28 October 2011
EMA/867379/2011
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 research at 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	European Cystic Fibrosis Society - Clinical Trials Network (ECFS-CTN) Legal address: ECFS Kastanieparken 7 7470 Karup J. Denmark	Include legal address, define acronyms
Type	Disease specific European network The aim of the European Cystic Fibrosis Clinical Trials Network is to intensify clinical research in the area of cystic fibrosis and to bring new medicines to the patients as quickly as possible. 1. Maintain a network of clinical trial sites according to state-of-the-art quality criteria 2. Keep appropriate structures supporting the network in the acquisition, planning and conduct of clinical trials 3. Attract projects in cooperation with non-profit organizations, academic centres and pharmaceutical or medical-device companies	Indicate type of reporting party, e.g. national or speciality network. May include short mission statement
Street	Postal address (see above for legal address): UZ Gasthuisberg ECFS-CTN Mucoteam-Kindergeneeskunde Herestraat 49	
Postal code	3000	
Town	Leuven	
Country	Belgium	
Telephone 1	+32 479 983839	
Telephone 2	+32 16 343831	
Mobile phone	+32 479 983839	

Fax	+32-16 343817	
Web site	http://www.ecfs.eu/ctn	If available (see criterion 4)
Email for general enquiries	ecfs-ctn@uzleuven.be	If available (see criterion 4)
Representative (main) contact	---	Include first and second name, email, telephone, address, as far as available
First name	Veerle	
Second name	Bulteel	
Telephone	+32 479 983839	
Mobile phone	+32 479 983839	
Email	ecfs-ctn@uzleuven.be	
Further contact(s)	---	Include first and second name, email, telephone, address, as far as available
First name	Kris	
Second name	De Boeck	
Telephone	+32 16 343856	
Mobile phone		
Email	christiane.deboeck@uzleuven.be	
The data in this document are 'current' as of	28/10/2011	Provide the date when the criteria were last updated
State how this document can be accessed by the public	http://www.ecfs.eu/ctn	This should be a link to a webpage, but other means and formats to make public are possible

Description [M]

Year of foundation	2008	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	

Specialities / Conditions covered	Cystic Fibrosis, network also includes adult CF patients	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	No	For example, oncology or infectious diseases
Speciality or disease specific? Specify	Disease specific: Cystic Fibrosis	For example, cardiology only
Conditions covered? Specify	Cystic Fibrosis	E.g. hypertension (within cardiology) or asthma (within respiratory diseases)
Procedure / intervention specific? Specify	No	For example, surgery, organ or stem cell transplantation
Number of collaborating countries	8 European countries (11 as from January 2012) List all collaborating countries: Belgium, Germany, France, Italy, Portugal, Sweden, The Netherlands, UK In 2012, Denmark, Spain and Czech Republic will be added	State the number of collaborating countries. Indicate "1" if national; Indicate if Europe, outside of Europe, other……. (describe)
Number of collaborating centres	Currently 18 12 additional sites as from January 2012 will bring total to 30 List all collaborating centres: http://www.ecfs.eu/ctn/list-ctn-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	Site Training Standardization of procedures (outcome parameters) Protocol review Networking DSMB	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]	1 completed pediatric trial 2 pediatric trials ongoing (+ 5 in start-up phase)	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	Total pediatric recruitment capacity of the network is 3129 pts. As from 2012 this will be 6264 pts. 2010: 45 pediatric patients recruited (1 pediatric study) Sites consult local databases on request pharma company or coordinated by the network	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?
1.3 Total number of collaborating centres	15	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 completed clinical trials	Absolute number: 0 Proportion of all studies: 0	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)
1.5 Number of paediatric specialities covered by paediatric trials	NA	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.6 Number of paediatric conditions covered by paediatric trials	NA	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 research studies / programs	NA	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.
1.8 Indicate the proportion of public funding	Proportion of academic initiated studies: NA Proportion of budget: NA	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)	NA	
Industry-sponsored trials	---	
1.10 Number of ongoing and completed trials	1 completed and 2 ongoing	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	2 (respiratory + general)	Count specialities, without repetition, across all ongoing or completed

paediatric trials		paediatric trials
1.12 Number of paediatric conditions covered by paediatric trials	1 (cystic fibrosis)	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)	2010: 45 pediatric patients recruited (1 pediatric study)	

Criterion 2: Network organisation and processes

2.1 Existence of an identified contact person for external enquiries [M]	☒ Yes ☐ No 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 Existence of an internal steering committee [M]	☒ Yes ☐ No Comments: http://www.ecfs.eu/ctn/ctn-organisation-chart	Minimum requirement ([M]): either an internal steering committee (2.2) or an external advisory / steering committee (2.3).
2.3 Existence of an external advisory / steering committee directing the reporting party [M]	☒ Yes ☐ No Comments: = ECFS Board. http://www.ecfs.eu/ctn/ctn-organisation-chart	Minimum requirement ([M]): either an internal steering committee (2.2) or an external advisory / steering committee (2.3).
2.4 Existence of a website	☒ Yes ☐ No Comments:	If available, mention in "identification" above
2.5 Existence of newsletter	☒ Yes ☐ No Comments: See "CTN news" on general website. Also active email distribution.	Newsletter of any format (electronic, surface mail), distributed actively to selected recipients.
2.6 Existence of an internal database(s) for disease, condition, treatment and / or outcome [M] If yes, please describe	☒ Yes ☐ No Comments / description: All CTN sites have internal patient database + close cooperation with the ECFS European Patient Registry http://www.ecfs.eu/ecfs_supported_initiatives/european_cf_registry	For example, data base or disease registry to facilitate planning or conducting future trials (may or may not contain individual patient data)
2.7 Provisions to ascertain data protection and data security [M]	☒ Yes ☐ No Comments: Network is not collecting study data (done by pharma company) Sites follow internal procedures for data protection. EU registry procedures: see http://www.ecfs.eu/projects/ecfs-patient-registry/intro	Are provisions in place to ascertain patients' /study participants' data protection and data safety within network

2.1 Existence of an identified contact person for external enquiries [M]	☒ Yes ☐ No 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.
2.8 Procedure(s) to access the database by third parties	☒ Yes ☐ No Comments: Indirect access to data provided upon request and after approval	Are provisions in place that data can be shared for planning, conducting or analysing a trial(s)?
2.9 Access to external databases /registries	☒ Yes ☐ No Comments:	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:	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)	• Guideline on the design and conduct of cystic fibrosis clinical trials: the European Cystic Fibrosis Society – Clinical Trials Network (ECFS-CTN) Journal of Cystic Fibrosis Volume 10 Suppl 2 (2011) S67-S74 • Developing an international network for clinical research: the European Cystic Fibrosis Society – Clinical Trials Network experience Clinical Investigation, 1(6), 775-780 (2011)	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	0	Grants obtained by reporting party (exclusively or not).
3.3 Access to expert groups M	☒ Yes ☐ No Comments: Close contact with ECFS, ERS, TDN,... Networking committee existing	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: Via CTN coordinating centre: ECFS-CTN@uzleuven.be	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:	---	
3.5 Site feasibility	☒ Yes ☐ No Comments: Via CTN coordinating centre. Exact procedure is discussed with the sponsor	This concerns the suitability of a site for conducting a given trial

3.6 Participant recruitment	☒ Yes ☐ No Comments: 3-Monthly follow up by CTN coordinating centre	This concerns provisions to regularly monitor recruitment progress for a trial.
3.7 Budget calculation for studies	☒ Yes ☐ No Comments: Budget calculation tools are provided but not mandatory	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: Pharma studies conducted should comply with the EU directive. CTN investigators are GCP trained	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: CTN investigators know these guidelines. They are part of the documents on clinical trial regulations posted on http://www.ecfs.eu/ctn/	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: Reporting party is not setting up studies. Approval request is fulfilled by the study sponsor. At site level, pediatrician is part of IRBs	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 For study conduct: Network performs Pharma initiated studies, following their SOPs For measuring of outcome parameters SOPs of the US network (CFF-TDN) are made available to all sites and EU versions will be available by end of 2011. SOPs are posted on the internal (non-public) website but can be obtained upon request (ecfs-ctn@uzleuven.be)	Indicate existence of SOP e.g. for study management, adverse events reporting etc.
4.5 Capacity to monitor studies (academic trials, industry sponsored trials) [M]	☐ Yes ☒ No Comments: The monitoring is the responsibility of the pharma company or assigned CRO	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: CTN coordinating centre follows up on recruitment and possible associated problems and delays	Indicate if the reporting party implements the monitoring of performance of collaborating centres.
4.7 Quality control and quality assurance, traceability and data safety [M]	☐ Yes ☒ No Comments: A person is hired to start general quality control activities as from July 2010 CTN is not handling study data: = responsibility of the pharma sponsor	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: CTN is in discussion with EMA regarding the specific guidelines for cystic fibrosis clinical trials	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: CTN members have served as experts in EMA meetings	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: Are organized by the pharma company	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: 2 Half day Training course for CTN investigators and study coordinators: June 16th 2010 at the ECFS conference in Valencia June 8th 2011 at the ECFS conference in Hamburg	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).
5.5 Training courses received over the last 2 years [M] If yes, provide number	☒ Yes ☐ No Comments: January 2010: 35 people (study personel from CTN sites) finished successfully a DIA GCP course. Certificates are stored at the CTN coordinating centre.	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:	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: Protocol is designed by pharma company. Protocol acceptance in CTN is voted in executive committee that includes 1 patient organizaton representative.	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: Study specific protocol information package is designed by pharma company. General information packages on clinical trials are developed with input from patient organizatons.	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: Taskforce has been created to connect with EMA for prioritization of clinical trials. This taskforce includes patient organization representatives. 2 Patients representatives attended the consensus conference on outcome parameters. http://www.ecfs.eu/projects/clinical-trials-network/consensus-conference-outcome-parameters for clinical trials (Venice, March 2010)	Indicate if public stakeholders are /have been involved