EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2 March 2012
EMA/817615/2010
Human Medicines Development and Evaluation

European network of paediatric research (EnprEMA)

Recognition criteria for self assessment

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

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

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

END OF SELF-ASSESSMENT PERIOD	31 July 2010

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EnprEMA

European network of paediatric 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	**A European paediatric oncology off-patent medicines consortium (EPOC)**	**Include legal address, define acronyms**
Type	Multinational - aim of conducting and supporting pharmacological studies in paediatric oncology, specifically addressing the EMEA priority lists.	Indicate type of reporting party, e.g. national or speciality network. May include short mission statement
Street	Northern Institute for Cancer Research	
Postal code	NE2 4HH	
Town	Newcastle upon Tyne	
Country	UK	
Telephone 1	+44 191 246 4412	
Telephone 2		
Mobile phone		
Fax	+44 191 246 4301	
Web site	www.epocstudy.org	If available (see criterion 4)
Email for general enquiries	alison.steel@newcastle.ac.uk	If available (see criterion 4)
Representative (main) contact	---	Include first and second name, email, telephone, address, as far as available
First name	Alan	
Second name	Boddy	
Telephone	+44 191 246 4412	
Mobile phone		
Email	alan.boddy@ncl.ac.uk	
Further contact(s)	---	Include first and second name, email, telephone, address, as far as available
First name	Joachim	
Second name	Boos	
Telephone	+49 251 83 47865	
Mobile phone		
Email	boosj@uni-muenster.de	
The data in this document are 'current' as of	05/01/2012	Provide the date when the criteria were last updated

State how this document can be accessed by the public	Epoc website: www.epocstudy.org	This should be a link to a webpage, but other means and formats to make public are possible

Description M

Year of foundation	**2007**	**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	Paediatric oncology	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	Paediatric oncology only	For example, cardiology only
Conditions covered? Specify	Cancer	E.g. hypertension (within cardiology) or asthma (within respiratory diseases)
Procedure / intervention specific? Specify	Chemotherapy and clinical pharmacology studies	For example, surgery, organ or stem cell transplantation
Number of collaborating countries	4 List all collaborating countries: UK, Germany, France, Italy	State the number of collaborating countries. Indicate "1" if national; Indicate if Europe, outside of Europe, other……. (describe)

Number of collaborating centres	21 List all collaborating centres: Attached	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		Describe type of activities other than clinical and/or non-clinical studies

Evidence for each criterion

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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**	**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	57 Patients recruited during 2011 Plan to recruit 100 patients, in the following age-groups: •Children 12-17 years (30 patients) •Children 3 to 11 years of age (50 patients) •Children < 3 year (20 patients) A major focus of the recruitment will be to target patients younger than 3 years, including at least 5 patients that are younger than 1 year. Patients who plan to receive at least two cycles of doxorubicin and who are enrolled in a national or European protocol for treatment of Wilms Tumours, Neuroblastoma, Soft tissue sarcoma, Ewing Sarcoma or Acute lymphoblastic leukaemia, or patients < 3 years enrolled or listed in any national or European study protocol for any paediatric malignancy will be recruited. patient, parent or legal representative consent must be obtained.	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	20	For completed and ongoing (open) paediatric trials. Do

centres		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: 1 Proportion of all studies: 100%	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	1: Oncology	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.6 Number of paediatric conditions covered by paediatric trials	1: Cancer	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	Translational research projects and other clinical pharmacology studies	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: 100% Proportion of budget: 100%	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)	EudraCT number 2009-011454-17: 57 patients	
Industry-sponsored trials	---	
1.10 Number of ongoing and completed trials	N/A	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	N/A	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.12 Number of paediatric conditions covered by paediatric trials	N/A	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)	N/A	

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: The network is under the management of an executive board.	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: Data integrity and conduct of study are monitored by an independent data safety monitoring and ethics committee	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: www.epocstudy.org	If available, mention in "identification" above
2.5 Existence of newsletter	☒ Yes ☐ No Comments: Newsletter no. 5 distributed Dec 2011 to clinical sites	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: Database containing pharmacokinetic, pharmacodynamic and pharmacogenetic data	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: Governed by UK National Health Service data protection regulations, the data protection act 1998 and the declaration of Helsinki.	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)?

2.1 **Existence of an identified contact person for external enquiries** [M]	☒ **Yes** ☐ **No** **Comments:**	**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.**
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)**	**Members of the network have strong publication record in the field of paediatric oncology with over 200 peer reviewed publications.** **'Minimization of the Preanalytical Error in Plasma Samples for Pharmacokinetic Analyses and Therapeutic Drug Monitoring - Using Doxorubicin as an Example', Kontny, Nina E; Hempel, Georg; Boos, Joachim; Boddy, Alan V; Krischke, Miriam, Therapeutic Drug Monitoring. 33(6):766-771, December 2011.** **This paper is an EPOC study 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	1	Grants obtained by reporting party (exclusively or not).
3.3 Access to expert groups M	☒ Yes ☐ 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	☒ Yes ☐ No Comments: Members of the network have extensive experience in conducting clinical pharmacology studies in children with cancer. We have previously provided expert opinion to pharmaceutical companies and other agencies regarding the conduct of such studies.	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: Initiation visits and site audits.	This concerns the suitability of a site for conducting a given trial

3.6 Participant recruitment	☒ Yes ☐ No Comments: We have plans to monitor recruitment and provide support to clinical centres.	This concerns provisions to regularly monitor recruitment progress for a trial.
3.7 Budget calculation for studies	☒ Yes ☐ No Comments: Budget for this project was reviewed under the seventh framework of the European Commission.	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:** **All members of the consortium have experience of conducting GCP compliant studies and appropriate GCP training is undertaken regularly. Procedures are in place to ensure GCP compliance of current study.**	**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: Ethical approval has been obtained for the current study in four participating countries. Provisions highlighted in the 'Ethical considerations' document, including acceptable blood volumes and frequency of sampling in children have been taken into account in this study.	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: Any studies performed by the network would obtain appropriate ethical approval.	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 management, serious adverse event reporting,data safety and monitoring committee SOP	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: All centres are monitored using an approach implemented based on ICH 6 Good Clinical Practice Guidelines.	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: Clinical centres will be initiated and monitored.	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: Procedures are in place.	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:** **Members of the network have been involved in successful bids for FP7 projects relating to adapting off-patent medicines to the specific needs of paediatric populations, involving interaction with regulatory authorities in terms of study design. In addition, based on EC directive documents relating to the design of clinical trials in paediatric populations, studies have been carried out by members of the network to investigate the issue of acceptable blood volumes and frequency of blood sampling in children participating in research studies.**	**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: Development of regulatory aspects of this study was a collaborative effort between the EMEA and the EPOC consortium.	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: Investigator meetings and initiation meetings with clinical centres.	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: Training provided to clinical centres on sample management and data collection during Site Initiation Visits.	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: GCP training received for all relevant staff and current competence maintained in compliance with sponsor requirements. Updated GCP training for staff.	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: May form part of future activities.	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:** **International Confederation of Childhood Cancer Parent Organisations (ICCCPO)**	**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: ICCCPO have been a full partner in the development of the project and the protocol.	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