



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 December 2010
EMA/770017/2010
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



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	Futurenest Clinical Research Lc.	Include legal address, define acronyms
Type	Futurenest has been founded in 2009 by paediatricians experienced in paediatric clinical studies. Our mission is to contribute to the development of paediatric clinical studies and research. We want to take an active role in ensuring that clinical studies in which minors participate are conducted in an efficient way. Headquarter of the company is in Miskolc, Hungary which is the home of around 20000 children. The paediatric care of over 3000 of them is provided by physicians of our company. We have taken part in epidemiological, phase II and III-IV studies involving both healthy (Vaccines) and unhealthy (infectology, pain relief, etc.) children.	Indicate type of reporting party, e.g. national or speciality network. May include short mission statement
Street	Selyemrét utca 1	
Postal code	3527	
Town	Miskolc	
Country	Hungary	
Telephone 1	+36-70-522-5945	
Telephone 2		
Mobile phone	+36-70-522-5945	
Fax	+36-46-322442	
Web site		If available (see criterion 4)
Email for general enquiries	futurenest@t-online.hu	If available (see criterion 4)
Representative (main) contact	---	Include first and second name, email, telephone, address, as far as available
First name	Gabriella	
Second name	Hajdú	
Telephone	+36-70-522-5945	
Mobile phone	+36-70-522-5945	
Email	futurenest@t-online.hu	

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	2009.	Provide the date when the criteria were last updated
State how this document can be accessed by the public	No own web page currently. Name general data could be published.	This should be a link to a webpage, but other means and formats to make public are possible

Description ^M

Year of foundation	2009	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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Newborn: from birth to less than 28 days of age
Infants from 1 month to less than 24 months of age	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Children from 2 years to less than 12 years of age	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Adolescents from 12 years to less than 18 years	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Specialities / Conditions covered	General Paediatrics - Outpatient care : vaccines, otorhinolaryngology, gastroenterology pulmonology, allergology, dermatology, infection diseases neurology, psychiatry and ophthalmology	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	General Paediatrics - Outpatient care : vaccines, otorhinolaryngology, gastroenterology pulmonology, allergology, dermatology, infection diseases neurology, psychiatry and ophthalmology	For example, oncology or infectious diseases

Speciality or disease specific? Specify	Out patient care only, no hospitalised patients	For example, cardiology only
Conditions covered? Specify	general paediatric care	E.g. hypertension (within cardiology) or asthma (within respiratory diseases)
Procedure / intervention specific? Specify	Only performed in outpatient clinic	For example, surgery, organ or stem cell transplantation
Number of collaborating countries	1 List all collaborating countries:	State the number of collaborating countries. Indicate "1" if national; Indicate if Europe, outside of Europe, other..... (describe)
Number of collaborating centres	2 List all collaborating centres: Futurnest in Budapest Futurnest in Debrecen	State the number of collaborating centres and provide a list of all collaborating centres (attachment or link possible)
Type of activity/studies		
Clinical studies	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Experimental research	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Other activity	Epidemiological studies	Describe type of activities other than clinical and/or non-clinical studies

Evidence for each criterion

Criterion 1: Research experience and ability7
Criterion 2: Efficiency requirements..... 10
Criterion 3: Scientific competencies and capacity to provide expert advice12
Criterion 4: Quality management 13
Criterion 5: Training and educational capacity to build competences..... 14
Criterion 6: Public involvement..... 16

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.

<p>1.1</p> <p>Number of completed trials ^M</p> <p>Number of ongoing trials ^M</p>	<p>The previous trials (5) were completed by the same specialist who formed the Futurenest company .</p> <p>2</p>	<p>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.</p>
<p>1.2</p> <p>Total number of participants actually recruited each year</p> <p>Proportion of eligible participants actually recruited each year</p> <p>Describe way of screening and participant recruitment</p>	<p>43 subject in 2009</p> <p>GPPs are participating with their own patients in the investigational center supervised by an experienced PI in vaccine studies. GPPs are invited to refer their subject to a clinical study.</p>	<p>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?</p>
<p>1.3</p> <p>Total number of collaborating centres</p>	<p>3</p>	<p>For completed and ongoing (open) paediatric trials. Do not include sites in set-up.</p>
<p>Academic (investigator) initiated studies</p>	<p>---</p>	<p>Studies conducted independently from pharmaceutical companies (no sponsorship and no funding). There is a separate category (below) for industry-funded studies.</p>
<p>1.4</p> <p>Number of ongoing and completed clinical trials</p>	<p>Absolute number: 2 (from 2009)</p> <p>Proportion of all studies: Phase II: 1 study Phase III:1 study</p>	<p>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</p>

		development see below)
1.5 Number of paediatric specialities covered by paediatric trials	2	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.6 Number of paediatric conditions covered by paediatric trials	2	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	0	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: 0 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)	43	
Industry-sponsored trials	---	
1.10 Number of ongoing and completed trials	2	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	2	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.12	2	If not all areas within one

Number of paediatric conditions covered by paediatric trials		speciality covered count conditions, without repetition, across all ongoing or completed paediatric trials
1.13 Number of registered study participants (all studies)	43	

Criterion 2: Network organisation and processes

<p>2.1 Existence of an identified contact person for external enquiries ^M</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments:</p>	<p>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.</p>
<p>2.2 Existence of an internal steering committee ^M</p>	<p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Comments:</p>	<p>Minimum requirement (^M): either an internal steering committee (2.2) or an external advisory / steering committee (2.3).</p>
<p>2.3 Existence of an external advisory / steering committee directing the reporting party ^M</p>	<p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Comments:</p>	<p>Minimum requirement (^M): either an internal steering committee (2.2) or an external advisory / steering committee (2.3).</p>
<p>2.4 Existence of a website</p>	<p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Comments:</p>	<p>If available, mention in "identification" above</p>
<p>2.5 Existence of newsletter</p>	<p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Comments:</p>	<p>Newsletter of any format (electronic, surface mail), distributed actively to selected recipients.</p>
<p>2.6 Existence of an internal database(s) for disease, condition, treatment and / or outcome ^M If yes, please describe</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments / description:</p>	<p>For example, data base or disease registry to facilitate planning or conducting future trials (may or may not contain individual patient data)</p>
<p>2.7 Provisions to ascertain data protection and data security ^M</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments:</p>	<p>Are provisions in place to ascertain patients' /study participants' data protection and data safety within network</p>
<p>2.8 Procedure(s) to access the database by third parties</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments:</p>	<p>Are provisions in place that data can be shared for planning, conducting or analysing a trial(s)?</p>

<p>2.1</p> <p>Existence of an identified contact person for external enquiries ^M</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments:</p>	<p>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.</p>
<p>2.9</p> <p>Access to external databases /registries</p>	<p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>Comments:</p>	<p>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</p>
<p>2.10</p> <p>Standardised process to access an external database(s)</p>	<p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>Comments:</p>	<p>Is a standardised process in place to access external/national databases?</p>

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)	0	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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments:	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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments:	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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments:	This concerns the suitability of a site for conducting a given trial
3.6 Participant recruitment	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments:	This concerns provisions to regularly monitor recruitment progress for a trial.
3.7 Budget calculation for studies	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments:	This concerns, for example, quotes and prospective financial planning for a trial.

Criterion 4: Quality management

<p>4.1 Documented adherence to Good Clinical Practice (GCP) guideline ^M</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments:</p>	<p>Declare whether studies conducted comply with the EU Directive 2001/20/EC on Clinical Trials.</p>
<p>4.2 Documented adherence to the ethical considerations for clinical trials in children ^M</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments: All GPPs has updated GCP cours. One GPP has a spacialty of Clinical Pharmacology . Local Ethical Com. leaded by a Paediatrisen is covering ethica tasks.</p>	<p>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".</p>
<p>4.3 Documented adherence to ethical considerations</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments: Hungary has a Central Ethical Committee responsible for clinical trial approval.</p>	<p>Declare whether reporting party requests approval by an independent ethics committee with paediatric expertise for all studies conducted.</p>
<p>4.4 Availability of Standard Operation Procedures (SOP)</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, provide reference to available SOPs Study conduct, IP storage, AE reporting, Data protection-entry, Study procedures : as obtain ICF, etc</p>	<p>Indicate existence of SOP e.g. for study management, adverse events reporting etc.</p>
<p>4.5 Capacity to monitor studies (academic trials, industry sponsored trials) ^M</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments:</p>	<p>Indicate if the reporting party implements the monitoring of paediatric trials according to ICH 6 Good Clinical Practice Guideline.</p>
<p>4.6 Capacity to monitor performance of collaborating centres</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments:</p>	<p>Indicate if the reporting party implements the monitoring of performance of collaborating centres.</p>
<p>4.7 Quality control and quality assurance, traceability and data safety ^M</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments:</p>	<p>Indicate if this is implemented in the reporting party's remit.</p>

Criterion 5: Training and educational capacity to build competences

<p>5.1 Evidence of collaboration with regulatory authorities ^M</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments:</p>	<p>Indicate awareness of regulatory requirements for developing medicines; for example, implementation of guidelines from regulatory authorities.</p>
<p>5.2 Capacity to provide competent consultation to regulatory authorities</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments:</p>	<p>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).</p>
<p>5.3 Formal meetings for clinical trials If yes, provide number</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments: Participation in 2 international meeting. Before study start an during the study local meetings are conducted.</p>	<p>For example, investigator meetings, trainings specific to a given ongoing or planned trial.</p>
<p>5.4 Training courses given over the last 2 years ^M If yes, provide number</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments:</p>	<p>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).</p>
<p>5.5 Training courses received over the last 2 years ^M If yes, provide number</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments:</p>	<p>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).</p>

<p>5.6 Promotion of participation in clinical trials in countries with limited resources</p> <p>Provide list of countries</p>	<p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>Comments:</p>	<p>Indicate if support for such trials is provided by the reporting party.</p>
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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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Comments:	Indicate if public stakeholders are /have been involved
6.2 Involvement of patients, parents or their organisations in creating the protocol information package	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Comments:	Indicate if public stakeholders are /have been involved