30 July 2010
EMA/241053/2010
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

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 **Website** 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	**AMIKI – The Paediatric Trial Network**	**Include legal address, define acronyms**
Type	AMIKI is a private and public organisation specialized in clinical studies in Paediatrics, with a past emphasis on Paediatric Endocrinology and Diabetology, but offers clinical trial services in all areas of Paediatrics. The network combines paediatric experts in clinic (childrens hospital, Univ. of Hamburg), medical practice (Inst. of Paediatric Endocrinology & Diabetology, Frankfurt) with CRO (CTC-Nnorth) and a publishing Company (Biomedpark), specialized for paediatric deseasesdiseases.	Indicate type of reporting party, e.g. national or speciality network. May include short mission statement
Street	1: c/o Biomedpark Medien GmbH, Sofienstr. 5-7 2: c/o CTC-North, Klinikum der Univ.University Medical Center Hamburg Eppendorf, Martinistr. 52	
Postal code	1: D-c/o Biomedpark Medien GmbH, Sofienstr. 5-769115 2: D-c/o CTC-North, Klinikum der Univ. Hamburg Eppendorf, Martinistr. 5220246	
Town	1: Heidelberg 2: Hamburg	
Country	Germany	
Telephone 1	+49 6221 13747 0	
Telephone 2	+49 40 7140 7410 516640	
Mobile phone	+49 163 816 0861	
Fax	+49 6221 13747 77	
Web site	http://… to be announced shortly	If available (see criterion 4)
Email for general enquiries	hartmann@biomedpark.de	If available (see criterion 4)
Representative (main) contact	Dr. med. Klaus Hartmann Biomedpark Medien GmbH, Sofienstr. 5-7, 69115 Heidelberg	Include first and second name, email, telephone, address, as far as available
First name	Klaus	

Name	**AMIKI – The Paediatric Trial Network**	**Include legal address, define acronyms**
Second name	Hartmann	
Telephone	+49 6221 137470	
Mobile phone	+49 163 8160861	
Email	hartmann@biomedpark.de	
Further contact(s)	Dr. Anke Wahlers CTC North, Martinistr. 52 D-20246 Hamburg, Germany	Include first and second name, email, telephone, address, as far as available
First name	Anke	
Second name	Wahlers	
Telephone	+49-40-7410-51623	
Mobile phone		
Email	a.wahlers@uke.uni-hamburg.de	
The data in this document are 'current' as of	July 29,2010	Provide the date when the criteria were last updated
State how this document can be accessed by the public	http://… to be announced shortly	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	Yes	Newborn: from birth to less than 28 days of age
Infants from 1 month to less 24 months of age	yes	
Children from 2 years to less than 12 years of age	yes	
Adolescents from 12 years to less than 18 years	yes	
Specialities / Conditions covered	UKE Department of Paediatrics mainly focuses on the fields of neonatology/intensive care, neuropaediatrics (children's migraine), nephrology with kidney replacement therapy, kidney transplantation, gastroenterology, congenital metabolic diseases, orthopaedics, neurosurgery, bronchial asthma, allergies and respiratory diseases,	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

Year of foundation	**2009**	**Of the network, or of the investigator's or site's specific paediatric research activities**
	mucoviscidosis, diabetes mellitus, pediatric surgery und endocrinological diseases. In addition, there is a large collaborative network of (300) Paediatricians in private office throughout Germany who cover most areas of Paediatrics, incl. general paediatrics, - Inst. for Pediatric Endocrinology & Diabetology, Frankfurt/Main: in the fields of Pediatric Endocrinology & Diabetology	
Multispeciality? Specify	Endocrinology, Diabetology	For example, oncology or infectious diseases
Speciality or disease specific? Specify	Growth, puberty, thyroid disorders, Diabetes mellitus, Pituitary Dysfunction	For example, cardiology only
Conditions covered? Specify	grwowth disorders: dwarfism, tall stature, Ullrich Turner Syndrome. Puberty disorders: precocious puberty, delayed puberty. Polycystic Ovar Syndrome. Adipositas. Diabetes mellitus. Diabetes insipidus. Hyo- and Hyperthyreodism. Congenital Adrenal Hypertrophy (CAH). Klinefelder Syndrome.	E.g. hypertension (within cardiology) or asthma (within respiratory diseases)
Procedure / intervention specific? Specify	Paediatric specific laboratory investigation	For example, surgery, organ or stem cell transplantation
Number of collaborating countries	1 List all collaborating countries: Germany	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: - University Medical Center Hamburg-Eppendorf Children`s Hospital Biomedpark Medien GmbH (300) of Paediatricians in private office	State the number of collaborating centres and provide a list of all collaborating centres (attachment or link possible)

Year of foundation	**2009**	**Of the network, or of the investigator's or site's specific paediatric research activities**
	(www.paedinfoline.de) - Inst. for Pediatric Endocrinology & Diabetology, Frankfurt/Main	
Type of activity/studies		
Clinical studies	☒ Yes ☐ No	
Experimental research	☒ Yes ☐ No	
Other activity	Software programming for electronic patient file and data capture (Biomedpark) Publication of a pediatric journal (Pädiatrix, incoudes also a section for clinical studies in childhood) for pediatricians in clinic and private praxis (7 x 11000 issues per year): www.paediatrix.com	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]	**0** **7 / (Hamburg 2+ 2 to be inititated within next few weeks)**	**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	50-100	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	2	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: - Inst. for Pediatric Endocrinology & Diabetology, Frankfurt/Main: Taking part in 6 phase IV trials Proportion of all studies:	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

1.1 **Number of completed trials** [M] **Number of ongoing trials** [M]	**0** **7 / (Hamburg 2+ 2 to be inititated within next few weeks)**	**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.**
		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	3	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	2	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: Proportion of budget:	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)	More than 700 (phase IV clinical trials)	
Industry-sponsored trials	---	
1.10		Paediatric interventional

1.1 **Number of completed trials** [M] **Number of ongoing trials** [M]	**0** **7 / (Hamburg 2+ 2 to be inititated within next few weeks)**	**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.**
Number of ongoing and completed trials		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		Count specialities, without repetition, across all ongoing or completed paediatric trials
1.12 Number of paediatric conditions covered by paediatric trials		If not all areas within one speciality covered count conditions, without repetition, across all ongoing or completed paediatric trials
1.13 Number of registered study participants (all studies)		

Criterion 2: Network organisation and processes

2.1 **Existence of an identified contact person for external enquiries** [M]	**Yes** **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]	No Comments: will be established	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]	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	☐ No Comments: In progress	If available, mention in "identification" above
2.5 Existence of newsletter	☐ No Comments: expected in early 2011	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:	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:	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:	Are provisions in place that data can be shared for planning, conducting or analysing a trial(s)?
2.9 Access to external databases	☐ Yes ☒ No Comments:	For example, national databases that are not

2.1 **Existence of an identified contact person for external enquiries** [M]	**Yes** **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.**
/registries		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** **1 study in publication**	**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 Comments: - University Medical Center Hamburg Eppendorf and The Altona Children´s Hospital - Inst. for Pediatric Endocrinology & Diabetology, Frankfurt/Main	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 Comments: Collaboration with University Medical Center Hamburg Eppendorf and - Inst. for Pediatric Endocrinology & Diabetology, Frankfurt/Main	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:	This concerns the suitability of a site for conducting a given trial
3.6 Participant recruitment	☐ Yes Comments:	This concerns provisions to regularly monitor recruitment progress for a trial.
3.7 Budget calculation for studies	☐ Yes Comments: Done by finance department of CTC North	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:** **CTC North has repeatedly been audited based on 2001/20/EC and is certified according to DIN EN 9001:2000**	**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:	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:	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)	☐ No If yes, provide reference to available SOPs	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 Comments: Clinical monitoring department is part of CTC North	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 Comments: Monitoring is performed by CRAs of CTC North in collaborating centres	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 Comments: QA system of CTC North is certified according to DIN ISO 9001:2000, recertification in 2009 QA-System according to commercial Phase I-CROs (SOP System, internal	Indicate if this is implemented in the reporting party's remit.

4.1 **Documented adherence to Good Clinical Practice (GCP) guideline** [M]	☐ **Yes** ☐ **No** **Comments:** **CTC North has repeatedly been audited based on 2001/20/EC and is certified according to DIN EN 9001:2000**	**Declare whether studies conducted comply with the EU Directive 2001/20/EC on Clinical Trials.**
	Audits, QA Manager certified by European Organisation of Quality). Process/SOP Structure according EMEA Guideline „GCP Inspectors Working Group; Procedure for Conducting Inspections in Phase I Units“	

Criterion 5: Training and educational capacity to build competences

5.1 **Evidence of collaboration with regulatory authorities** [M]	☐ **Yes** **Comments:** Established communication with Ethics Committee, Federal Agencies in Germany (BfArM, PEI), and local Supervising Authority	**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:	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 Comments: is performed routinely in all trials organized by CTC North	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 Comments: CTC North organizes and performs Investigators trainings (1-day and 2-day courses), Study Nurse training (6 months course), GCP refresher trainings (half day courses) regularly and each 3 – 8 times per year	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 Comments: CTC North staff is trained regularly according to GCP requirements; training is documented in training log; study-specific training and dry run is performed with staff involved in the trial for each study	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	☐ No Comments: Not yet	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**	☐ **No** **Comments:** **Not yet**	**Indicate if public stakeholders are /have been involved**
6.2 Involvement of patients, parents or their organisations in creating the protocol information package	☐ 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	☐ No Comments:	Indicate if public stakeholders are /have been involved