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

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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	Irish Paediatric Clinical Research Network (IPCRN) National Children's Research Centre (NCRC)	Include legal address, define acronyms
Type	National Network	Indicate type of reporting party, e.g. national or speciality network. May include short mission statement
Street		
Postal code		
Town	Irish Paediatric Clinical Research Network (IPCRN) National Children's Research Centre (NCRC)	
Country	IRELAND	
Telephone 1	00 353 1 409 6419	
Telephone 2	00 353 1 409 6585 or 00 353 1 409 6447	
Mobile phone	NA	
Fax	00 353 1 455 0201	
Web site	http://www.childrensresearchcentre.org/page/view/irish-paediatric-research-network We need to add the relevant content to the website; this will be actioned in Jan 2011.	If available (see criterion 4)
Email for general enquiries	info@nationalchildrensresearchcentre.org	If available (see criterion 4)
Representative (main) contact	---	Include first and second name, email, telephone, address, as far as available
First name	Dr. Colm	
Second name	O'Donnell Consultant Neonatologist National Maternity Hospital & OLCHC Director Clinical Research Unit National Children's Research Centre	

Telephone	00 353 1 4096419	
Mobile phone		
Email	codonnell@nmh.ie cpf.odonnell@ucd.ie	
Further contact(s)	---	Include first and second name, email, telephone, address, as far as available
First name	Dr. Sinéad Maria	
Second name	Nally Clinical Research Project Manager National Children's Research Centre	
Telephone	00 353 1 409 6806	
Mobile phone		
Email	sinead.nally@ncrc.ie	
The data in this document are 'current' as of	29 February 2012	Provide the date when the criteria were last updated
State how this document can be accessed by the public	http://www.nationalchildrensresearchcentre.org	This should be a link to a webpage, but other means and formats to make public are possible

Description M

Year of foundation	2009 The Children's Research Centre was founded in 1965 as the first dedicated research centre on the site of an Irish hospital The Irish Paediatric Clinical Research Network was founded in 2009 under the direction of the renamed National Children's Research Centre	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	Neonatology Paediatric Emergency Medicine Paediatric Dermatology Paediatric Respiratory Medicine Paediatric Gastroenterology Child & Adolescent Psychiatry Cancer Genetics Childhood Diabetes and Obesity Immunology/Chronic Inflammation/Infectious Disase Paediatric Cardiology Disruption of Development All conditions covered by specialties and subspecialties	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	All areas of paediatric research considered	For example, oncology or infectious diseases
Speciality or disease specific? Specify	All areas of paediatric research considered	For example, cardiology only
Conditions covered? Specify	All areas of paediatric research considered	E.g. hypertension (within cardiology) or asthma (within respiratory diseases)
Procedure / intervention specific? Specify	All areas of paediatric research considered	For example, surgery, organ or stem cell transplantation
Number of collaborating countries	Currently 1 European Collaborator IPRCN has the potential to collaborate within the EU and currently collaborates with the UK on an eczema and food allergy study List all collaborating countries: UK	State the number of collaborating countries. Indicate "1" if national; Indicate if Europe, outside of Europe, other……. (describe)

Number of collaborating centres	13 List all collaborating centres: - The National Children's Research Centre, Dublin - The National Maternity Hospital, Dublin - Our Lady's Children's Hospital, Crumlin, Dublin - The Children's University Hospital, Temple Street, Dublin - The Rotunda Hospital, Dublin - The Coombe Women's and Infants University Hospital, Dublin - Cork University Maternity Hospital - Royal College of Surgeons, Dublin - Trinity College Dublin - University College Dublin - University College Cork - University College Galway - University of Limerick	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	Funding Site training Standardization of operating procedures Assistance with grant applications Feasibility studies Study set-up activities Protocol design Medical writing Risk assessment Assistance with ethics and regulatory submissions Assistance with trial costings and resource planning Database design Data handing and validation Study management and monitoring GCP advice and training Laboratory facilities Consultations by clinical experts Networking Video conferencing facilities, which facilitate communication and negotiation between investigators and clinical research institutes at a national and international level	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]	2 Completed NEONATOLOGY 1. A randomised trial of prongs or masl for nasal continuous posiive airway pressure in preterm infants: the POM trial (ISRCTN43000196) 2. Randomised controlled clinical investigation of polyethylene bag and exothermic matress versus polyethylene bag alone for thermoregulation in preterm infants in the delivery room: the BAMBINO trial (ISRCTN31707342) 5 CTIMP/Clinical Investigations Ongoing PAEDIATRIC EMERGENCY MEDICINE 3. Non-inferiority study in the management of acute asthma (single-centre in the ethics and regulatory submission stage) (ISRCTN26944158) 77% of recruitment complete. 4. A Randomised Trial of Intranasal Fentanyl vs. Oral Morphine in the Treatment of Severe Painful Sickle Cell Crises in Children who Attend the Emergency Department - Study has all ethical and regulatory approvals in place. Once all contracts have been executed, this study will be initiated (anticipated Mar 2012). ISRCTN67469672). CHILD & ADOLSECENT PSYCHIATRY 5. SPD503-316 – A Phase III, Randomised, Double-Blind, Multi-Centre, Parallel-Group, Placebo- and Active-Reference, Dose-Optimisation Efficacy and Safety Study of Extended-Release Guanfacine Hydorchloride (SPD503) in Children and Adolescents Aged 6-17 with Attention-Deficit/Hyperactivity Disorder - Study initiated and recuriting (commerical	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.

	study). NEONATOLOGY 6. Randomised controlled trial comparing respiratory support via a face mask to single nasal prong for premature babies at birth (ISRCTN59061709) Recruitment (117/142) 82% complete 7. A randomised controlled trial of 2% chlorhexidine in 70% isopropyl alcohol versus 10% povidone iodine for skin antisepsis before central venous catheter insertion in preterm infants: the SKA trial (EudraCT No. 2011-002962-19) Recruitment (26/304) 9% complete NUMBEROUS NON-CTIMPS: EG FIRST IRISH BABY COHORT STUDY: Babies after SCOPE: Evaluating the Longitudinal Impact using Neurological and Nutritional Endpoints (BASLINE) (500 babies seen at 2 months by Apr 2010; over the first two years of a child's life the study will focus allergy, eczema, vitamin D levels and the effect of poor growth in the womb) http://www.baselinestudy.net/ DERMATOLOGY: Case collection in eczema and food allergy (multi-centre with sites in Ireland, Scotland and England; actively recruiting) We also have a childhood diabetes and obestity research programme and an immunology and inflammation programme in development E.g, Chronic Inflammation and Innate Immune Cell Dysregulation In Obese Children and Adolescent	

	Investigating the role of the innate immune system in paediatric coeliac disease Biosignatures in Undifferentiated Febrile Illness in Children	
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	~3812 patients recruited to date Variable dependent on study, but ingeneral 70 - 80% of elegible patients have been recruited to RCTs Screening and recruitment is achieved through direct patient contact from hospital in-patients and paediatric clinics.	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	- Our Lady's Hosptial for Sick Children, Dublin - The National Maternity Hospital, Dublin - The Coombe Women's and Infants University Hospital, Dublin - Rotunda Hospital, Dublin - Cork University Maternity Hospital - Our Lady's Children's Hospital, Crumlin, Dublin - The Children's University Hospital, Temple Street, Dublin - Trinity College Dublin - University of Limerick - University College Dublin The eczema and allergy study currently recruiting in Our Lady's Hospital for Sick Children also have three open sites in Scotland, England and Northern Ireland with an additional Irish site and 4-5 English sites to come on board within the next few months	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: 6 investigator-led clinical trials - 4 trials of investigational medicinal products Proportion of all studies: 20%	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	2 (Neonatology, Paediatric Emergency Medicine)	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.6 Number of paediatric conditions covered by paediatric trials	4 (infant respiratory distress syndrome; newborn hypothermia; Acute asthma; Painful Sickle Cell Crisis)	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	There are numerous molecular medicine and pre-clinical studies which investigate the pathogenesis of children's disease and ailments	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: 0% - all chartiable donations	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)	~3,812	
Industry-sponsored trials	---	
1.10 Number of ongoing and completed trials	1 Industry-sponsored trial	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	1 (Child & Adolescent Psychiatry)	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.12 Number of paediatric conditions covered by paediatric trials	Attention Deficit Hyperactivity Disorder	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)	1	

Criterion 2: Network organisation and processes

2.1 Existence of an identified contact person for external enquiries [M]	☒ Yes ☐ No Comments: info@nationalchildrensresearchcentre.org OR sinead.nally@ncrc.ie	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: Organisation chart for the steering committee will be posted on the revised website - in the meantime I have attached the committe list to the application.	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: info@nationalchildrensresearchcentre.org The IPCRN will have its own portal, which will be accessed through the National Children's Research Centre website via: http://www.childrensresearchcentre.org/page/view/irish-paediatric-research-network	If available, mention in "identification" above
2.5 Existence of newsletter	☐ Yes ☒ No Comments: However, the clinical research project manager wishes to produce a quarertly newsletter for specific studies and for the IPCRN	Newsletter of any format (electronic, surface mail), distributed actively to selected recipients.

2.1 Existence of an identified contact person for external enquiries [M]	☒ Yes ☐ No Comments: info@nationalchildrensresearchcentre.org OR sinead.nally@ncrc.ie	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.
2.6 Existence of an internal database(s) for disease, condition, treatment and / or outcome [M] If yes, please describe	☐ Yes ☒ No Comments / description: However, the clinical data manager wishes to establish an internal disease registry	For example, data base or disease registry to facilitate planning or conducting future trials (may or may not contain individual patient data)
2.7 Provisions to ascertain data protection and data security [M]	☒ Yes ☐ No Comments: All studies will be managed and conducted as per ICH GCP, the Declatation of Helsinki and the Data Protection Act (2003). The clinical data manager is in the process of organing a training session with a representative of the Data Protection Commission.	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 /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: Standardised national processes for access to relevant external national databases for research	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)	By the IPCRN Network: 0 Publications by the network members and by the National Children's Research Centre See attached publication list	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	By the IPCRN Network: 0 Grants are handled by network members and the legal entities that they represent See attached list	Grants obtained by reporting party (exclusively or not).
3.3 Access to expert groups M	☒ Yes ☐ No Comments: IPCRN network has close contact to paediatric key opinion leaders, clinical research advisors, clinical researh nurses, statisticians, database programmerse etc.	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: info@nationalchildrensresearchcentre.org OR Dr. Sinéad Nally, sinead.nally@ncrc.ie The IPCRN will also have a dedicated email address shortly.	Indicate if coordinated capacity (staff, process) is available to answer external scientific questions in relation to clinical trials during daily business.
Standardized procedures for assessment of:	---	

3.5 Site feasibility	☒ Yes ☐ No Comments: Via the National Children's Research Centre	This concerns the suitability of a site for conducting a given trial
3.6 Participant recruitment	☒ Yes ☐ No Comments: Recruitment will be monitored by the National Children's Research Centre/IPCRN as per each study/protocol requirements	This concerns provisions to regularly monitor recruitment progress for a trial.
3.7 Budget calculation for studies	☒ Yes ☐ No Comments: Not performed exclusivley by the Network but with the assistance of the various university and hospital institutions of the network members	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 studies conducted will comply with the EU directive All paediatric investigators will receive GCP training	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: Adherence to ethical considerations for clinical trials in children forms one of the core principals and objectives of IPCRN	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: All studies conducted will seek favourable ethical approval (and regulatroy approval, where appropriate)	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 SOPs currently in development - SOPs and various routemaps will be posted on the IPCRN portal when finalised.	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: Studies will be monitored by the National Children's Research Centre as per ICH GCP	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: All investigators will regularly provide status reports to the National Children's Research Centre The National Children's Research Centre will act as the issue escalation point of contact, via the Clinical Research Project Manager	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: QA/QC personnel may be hired in the future; for the moment the Clinical Research Project Manager and Clinical Data Manger will oversee quality activitie and data safety	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 interventiomal clinical trials will seek favourable opinion form the Irish Medicines Board The Clinical Research Project Manager is in regular contact with the IMB with regards to the implementation of regulatory guidelines	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 ☐ No Comments: Formal investigator and study management meetings are underway for the ezcema and allergy, emergency medicine, respiratory medicine, neonatology, endocrinology and BASELINE studies.	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: The National Children's Research Centre also provides structured training programmes for PhD and MD students, including a GCP course, a Data Protection course and workshops on elements of paediatric research.	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 course BC/CLIN data managment system training Risk Management course Project Management course	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: Not protocol design	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: Parent representatives may become involved in the design/review of age-appropriate patient infomation leaflets, informed consent forms, picture cards etc., via the Irish Platform for Patient's Organisations, Science and Industry (IPPOSI)	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: The National Children's Research Centre corresponds with the Irish Platform for Patient's Organisations, Science and Industry (IPPOSI)	Indicate if public stakeholders are /have been involved