☐ Yes ☐ No<br><br>Comments: | Declare whether studies conducted comply with the EU Directive 2001/20/EC on Clinical Trials. Clarify if adherence to GCP is included in the documentation of the organisation (e.g. mission statement/statute).<br>Specify how frequently clinical research staff is trained on ICH GCP requirements. |
| 4.2<br>Documented adherence to the ethical considerations for clinical trials in children [M] | ☐ Yes ☐ No<br>Comments: | Indicate if adherence to "ethical considerations for clinical trials in children" is included in the documentation of the organisation (e.g. mission statement/statute).<br>Provide relevant SOPs and indicate if they are publicly accessible. |
| 4.3<br>Documented adherence to ethical considerations | ☐ Yes ☐ No<br>Comments: | Indicate whether paediatric experts are involved in the ethics committees approached for approval of studies conducted by the reporting party. |
| 4.4<br>Availability of Standard Operation Procedures (SOP) | ☐ Yes ☐ No<br>If yes, provide reference to available SOPs | Indicate existence of SOPs e.g. for study management, adverse events reporting etc. |
| 4.5<br>Capacity to monitor studies (academic trials, industry sponsored trials) [M] | ☐ Yes ☐ No<br>Comments: | Indicate if the reporting party implements the monitoring of paediatric trials according to ICH 6 Good Clinical Practice Guideline or if monitoring is delegated to external bodies, e.g. CROs. |

| | | |
|---|---|---|
| 4.6<br>Capacity to monitor performance of collaborating centres | ☐ Yes ☐ No<br>Comments: | Describe how performance of collaborating centres is evaluated and whether this is publicly described.<br>Please clarify whether an SOP for sites' performance monitoring is available, publicly accessible and/or provide link(s). |
| 4.7<br>Quality control and quality assurance, traceability and data safety [M] | ☐ Yes ☐ No<br>Comments: | Clarify if these processes are described in any document of the reporting party (e.g. mission statement/statute), and whether they are publicly accessible. If yes, provide reference(s) or link(s) (e.g. to national law). |

## Criterion 5: Training and educational capacity to build competences

| | | |
|---|---|---|
| 5.1<br>Evidence of collaboration with regulatory authorities [M] | ☐ Yes ☐ No<br>Comments: | Indicate awareness of regulatory requirements for developing medicines; for example, implementation of guidelines of regulatory authorities. Clarify what type of collaboration is established and provide supporting evidence. |
| 5.2<br>Capacity to provide competent consultation to regulatory authorities | ☐ Yes ☐ No<br>Comments: | Indicate capacity to provide expert advice to regulatory authorities. For example, nominations to standing scientific committees of regulatory authorities, registration(s) as authorities' external expert(s). |
| 5.3<br>Formal meetings for clinical trials<br>If yes, provide number | ☐ Yes ☐ No<br>Comments: | For example, investigator meetings, trainings specific to a given ongoing or planned trial.<br>Please attach a list of formal meetings for clinical trials, if available. |
| 5.4<br>Training courses given/organised by the network over the last 2 years [M]<br>If yes, provide number | ☐ Yes ☐ No<br>Comments: | For example, training specific to a trial or in general for trial(s), with external participants or from the reporting party.<br>Clarify if organisation of training courses constitute a requirement within the network's rules/operations, and if so, if this is included or described in any document of the organisation such as its mission statement/statute and publicly available.<br>Minimum requirement ([M]): training courses either given (5.4) or received (5.5).<br>Please attach a list of training courses organised, if available. |

| | | |
|---|---|---|
| 5.5<br>Network-wide training courses received over the last 2 years [M]<br>If yes, provide number | ☐ Yes ☐ No<br>Comments: | For example, training specific to a trial or in general for trial(s), with external participants or from the reporting party.<br>Clarify if attendance of training courses constitute a requirement within the network's rules/operations, and if so, if this is included or described in any document of the organisation such as its mission statement/statute and publicly available.<br>Minimum requirement ([M]): training courses either given (5.4) or received (5.5).<br>Please attach a list of network-wide training courses received, if available. |
| 5.6<br>Promotion of participation in clinical trials in countries with limited resources<br><br>Provide list of countries | ☐ Yes ☐ No<br>Comments: | Indicate if support for such trials is provided by the reporting party. |

### Criterion 6: Public involvement [M]

Minimum requirement ([M]): involvement in at least one of the below items.

| | | |
|---|---|---|
| 6.1<br><br>Involvement of patients, parents or their organisations in protocol design | ☐ Yes ☐ No<br><br>Comments: | Indicate if parent groups/patient groups/young people advisory groups are/have been involved and provide specific examples. Please describe the type of input received and if it is publicly available on the network's website. |
| 6.2<br>Involvement of patients, parents or their organisations in creating the protocol information packages | ☐ Yes ☐ No<br>Comments: | Indicate if parent groups/patient groups/young people advisory groups are/have been involved and provide specific examples. Please describe the type of input received and if it is publicly available on the network's website. |
| 6.3<br>Involvement of patients, parents or their organisations in the prioritisation of needs for clinical trials in children | ☐ Yes ☐ No<br>Comments: | Indicate if parent groups/patient groups/young people advisory groups are/have been involved and provide specific examples (e.g. organisation of specific meetings). Please describe the type of input received and if it is publicly available on the network's website. |

# European Medicines Agency data protection statement for **Enpr-EMA network database**

## 1. Purpose of processing

The purpose of the present data processing activity is to provide information on research networks and centres with recognised specific expertise in the performance of studies in the paediatric population to relevant stakeholders who are involved and/or interested in identifying research networks for paediatric clinical trials in Europe (e.g. pharmaceutical companies, investigators, patients/parents) via the Enpr-EMA network database.

## 2. What personal information do we collect and through which technical means?

### *2.1. Identification Data*

The self-assessment form submitted by networks in order to become a member of Enpr-EMA, contains information about the networks' nominated contact persons, such as name, surname, phone number, e-mail and postal address.

### *2.2. Legal Basis*

The European network of paediatric research at the EMA (Enpr-EMA) was developed by the European Medicines Agency in accordance with Article 44(1) of Regulation (EC) No 1901/2006.

The legal basis for the processing of personal data in this specific context is your consent, in accordance with Regulation (EU) 2018/1725 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC. For personal data of third-parties such as individuals other than the network's nominated main contact person (e.g. further contact persons) that are submitted in the context of the self-assessment form, you declare that you have obtained the adequate consent as to this processing.

### *2.3. Technical information*

The Enpr-EMA network database will make publicly available on the EMA website the following data:

- Network identification and contact details
- Network description (including size of the network)
- Research experience and ability
- Scientific competencies and capacity to provide expert advice
- Quality management
- Training and educational capacity to build competences
- Public involvement

## 3. Who has access to your information and to whom is it disclosed?

The access to information provided in self-assessment forms is granted to the public.

The relevant data fields concerning details of the nominated contact persons are published.

Data contained in non-active self-assessment forms for registration in the Enpr-EMA database are retained within EMA servers for the purpose of legal certainty for 2 years after the end of membership with Enpr-EMA.

## 4. How do we protect and safeguard your information?

Information provided in self-assessment forms, is recorded in a secured and protected database hosted by the EMA, the operations of which abide by the EMA security policy. The database is not accessible from outside the EMA. Inside the EMA the database can only be accessed using a user ID and password. Access to the application is via a non-encrypted connection using the normal http protocol.

## 5. How can you verify, modify or delete your information?

Any person whose personal data has been processed by EMA has the right to access their data at any time. In case you wish to verify which personal data is stored by the responsible data Controller, have it modified, corrected or deleted, please contact the data Controller by using the Contact information at the end of this statement and by explicitly specifying your request.

*Please see detailed information on your rights in the general EMA Privacy Statement: www.ema.europa.eu/en/about-us/legal/privacy-statement*

## 6. How long do we keep your data?

Your personal data will remain in the Enpr-EMA database until the Enpr-EMA secretariat is informed of changes to the contact person(s), that the registered network is no longer active or wishes to withdraw its membership.

## 7. Contact information

In case you wish to verify which personal data is stored on your behalf by the responsible data Controller, have it modified, corrected, or deleted, or if you have questions regarding the Enpr-EMA network database or concerning any information processed in the context of Enpr-EMA membership, or on your rights, you are invited to contact the support team, operating under the responsibility of the data Controller using the following contact information:

enprema@ema.europa.eu

## 8. Recourse

Complaints, in case of conflict, can be addressed to:

- Data Controller: enprema@ema.europa.eu; or
- EMA Data Protection Officer: dataprotection@ema.europa.eu; or
- European Data Protection Supervisor. For more information on the complaint procedure: https://edps.europa.eu/data-protection/our-role-supervisor/complaints_en

Print Form  Submit by E-mail