



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 May 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



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	Mother Infant Child Youth Research Network - Réseau de Recherche en Santé des Enfants et des Meres "MICYRN"	Include legal address, define acronyms
Type	MICYRN was founded in 2006 as a collaborative national initiative to build capacity for high quality clinical research in Canada. MICYRN links the 17 participating paediatric academic health centres and hundreds of investigation teams across Canada.	Indicate type of reporting party, e.g. national or speciality network. May include short mission statement
Street	Room K4-135, 4480 Oak Street	
Postal code	V6H 3V4	
Town	Vancouver, British Columbia	
Country	Canada	
Telephone 1	Executive Assistant – Maureen Lowe 604-875-2345 (4788)	
Telephone 2		
Mobile phone		
Fax	604-875-2414	
Web site	www.micyrn.ca	If available (see criterion 4)
Email for general enquiries	ajunker@cw.bc.ca	If available (see criterion 4)
Representative (main) contact	---	Include first and second name, email, telephone, address, as far as available
First name	Anne	
Second name	Junker	
Telephone	604-875-3591	
Mobile phone		
Email	ajunker@cw.bc.ca	
Further contact(s)	---	Include first and second name, email, telephone, address, as far as available
First name	Aubrey	
Second name	Tingle	
Telephone	604-875-2475	
Mobile phone		
Email	atingle@cw.bc.ca	

The data in this document are 'current' as of	July 2010	Provide the date when the criteria were last updated
State how this document can be accessed by the public	www.micyrn.ca	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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Newborn: from birth to less than 28 days of age
Infants from 1 month to less than 24 months of age	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Children from 2 years to less than 12 years of age	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Adolescents from 12 years to less than 18 years	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Specialities / Conditions covered	all: anesthesiology; allergy; behavioural medicine; cardiology; cystic fibrosis; critical care; dermatology; diabetes; emergency medicine; endocrinology; gastroenterology; infectious diseases (incl. antimicrobial, HIV, vaccine); hematology; immunology; mental health; metabolic diseases; neonatology; nephrology; neurology (incl. epilepsy, stroke, muscular dystrophy); nutrition; oncology; ophthalmology; orthopedics; pain management; pulmonology; rheumatology; surgery; transplantation;	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	As above. Disciplines involved include physician, surgeon, nursing, pharmacology, rehabilitation medicine, nutrition	For example, oncology or infectious diseases
Speciality or disease specific? Specify	As above.	For example, cardiology only

Conditions covered? Specify	Many, as above.	E.g. hypertension (within cardiology) or asthma (within respiratory diseases)
Procedure / intervention specific? Specify	Exceptions are gene and stem cell transplantation: not done.	For example, surgery, organ or stem cell transplantation
Number of collaborating countries	1 List all collaborating countries: Canada	State the number of collaborating countries. Indicate "1" if national; Indicate if Europe, outside of Europe, other..... (describe)

<p>Number of collaborating centres</p>	<p>17</p> <p>List all collaborating centres:</p> <ol style="list-style-type: none"> 1. Child and Family Research Institute University of British Columbia, Vancouver, British Columbia 2. Women and Children's Health Research Institute, University of Alberta, Edmonton, Alberta 3. Institute of Maternal and Child Health, University of Calgary, Calgary, Alberta 4. Royal University Hospital, University of Saskatchewan, Saskatoon, Saskatchewan 5. Manitoba Institute of Child Health, University of Manitoba, Winnipeg, Manitoba 6. Children's Health Research Institute, University of Western Ontario, London, Ontario 7. McMaster Children's Hospital, McMaster University, Hamilton, Ontario 8. The Hospital for Sick Children, University of Toronto, Toronto, Ontario 9. Kingston General Hospital, Queen's University, Kingston, Ontario 10. Children's Hospital of Eastern Ontario (CHEO), University of Ottawa, Ottawa, Ontario 11. Laurentian University, Sudbury, Ontario 12. Montreal Children's Hospital Research Institute, McGill University, Montreal, Quebec 13. Le Centre de recherche du CHU Sainte-Justine, Université de Montréal, Montreal, Quebec 14. Université de Sherbrooke, Sherbrooke, Quebec 15. Hospitalier Université Laval (CHUL), Université de Laval, Quebec City, Quebec 16. IWK Health Centre Dalhousie University, Halifax, Nova Scotia 17. Janeway Children's Health and Rehabilitation Centre, Memorial University, St. John's, Newfoundland 	<p>State the number of collaborating centres and provide a list of all collaborating centres (attachment or link possible)</p>
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Type of activity/studies		
Clinical studies	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Experimental research	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Other activity	Study of social, environmental and cultural factors that affect population health; policy development; research on health system and services delivery; research on ethics	Describe type of activities other than clinical and/or non-clinical studies

Evidence for each criterion

Criterion 1: Research experience and ability	9
Criterion 2: Efficiency requirements	12
Criterion 3: Scientific competencies and capacity to provide expert advice	15
Criterion 4: Quality management	16
Criterion 5: Training and educational capacity to build competences	19
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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.

<p>1.1</p> <p>Number of completed trials ^M</p> <p>Number of ongoing trials ^M</p>	<p>640 (July 2005-2010)</p> <p>467 (July 2005-2010)</p>	<p>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.</p>
<p>1.2</p> <p>Total number of participants actually recruited each year</p> <p>Proportion of eligible participants actually recruited each year</p> <p>Describe way of screening and participant recruitment</p>	<p>10,875 subjects were recruited in 45 studies registered in 2009 and now completed. Projected enrolment for a further 84 studies registered in 2009 and actively recruiting is 19,129.</p> <p>don't know</p> <p>The investigator(s) should be able to demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period. Patient registries and databases maintained by disease or discipline-focussed networks can provide information on potential numbers. Potential subjects are identified and first approached for an expression of interest to be involved in research by their care provider. Researchers must provide, to prospective subjects or authorized third parties, full and frank disclosure of all information relevant to free and informed consent. Throughout the process of free and informed consent, the researcher must ensure that prospective subjects are given adequate opportunities to discuss and contemplate their participation.</p>	<p>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?</p>

	Subject screening logs are required Study Essential Documents to be maintained during the conduct of the study.	
1.3 Total number of collaborating centres	17	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: 74 (registered in 2009) Proportion of all studies: 56% of Clinical Trials are academic-initiated. Trials represent about 1% of all clinical research	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	25	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.6 Number of paediatric conditions covered by paediatric trials	ranges from contact lenses to rare metabolic diseases. Common studies involve cancer, infectious diseases, surgery, anesthesia, neurology..	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	At present there are over 50 birth cohort studies recruiting around 40,000 pregnancies - a searchable inventory has been modeled after the EU birthcohorts.net to show this information at www.micyrn.ca . We as yet have not collated national data on cohort studies beyond birth; or outcome studies. In 2009, 23 clinical observational studies projecting enrolment of 5371 subjects were registered.	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: 56% of clinical trials registered in 2009 were academic-initiated. Proportion of budget: not known	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)	6,718 subjects enrolled in trials and observational studies registered in 2009, now completed; an additional 15,765 subjects were projected to be enrolled in trials and observational studies registered in 2009, actively recruiting.	
Industry-sponsored trials	---	
1.10 Number of ongoing and completed trials	55 clinical trials were registered in 2009	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	broad, as above, 1.6	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.12 Number of paediatric conditions covered by paediatric trials	diverse, as above, 1.6	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)	4832 subjects were enrolled in industry-sponsored clinical trials registered in 2009, now completed. An additional 8,309 subjects were projected to be enrolled in industry-sponsored clinical trials registered in 2009, actively recruiting.	

Criterion 2: Network organisation and processes

<p>2.1 Existence of an identified contact person for external enquiries ^M</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments: Director: Dr. Anne Junker Associate Director: Dr. Aubrey Tingle</p>	<p>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.</p>
<p>2.2 Existence of an internal steering committee ^M</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments: The internal steering committee is comprised of 5 clinical research directors from the 17 participating sites.</p>	<p>Minimum requirement (^M): either an internal steering committee (2.2) or an external advisory / steering committee (2.3).</p>
<p>2.3 Existence of an external advisory / steering committee directing the reporting party ^M</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments: The external advisory committees include the national Canadian Council of Child Health Research, representing all (basic and clinical) research interests; and the Canadian Child & Youth Child Health Coalition, which considers research in the broader context of health/health care interests.</p>	<p>Minimum requirement (^M): either an internal steering committee (2.2) or an external advisory / steering committee (2.3).</p>
<p>2.4 Existence of a website</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments:</p>	<p>If available, mention in "identification" above</p>
<p>2.5 Existence of newsletter</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments:</p>	<p>Newsletter of any format (electronic, surface mail), distributed actively to selected recipients.</p>
<p>2.6 Existence of an internal database(s) for disease, condition, treatment and / or outcome ^M If yes, please describe</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments / description: The data base available to the Reporting body comprises the inventory of research networks involved in multicentre studies. Each specialty network (condition, discipline, population) maintains its own database(s).</p>	<p>For example, data base or disease registry to facilitate planning or conducting future trials (may or may not contain individual patient data)</p>

<p>2.1</p> <p>Existence of an identified contact person for external enquiries ^M</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments:</p> <p>Director: Dr. Anne Junker</p> <p>Associate Director: Dr. Aubrey Tingle</p>	<p>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.</p>
<p>2.7</p> <p>Provisions to ascertain data protection and data security ^M</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments:</p> <p>For research studies undertaken by members of the network, sponsors are required to utilize appropriately qualified individuals to supervise the overall conduct of the trial, to handle the data, to verify the data, to conduct the statistical analyses, and to prepare the trial reports. When using electronic trial data handling and/or remote electronic trial data systems, sponsors are required to:</p> <p>a. Ensure and document that the electronic data processing system(s) conforms to established requirements for completeness, accuracy, reliability, and consistent intended performance (i.e., validation).</p> <p>b. Maintain SOPs for using these systems.</p> <p>c. Ensure that the systems are designed to permit data changes in such a way that the data changes are documented and that there is no deletion of entered data (i.e., maintain an audit trail, data trail, edit trail).</p> <p>d. Maintain a security system that prevents unauthorized access to the data.</p> <p>e. Maintain a list of the individuals who are authorized to make data changes.</p> <p>f. Maintain adequate backup of the data.</p> <p>g. Safeguard the blinding, if any (e.g., maintain the blinding during data entry and processing).</p>	<p>Are provisions in place to ascertain patients' /study participants' data protection and data safety within network</p>

<p>2.1</p> <p>Existence of an identified contact person for external enquiries ^M</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments:</p> <p>Director: Dr. Anne Junker</p> <p>Associate Director: Dr. Aubrey Tingle</p>	<p>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.</p>
<p>2.8</p> <p>Procedure(s) to access the database by third parties</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments:</p> <p>The sponsor is required to ensure that it is specified in the protocol or other written agreement that the investigator(s)/institution(s) provide direct access to source data/documents for trial-related monitoring, audits, IRB/IEC review, and regulatory inspection.</p> <p>The sponsor needs to verify that each subject has consented, in writing, to direct access to his/her original medical records for trial-related monitoring, audit, IRB/IEC review, and regulatory inspection.</p> <p>Researchers and REBs are required to ensure that final analysis and interpretation of such data remains with the researchers, whose duty it is to ensure the integrity of their research. When stopping rules are required in Phase I, II and III clinical trials, monitoring of the interim results must be done independently.</p>	<p>Are provisions in place that data can be shared for planning, conducting or analysing a trial(s)?</p>
<p>2.9</p> <p>Access to external databases /registries</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments:</p> <p>National databases are available. The reporting party does not have open or privileged access, but can apply for information.</p>	<p>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</p>
<p>2.10</p> <p>Standardised process to access an external database(s)</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments:</p> <p>By formal application.</p>	<p>Is a standardised process in place to access external/ national databases?</p>

Criterion 3: Scientific competencies and capacity to provide expert advice

<p>3.1</p> <p>Number of peer-reviewed publications in the last 5 years</p> <p>Provide exact reference(s)</p> <p>Describe the network's contribution to publication(s)</p>	<p>do not have this figure available</p> <p>do not have all this information</p>	<p>The publications should indicate that they are related to and reference the reporting party.</p>
<p>3.2</p> <p>Number of competitive grants obtained in the last 5 years</p>	<p>do not have this figure available</p>	<p>Grants obtained by reporting party (exclusively or not).</p>
<p>3.3</p> <p>Access to expert groups ^M</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments:</p>	<p>Indicate if the reporting party has specific access to established expert groups, such as learned societies</p>
<p>3.4</p> <p>Capacity to answer external scientific questions ^M</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments:</p>	<p>Indicate if coordinated capacity (staff, process) is available to answer external scientific questions in relation to clinical trials during daily business.</p>
<p>Standardized procedures for assessment of:</p>	<p>---</p>	
<p>3.5</p> <p>Site feasibility</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments:</p>	<p>This concerns the suitability of a site for conducting a given trial</p>
<p>3.6</p> <p>Participant recruitment</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments:</p>	<p>This concerns provisions to regularly monitor recruitment progress for a trial.</p>
<p>3.7</p> <p>Budget calculation for studies</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments:</p>	<p>This concerns, for example, quotes and prospective financial planning for a trial.</p>

Criterion 4: Quality management

<p>4.1</p> <p>Documented adherence to Good Clinical Practice (GCP) guideline ^M</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments:</p> <p>Studies are required to adhere to guidelines set by Health Canada (www.hc-sc.gc.ca) ICH Guidance E6: Good Clinical Practice: Consolidated guidelines. Audits are required to be conducted by study sponsors. Audits are also conducted Health Canada; Canadian Institutes for Health Research (CIHR), the national funding agency; the USA FDA for those studies; and by site-associated organizations.</p>	<p>Declare whether studies conducted comply with the EU Directive 2001/20/EC on Clinical Trials.</p>
<p>4.2</p> <p>Documented adherence to the ethical considerations for clinical trials in children ^M</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments:</p> <p>see www.pediagen.org "Best Practices for Research Involving Children & Youth" which reviews current and proposed conditions.</p>	<p>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".</p>

<p>4.3 Documented adherence to ethical considerations</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments: REBs are required to consist of at least five members, including both men and women, of whom:</p> <p>a. At least two members have broad expertise in the methods or in the areas of research that are covered by the REB, which would include paediatric expertise;</p> <p>b. At least one member is knowledgeable in ethics;</p> <p>c. For biomedical research, at least one member is knowledgeable in the relevant law; this is advisable but not mandatory for other areas of research; and</p> <p>d. At least one member has no affiliation with the institution, but is recruited from the community served by the institution</p> <p>Of the 17 participating sites, there are 6 (the largest) with autonomous child/child-maternal REBs.</p>	<p>Declare whether reporting party requests approval by an independent ethics committee with paediatric expertise for all studies conducted.</p>
<p>4.4 Availability of Standard Operation Procedures (SOP)</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, provide reference to available SOPs</p> <p>MICYRN is partner in a nationally-sponsored organization (N2) which has developed CanReg approved SOPs and access to on-line GCP training modules (http://www.cihr-irsc.gc.ca/e/34791.html)</p>	<p>Indicate existence of SOP e.g. for study management, adverse events reporting etc.</p>
<p>4.5 Capacity to monitor studies (academic trials, industry sponsored trials) ^M</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments: Study sponsors are required to ensure that the trials are adequately monitored. The sponsor should determine the appropriate extent and nature of monitoring. The determination of the extent and nature of monitoring should be based on considerations such as the objective, purpose, design, complexity, blinding, size, and endpoints of the trial.</p>	<p>Indicate if the reporting party implements the monitoring of paediatric trials according to ICH 6 Good Clinical Practice Guideline.</p>

<p>4.6 Capacity to monitor performance of collaborating centres</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments: In general there is a requirement for on-site monitoring, before, during, and after the trial; however in exceptional circumstances the sponsor may determine that central monitoring in conjunction with procedures such as investigators' training and meetings, and extensive written guidance can assure appropriate conduct of the trial in accordance with GCP.</p>	<p>Indicate if the reporting party implements the monitoring of performance of collaborating centres.</p>
<p>4.7 Quality control and quality assurance, traceability and data safety ^M</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments: The purposes of trial monitoring are to verify that: a. The rights and well-being of human subjects are protected. b. The reported trial data are accurate, complete, and verifiable from source documents. c. The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s)</p>	<p>Indicate if this is implemented in the reporting party's remit.</p>

Criterion 5: Training and educational capacity to build competences

<p>5.1</p> <p>Evidence of collaboration with regulatory authorities ^M</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Comments:</p> <p>Clinical trials in Canada in Phases I to III or for a new indication in Phase IV are required to conform to specific regulations that are monitored by Health Canada. These regulations apply to manufacturers and independent researchers. The process involves a Clinical Trials application, required practices that are performed during and after the clinical trial and inspection activities. Trials in Canada are subject to the Clinical Trial Regulations defined in Division 5 of the Food and Drug Regulations. The regulations are consistent with Good Clinical Practice as defined by the International Conference on Harmonization (ICH).</p>	<p>Indicate awareness of regulatory requirements for developing medicines; for example, implementation of guidelines from regulatory authorities.</p>
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<p>5.2 Capacity to provide competent consultation to regulatory authorities</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments: The outstanding Canadian expertise in several disciplines related to the pursuit of innovative drug therapy for children is recognized internationally. Canada has been a world leader in pediatric pharmacology and pharmacy with particular expertise in relevant clinical areas and in the development of appropriate trials methods. This expertise has evolved over 30 years and is recognized through the involvement of Canadian experts nationally at Health Canada and the Canadian Institutes for Health Research, and with international agencies such as WHO and UNICEF. Canadian expertise is also supported by the International Federation of Pharmaceutical Manufacturer Associations and by the European Community, European Medicines Agency. Furthermore, Canadian experts have been engaged in efforts with the International Conference of Drug Regulatory Associations to improve the regulatory framework supporting the improved drug therapy for children worldwide. The Canadian academics involved with this applicaiton are also experts in educational methods and knowledge transfer to support more effect drug investigation and consequently better health outcomes for children worldwide.</p>	<p>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).</p>
<p>5.3 Formal meetings for clinical trials If yes, provide number</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments:</p>	<p>For example, investigator meetings, trainings specific to a given ongoing or planned trial.</p>

<p>5.4 Training courses given over the last 2 years^M If yes, provide number</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments: Training specific to a trial is a requirement. Training in general for trials is part of the educational curriculum offered to investigators, research associates, REB members, and research administrators at all participating sites.</p>	<p>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).</p>
<p>5.5 Training courses received over the last 2 years^M If yes, provide number</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments:</p>	<p>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).</p>
<p>5.6 Promotion of participation in clinical trials in countries with limited resources Provide list of countries</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments: see 5.2 above. MICYRN is a partner in StaR Child Health, which is an international movement to improve the quality, reporting and outcomes of paediatric clinical trials, world-wide. MICYRN is organizing the 2010 StaR Child Health Summit to be held in Vancouver, British Columbia. MICYRN has been involved in workshops to address the design, implementation and ethics of clinical trials in low and middle income countries, including Copenhagen (July 2010) and those affiliated with StaR Child Health meetings (Amsterdam, 2009; Vancouver 2010).</p>	<p>Indicate if support for such trials is provided by the reporting party.</p>

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	<input type="checkbox"/> Yes <input type="checkbox"/> No Comments:	Indicate if public stakeholders are /have been involved
6.2 Involvement of patients, parents or their organisations in creating the protocol information package	<input type="checkbox"/> Yes <input type="checkbox"/> 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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Comments: Patient/disease organizations provide funding to scientifically-competative, peer-reviewed studies (ie. cancer, diabetes, cystic fibrosis, arthritis, immunology, rare diseases, genetics, heart & stroke, etc.). On a national basis, a recent workshop (May 2010) involved patients and families to set research priorities for mental health.	Indicate if public stakeholders are /have been involved