EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

7 March 2012
EMA/817613/2010
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
An agency of the European Union

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	Scottish Children's Research Network formerly Scottish Medicines for Children Network	Include legal address, define acronyms
Type	National Network to support high quality clinical trials in children to increase the safety and efficacy of medicines and/or medical treatments	Indicate type of reporting party, e.g. national or speciality network. May include short mission statement
Street	3rd Floor, Royal Aberdeen Children's Hospital.	
Postal code	AB25 2ZG	
Town	Aberdeen	
Country	Scotland UK	
Telephone 1	+44 1224 551125	
Telephone 2	+44 1224 554058	
Mobile phone		
Fax	+44 1224 551919	
Web site	www.scotmcn.org/ scotcrn.org	If available (see criterion 4)
Email for general enquiries	secretariat@scotmcn.org p.dicks@abdn.ac.uk	If available (see criterion 4)
Representative (main) contact	---	Include first and second name, email, telephone, address, as far as available
First name	Peter	
Second name	Helms	
Telephone	+44 1224 554058	
Mobile phone		
Email	p.j.helms@abdn.ac.uk	
Further contact(s)	---	Include first and second name, email, telephone, address, as far as available
First name	Pamela	
Second name	Dicks	
Telephone	+44 1224 559936	
Mobile phone		
Email	p.dicks@abdn.ac.uk	
The data in this document are 'current' as of	31.01.12	Provide the date when the criteria were last updated

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

Description ***M***

Year of foundation	2006	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	All areas of paediatrics	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		For example, oncology or infectious diseases
Speciality or disease specific? Specify		For example, cardiology only
Conditions covered? Specify		E.g. hypertension (within cardiology) or asthma (within respiratory diseases)
Procedure / intervention specific? Specify		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	4 List all collaborating centres: Royal Aberdeen Children's Hospital, Aberdeen Royal Infirmary. www.nhsgrampian.org Royal Hospital for Sick Children, Edinburgh Royal Infirmary www.nhslothian.scot.nhs.uk/hospitals/rhsc.asp Tayside Children's Hospital, Ninewells Hospital, Dundee www.dundee.ac.uk/mchs/tich/opening.html Royal Hospital for Sick Children, Yorkhill, Glasgow www.nhsggc.org.uk/content/	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

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]	23 31	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	1682 The proportion of eligible participants recruited to each trial varies enormously depending on the inclusion criteria, the intensity of the protocol, the duration of the study, the tolerability of the treatment and the number of visits required. Initial screening of patients by searching patient records to identify those that meet the inclusion criteria prior to invitation to attend screening visit. Screening visit to assess if patient meets inclusion criteria.	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	4 core centres in the teaching hospital centres with paediatric clinical research facilities. Each core works closely with District General Hospitals and General Practice Surgeries in their region.	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: 31 Proportion of all studies: (31/23)	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	11 Respiratory, anaesthesia, rheumatology, endocrinology, gastroenterology, neurology, psychiatry, renal, dermatology, neonatology, general paediatrics	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.6 Number of paediatric conditions covered by paediatric trials	21	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	3	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: All of our budget is received from Chief Scientist Office NHS Scotland to support paediatric trials which may be funded from public funding sources. The cost of of research nurse support provided to commercial trials is recovered.	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	1682	

participants (all studies)		
Industry-sponsored trials	---	
1.10 Number of ongoing and completed trials	13	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	11 Respiratory, anaesthesia, rheumatology, endocrinology, gastroenterology, neurology, psychiatry, renal, dermatology, neonatology, general paediatrics	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.12 Number of paediatric conditions covered by paediatric trials	21	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)	1682	

Criterion 2: Network organisation and processes

2.1 Existence of an identified contact person for external enquiries [M]	☒ Yes ☐ No Comments: Details provided in 'Identification' section above.	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: Management Board that meets quarterly to review strategic direction, recruitment to studies, training and finances. Study Adoption Committee to assess potential studies for adoption by the Network.	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: ScotMCN meets six monthly with our funder CS0 /NHS Scotland and the Research and Development Directors in the four Academic Centres. Produce an Annual Report. ScotCRN underwent a substantive review by the CSO.	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: Details provided in 'Identification' section above.	If available, mention in "identification" above
2.5 Existence of newsletter	☐ Yes ☒ No Comments: Due to the size of the Network,the unified health service in Scotland and the excellent communication between staff this is not deemed as necessary. The minutes of the research nurse meetings and board meetings are distributed to all network staff.	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: Details provided in 'Identification' section above.	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: Database of adopted clinical trials in preparation, on going or completed is maintained. This holds information regarding recruitment and is updated quarterly.	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: Compliant with data protection act and GCP	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: Access to Scottish Health service datasets managed by Information Services Directorate (ISD) of Scottish NHS.	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: Privacy Advisory Committee of ISD Scotland and Primary Care Informatics Centre Aberdeen.	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)	6 Catherine,C. Blaylock,M. Douglas,J Brooker,R. Helms,P. Walsh,G. Nasal epithelial cells as surrogates of bronchial epithelial cells in airway inflammation studies. American Journal of Respiratory Cell and Molecular Biology. Am. J. Respir. Cell Mol. Biol. 2008; 39: 560-568. Naina M, I, Helms PJ, Simpson CR, McLay JS. Using Routinely Collected Prescribing Data to Determine Drug Persistence for the Purpose of Pharmacovigilance. J.Clin.Pharmacol. 2010. Elkout ,H, McLay JS, Simpson CR Helms PJ. Use and safety of long-acting β2-agonists for pediatric asthma. Pediatric Health 2010 ;4: 295-310 Tobaiqy M, Stewart D, Helms PJ, Bond C, Lee AJ, Bateman N et al. A pilot study to evaluate a community pharmacy-based monitoring system to identify adverse drug reactions associated with paediatric medicines use. Eur.J.Clin.Pharmacol. 2010. Mohammed BS, Cameron GA, Cameron L, Hawksworth GH, Helms PJ, McLay JS.Can finger-prick sampling replace venous sampling to determine the pharmacokinetic profile of oral paracetamol? Br.J.Clin.Pharmacol. 2010;70:52-56 R M Lynn, K Riding and N McIntosh The use of electronic reporting to aid surveillance of ADRs in children: a proof of concept study Arch Dis Child 2010 95: 262-265 support provided by ScotMCN research nurse or core staff.	The publications should indicate that they are related to and reference the reporting party.
	Provision of research nurses, paediatric pharmacy advice, provide access to patient populations and data.	

3.2 Number of competitive grants obtained in the last 5 years	As ScotMCN is not a legal entity it cannot apply for grants directly , however we support applicants in the development of protocols, patient information sheets, pharmacy protocols, applications for ethical and Reasearch and Development approvals	Grants obtained by reporting party (exclusively or not).
3.3 Access to expert groups M	☒ Yes ☐ No Comments: Scottish Medicines Consortium. Royal College Paediatrics Child Health. Access to Statistical and Health Service Research experts through affiliation with the four teaching hospitals and Academic Institutions.	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: ScotCRN provides paediatric expert advice to Scottish Medicines Consortium (SMC). SMC identifies which medicines will be reimbused by NHS Scotland. ScotCRN provides Paediatric expertise among the clinicians and researchers on ScotCRN board and access to clinicians and scientists working in the Scottish NHS and Universities.	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 conducted at each network centre by lead paediatric research nurses and potential PI's and local investigators.	This concerns the suitability of a site for conducting a given trial
3.6 Participant recruitment	☒ Yes ☐ No Comments: Updates on recruitment montitored by ScotCRN staff and reported to board quarterly.	This concerns provisions to regularly monitor recruitment progress for a trial.
3.7 Budget calculation for studies	☒ Yes ☐ No Comments: Using budget guidance available in NHS Scotland and partner academic institutions.	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 network staff are GCP trained, all studies are conducted in compliance with GCP guidelines.	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 studies adopted by ScotMCN have ethical approval from the National Health Service Research Ethics Committee which in the UK operates in accordance with the Department of Health's 'Research Governance Framework for Health and Social Care' (second edition 2005). The National Research Ethics Service (NRES) oversees operation of NHS RECs, with the dual mission: •to protect the rights, safety, dignity and well-being of research participants; and •to facilitate and promote ethical research that is of potential benefit to participants, science and society. The NRES website at http://www.nres.npsa.nhs.uk/ is the primary source of guidance on ethical issues that need to be addressed and application procedures. Specific information on the role, remit constitution and membership of NHS RECs is set out in the Department of Health's 'Governance Arrangements for RECs' (GafREC, 2001). For Scotland the relevant GafREC document is attached. http://www.nres.npsa.nhs.uk/search/?q=Gafrec NHS RECs are also guided by the 'Standard Operational Procedures (SOPs) for Research Ethics Committees' (version 4). The Department of Health's 'Research Governance Framework for Health and Social Care' is the primary context of operation, together with applicable laws, including: •Data Protection Act 1998 •Human Rights Act 1998 •Freedom of Information Act 2000 •EC Clinical Trials Directive 2001/20/EC •Human Tissue Act 2004 •EC Tissues and Cells Directive 2004/23/EC •Mental Capacity Act 2005 •Human Fertilization and Embryo Act 2008	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: Annual reports and an end of study reports for each trial are provided to the relevant ethics committee, all of which have paediatric expertise	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 SOP's are available on ScotCRN website www.scotcrn.org	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: ScotCRN does not operate as a Clinical Research Organisation however ScotCRN adopted trials are monitored by the respective sponsoring commercial company or contracted CRO, the MHRA , NHS Scotland Research and Development or if sponsored by an academic institution by the respective research governance committee. All studies are conducted in compliance with 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: Regular review of recruitment in each centre and of each trial by Network board.	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: Compliance with Good Clincial Practice, Good Laboratory Practice and Data Protection.	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: Compliant with MHRA and EMA procedures e.g. application for clinical trial authorisation	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: Provide paediatric advice to the Scottish Medicines Consortium - the body that advises adoption of medicines by NHS Scotland.	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 meeetings, initiation site visits provided/or attended for each trial.	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: ScotCRN does not provide courses but does ensure that all staff participating in trials are appropriately trained. ScotCRN provides access to the required training courses provided by NHS, NIHR-CRN and external bodies and where required funding for attendance.	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: All staff are GCP trained and access training courses and conferences appropriate to their continuous professional development (cpd) or in relation to specific trials.	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: Not relevant to the remit of ScotCRN.	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: ScotCRNhave established a young person's advisory group of 11-17 year old young people to advise on protocol design and patient information sheets. The group act as advocates for children in research. Key opinion leaders (professionals, parents and young people) have been consulted as part of the adopted CHIMES research programme. CHIMES (Child Medical Records for Safer Medicines) is developing pharmacovigilance systems from routinely collated Scottish NHS data.	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: ScotCRN have established a young person's advisory group of 11-17 year old young people to advise on protocol design and patient information sheets.	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 ScotCRN Young Person's Group comment on future grant proposals	Indicate if public stakeholders are /have been involved