EMA/354107/2021, Rev 5
Human Medicines

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

Declaration:

By submitting this self-assessment form, you confirm that:

- you have read and understood the privacy statement provided in Section 3 of this document,
- you consent to the processing of your personal data as explained therein, and
- regarding personal data of third persons included in your submission, the individuals whose data is included have consented to its sharing with EMA and the public on the same basis as your own personal data.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands

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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 s 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 the paediatric population has been created.

Contents

1. Enpr-EMA membership

To become a member of Enpr-EMA, all applicants are required to fill in this application form ("self-assessment form"), which includes specific recognition criteria (I-VI), which are the basis for membership.

The form includes data fields for network identification and description of the network as well as 6 specific recognition criteria (I-VI) with several subcategories (items) for the self-assessment.

The purpose of the self-assessment form is to report on the status of the network (i.e. applicant), not on individual investigators or sites. All sections of the form including all subcategories (items) should be filled in, according to the guidance text provided. For transparency and to permit public scrutiny, the completed self-assessment form should be made public by the network, for example on their website. The network 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 self-assessment 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/**.

1.1. Membership requirements

Criteria I-VI include the minimum requirements (marked with a superscript "M"), which all need to be fulfilled in order to become a Category 1 Enpr-EMA member:

Criteria	Minimum requirements
Criterion I: Research experience and ability	• One ongoing *or* one completed paediatric trial
Criterion II: Network organisation and processes	• Identified contact person for external enquiries • Either an internal steering committee *or* an external advisory/steering committee. • Internal database(s) for disease, condition, treatment and/or outcome • Provision to ascertain data protection and data security
Criterion III: Scientific competencies and capacity to provide expert advice	• Access to expert groups • Capacity to answer external scientific questions
Criterion IV: Quality management	• Documented adherence to clinical trial legislation and Good Clinical Practice (GCP) guideline *(latest implemented versions)* • Documented adherence to the ethical considerations for clinical trials in children • Capacity to monitor studies (academic trials, industry sponsored trials) • Quality control and quality assurance, traceability and data safety

Criterion V: Training and educational capacity to build competences	• Evidence of collaboration with regulatory authorities • Training courses either given by the network over the last 2 years *or* received by the network over the last 2 years
Criterion VI: Public involvement	*At least one of these three items:* 1 Involvement of patients, parents or their organisations in protocol design 2 Involvement of patients, parents or their organisations in creating the protocol information packages 3 Involvement of patients, parents or their organisations in the prioritisation of needs for clinical trials in children

1.2. Membership categories 1-3

Enpr-EMA membership is divided into the following 3 categories depending on the fulfilment of the minimum requirements / items (marked with a superscript "M"):

- **Category 1**: networks fulfilling all minimum requirements (^{M})

  To become a Category 1 member of Enpr-EMA, the applicant must fulfil all the minimum requirements of the 6 recognition criteria (I-VI).

- **Category 2**: networks not currently fulfilling all minimum requirements (^{M})

  A Category 2 member is a network which is not yet able to fulfil all the minimum requirements. The missing requirements can be added later as the network matures and develops, by submitting an updated self-assessment form. Once all minimum requirements are achieved, the network can be upgraded to Category 1.

- **Category 3**: networks that do not run paediatric clinical trials but have expertise in clinical trial methodology or support clinical research infrastructure

  A Category 3 member is generally a non-clinical network (i.e. not performing clinical trials with paediatric patients) but has a different type of expertise to support paediatric clinical trials in the areas of trial design, safety (pharmacovigilance) or ethical aspects, which have significant impact for the conduct of high-quality trials.

1.3. Providing evidence for the membership application

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 across Criteria I-VI.** In such cases, it should be **stated why the item cannot be completed as requested.**

2. Self-assessment form

Identification of the network

Name	SwissPedNet c/o SCTO, Effingerstrasse 35, 3008 Bern, Switzerland	*Include legal address, define acronyms*
Network type and information on funding	Swiss Research Network of Clinical Pediatric Hubs; national infrastructure network	*Indicate type of network, 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. Enpr-EMA networks funding sources form.*
Street	Effingerstrasse 35	*Contact for public enquires*
Postal code	3008	*Contact for public enquires*
Town	Bern	*Contact for public enquires*
Country	Switzerland	*Contact for public enquires*
Telephone 1	0041 31 307 10 43	*Contact for public enquires*
Telephone 2		*Contact for public enquires*
Mobile phone		*Contact for public enquires*
Fax		*Contact for public enquires*
Website URL	www.swisspednet.ch/	*Contact for public enquires*
Email for general enquiries	info@swisspednet.ch	*Contact for public enquires*
Representative (main) contact Please enter information in the fields below, as far as available.		
First name	Anna	
Surname	Naef	
Telephone	0041 31 307 10 43	*EMA internal database*
Mobile phone		*EMA internal database*
E-mail	a.naef@scto.ch	*EMA internal database*
Further contact(s) Please enter information in the fields below, as far as available.		
First name	Matthias	
Surname	Baumgartner	
Telephone		*EMA internal database*
Mobile phone		*EMA internal database*
E-mail	Matthias.Baumgartner@kispi.uzh.ch	*EMA internal database*
The data in this document are 'current' as of	21 Nov 2024	*Provide the date when the criteria were last updated.*
State how this document can be accessed by the public	https://www.swisspednet.ch/header/collaborations and via Enpr-EMA publication	*This should be a link to a webpage, but other means and formats to make public are possible.*

Description of the network

Year of foundation	2012	*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	0- 18 years	
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	Adolescent medicine Allergology Anaesthesia Behavioural medicine Bone marrow transplantation Cardiology Clinical Genetics Clinical Pharmacology Cystic Fibrosis Select all	*Select all specialties covered. If the network covers more than one specialty also select the term "multispecialty". By holding CTRL you can select (or de-select) multiple values, one by one. By holding Shift you can select all values starting from one value to another. By pressing the button "Select all" you can select all the values of the list.*
Multispecialty? Specify	SwissPedNet covers all specialites within the n ⊞	*You may provide further information on the multispecialty nature of the network.*
Specialty or disease specific? Specify	unspecific, with the exception of oncology (SP ⊞	*For example: cardiology only. If not all areas within one specialty are covered specify conditions/diseases and/or procedures/interventions in the following two fields.*
Conditions covered? Specify	all	*E.g. hypertension (within cardiology) or asthma (within respiratory diseases)*
Procedure/intervention specific? Specify	unspecific	*For example, surgery, organ or stem cell transplantation*

Number of collaborating countries	1 List all collaborating countries: national network. The network is collaborating with c4c / c4c-Stichting	*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	12 List all collaborating centres: hildren's Hospital Aarau; University Children's Hospital Basel; Ente Ospedaliero Cantonale, Pediatria, Bellinzona; University Children's Hospital Bern; University Children's Hospital Geneva; University Children's Hospital Lausanne; Children's Hospital Luzern;	*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	Coordinated teaching in clinical paediatric research; Data standardisation projects; Build public awareness of and political support for the needs of paediatric research; Development of pediatric registries; Development of PPI tools and documents in pediatrics; invention, translation, and implementation of intelligent digital health solutions and child-friendly formulations (SwissPedPha)	*Describe type of activities other than clinical and/or non-clinical studies*

Criterion I: Research experience and ability

1.1 Number of completed paediatric[1] trials [M]	3	***Minimum requirement*** *([M]):* *One ongoing or one completed trial. Any (interventional or observational) paediatric clinical trials, whether non-commercial, investigator-initiated, industry-sponsored or commercial, which have been conducted by the network (as opposed to trials conducted by individual investigators or collaborating centres). Listed trials must have a reference/mention of the network in the public trial record. Please provide references as links or attachments (e.g. to EU-CTR, publications). Do not include planned trials, but only ongoing and completed trials.*
Number of ongoing paediatric trials [M]	2	
1.2 Total number of paediatric participants screened per year	300	*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?*
Total number of paediatric participants eligible per year	200	
Describe methods of screening and participant recruitment	According to local SOPs of participating centers.	
1.3 Total number of collaborating centres which enrolled paediatric participants	13	*Provide the number of centres which enrolled participants into completed or ongoing trials listed in item 1.1.*

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

Academic (investigator) initiated studies *Studies conducted independently from pharmaceutical companies. There is a separate category (below) for industry-funded studies.*		
1.4 Number of ongoing and completed paediatric trials	Absolute number: 600 Proportion of all paediatric trials: 80%	*Paediatric interventional 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 below).* *Please provide references as links or attachments (e.g. to EU-CTR, publications).*
1.5 Number of paediatric specialties covered by paediatric trials	10	*Count specialties, without repetition, across all ongoing or completed paediatric trials. Please list the specialties covered.*
1.6 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 Number of other ongoing research studies/programmes	1	*For example, epidemiological studies, outcome studies, translational research in which the network 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 Proportion of budget for academic (investigator) initiated studies deriving from public funding	80% 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 Number of enrolled participants (all academic paediatric trials)		

Industry-sponsored trials		
1.10 Number of ongoing and completed paediatric trials	30	*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)* *Please provide references as links or attachments (e.g. to EU-CTR, publications).*
1.11 Number of paediatric specialties covered by paediatric trials	10	*Count specialties, without repetition, across all ongoing or completed paediatric trials*
1.12 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 Number of enrolled participants (all industry-sponsored paediatric trials)		

Criterion II: Network organisation and processes

2.1 Existence of an identified contact person for external enquiries [M]	☑ Yes ☐ No Comments:	***Minimum requirement ([M]):*** *Enquiries from patients, parents, organisations, researchers, pharmaceutical companies or regulatory authorities are co-ordinated or answered by a nominated contact person. Provide contact details in section "Identification" above.*
2.2 Existence of an internal steering committee [M]	☑ Yes ☐ No Comments: according to bylaws - 3-6 members. Elected at General Assembly, communicated on website.	***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 Existence of an external advisory/ steering committee directing the network [M]	☑ Yes ☐ No Comments: Advisory Board members are selected by the board and listed on the website.	***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 Existence of a website	☑ Yes ☐ No Comments: www.swisspednet.ch	*If available, mention in "identification" above*
2.5 Existence of newsletter	☐ Yes ☑ No Comments: No SwissPedNet newsletter. News are shared through the Newsletter of the Swiss Clinical Trial Organisation and the website. Internal newsletter goes to network members of SCTO and SwissPedNet, external newsletter is on subscription	*Newsletter of any format (electronic, surface mail), distributed actively to selected recipients. Clarify how the newsletter is made available and to whom.*

2.6 Existence of an internal database(s) for disease, condition, treatment and/or outcome [M]	☑ Yes ☐ No Comments/description: Database on site profiles available centrally, managed by the network. No individual patient data available. Specific experience of relevant research fields covered. DB is managed by the network. Several disease or population specific databases /registries available in Switzerland, managed by individual centres.	***Minimum requirement ([M]):*** *Existence of a 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 network 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 Provisions to ascertain data protection and data security [M]	☑ Yes ☐ No Comments: Data Protection Officer implemented at SwissPedNet. The DPO is overseeing all data protection aspects. Data protection declaration available on website. Individual centres have their own DPO.	***Minimum requirement ([M]):*** *Provisions 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 network (e.g. mission statement/statute) in SOPs, and whether they are publicly accessible.*
2.8 Procedure(s) to access the database by third parties	☑ Yes ☐ No Comments: no access to third parties granted for site profile database. Access according to local SOPs for registries managed by centres or SwissPedRegistry.	*Describe the procedure for third parties to access the database, for planning, conducting or analysing clinical trials.*
2.9 Access to external databases/ registries	☑ Yes ☐ No Comments: Access according to local SOPs for registries managed by centres or SwissPedRegistry.	*Describe the access of the network to relevant external databases, e.g. national databases that are not publicly accessible.*

2.10 Standardised process to access an external database(s)	☑ Yes ☐ No Comments: Access according to local SOPs for registries managed by centres or SwissPedRegistry.	*Describe the standardisation (e.g. SOPs)*

Criterion III: Scientific competencies and capacity to provide expert advice

3.1 Number of peer-reviewed publications in the last 5 years Provide reference(s) Describe the network's contribution to each publication	1 Lancet Child Adolesc Health. 2023 Feb 3;7(4):238–248. Contribution of SwissPedNet to trial conduct, monitoring and study coordination. Review of the manuscript for publication.	*The publications should include a reference to the network.*
3.2 Number of competitive grants obtained in the last 5 years	2	*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 Access to expert groups M	☑ Yes ☐ No Comments: part of committees of: SwissPedHealth, swiss pediatric society, swiss academy of medical science, Swiss National Science Foundation. Contact to: SwissNeoNet, Pediatric Swiss Oncology Group, Swiss Tropical and Public Health Institute, several patient organisation	***Minimum requirement (M):*** *Access to expert groups. Describe how the network has specific access to established expert groups, such as learned societies.*
3.4 Capacity to answer external scientific questions M	☑ Yes ☐ No Comments: single point of contact: SwissPedNet coordinator -> distribution of request within the network	***Minimum requirement (M):*** *Capacity to answer external scientific questions. 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: *Please enter information in the fields below.* *Clarify if SOPs are publicly accessible. Provide links or attach documents.*		
3.5 Site feasibility	☑ Yes ☐ No Comments: not publicly available. Local SOPs at centres available, central SOPs at network level planned.	*This concerns the suitability of a site for conducting a given trial.*
3.6 Participant recruitment	☑ Yes ☐ No Comments: not publicly available. Local SOPs at centres available.	*This concerns provisions to regularly monitor recruitment progress for a trial.*
3.7 Budget calculation for studies	☑ Yes ☐ No Comments: not publicly available. Local SOPs at centres available.	*This concerns, for example, quotes and prospective financial planning for a trial.*

Criterion IV: Quality management

4.1 Documented adherence to clinical trial legislation and Good Clinical Practice (GCP) guideline [M]	☑ Yes ☐ No Comments: Link to documentation of organisation: https://www.swisspednet.ch/header/about-us/ organisation --> quality policy frequency of training: at least every 2 years	***Minimum requirement ([M]):*** *Studies conducted comply with EU Directive 2001/20/EC on Clinical Trials (or – after its coming into application - EU Regulation 536/2014) and GCP. Clarify if adherence to above mentioned legal requirements and GCP is included in the documentation of the organisation (e.g. mission statement/statute) and provide relevant documentation. Specify how frequently clinical research staff is trained on ICH GCP requirements.*
4.2 Documented adherence to the ethical considerations for clinical trials in children [M]	☑ Yes ☐ No Comments: Link to documentation of organisation: https://www.swisspednet.ch/header/about-us/ organisation --> quality policy	***Minimum requirement ([M]):*** *Adherence to "ethical considerations for clinical trials in children" is included in the documentation of the organisation (e.g. mission statement/statute). Provide relevant SOPs and indicate if they are publicly accessible.*
4.3 Documented adherence to ethical considerations	☑ Yes ☐ No Comments pediatric experts are part of cantonal ethic committees	Indicate whether paediatric experts are involved in the ethics committees approached for approval of studies conducted by the network.
4.4 Availability of Standard Operation Procedures (SOP)	☑ Yes ☐ No If yes, provide reference to available SOPs Each study site has their own QMS	*Indicate existence of SOPs e.g. for study management, adverse events reporting etc.*

4.5 Capacity to monitor studies (academic trials, industry sponsored trials) [M]	☑ Yes ☐ No Comments: Directly by the members of SwissPedNet or by collaborating CTUs of the Swiss Clinical Trial Organisation	***Minimum requirement ([M]):*** *Capacity to monitor studies. Indicate if the network 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 Capacity to monitor performance of collaborating centres	☑ Yes ☐ No Comments: In responsibility of the Sponsor	*Describe how performance of collaborating centres is evaluated and whether this is publicly described. Please clarify whether an SOP for sites' performance monitoring is available, publicly accessible and/or provide link(s).*
4.7 Quality control and quality assurance, traceability and data safety [M]	☑ Yes ☐ No Comments: Link to documentation of organisation: https://www.swisspednet.ch/header/about-us/ organisation --> quality policy	***Minimum requirement ([M]):*** *Quality control, quality assurance and traceability related processes are described in documents of the network (e.g. mission statement/statute). Clarify if such documents exist and whether they are publicly accessible. If yes, provide reference(s) or link(s) (e.g. to national law).*

Criterion V: Training and educational capacity to build competences

5.1 Evidence of collaboration with regulatory authorities [M]	☑ Yes ☐ No Comments: Yearly roundtable with the authorities (Swissmedic /Swissethics). Participation in training events by authorities (e.g. Swissmedic Symposium)	***Minimum requirement ([M]):*** *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 Capacity to provide competent consultation to regulatory authorities	☑ Yes ☐ No Comments: e.g. president of SPHN Data Coordination Centre (Matthias Baumgartner)	*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 Formal meetings for clinical trials If yes, provide number	☑ Yes ☐ No Comments: There are several trial specific meetings every week within the network	*For example, investigator meetings, trainings specific to a given ongoing or planned trial.* *Please attach a list of formal meetings for clinical trials, if available.*
5.4 Training courses given/organised by the network over the last 2 years [M] If yes, provide number	☑ Yes ☐ No Comments: 6; 1 Yearly teaching event for young researchers. NextGen Research Day https://www.swisspednet.ch/events/nextgen-research-day 2 Field Trips within the network including teaching 2 Hub Staff Meetings within the network on a specific topic 1 Annual meeting including teaching	***Minimum requirement ([M]):*** *training courses either given (5.4) or received (5.5).* *For example, training specific to a trial or in general for trial(s), with external participants or from the network. Clarify if organisation of training courses constitutes 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.* *Please attach a list of training courses organised, if available.*

5.5 Network-wide training courses received over the last 2 years [M] If yes, provide number	☑ Yes ☐ No Comments: 6; same list as trainings given. Participation is encouraged in Service Level Agreements, but not compulsory. Usually, all members are present with at least 1 representative.	***Minimum requirement ([M]):*** *training courses either given (5.4) or received (5.5).* *For example, training specific to a trial or in general for trial(s), with external participants or from the network. Clarify if attendance of training courses constitutes 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.* *Please attach a list of network-wide training courses received, if available.*
5.6 Promotion of participation in clinical trials in countries with limited resources Provide list of countries	☐ Yes ☑ No Comments:	*Indicate if support for such trials is provided by the network.*

Criterion VI: Public involvement

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

6.1 Involvement of patients, parents or their organisations in protocol design	☑ Yes ☐ No Comments: SwissPedHealth All SNSF IICT projects initiated within the network include a PPI plan. Central PPI working group will be implemented early 2025.	*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 Involvement of patients, parents or their organisations in creating the protocol information packages	☑ Yes ☐ No 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 Involvement of patients, parents or their organisations in the prioritisation of needs for clinical trials in children	☑ Yes ☐ No 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.*

NOTE: Please read the privacy statement below before submitting the self-assessment form.

3. EMA privacy statement for Enpr-EMA network database

The European Medicines Agency (hereinafter "EMA" or "Agency") is committed to respect the right to data protection of individuals. The Agency collects and uses personal data in accordance with Regulation (EU) 2018/1725[2] (hereinafter "Regulation").

This Privacy Statement explains how the Agency collects and uses personal data for purposes related to the European network of paediatric research at the EMA (Enpr-EMA) database in accordance with the Agency's data protection obligations under the Regulation. This includes the collection, storage, internal use and publication of the personal details of the representative and further contact person of each network.

3.1. Who is the data controller?

The Agency is ultimately responsible for complying with Regulation (EU) 2018/1725. Internally, the Head of Human Medicines Research and Development Support Division has been appointed to act as the data controller.

Should you wish to get in touch with the Data Controller, please contact:

datacontroller.HumanMedicines@ema.europa.eu

3.2. Purpose of processing

On the self-assessment form[3] submitted by networks in order to become a member of Enpr-EMA, EMA collects contact details of their appointed representatives and other contact persons. Such data will be entered into the Enpr-EMA network database and made available to the public via this database.

In particular, EMA makes available the full name and contact details of the appointed representative(s) and further contact person(s) as provided in the self-assessment form with the aim of providing at least one contact point with the network to be used by any stakeholder interested in identifying research networks for paediatric clinical trials in Europe (e.g. pharmaceutical companies, investigators, patients/parents).

3.2.1. Personal data concerned

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

3.2.2. Legal basis

This processing of the personal data is in accordance with Article 5(d) of Regulation (EU) 2018/1725 where the data is directly submitted by the person concerned ("data subject") and therefore processing is based on the consent of the data subject.

When you provide your personal data, you consent to the processing of that data in accordance with this Privacy Statement. You may withdraw your consent to the processing in an e-mail to the data controller [see section 3.5.].

2 Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 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, Available: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32018R1725

3 Form available here: http://enprema.ema.europa.eu/enprema/images/Self_Assessment_PDF_Form_v4.pdf

You also have the right to withdraw your consent at any time. Please note that such withdrawal does not affect the lawfulness of processing carried out by the EMA before the withdrawal of your consent.

For personal data of third-parties, for example of further contact persons provided in the self-assessment form (i.e. when the data is not directly submitted by the person concerned) the person submitting the self-assessment form declares, by submitting the form, that the individuals whose data is included consent to its sharing with EMA and the public.

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

Personal data submitted in the self-assessment form is processed (e.g. entered into the Enpr-EMA network database, amended when necessary) by authorised staff within the Product Development Scientific Support Department of EMA (hereinafter: Enpr-EMA secretariat).

Personal data of the appointed representative and further contact persons as provided in the self-assessment form are made accessible to the general public on the external website of the Enpr-EMA network database[4].

3.4. How long do we keep your data?

Your personal data will be retained during the period when the relevant network is registered in Enpr-EMA or until the Enpr-EMA secretariat is informed that:

- you are not anymore acting as representative/contact person of the relevant registered network;
- the relevant registered network is no longer active or wishes to withdraw its membership;
- you wish to withdraw your consent regarding this data processing.

When the Enpr-EMA secretariat is notified of the above, EMA will securely dispose of your personal data in accordance with the applicable legislation.

3.5. Your data protection rights

- Data subjects (i.e. the individuals whose personal data is processed in accordance with the above), have the following rights:
- **Right to withdraw consent –** You have the right to withdraw your consent at any time where EMA is relying on consent to process your personal data. The withdrawal of your consent will not affect the lawfulness of processing based on consent before its withdrawal.
- **Right to be informed –** This Privacy Statement explains how EMA collects and uses your personal data
- *Right to access* **–** You have the right to access your personal data, i.e., request and obtain a copy of the personal data held by EMA.
- **Right to rectification –** You have the right to obtain the rectification or completion of inaccurate or incomplete personal data.
- **Right to erasure –** You have the right to request EMA to delete or stop processing your data, for example where the data is no longer necessary for the purposes of processing.

4 Available: http://enprema.ema.europa.eu/enprema/index.php

- **Right to restrict processing –** In a few, codified cases, you have the right to obtain the restriction of the processing, meaning that your data will only be stored, but not actively processed for a limited period of time. For more information about this right and its limitations, see the EMA General Privacy Statement, hosted at www.ema.europa.eu/en/about-us/legal/privacy-statement

- **Right to portability -** Where the processing is carried out based on your consent and in automated means you have the right to receive your personal data (which was provided to the EMA directly by you) in a machine-readable format. You may also ask the EMA to directly transfer such data to another controller.

These rights can be exercised in accordance with the provisions of Regulation (EC) 2018/1725. More detailed information concerning your rights is available in the EMA General Privacy Statement: www.ema.europa.eu/en/about-us/legal/privacy-statement

3.6 . Recourse

In case you have any questions regarding the processing of your personal data, or you think that the processing is unlawful or that it is not carried out in compliance with this Privacy Statement or the EMA General Privacy Statement, please feel free to contact the Data Controller or the EMA Data Protection Officer.

The contact details of the **Data Controller** are the following:

datacontroller.HumanMedicines@ema.europa.eu

The contact details of the **Data Protection Officer** are the following:

dataprotection@ema.europa.eu.

You also have the right to lodge a complaint with the **European Data Protection Supervisor**:

- Email: edps@edps.europa.eu
- Website: www.edps.europa.eu
- Further contact information: www.edps.europa.eu/about-edps/contact_en

Print Form Submit form by Email