4 May 2011
EMA/817561/2010
Human Medicines Development and Evaluation

European network of paediatric research (EnprEMA)

Recognition criteria for self assessment

The European Medicines Agency is tasked with developing a European paediatric network of existing national and European networks, investigators and centers with specific expertise in the performance of studies in the paediatric population.

Following a test pilot phase, public consultation and the outcome of the second workshop with participants of 28 networks and/or clinical trial centres in March 2010, recognition criteria have been finalised which will have to be fulfilled by existing networks to become a member of the European paediatric network. All networks wishing to become a member of EnprEMA are invited to perform self-assessment and to send the filled-in document to the European Medicines Agency.

The document should be sent to Merja.Heikkurinen@ema.europa.eu

END OF SELF-ASSESSMENT PERIOD	31 July 2010

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EnprEMA

European network of paediatric researchat the European Medicines Agency

Recognition criteria for self-assessment

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 is to be formed of national and European networks, investigators and centres with specific expertise in performing drug trials in the paediatric population. General information can be found at:

http://www.emea.europa.eu/htms/human/paediatrics/network.htm

Minimum criteria that have to be fulfilled to be recognised as a member of the EnprEMA

This document defines 6 criteria with several subcategories (items) for self-assessment. The criteria and their items have been set up in a public process. Minimum criteria were defined that networks should fulfil to be recognised as a member of the EnprEMA. The defined minimum criteria are flagged with a superscript "**M**".

Irrespective of whether or not only minimum criteria / items are fulfilled, the full list of the criteria and items as well as the network identification should be completed to the extent possible.

Use of the document and application of the recognition criteria

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 document, the highest level is called the reporting party.

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

For the same purpose, the reporting party should also make publicly accessible the actual data on which the statements are based. For example, if numbers of paediatric trials are provided, references to clinical trial registration numbers could be made publicly accessible.

The self-assessment should be updated annually.

This document should be sent to the European Medicines Agency; it will be published on the EMA webpage.

Criteria for the recognition of an investigator, site* or network as a member of the EnprEMA*

* only when the investigator or the site is not part of a network

Identification M

Name	Paediatric Network of Clinical Investigation Centers - CICPed	Include legal address, define acronyms
Type	National French Network dedicated to investigations in children (see attached leaflet) The CIC are INSERM research structures integrated into treaching hospitals and dedicated to paediatric clinical research. They have both a research team (paeditrician, research nurses and technicians) and facilities specifically adapted to the conduct of trials in children. SPECIFIC OBJECTIVES : -Create interactions between researchers, paediatricians and pharmaceutical industries to conduct clinical research projects (including translational research) under good clinical and laboratory practices in order to : SHORT MISSION STATEMENT : - Identify areas of research - Promote new designs and methodologies adapted to children - Develop investigation methods - Conduct clinical trials - Enrol paediatric patients - Analyze data - Share knowledge that improves care of paediatric patients - Participate to training programs for all partners of research, including paediatricians, nurses ...	Indicate type of reporting party, e.g. national or speciality network. May include short mission statement
Street	Coordination center - Hopital Robert Debré - 48 boulevard Serurier	
Postal code	75019	
Town	Paris	
Country	France	

Name	Paediatric Network of Clinical Investigation Centers - CICPed	Include legal address, define acronyms
Telephone 1	00 33 1 4003 2150	
Telephone 2	00 33 1 4003 2492	

Mobile phone

Fax	00 33 1 40 03 47 59	
Web site	http://www.cic-pediatriques.fr	If available (see criterion 4)
Email for general enquiries	florence.emmanuel@rdb.aphp.fr christelle.conde@rdb.aphp.fr	If available (see criterion 4)
Representative (main) contact	---	Include first and second name, email, telephone, address, as far as available
First name	Jacqz-Aigrain	
Second name	Evelyne	
Telephone	00 33 1 4003 2150	

Mobile phone

Email	evelyne.jacqzaigrain@gmail.com	
Further contact(s)	---	Include first and second name, email, telephone, address, as far as available
First name		
Second name		
Telephone		

Mobile phone

Email		
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	http://www.cic-pediatriques.fr/ http://www.extranet.inserm.fr	This should be a link to a webpage, but other means and formats to make public are possible

Description M

Year of foundation	The first paediatric CIC was created in Robert Debré hospital in 1996. Paediatric activities progressively started in the different CIC of the network : 4 CIC in 2002 and 13 in 2010 when the last two centers were included in the network Two new centers will join the Network in 2012 : CIC Necker EM (Paris) and CIC Grenoble	Of the network, or 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 newborn	☒ Yes ☐ No	Newborn: from birth to less than 28 days of age
Infants from 1 month to less 24 months 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	☒ Yes ☐ No	

Year of foundation	The first paediatric CIC was created in Robert Debré hospital in 1996. Paediatric activities progressively started in the different CIC of the network : 4 CIC in 2002 and 13 in 2010 when the last two centers were included in the network Two new centers will join the Network in 2012 : CIC Necker EM (Paris) and CIC Grenoble	Of the network, or of the investigator's or site's specific paediatric research activities
Specialities / Conditions covered	THe CIC are dedicated to clinical research and investigations and therefore to all paediatric specialities or conditions are not selected. However, each CIC within the network has recognized expertise in one or two specialities or conditions, the corresponding paediatrician acting as an expert related to these fields for the network. As examples: - Gastroenterology CIC Lille Pr Gottrand - Pneumology CIC Bordeaux Pr Fayon - Nephrology CIC Marseille Pr Tsimaratos - Endocrinologie CIC Toulouse Pr Salles - Neonatalogy CIC Robert Debré Pr Jacqz-Aigrain - Pharmacology / Modelisatiion CIC Robert Debré Pr Jacqz-Aigrain - Methodology / Pharmacology CIC Lyon Dr Kassai - Epidemiology CICEC Robert Debré Pr Alberti	ENPREMA will cover a range of different networks, from single speciality trials groups to those covering all paediatrics. If not all areas within one speciality are covered, specify conditions
Multispeciality? Specify	As previously stated, all paediatric CIC are involved in trials conducted in the different paediatric subspecialties, without restriction, the research activities only pending on the hospital environment and medical activities Close connections are established with speciality networks such as neonatalogy, cystic fibrosis, hemato-oncology ..	For example, oncology or infectious diseases

Year of foundation	The first paediatric CIC was created in Robert Debré hospital in 1996. Paediatric activities progressively started in the different CIC of the network : 4 CIC in 2002 and 13 in 2010 when the last two centers were included in the network Two new centers will join the Network in 2012 : CIC Necker EM (Paris) and CIC Grenoble	Of the network, or of the investigator's or site's specific paediatric research activities
Speciality 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	Procedures and interventions: Pharmacokinetics and sampling Scanning Calorimetry Sleep studies Tests in endocrinology Microodialysis etc All laboratory procedures .. Paediatric surgery Medical devices	For example, surgery, organ or stem cell transplantation
Number of collaborating countries	The network has a national status but collaborations are ongoing with most european countries within FP7 projects List all collaborating countries: Collaboration within FP7 projects	State the number of collaborating countries. Indicate "1" if national; Indicate if Europe, outside of Europe, other……. (describe)

Year of foundation	The first paediatric CIC was created in Robert Debré hospital in 1996. Paediatric activities progressively started in the different CIC of the network : 4 CIC in 2002 and 13 in 2010 when the last two centers were included in the network Two new centers will join the Network in 2012 : CIC Necker EM (Paris) and CIC Grenoble	Of the network, or of the investigator's or site's specific paediatric research activities
Number of collaborating centres	13 (+2 in 2012) List all collaborating centres: Clinical Investigation Centers from : Bordeaux (Pr. M Fayon) Clermont-Ferrand (Pr. F Demeocq) Dijon (Pr. M Bardou) Lille (Pr. F Gottrand) Lyon (Pr. M Nicolino, Dr Kassai) Marseille (Pr. M Tsimaratos) Montpellier (Pr. F Rivier) Nantes (Pr. J-C Rozé) Poitiers (Pr. R Hankard) Paris Robert Debré (Pr. E Jacqz-Aigrain, Pr Alberti) Rouen (Pr. E Mallet) Toulouse (Pr. J-P Salles) Tours (Pr. F Labarthe) Two new centers will join the Network in 2012 : CIC Necker EM (Paris) and CIC Grenoble	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	Pharmacology - pharmacogenetics Modelisation and simulation Epidemiology Protocol design (small numbers)	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 in the last 5 years.
2. Evidence used in this document should have a reference (e.g., publication, annual or periodic report or internal network document).
3. The self-assessment document is to cover a range of different network types. It is recognised that some networks may not be able to accurately respond to every item. In such circumstances, state why it is not possible to respond.
4. 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 Number of completed trials[M] Number of ongoing trials[M]	Total Nr of completed trials : in 2006 : 12 ; in 2007 : 19 in 2008 : 31 ; in 2009 : 26 Total Nr of opened trials : in 2006 : 20 ; in 2007 : 23 in 2008 : 30 ; in 2009 : 46 February 2012 update for Industrial clinical Trials : Total Nr of completed trials : in 2010 : 27 ; in 2011 : 24 Total Nr of opened trials : in 2010 : 35 ; in 2011 : 32 Total Nr of ongoing trials : in 2010 : 92 ; in 2011 : 103 Update for Institutionnal clinical trials is ongoing	Any interventional clinical trial, whether non-commercial, investigator-initiated, industry-sponsored or commercial, in which the reporting party actively took part. Minimum requirement ([M]): one ongoing or one completed trial.
1.2 Total number of participants actually recruited each year Proportion of eligible participants actually recruited each year Describe way of screening and participant recruitment	Only for completed trials : in 2006 : 108 ; in 2007 : 165 in 2008 : 330 ; in 2009 : 370 February 2012 update for industrial clinical trials : in 2010 : 1540 ; in 2011 : 528 Update for Institutionnal clinical trials is ongoing Eligible participants : Mainly dependant on the trial, subspecialty and age group	Relevant to speciality specific networks. State total recruitment capacity for any interventional clinical trial, whether non-commercial, investigator-initiated, industry-sponsored or commercial, in which the reporting party actively took part. Which strategies or pathways are used to screen and recruit participants?

1.1 Number of completed trials[M] Number of ongoing trials[M]	Total Nr of completed trials : in 2006 : 12 ; in 2007 : 19 in 2008 : 31 ; in 2009 : 26 Total Nr of opened trials : in 2006 : 20 ; in 2007 : 23 in 2008 : 30 ; in 2009 : 46 February 2012 update for Industrial clinical Trials : Total Nr of completed trials : in 2010 : 27 ; in 2011 : 24 Total Nr of opened trials : in 2010 : 35 ; in 2011 : 32 Total Nr of ongoing trials : in 2010 : 92 ; in 2011 : 103 Update for Institutionnal clinical trials is ongoing	Any interventional clinical trial, whether non-commercial, investigator-initiated, industry-sponsored or commercial, in which the reporting party actively took part. Minimum requirement ([M]): one ongoing or one completed trial.
	Screening is performed with computer tools (medical records), byparticipating to medical meetings and by technical or research nurses within wards	
1.3 Total number of collaborating centres	13 (see list in Description). Two new centers will join the Network in 2012 : CIC Necker EM (Paris) and CIC Grenoble	For completed and ongoing (open) paediatric trials. Do not include sites in set-up.
Academic (investigator) initiated studies	---	Studies conducted independently from pharmaceutical companies (no sponsorship and no funding). There is a separate category (below) for industry-funded studies.
1.4 Number of ongoing and	Absolute number: in 2006 : 4 ; in 2007 : 9	Paediatric interventional trials of any phase of the

1.1 Number of completed trials[M] Number of ongoing trials[M]	Total Nr of completed trials : in 2006 : 12 ; in 2007 : 19 in 2008 : 31 ; in 2009 : 26 Total Nr of opened trials : in 2006 : 20 ; in 2007 : 23 in 2008 : 30 ; in 2009 : 46 February 2012 update for Industrial clinical Trials : Total Nr of completed trials : in 2010 : 27 ; in 2011 : 24 Total Nr of opened trials : in 2010 : 35 ; in 2011 : 32 Total Nr of ongoing trials : in 2010 : 92 ; in 2011 : 103 Update for Institutionnal clinical trials is ongoing	Any interventional clinical trial, whether non-commercial, investigator-initiated, industry-sponsored or commercial, in which the reporting party actively took part. Minimum requirement ([M]): one ongoing or one completed trial.
completed clinical trials	in 2008 : 6 ; in 2009 : 4 Proportion of all studies: 60% Update for Institutionnal clinical trials is ongoing	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)
1.5 Number of paediatric specialities covered by paediatric trials	8 to 12 depending on the year reported Hemato-oncology, endocrinology, infectiology, gastroenterology, nutrition, pneumology, ...	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.6 Number of paediatric conditions covered by paediatric trials	20 to 30 depending of the year reported (estimation) As examples within endocrinology: - treatment with growth hormone - diabetes..	If not all areas within one speciality covered count conditions, without repetition, across all ongoing or completed paediatric trials
1.7 Number of other ongoing	8 to 10 depending of the year reported	For example, epidemiological studies,

1.1 Number of completed trials[M] Number of ongoing trials[M]	Total Nr of completed trials : in 2006 : 12 ; in 2007 : 19 in 2008 : 31 ; in 2009 : 26 Total Nr of opened trials : in 2006 : 20 ; in 2007 : 23 in 2008 : 30 ; in 2009 : 46 February 2012 update for Industrial clinical Trials : Total Nr of completed trials : in 2010 : 27 ; in 2011 : 24 Total Nr of opened trials : in 2010 : 35 ; in 2011 : 32 Total Nr of ongoing trials : in 2010 : 92 ; in 2011 : 103 Update for Institutionnal clinical trials is ongoing	Any interventional clinical trial, whether non-commercial, investigator-initiated, industry-sponsored or commercial, in which the reporting party actively took part. Minimum requirement ([M]): one ongoing or one completed trial.
research studies / programs		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.
1.8 Indicate the proportion of public funding	Proportion of academic initiated studies: 40 % Proportion of budget: 40 to 50%	Indicate the proportion of the budget handled for completed and ongoing paediatric trials that is derived from public funding sources such as governmental programs, competitive public grants, university contributions
1.9 Number of registered study participants (all studies)	in 2006 : 74 ; in 2007 : 77 in 2008 : 56 ; in 2009 : 21 Update for Institutionnal clinical trials	

1.1 Number of completed trials[M] Number of ongoing trials[M]	Total Nr of completed trials : in 2006 : 12 ; in 2007 : 19 in 2008 : 31 ; in 2009 : 26 Total Nr of opened trials : in 2006 : 20 ; in 2007 : 23 in 2008 : 30 ; in 2009 : 46 February 2012 update for Industrial clinical Trials : Total Nr of completed trials : in 2010 : 27 ; in 2011 : 24 Total Nr of opened trials : in 2010 : 35 ; in 2011 : 32 Total Nr of ongoing trials : in 2010 : 92 ; in 2011 : 103 Update for Institutionnal clinical trials is ongoing	Any interventional clinical trial, whether non-commercial, investigator-initiated, industry-sponsored or commercial, in which the reporting party actively took part. Minimum requirement ([M]): one ongoing or one completed trial.

is ongoing

Industry-sponsored trials	---	
1.10 Number of ongoing and completed trials	Nr of completed trials : in 2006 : 12 ; in 2007 : 15 in 2008 : 29 ; in 2009 : 24 in 2010 : 27 ; in 2011 : 24 Nr of opened trials : in 2006 : 15 ; in 2007 : 23 in 2008 : 30 ; in 2009 : 44 in 2010 : 35 ; in 2011 : 32 Total Nr of ongoing trials : in 2010 : 92 ; in 2011 : 103	Paediatric interventional trials of any phase of the pharmaceutical development (phase I to IV, including therapy optimising trials if requiring authorisation)
1.11 Number of paediatric specialities covered by paediatric trials	13 (oncology, hematology, cardiology, surgery, endocrinology,gastroenterology, genetics,hepathology, neonatology, nephrology, neurology, pneumology,	Count specialities, without repetition, across all ongoing or completed paediatric trials

1.1 Number of completed trials[M] Number of ongoing trials[M]	Total Nr of completed trials : in 2006 : 12 ; in 2007 : 19 in 2008 : 31 ; in 2009 : 26 Total Nr of opened trials : in 2006 : 20 ; in 2007 : 23 in 2008 : 30 ; in 2009 : 46 February 2012 update for Industrial clinical Trials : Total Nr of completed trials : in 2010 : 27 ; in 2011 : 24 Total Nr of opened trials : in 2010 : 35 ; in 2011 : 32 Total Nr of ongoing trials : in 2010 : 92 ; in 2011 : 103 Update for Institutionnal clinical trials is ongoing	Any interventional clinical trial, whether non-commercial, investigator-initiated, industry-sponsored or commercial, in which the reporting party actively took part. Minimum requirement ([M]): one ongoing or one completed trial.
	nutrition)	
1.12 Number of paediatric conditions covered by paediatric trials	15-20 (leukaemia, thrombosis, anaemia, sickle cell disease, arrhithmia, hypertension, digestion, diabetes, growth, antibiotic, aneuploidy, parenteral nutrition, influenza, cystic fibrosis, Attention-Deficit/Hyperactivity, gastro œsophageal reflux, hemolytic uremic syndrome, …)	If not all areas within one speciality covered count conditions, without repetition, across all ongoing or completed paediatric trials
1.13 Number of registered study participants (all studies)	data are only available for completed trials : in 2006 : 34 ; in 2007 : 88 in 2008 : 274 ; in 2009 : 349 in 2010 : 1540 ; in 2011 : 528	

Criterion 2: Network organisation and processes

2.1 Existence of an identified contact person for external enquiries [M]	☒ Yes ☐ No Comments: One contact person dedicated to industry sponsored trials (Florence Emmanuel) One contact person - medical doctor specialized in paediatrics - in each CIC dedicated to institutional sponsored trials Medical contacts in all the major paediatric subspecialties (paediatric nephrology, paediatric oncology, paediatric endocrinolgy…within the scientific committee of the network) THe network is organized with paediatric experts in all subsecialitiies, who are able of evaluating the scientific question and faisability of the trial within the network. Each expert is contacted by the coordinator, when his specialized expertise is required for one protocol: he has to provide scientific expertise and faisability to the coordinator.	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 Existence of an internal steering committee [M]	☒ Yes ☐ No Comments: THe members include all the paediatricians of the participating CIC plus one epidemiologist and one methodiologist	Minimum requirement ([M]): either an internal steering committee (2.2) or an external advisory / steering committee (2.3).

2.1 Existence of an identified contact person for external enquiries [M]	☒ Yes ☐ No Comments: One contact person dedicated to industry sponsored trials (Florence Emmanuel) One contact person - medical doctor specialized in paediatrics - in each CIC dedicated to institutional sponsored trials Medical contacts in all the major paediatric subspecialties (paediatric nephrology, paediatric oncology, paediatric endocrinolgy…within the scientific committee of the network) THe network is organized with paediatric experts in all subsecialitiies, who are able of evaluating the scientific question and faisability of the trial within the network. Each expert is contacted by the coordinator, when his specialized expertise is required for one protocol: he has to provide scientific expertise and faisability to the coordinator.	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.
2.3 Existence of an external advisory / steering committee directing the reporting party [M]	☒ Yes ☐ No Comments: THe CICP network is part of the national network of the CIC at Inserm. The committee includes the coordinator of all the 9 national networks, organized by medical specialities (paediatrics, cardiology, neurology, endocrinology etc…). Teleconferences every month, face to face meetings every semester, scientific meeting every year during the congres of the natioal Society of Physiology, Pharmacology and Therapeutics (P2T).	Minimum requirement ([M]): either an internal steering committee (2.2) or an external advisory / steering committee (2.3).

2.1 Existence of an identified contact person for external enquiries M	☒ Yes ☐ No Comments: One contact person dedicated to industry sponsored trials (Florence Emmanuel) One contact person - medical doctor specialized in paediatrics - in each CIC dedicated to institutional sponsored trials Medical contacts in all the major paediatric subspecialties (paediatric nephrology, paediatric oncology, paediatric endocrinolgy…within the scientific committee of the network) THe network is organized with paediatric experts in all subsecialitiies, who are able of evaluating the scientific question and faisability of the trial within the network. Each expert is contacted by the coordinator, when his specialized expertise is required for one protocol: he has to provide scientific expertise and faisability to the coordinator.	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.
2.4 Existence of a website	☒ Yes ☐ No Comments: The website includes - an extranet site dedicated to the public, presenting the different structures of the network - an intranet site dedicated to the partners and allowing exchanges of documents, informations and discussions…	If available, mention in "identification" above
2.5 Existence of newsletter	☒ Yes ☐ No Comments: all the minuts of teleconferences and meetings are available, as well as newsletters, dedicated to specific protocols.	Newsletter of any format (electronic, surface mail), distributed actively to selected recipients.

2.1 Existence of an identified contact person for external enquiries M	☒ Yes ☐ No Comments: One contact person dedicated to industry sponsored trials (Florence Emmanuel) One contact person - medical doctor specialized in paediatrics - in each CIC dedicated to institutional sponsored trials Medical contacts in all the major paediatric subspecialties (paediatric nephrology, paediatric oncology, paediatric endocrinolgy…within the scientific committee of the network) THe network is organized with paediatric experts in all subsecialitiies, who are able of evaluating the scientific question and faisability of the trial within the network. Each expert is contacted by the coordinator, when his specialized expertise is required for one protocol: he has to provide scientific expertise and faisability to the coordinator.	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.
2.6 Existence of an internal database(s) for disease, condition, treatment and / or outcome M If yes, please describe	☒ Yes ☐ No Comments / description: Multiple investigator driven databases in paediatric subspecialties are available and may help in the selection of patients (for example nephrotic syndrome, acute lymphoblastic leukemia, cystic fibrosis, sickle cell disease…). However, due to the specificities of our network, many implicated in "investigations and methodology", our database is oriented more through the analysis of projects and quality criterias than patients or diseases oriented.	For example, data base or disease registry to facilitate planning or conducting future trials (may or may not contain individual patient data)

2.1 Existence of an identified contact person for external enquiries [M]	☒ Yes ☐ No Comments: One contact person dedicated to industry sponsored trials (Florence Emmanuel) One contact person - medical doctor specialized in paediatrics - in each CIC dedicated to institutional sponsored trials Medical contacts in all the major paediatric subspecialties (paediatric nephrology, paediatric oncology, paediatric endocrinolgy…within the scientific committee of the network) THe network is organized with paediatric experts in all subsecialitiies, who are able of evaluating the scientific question and faisability of the trial within the network. Each expert is contacted by the coordinator, when his specialized expertise is required for one protocol: he has to provide scientific expertise and faisability to the coordinator.	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.
2.7 Provisions to ascertain data protection and data security [M]	☒ Yes ☐ No Comments: In each CIC, protection and data security follow the procedures of good clinical practices, including data anonymisation, protection of computers with codes, protection of all offices with codes and keys, alarms…. Each CIC has a secured filing place. In addition all CICs require an official regulatory authorisation to perform clinical research (article L1112 - 13 - Code de la santé publique)	Are provisions in place to ascertain patients' /study participants' data protection and data safety within network
2.8 Procedure(s) to access the database by third parties	☒ Yes ☐ No Comments: Protocoles data base" of the network, under the responsibility of the coordinators, is open to all members of the sceintific committee	Are provisions in place that data can be shared for planning, conducting or analysing a trial(s)?

2.1 Existence of an identified contact person for external enquiries M	☒ Yes ☐ No Comments: One contact person dedicated to industry sponsored trials (Florence Emmanuel) One contact person - medical doctor specialized in paediatrics - in each CIC dedicated to institutional sponsored trials Medical contacts in all the major paediatric subspecialties (paediatric nephrology, paediatric oncology, paediatric endocrinolgy…within the scientific committee of the network) THe network is organized with paediatric experts in all subsecialitiies, who are able of evaluating the scientific question and faisability of the trial within the network. Each expert is contacted by the coordinator, when his specialized expertise is required for one protocol: he has to provide scientific expertise and faisability to the coordinator.	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.
2.9 Access to external databases/registries	☒ Yes ☐ No Comments: A limited number of databases are open to members of the network upon specific request: EORTC data base of paediatric ALL A listing of clinical data based is currenly ongoing. Data base on the ongoing trials in the network is available on request.	For example, national databases that are not publicly accessible but to which the reporting party has open or privileged access; database(s) immediately relevant to area and / or scope
2.10 Standardised process to access an external database(s)	☒ Yes ☐ No Comments: Depending of the data base : Access to the EORTC data base for example is only upon request after precise definitions of the hypothesis, objectives, plan of analysis of the data.	Is a standardised process in place to access external/ national databases?

Criterion 3: Scientific competencies and capacity to provide expert advice

3.1 Number of peer-reviewed publications in the last 5 years Provide exact reference(s) Describe the network's contribution to publication(s)	More than 50 peer-reviewed publications (see "CICPed Network Publications" document attached) Mainly for institutional protocols (as publications of industry sponsored trials are limited) Optimisation of the protocole, Inclusion of patients, data analysis… Publication of industry sponsored trials remain limited.	The publications should indicate that they are related to and reference the reporting party.
3.2 Number of competitive grants obtained in the last 5 years	10 Research on research Pharmacokinetics and Pharmacogenetics	Grants obtained by reporting party (exclusively or not).
3.3 Access to expert groups M	☒ Yes ☐ No Comments: As previously stated, the paediatrician responsible for the clinical investigations within each CIC has an expertise in a paediatric specialty, being an expert in the field. In addition, specificities include pharmacology, epidemiology and methodology.	Indicate if the reporting party has specific access to established expert groups, such as learned societies
3.4 Capacity to answer external scientific questions M	☒ Yes ☐ No Comments: the paediaricians of the CIC network (scientific committee) organize - a teleconference each month to discuss new and ongoing protocoles, require an expertise on new protocoles - a face to face meeting every 4 to 6 months to organize the activities of the network discuss new projects etc…	Indicate if coordinated capacity (staff, process) is available to answer external scientific questions in relation to clinical trials during daily business.
Standardized procedures for assessment of:	---	

3.1 Number of peer-reviewed publications in the last 5 years Provide exact reference(s) Describe the network's contribution to publication(s)	More than 50 peer-reviewed publications (see "CICPed Network Publications" document attached) Mainly for institutional protocols (as publications of industry sponsored trials are limited) 0ptimisation of the protocole, Inclusion of patients, data analysis… Publication of industry sponsored trials remain limited.	The publications should indicate that they are related to and reference the reporting party.
3.5 Site feasibility	☒ Yes ☐ No Comments: Procedure of faisability is available discussed and filled in with the investigators (enclosed)	This concerns the suitability of a site for conducting a given trial
3.6 Participant recruitment	☒ Yes ☐ No Comments: Follow-up of patients inclusion in each CIC in order to balance and compensate recruitment and reach the total targeted number of inclusions A strict follow-up of the patients screened is organized, in order to analyze reasons for refusal.	This concerns provisions to regularly monitor recruitment progress for a trial.
3.7 Budget calculation for studies	☒ Yes ☐ No Comments: THe financilal planning of the trial , always prospective, differs between sponsors. With industrial sponsors, financial planning is generaly centralized by the research department of the hospital and will be common (or very similar) between involved centers. Quotes as made as a function of time spent and staff status (physician, nurse, research technician, …) involvement. With insitutional trials, grants should cover the cost of the trial	This concerns, for example, quotes and prospective financial planning for a trial.

Criterion 4: Quality management

4.1 Documented adherence to Good Clinical Practice (GCP) guideline M	☒ Yes ☐ No Comments: Procedures specific to paediatric research and/or to both paediatric and adult research within the national CIC network, complying with the EU Directive 2001/20/EC	Declare whether studies conducted comply with the EU Directive 2001/20/EC on Clinical Trials.
4.2 Documented adherence to the ethical considerations for clinical trials in children M	☒ Yes ☐ No Comments: Procedures for information and consent in paediatrics (see "ADM-MO-005 - Consent collection procedure" document attached) In addition, the document "Ethical considerations " is given to all new investigators entering the CIC team.	Indicate if documented data / information are publicly available on implementation of / provisions for special ethical requirements for the paediatric trial(s) according to the document "Ethical considerations for clinical trials on medicinal products conducted with the paediatric population".
4.3 Documented adherence to ethical considerations	☐ Yes ☐ No Comments: All protocoles are submitted to a national and mandatory ethic committee (CPP) that should include a paedatrician. In addition, a procedure is definded for information of parents and consent and a strict follow-up of the quality of all individual consent forms is performed.	Declare whether reporting party requests approval by an independent ethics committee with paediatric expertise for all studies conducted.
4.4 Availability of Standard Operation Procedures (SOP)	☒ Yes ☐ No If yes, provide reference to available SOPs SOP available for all research operations, including procedure to declare adverse events in clinical trials, for inform consent, for storage, for laboratory procedures ...(4 documents related to Procedures are attached)	Indicate existence of SOP e.g. for study management, adverse events reporting etc.

4.1 Documented adherence to Good Clinical Practice (GCP) guideline M	☒ Yes ☐ No Comments: Procedures specific to paediatric research and/or to both paediatric and adult research within the national CIC network, complying with the EU Directive 2001/20/EC	Declare whether studies conducted comply with the EU Directive 2001/20/EC on Clinical Trials.
4.5 Capacity to monitor studies (academic trials, industry sponsored trials) M	☒ Yes ☐ No Comments: Monitors from Inserm and hospitals (Unité de recherche clinique) are available. For industry sponsored trials, monitoring is regularly performed under sponsor responsibility.	Indicate if the reporting party implements the monitoring of paediatric trials according to ICH 6 Good Clinical Practice Guideline.
4.6 Capacity to monitor performance of collaborating centres	☐ Yes ☒ No Comments: Under implementation Criterias already selected include: performance in recruitment / reaching objectives Delay in organizing the trial Number of studies accepted and performed Training of investigators	Indicate if the reporting party implements the monitoring ofperformance of collaborating centres.

4.1 Documented adherence to Good Clinical Practice (GCP) guideline[M]	☒ Yes ☐ No Comments: Procedures specific to paediatric research and/or to both paediatric and adult research within the national CIC network, complying with the EU Directive 2001/20/EC	Declare whether studies conducted comply with the EU Directive 2001/20/EC on Clinical Trials.
4.7 Quality control and quality assurance, traceability and data safety[M]	☒ Yes ☐ No Comments: see attached documents related to procedures. For industry sponsored trials, the rule is that “data related to the trials, even “multicentric and involving the network” are the property of the sponsor. They are never released to academic institutions without agreement of the sponsor. For institutional trials, the rules are defined for each trial, with the agreement of all partners.All trials are supervised by a paediatrician trained in GCP and additional staff members (nurse or clinical research associate) . All the individuals working in the CICs are required to be trained to GCP and now recruited with a diploma delivered by the University. We collaborate with the Epidemiology and BioStatistics Unit when required (mainly in institutional trials). In our experience with industry, we are dependant on their organisation: in almost all cases: each individual declared to the sponsor and accessing the electronic CRF has to be declared to have a password and all data and changes are recorded automatically. For institutional trials, the CRF is developed outdoor and maintained by the company under the control of the Hospital Research Office. In addition, one computer is dedicated to the CRF and protected by local rules (password, key etc…).	Indicate if this is implemented in the reporting party’s remit.

Criterion 5: Training and educational capacity to build competences

5.1 Evidence of collaboration with regulatory authorities M	☒ Yes ☐ No Comments: AFSSAPS (paediatric committee), Ethics Committee Expertise of PIPs and/or marketing dossiers EMA paediatric meetings	Indicate awareness of regulatory requirements for developing medicines; for example, implementation of guidelines from regulatory authorities.
5.2 Capacity to provide competent consultation to regulatory authorities	☒ Yes ☐ No Comments: Peadiatricians within the network are - experts to AFSSAPS (within the Paediatric Committee) - experts for Ethics committees (CPP)	Indicate the capacity of the reporting party to provide expert advice to regulatory authorities. For example, nominations into standing scientific committees to regulatory authorities, registration(s) as authorities' external expert(s).
5.3 Formal meetings for clinical trials If yes, provide number	☒ Yes ☐ No Comments: In each center, all protocols are discussed in a "technical - acceptance meeting with the paediatric specialist, in norder to analyze both the local faisability and the tasks of the different partners. At the network level, discussions during teleconferences, meetings for initiation of the protocole in the participating centers… 4 per year	For example, investigator meetings, trainings specific to a given ongoing or planned trial.
5.4 Training courses given over the last 2 years M If yes, provide number	☒ Yes ☐ No Comments: Formal training of new investigators : - University Practical trainings of nurses, young investigators, research technicians (short 2 months stay and long-term training for 6 moths in the clinical investigation centers) - Exchange of nurses between CIC	For example, training specific to a trial or in general for trial(s), with external participants or from the reporting party. Minimum requirement (M): training courses either given (5.4) or received (5.5).

5.1 Evidence of collaboration with regulatory authorities [M]	☒ Yes ☐ No Comments: AFSSAPS (paediatric committee), Ethics Committee Expertise of PIPs and/or marketing dossiers EMA paediatric meetings	Indicate awareness of regulatory requirements for developing medicines; for example, implementation of guidelines from regulatory authorities.
5.5 Training courses received over the last 2 years [M] If yes, provide number	☒ Yes ☐ No Comments: Afssaps training (coordinator) Different trainings in the participating CICs (see list of training)	For example, training specific to a trial or in general for trial(s), with external participants or from the reporting party. Minimum requirement (M): training courses either given (5.4) or received (5.5).
5.6 Promotion of participation in clinical trials in countries with limited resources Provide list of countries	☒ Yes ☐ No Comments: Within European projects (FP7) and Penta projects Hungary	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 Involvement of patients, parents or their organisations in the protocol design	☒ Yes ☐ No Comments: Involvement is mainly related to institutional trials Protocol design with Association for rare diseases (Cystic fibrosis, Friedrich) Comments related to informed consent and/or PK sampling (limited to cystic fibrosis)	Indicate if public stakeholders are /have been involved
6.2 Involvement of patients, parents or their organisations in creating the protocol information package	☐ Yes ☒ No Comments:	Indicate if public stakeholders are /have been involved
6.3 Involvement of patients, parents or their organisations in the prioritisation of needs for clinical trials in children	☐ Yes ☒ No Comments:	Indicate if public stakeholders are /have been involved