



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
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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	Children Leukemia Group (CLG) of the EORTC Avenue Mounierlaan, 83/11 Brussel 1200 - ,Belgium	Include legal address, define acronyms
	the EORTC - CLG is also participating in the I-BFM Group	

Type	mission of EORTC : The aims of the European Organisation for Research and Treatment of Cancer (EORTC) are to develop, conduct, coordinate, and stimulate translational and clinical research in Europe to improve the management of cancer and related problems by increasing survival but also patient quality of life. Extensive and comprehensive research in this wide field is often beyond the means of individual European hospitals and can be best accomplished through the multidisciplinary multinational efforts of basic scientists and clinicians. The ultimate goal of the EORTC is to improve the standard of cancer treatment through the testing of more effective therapeutic strategies based on drugs, surgery and/or radiotherapy that are already in use and also through the development of new drugs and other innovative approaches. This is accomplished mainly by conducting large, multicentre, prospective, randomised, phase III clinical trials. In this way, the EORTC facilitates the passage of experimental discoveries into state-of-the-art treatments.see: -CLG is an international network working in the field of hematologic malignancies Mission statement of CLG - To improve the cure rates of children and adolescents with leukaemia's and related malignancies (lymphomas, myelodysplastic syndromes, ...) by ameliorating treatment in an evidence based way (randomised clinical trials). -To promote the study of these diseases with regard to their epidemiology, their clinical behaviour and to the long term sequellae of treatment. -To promote the clinical application of new biologic techniques (translational research) on a large number of patients.	Indicate type of reporting party, e.g. national or speciality network. May include short mission statement
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Street	Avenue Mounierlaan, 83/11	
Postal code	1200	
Town	Brussels	
Country	Belgium	
Telephone 1	please look at the website for phone and fax	
Telephone 2		
Mobile phone		
Fax		
Web site	www.eortc.be = general website of EORTC www.eortc.be/home/CLG/default.html = website of the group	If available (see criterion 4)
Email for general enquiries	chairman: yves.benoit@ugent.be secretary: yves.bertrand@chu-lyon.fr	If available (see criterion 4)
Representative (main) contact	---	Include first and second name, email, telephone, address, as far as available
First name	Benoit	
Second name	Yves	
Telephone	address: chairman Dept. Ped. Haemato-Oncology & Stem Cell transplantation University Hospital Ghent De Pintelaan 185 B 9000 GENT Belgium Phone sec. : +32 (0)9 332 2416	
Mobile phone		
Email	Yves.benoit@ugent.be	
Further contact(s)	---	Include first and second name, email, telephone, address, as far as available
First name	Bertrand	
Second name	yves	
Telephone	address secretary CHU Lyon - Institut d'Hematologie et d'Oncologie Pediatrique1, Place Joseph Renaut FR 69008 Lyon France	
Mobile phone		
Email		
The data in this document are 'current' as of	28 july 2010	Provide the date when the criteria were last updated

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

Year of foundation	EORTC is founded in 1962 Leukemia (adults and children) Group started in 1974 Children Leukemia Group: 1982 first trials were conducted together with the adult group	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 than 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	EORTC Children Leukemia Group = ped. hematologic malignancies	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	EORTC as main organisation has: Tumor-specific groups: - Brain Tumor - Breast Cancer - Children's Leukemia - Lung Cancer - Leukemia - Lymphoma - Melanoma - Soft Tissue and Bone Sarcoma - Gastro-Intestinal Tract Cancer - Genito-Urinary Tract Cancer - Gynaecological Cancer - Head and Neck Cancer Other clinical groups - Infectious Diseases - Quality of Life - Radiation Oncology Task Forces - Elderly - Cutaneous Lymphoma	For example, oncology or infectious diseases
Speciality or disease specific? Specify	EORTC TRANSLATIONAL RESEARCH DIVISION Comprises three groups: - Pharmacology and Molecular Mechanisms - Functional Imaging - Pathobiology(gastro, pneumo, urologic etc)	For example, cardiology only
Conditions covered? Specify	EORTC - CLG covers only the pediatric hematologic malignancies	E.g. hypertension (within cardiology) or asthma (within respiratory diseases)
Procedure / intervention specific? Specify	see supra	For example, surgery, organ or stem cell transplantation
Number of collaborating countries	3 countries in Europe List all collaborating countries: Belgium, France, Portugal	State the number of collaborating countries. Indicate "1" if national; Indicate if Europe, outside of Europe, other..... (describe)
Number of collaborating centres	25 centres List all collaborating centres: see website : www.eortc.be/home/CLG/List_of_Members.pdf	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	see supra: EORTC TRANSLATIONAL RESEARCH	Describe type of activities other than clinical and/or non-clinical studies

Evidence for each criterion

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How to provide evidence

1. The evidence for this self-assessment document should be based only on the activity of the network during in the last 5 years.
2. Evidence used in this document should have a reference (e.g., publication, annual or periodic report or internal network document).
3. The self-assessment document is to cover a range of different network types. It is recognised that some networks may not be able to accurately respond to every item. In such circumstances, state why it is not possible to respond.
4. The network is referred to as the “reporting party”.

Criterion 1: Research experience and ability

Do not include planned trials, but only ongoing and completed trials.

1.1 Number of completed trials M Number of ongoing trials M	7 2	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	200 - 250 depending on the studies if a study is open the proportion of the participants in the study is high (more than 95%) all patients entering the centres are recruited if possible	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	25	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: 2 open studies Proportion of all studies: there has been only academic studies in the last 5 years for CLG EORTC is of course an organisation with great possibilities to conduct for academia and also with industry	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	ped. hemato-oncology	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.6 Number of paediatric conditions covered by paediatric trials	infection therapy related to ped. hemato-oncology supportive therapy related ped. hemato-oncology	If not all areas within one speciality covered count conditions, without repetition, across all ongoing or completed paediatric trials
1.7 Number of other ongoing research studies / programs	2 Late effects study of ALL Cytogenetics study in AML	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: this is an estimate -difficult to calculate EORTC : 50% (and EORTC is also founded partially by different partners as charity, government) Charity Foundations : 50%	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)	approx. 3500 participants	
Industry-sponsored trials	---	
1.10 Number of ongoing and completed trials	none	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	Ped. Hematology-Oncology	Count specialities, without repetition, across all ongoing or completed

paediatric trials		paediatric trials
1.12 Number of paediatric conditions covered by paediatric trials		If not all areas within one speciality covered count conditions, without repetition, across all ongoing or completed paediatric trials
1.13 Number of registered study participants (all studies)		

Criterion 2: Network organisation and processes

2.1 Existence of an identified contact person for external enquiries ^M	☐ Yes ☐ No Comments: general informations www.eortc.be/default.htm EORTC Director General Francoise MEUNIER EORTC Director General's Office Avenue E. Mounier 83 bte 11 BE -1200 Brussels, Belgium Tel: + 32 2 7741630 Fax: + 32 2 7712004 E-mail: francoise.meunier@eortc.be please find also all information on the "investigators handbook" of the EORTC http://www.eortc.be/Services/Doc/handbook/default.htm	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.
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2.1 Existence of an identified contact person for external enquiries ^M	☐ Yes ☐ No Comments: general informations www.eortc.be/default.htm EORTC Director General Francoise MEUNIER EORTC Director General's Office Avenue E. Mounier 83 bte 11 BE -1200 Brussels, Belgium Tel: + 32 2 7741630 Fax: + 32 2 7712004 E-mail: francoise.meunier@eortc.be please find also all information on the "investigators handbook" of the EORTC http://www.eortc.be/Services/Doc/handbook/default.htm	Enquiries from patients, parents, organisations, researchers, pharmaceutical companies or regulatory authorities are co-ordinated or answered by a nominated contact person. Provide contact details in section "Identification" above.
2.2 Existence of an internal steering committee ^M	☒ Yes ☐ No Comments: EORTC New Drug Advisory Committee (NDAC) EORTC Translational Research Advisory Committee (TRAC) EORTC Protocol Review Committee (PRC) EORTC Scientific Audit Committee (SAC) EORTC Quality Assurance Committee (QAC) EORTC Independent Data Monitoring Committee (IDMC) EORTC Membership Committee (MC) EORTC Headquarters Institutional Review Board (IRB) please find all information on	Minimum requirement (^M): either an internal steering committee (2.2) or an external advisory / steering committee (2.3).
European network of paediatric research (Enpr) EMA/241053/2010	http://www.eortc.be/about/Directory2009-2010/07EORTCCommittees.htm	Page 15/23

2.1 Existence of an identified contact person for external enquiries ^M	☐ Yes ☐ No Comments: general informations www.eortc.be/default.htm EORTC Director General Francoise MEUNIER EORTC Director General's Office Avenue E. Mounier 83 bte 11 BE -1200 Brussels, Belgium Tel: + 32 2 7741630 Fax: + 32 2 7712004 E-mail: francoise.meunier@eortc.be please find also all information on the "investigators handbook" of the EORTC http://www.eortc.be/Services/Doc/handbook/default.htm	Enquiries from patients, parents, organisations, researchers, pharmaceutical companies or regulatory authorities are co-ordinated or answered by a nominated contact person. Provide contact details in section "Identification" above.
2.3 Existence of an external advisory / steering committee directing the reporting party ^M	☐ Yes ☐ No Comments: all committees have members from outside the EORTC HQ;	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: http://www.eortc.be	If available, mention in "identification" above
2.5 Existence of newsletter	☒ Yes ☐ No Comments: see http://newsletter.eortc.be/	Newsletter of any format (electronic, surface mail), distributed actively to selected recipients.
2.6 Existence of an internal database(s) for disease, condition, treatment and / or outcome ^M If yes, please describe	☒ Yes ☐ No Comments / description: http://www.eortc.be/Services/Doc/policies/default.htm	For example, data base or disease registry to facilitate planning or conducting future trials (may or may not contain individual patient data)

2.1 Existence of an identified contact person for external enquiries ^M	☐ Yes ☐ No Comments: general informations www.eortc.be/default.htm EORTC Director General Francoise MEUNIER EORTC Director General's Office Avenue E. Mounier 83 bte 11 BE -1200 Brussels, Belgium Tel: + 32 2 7741630 Fax: + 32 2 7712004 E-mail: francoise.meunier@eortc.be please find also all information on the "investigators handbook" of the EORTC http://www.eortc.be/Services/Doc/handbook/default.htm	Enquiries from patients, parents, organisations, researchers, pharmaceutical companies or regulatory authorities are co-ordinated or answered by a nominated contact person. Provide contact details in section "Identification" above.
2.7 Provisions to ascertain data protection and data security ^M	☐ Yes ☐ No Comments: see www.eortc.be/about/Directory2009-2010/10EORTClegalaspects.htm www.eortc.be/Services/Doc/policies/default.htm	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: www.eortc.be/Services/Doc/policies/default.htm	Are provisions in place that data can be shared for planning, conducting or analysing a trial(s)?

2.1 Existence of an identified contact person for external enquiries ^M	☐ Yes ☐ No Comments: general informations www.eortc.be/default.htm EORTC Director General Francoise MEUNIER EORTC Director General's Office Avenue E. Mounier 83 bte 11 BE -1200 Brussels, Belgium Tel: + 32 2 7741630 Fax: + 32 2 7712004 E-mail: francoise.meunier@eortc.be please find also all information on the "investigators handbook" of the EORTC http://www.eortc.be/Services/Doc/handbook/default.htm	Enquiries from patients, parents, organisations, researchers, pharmaceutical companies or regulatory authorities are co-ordinated or answered by a nominated contact person. Provide contact details in section "Identification" above.
2.9 Access to external databases /registries	☒ Yes ☐ No Comments: http://www.eortc.be/services/forms/erp/default.aspx	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: http://www.eortc.be/services/forms/erp/default.aspx	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)	10 http://www.eortc.be/home/CLG/publications.html some are exclusive network publications, some are the results of intergroup collaboration	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		Grants obtained by reporting party (exclusively or not).
3.3 Access to expert groups ^M	☒ Yes ☐ No Comments: all other (non-CLG) EORTC groups could be seen as "extern" expert groups and there is also a string collaboration between EORTC and the NCI	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: see www.eortc.be/about/Directory2009-2010/06%20EORTC%20Headquarters.htm	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: http://www.eortc.be/Services/Doc/policies/POL018.pdf	This concerns the suitability of a site for conducting a given trial
3.6 Participant recruitment	☒ Yes ☐ No Comments:	This concerns provisions to regularly monitor recruitment progress for a trial.
3.7 Budget calculation for studies	☒ Yes ☐ No Comments: EORTC has his own financial Dpt all studies must comply to stringent financial rules	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: see http://www.eortc.be/Services/Doc/policies/default.htm	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: see http://www.eortc.be/Services/Doc/policies/default.htm	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: see http://www.eortc.be/Services/Doc/policies/default.htm	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 http://www.eortc.be/Services/Doc/policies/default.htm	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:	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: as far as I know this is not done but I guess the organisation is indeed capable to do this if the resources are available	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: http://www.eortc.be/Services/Doc/policies/default.htm	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: http://www.eortc.be/Seminar/InternationalConferences.htm http://www.eortc.be/Seminar/UnderAuspices.htm	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:	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: http://www.eortc.be/Seminar/UnderAuspices.htm http://www.eortc.be/Seminar/Educationpgm/Programs/prog2010.htm http://www.eortc.be/jobs/documents/FellowshipProgram.htm	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: http://www.eortc.be/Seminar/UnderAuspices.htm http://www.eortc.be/Seminar/Educationpgm/Programs/prog2010.htm http://www.eortc.be/jobs/documents/FellowshipProgram.htm	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: eastern Europe countries are included in some EORTC adults trials but I know that this is not easy at all	Indicate if support for such trials is provided by the reporting party.
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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: http://www.eortc.be/About/Patients%20Brochure/default.htm in our group this depends from centres participating this is however not the rule in all centres ethics committees (national or local) have sometimes representatives from patients	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: http://www.eortc.be/About/Patients%20Brochure/default.htm see supra	Indicate if public stakeholders are /have been involved
6.3 Involvement of patients, parents or their organisations in the prioritisation of needs for clinical trials in children	☐ Yes ☒ No Comments:	Indicate if public stakeholders are /have been involved