EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Websi□e** www.ema.europa.eu

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 Ltd.	Include legal address, define acronyms
Type	National Network Futurenest was founded in 2009 by general paediatric practitioners 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. The network involves 15 family paediatricians in the biggest cities in Hungary:Budapest, Miskolc, Debrecen covering 18000 children. We have taken part in observational, epidemiological, phase II and III-IV studies, long term follow up studies involving both healthy (vaccines) and unhealthy (infectology, pain relief, etc.) children. In 2010 two further pediatric investigational sites have joined Futurenest from Budapest and Debrecen. The reasearch team and the facilities are specifically adapted to conduct trials in children. Our mission is :identify areas of research, conduct paediatric trials, share knowledge that imrpoves care of paediatric patients, develop investigation methods, participate to training programs for all partners of research.	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	2011.	Provide the date when the criteria were last updated
State how this document can be accessed by the public	No own web page currently. 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	Futurenest was founded in 2009. The participants GPPs have more than 10 years experience in clinical trials.	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	General Paediatrics - Outpatient care : adolescent medicine, allergology vaccines,otorhinolaringology, gastroenterology, pulmonology, dermatology, infectious diseases, neurology,nutrition, psychiatry, ophthalmology, nephrology, urology, paediatric rehabilitation, child pain management, paediatric clinical pharmacology.	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 : as listed abowe	For example, oncology or infectious diseases
Speciality or disease specific? Specify	Outpatient care only, no hospitalised patients	For example, cardiology only
Conditions covered? Specify	Covered by specialist and subspecialist.	E.g. hypertension (within cardiology) or asthma (within respiratory diseases)
Procedure / intervention specific? Specify	Only performed in outpatient clinic, no surgery, no hemato- oncology	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: Futurenest in Budapest Futurenest in Miskolc Futurenest 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	☒ Yes ☐ No	
Experimental research	☐ Yes ☒ No	
Other activity	Epidemiologial studies, prospective and restrospective data collection, feasibilities, assistens in drawing up reasearch project plan, protocol modifications and design, planning paediatric trials.	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]	Futurenest has not completed any trials yet, the company founders have nonetheless completed several trials individially already. Three ongoing trials. Eudract numbers: 2008-004847-12 2009-010106-11 2010-021528-81	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	43 subjects in 2010 131 subjects in 2011 The total recruitment potential of all age groups 0-18 years in thet network area are approx 20000 children.approx .50% Screening and enrollment is done by doctors attending the investigational center by direct contact. The study procedures are supervised by an experienced PI. Other paediatricians are invited to refere their patients to a clinical study. In studies requiring the participation of a specialist we are working in collaboration with them. The patients are recruited from the GPP's or the collaborating hospital's own database.	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	Three centers with ongoing studies .	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	0	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.6 Number of paediatric conditions covered by paediatric trials	0	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)	0	
Industry-sponsored trials	---	

1.10 Number of ongoing and completed trials	Three ongoing studies in 2011 phase II: 1 study phase III: 2 study	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	3 studies: 2. vaccines Eudract number 2009-010106-11 and 2010-021528-81 2. gastroenterology Eudract number 2008-004847-12	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.12 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
1.13 Number of registered study participants (all studies)	174	

Criterion 2: Network organisation and processes

2.1 Existence of an identified contact person for external enquiries [M]	☒ Yes ☐ No Comments: Futurenest's director is responsable for communication.	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 internal advisor committee is formed by Medical Director Dr. Stunya Edina, Research Director Dr. Simkó Róbert and a Specialist in Clinical Pharmacology Dr.Germán Gabriella participation of invite experts is optional.	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:	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: Mails and emails are sending regularly to GPPs about the study to invite their patients to study participation.	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: The participating GPPs and specialists driven databases are available and may help in the patient selection. Futurenest has his own internal data registry containing secured data. Sponsor and study specific information and documentation is also saved in Futurenest's database.	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: Futurenest's director is responsable for communication.	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: Data safety is managed based on the local and international regulation and data protection (GCP). Source data stored in fireproof cupboard and handled in the investigational center and accessible only for study personal.	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: Anonymisied data may be shared for planning trials, preparing feasibilities. During study conduct and analysis the subject's data protection is regulated by GCP. Inform consent details the study's specific data protection.	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)	0 Comment: Futurenest's founding members have publications in the last 5 years.	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: 1.Magyar Gyermekorvosok Társaság - Hungarian Paediatric Society 2.Házi Gyermekorvosok Országos Egyesülete - Society of General Paediatric Practitioners 3.Miskolci Vállalkozó Háziorvosi Rendszert Működtető Egyesülés-Family Doctor's Association of Miskolc 4.Gyermek-alapellátásban Praktizáló Orvosok Szakmai és Érdekvédelmi Egyesülete - Safeguarding and Professional Association Of General Paediatric Practitoners 5.Magyar Klinikai Vizsgálatszervezők Társasága-Clinical Trial Management Society Hungary 6. Magyar Hemofilia Egyesület-Hungarian Haemophilia Sociaty	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 internal advisory committee is responsable to answer global scientific questions. In daily business and in urgent cases the principal investigatior is responsable for study related questions. Regular monthly TC are orginised to discussed ongoing studys and new feasibilitys. F2F meeting are hold 2 times a year to organise network's activities and decide about new projects.	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: Feasibility is prepared by the planed PI based on the international, local regulation and sponsor requested procedure. SOP regulates how to prepar feasibility.	This concerns the suitability of a site for conducting a given trial
3.6 Participant recruitment	☒ Yes ☐ No Comments: SOP regulates how to recruite subjects.	This concerns provisions to regularly monitor recruitment progress for a trial.
3.7 Budget calculation for studies	☒ Yes ☐ No Comments: SOP regulates how to calculate study budget.	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: Studies conducted in the sites are complying with International, European (EU Directive 2011/20/EC and Hungarian regulations and law. The compliance are monitored by sponsors and supervised by Ethical Com and Local Autority.	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: All investigators have updated GCP courses. One member has a specialty of Clinical Pharmacology . Local Ethical Committee led by a paediatrician is concerning ethical issues.	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: Hungary has a Central Ethical Committee responsable for clinical trial approval. Local Ethical Committee is reponsable for site specific issues.	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 Study condact (including feasibility, budget, contracts, IP storage, AE/SAE reporting, data protection-entry, study procedures : as obtain ICF, etc	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: Futurenest complies with ICH 6 GCP Guideline and had a successful sponsor audit in 2010. Futurenest has the capacity for study monitoring- until no this activity was not requested.	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: The PIs in different centers have regular meetings and TCs. Futurenest's management is responsible to maintain the adequate compliance in all sites.	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: Futurenest's SOP regulates quality control and quality assurance, data safety, 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: All clinical trials - have to be approved by the Hungarain Authority : National Institute for Quality- and Organizational Development in Healthcare and Medicines - GYEMSZI.	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: Sponsor is responsible for clinical trial submission in Hungary. The PIs' suggestion about the trial (for example use of concomitant drugs, vaccines) is submitted through the sponsor.	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: Participation in 2 international investigator's meeting. Before and during the study local meetings are conducted.	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: 1.Training with the invited gastroenterologist was given for GPPs about the disease treated in clinical trial in the site. 2.Site staff received study specific training before Site initiation visit. 3.During study conduct – site staff receives training about modifications in the study as amendments, new guidelines, etc.	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: Protocol specific training was received before site initation and during the study from the sponsor and CRO . Training about audit preparation was received from the CRO.	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:	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