European network pf paediatric research at the European Medicines Agency (Enpr-EMA), UK

1. Respondent Profile	
1.1 Please indicate the type of organisation on behalf of which you are responding to this consultation:	Academic/public health and healthcare specialised institution/organisation (e.g. Institutes and University Departments of Public Health, Quality, Healthcare, Clinical Excellence)
Please indicate level:	European Union umbrella organisation
Please indicate Member States representation:	Pan European
Please indicate for what the administration is responsible:	
1.1.1. Other (please specify):	Enpr-EMA is an European-wide network of research networks, investigators and centres with recognised expertise in performing clinical trials in the paediatric population. Enpr-EMA members perform research in children (from newborns to adolescents)in multiple therapeutic areas. Enpr-EMA's main objectives are to foster high-quality, ethical research on the quality, safety and efficacy of medicines for use in children; to enable collaboration between networks.
1.2 Please indicate the name of your organisation or centre:	European network pf paediatric research at the European Medicines Agency (Enpr-EMA)

1.3 Please indicate the country where your organsation/centre is located/has its headquarters or main representative office in Europe:	UK
1.4 Please indicate the number of EU Member States and EEA countries (Norway, Iceland, Lichtenstein) and accessing country (Croatia) in which your organisation conducts business/is represented:	29
1.5 If need be, can we contact you by e-mail to obtain further information on your submission?	Yes
1.5.1 Please provide an e-mail address where we can contact you:	enprema@ema.europa.eu
1.6 Please provide us with a contact person (incl jobtitle and daytime phone number):	Dr.Irmgard Eichler, Scientific administrator Co-chair Enpr-EMA +44(0)2075237338
1.7 Please provide additional contact details if needed:	European Medicines Agency, 7 Westferry Circus, Canary Wharf, London E144HB

2. Involvement of your organisation in the matter of centres of excellence/reference (COE) and healthcare networks in highly specialised healthcare (HSHC).

2.1 How would you describe your organisation's knowledge of CoE and HSHC?	Very high
2.1.1 Space for further comments:	EnprEMA provides access to high quality networks across Europe experienced and capable of delivering clinical trials in children of all ages; to paed. expert opinion on trial designs and feasibility
2.2. What aspects or domains related to the topic of CoE and HSHC would correspond to your organisation's key knowledge? (cross any that applies)	Highly specialised healthcare provision Ethical analysis Professional performance, clinical practice, quality and safety of specialized healthcare

2.2.1. Space for further comments:	Enpr-EMA also provides access to experienced clinical trialists, to young people for public engagement, to young person advisor groups able to contribute to ethically acceptable trial protocols.
2.3 Is highly specialised healthcare a priority in your organisation's strategies and work plans?	Very high
2.3.1 Space for further comments:	Enpr-EMA includes highly specialised networks with proven expertise in rare childhood diseases and orphan products. http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/12/WC500100152.pdf
2.4. What specific field of healthcare services/specialities are most relevant for your centre/organisation's field of work?	Medical/Surgical speciality
Please specify:	expertise relevant to clinical trials in children
2.5. Has your organisation/centre been directly involved in the design or assessment of professional standards and criteria related with highly specialised healthcare?	Frequently
2.5.1 Please describe your role in such actions/projects:	Enpr-EMA members must fulfil demanding recognition criteria: research experience; network organisation; scientific competence; quality management; training and educational capacity; public involvement
2.6. Has your organisation been involved in projects/activities supported by the Commission in relation with HSHC or professional and technical criteria/standards in highly specialised healthcare?	No

2.7. Do you have concrete examples based on your own organisation's experience or could you provide us with references or links to documents related with professional criteria and standards in highly specialised healthcare/CoE or HSHC (e.g. quality criteria, guidelines, consensus documents)?	Yes
2.7.1 Space for further comments:	Recognition criteria published at http://www.ema.europa.eu/docs/en_GB/document_library/Template_or_form/2010/02/WC500073674.doc; and in Arch Dis Child 2012;97:3 185-188
2.13. What is the scope of the network?	
2.14. Which kind of network?	
2.14.1 Space for further comments:	
2.15. Would you be interested in applying to the process to be considered Centre of Excellence of the future European Reference Network? (1 = not interested at all, 5 = very interested)	
2.15.1 Space for further comments:	

3. Proposed criteria for ERN (scope, general and specific criteria)

3.1 Criteria related with diseases or conditions in order to be considered under the scope of the ERN	
3.1.1. Need of highly specialised healthcare	5
3.1.1.1. Complexity of the diagnosis and treatment	3
3.1.1.2. High cost of treatment and resources	3
3.1.1.3. Need of advanced/highly specialised medical equipment or infrastructures	3

3.1.2. Need of particular concentration of expertise and resources	5
3.1.2.1. Rare expertise/need of concentration of cases	5
3.1.2.2. Low prevalence/incidence/number of cases	5
3.1.2.3. Evaluated experiences of Member States	5
3.1.3. Based on high-quality, accessible and cost-effective healthcare	5
3.1.3.1. Evidence of the safety and favourable risk-benefit analysis	5
3.1.3.2. Feasibility and evidence of the value and potential positive outcome (clinical)	5
3.1.4. Do you recommend any additional criteria or option that would effectively address the issue?	Yes
3.1.4.1 Explain your proposal in free text:	Medicines frequently used off label/unlicensed in children; promoting clinical trials to enhance evidence of safe/effective therapies to be encouraged with adequate support for required infrastructure
3.1.5. Would you prioritise or suggest any concrete disesase or group of diseases to be addressed by the future ERN according to the above criteria?	Yes
3.1.5.1 Explain your proposal in free text:	In view of dearth of information on medicines effectiveness and safety in children and in conformity with Paed. Regulation 1901/2006 support for paed. clinical trial networks

3.2. General criteria of the centres wishing to join a European Reference Network	
3.2.1. Organisation and management	5
3.2.2. Patients empowerment and centered care	5
3.2.3. Patient care, clinical tools and health technology assessment	5
3.2.4. Quality, patient safety and evaluation framework policies	5
3.2.5. Business continuity, contingency planning and response capacity	4
3.2.6. Information systems, technology and e-health tools and applications	4
3.2.7. Overall framework and capacity for research and training	5
3.2.8. Specific commitment of the management/direction of the centre/hospital to ensure a full and active participation in the ERN	5
3.2.9. Do you recommend any additional option that would effectively address the issue?	Yes
3.2.9.1. Space for further comments:	to demonstrate effectiveness and expertise such as required by Enpr-EMA recognition criteria http://www.ema.europa.eu/docs/en_GB/document_library/Template_or_form/2010/02/WC500073674.doc

3.3. Specific criteria regarding the areas of expertise	
3.3.1. Competence, experience and good outcomes and care	5
3.3.2. Specific resources and organisation:	4
3.3.2.1. Human resources	5
3.3.2.2. Team/centre organisation	5
3.3.2.3. Structural conditions	4
3.3.2.4. Specific equipment	4
3.3.2.5. Presence and coordination with other required complementary units or services	5
3.3.3. Patient care pathways, protocols and clinical guidelines in the field of expertise	5
3.3.4. External coordination, care management and follow-up of patients	5
3.3.5. Research, training, health technology assessment in the field of expertise	5
3.3.6. Specific information systems	4
3.3.7. Do you recommend any additional criteria or option that would effectively address the issue?	Yes

3.3.7.1. Space for further comments:	Evidence of training and updating GCP should be provided. Units centres and networks should be involved in research and trials if they aspire to clinical excellence and leadership.