



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# European Network of Paediatric Research at the European Medicines Agency (EnprEMA)

Recognition Criteria for self-assessment:  
Additional Comments

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2<sup>nd</sup> Workshop on European Paediatric Network  
European Medicines Agency  
16<sup>th</sup> March 2010



## 1. Introduction

### European Paediatric Research Network

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- Evidence for each criterion:
  - **Criterion 1: Research experience and ability.**
  - **Criterion 2: Network organisation and processes.**
  - **Criterion 3: Scientific competences and capacity to provide expert advice.**
  - **Criterion 4: Quality management.**
  - **Criterion 5: Training and educational capacity to build competences.**
  - **Criterion 6: Public involvement.**
- Each criterion is composed of several parts with key information asked.
- During public consultation new additional comments have been received.

## 2. Additional Comments

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- The questionnaire is extremely detailed and it will be very time consuming to provide answers to all points. *(This may be an obstacle for some researchers!)*
- Need to identify the minimum criteria for recognition *(No guidance on the current form, if a Network does not meet all or some of the criteria is it excluded from EnprEMA?)*.
- Need to Identify criteria that would be essential *(e.g. adherence to GCP)* versus desirable. *(Some criteria may not come under the remit of a Network and may be better placed with CRO's and data monitoring committees e.g. providing an audit function).*
- The proposed self assessment criteria include an extensive list relating to organisation, processes and outputs. How these are to be assessed and how recommendations for recognition are to be made?.

## 2. Additional Comments

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- Provision of a Newsletter or a database of studies available to the public would require staff to support these roles (*problem for some of the smaller disease specific or national network*) and may be less relevant when communication links are very well established.
- Include a statement clarifying that this list might change as time goes on and new criteria might emerge.
- For some criteria newly established consortia might be excluded (e.g. joint publications in the last five years, past ongoing studies). Is this intentional or a mistake? *For example if a new multi-centre consortium from several EU countries will obtain EU funding for studying new or off label medicines, will this consortium only be able to join after five years or once they have established a “history”?*

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- Some information should be **further documented** on paediatric networks to be part of the European network:
  - *when the site was last inspected, by whom, and what were the critical findings.*
  - *information on whether a site is interested in doing industry sponsored studies.*
  - *age ranges proposed under the table “Description” may not be appropriate to characterize all potential candidates for the network. Define an alternative age range.*
  - *possible to state, for information, whether adult patients are also covered by the network / centre / investigator.*
  - *possible to state whether the network extends beyond Europe.*
  - *information should be documented to differentiate between a network of academic sites or independent investigators from that of a contract research organization.*

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- To clarify how the documentation on adherence to ethical considerations is done.
- Different types of Networks will take part in EnprEMA. A careful approach to manage interaction among Networks should be encouraged.
- In order to favour paediatric research, flexibility in criteria for Network inclusion should be taken into account. (*Networks specifically focused on methodological aspects or ethical issues could indirectly contribute to the amelioration of paediatric research*).

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- Not only Networks performing clinical or non clinical trials are included in EnprEMA. It is important to have the opportunity to include in the list of performed studies other kind of studies not always identified by a registration number. *These types of studies (i.e. non interventional studies, such as pharmacovigilance, post marketing studies, which are crucial in the paediatric population), could be assigned with a rank in order to better categorize the role of the Network within EnprEMA.*
- Enlarge the information requested about ongoing non interventional studies to be in line with information requested for interventional trials. *(Request for the following information: 1) number of patients enrolled; 2) total number of collaborating centres; 3) number of paediatric conditions covered).*

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- Several participants filled the recognition criteria questionnaire with no apparent problems.
- In addition, positive/encouraging feed back was also received:
  - *The Recognition Criteria is a good tool for recognition of active networks.*
  - *The list as it stands now is a good starting point in order to get research networks and consortia registered and getting some projects off the ground.*
  - *Could not find anything important that needs to be changed.*
  - *This proposal is comprehensive and well established.*

**Thank you for your attention!**

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