Recognition criteria and quality standards for members of the European Paediatric Research Network. Final results of the Delphi surveys

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Background

- **EMEA strategy January 2008**
- **Report February 2009**
- **Working group 2 members**
  - Nicola Ruperto - PRINTO
  - Giles Vassal - ECITCC
  - Mike Sharland - PENTA
  - Monika Seibert-Graf - German PaedNet
  - Lars Hjorth - Pan-ENCS
  - Adolf Valls-I-Soler - ENN

  - Irmgard Eichler - EMEA
  - Ralf Herold - EMEA
  - Agnes Saint Raymond - EMEA
  - Merja Heikkurinen - EMEA
Goal working group 2

- To elaborate and agree on recognition criteria and quality standards for self-assessment in the following areas
  - Capacity
    - to involve patients (for study design and for recruitment)
    - to manage trial and to perform trials according to GCP
    - to build up competence and to involve further centres
    - to innovate in trials (methodology, state-of-the art techniques, e.g., microassays)
  - Expertise in the therapeutic area
  - Established quality assurance systems of the network
  - Potential conflicts of interest
  - Ability and content to share in relation to competencies and experience
Methods: consensus techniques

- creative decision making facilitated by decision techniques in which a group’s members must pool their judgments to invent or discover a satisfactory course of action...


Consensus techniques

- **Delphi Technique** utilizes a series of well-defined mail questionnaires (each based on the results of the previous step)

- **Nominal group Technique** is a structured face-to-face meeting designed to facilitate reaching consensus, through round robin discussion
Flow chart of the overall project

Delphi I:
Free indication of recognition criteria

Delphi II:
Ranking of categories and items selection

EMEA NGT Consensus meeting:
Consensus on recognition criteria

Fine tuning of the recognition criteria
Delphi survey 1

Please list the recognition criteria (as many as you like) that you think should be used for identifying members of the European Paediatric Research Network. Suggestions can be explained.

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Update your contact details

See Delphi I
Delphi survey 1: results

- 30 surveys over 62 networks (48%)
- 335 lines of reply grouped into
  - 8 categories and 69 items
Delphi survey 1: categories

Numbers of repliers (over a total of 30) that indicated the category as important. The bars are proportional to percentages.
Please **rank** the 8 categories listed below in **alphabetical** order, assigning 8 to the most important and 1 to the least important.

Within each of the 8 categories you are required to **select the items** you deem essential to define the category (from a minimum of 1 to n items).

**Only criteria that can be quantified**, either **qualitatively** (e.g. yes or no or other scales) or **quantitatively** (e.g. numbers) were taken into account. Criteria that cannot be quantified (e.g. verbal description of the network) have not been considered.

**See Delphi II**
Example of Delphi survey 2

<table>
<thead>
<tr>
<th>Rank assigning 8 to the most important category and 1 to the least important (1-8)</th>
<th>ACQUIRED EXPERIENCE AND RESEARCH ABILITY OF THE NETWORK (REFER TO THE LAST 5 YEARS)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Items</td>
</tr>
<tr>
<td></td>
<td>Year of network foundation</td>
</tr>
<tr>
<td></td>
<td>Industry sponsored trials:</td>
</tr>
<tr>
<td></td>
<td>Number of paediatric conditions (e.g. diseases) covered by paediatric trials</td>
</tr>
<tr>
<td></td>
<td>Number of trials supervised or co-ordinated</td>
</tr>
</tbody>
</table>
Results of the II Delphi survey

- 41/62 (66%) network’s replies (+37% replies)
- 4 refused to participate
- 17 did not reply

- Several email reminders and phones calls
Categories: sum of the ranks

41 is the minimum possible sum of ranks for a category (every replier ranks it at the last place, there are 41 respondent)

328 is maximum possible sum of ranks for a category (every respondent ranks it at the first place)
Categories: means of the ranks

C1: ACQUIRED EXPERIENCE AND RESEARCH ABILITY OF THE NETWORK (REFER TO THE LAST 5 YEARS) 6.0
C2: EFFICIENCY 5.3
C3: AREA OF INFLUENCE AND SIZE OF THE NETWORK 5.1
C4: CAPACITY TO PROVIDE EXPERT ADVICE ON CLINICAL TRIAL PROTOCOLS 5.0
C5: QUALITY MANAGEMENT SYSTEM AT THE DEVELOPMENT LEVEL. EVIDENCE OF A QUALITY ASSURANCE PROGRAMME 4.5
C6: SCIENTIFIC COMPETENCES 4.0
C7: TRAINING AND EDUCATIONAL CAPACITY TO BUILD COMPETENCES 3.7
C8: FORMAL CONNECTIONS TO PAEDIATRIC PARENTS’ ORGANISATIONS 2.5
## Categories: individual ranks

<table>
<thead>
<tr>
<th>Categories</th>
<th>Number of repliers that attribute to the category the score of:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 (last place) 2 3 4 5 6 7 8 (first place)</td>
</tr>
<tr>
<td><strong>C1: ACQUIRED EXPERIENCE AND RESEARCH ABILITY OF THE NETWORK</strong></td>
<td>1 2 4 4 3 5 7 15</td>
</tr>
<tr>
<td><strong>C2: EFFICIENCY</strong></td>
<td>0 3 3 5 14 6 2 8</td>
</tr>
<tr>
<td><strong>C3: AREA OF INFLUENCE AND SIZE OF THE NETWORK</strong></td>
<td>7 2 2 2 6 7 8 7</td>
</tr>
<tr>
<td><strong>C4: CAPACITY TO PROVIDE EXPERT ADVICE ON CLINICAL TRIAL PROTOCOLS</strong></td>
<td>4 3 4 6 3 7 12 2</td>
</tr>
<tr>
<td><strong>C5: QUALITY MANAGEMENT SYSTEM AT THE DEVELOPMENT LEVEL. EVIDENCE OF A QUALITY ASSURANCE PROGRAMME</strong></td>
<td>3 6 7 5 6 5 5 4</td>
</tr>
<tr>
<td><strong>C6: SCIENTIFIC COMPETENCES</strong></td>
<td>6 8 4 7 6 4 2 4</td>
</tr>
<tr>
<td><strong>C7: TRAINING AND EDUCATIONAL CAPACITY TO BUILD COMPETENCES</strong></td>
<td>3 8 11 8 2 6 2 1</td>
</tr>
<tr>
<td><strong>C8: FORMAL CONNECTIONS TO PAEDIATRIC PARENTS’ ORGANISATIONS</strong></td>
<td>17 9 6 4 1 1 3 0</td>
</tr>
</tbody>
</table>
CAT 1: ACQUIRED EXPERIENCE AND RESEARCH ABILITY OF THE NETWORK (REFER TO THE LAST 5 YEARS)

Academic (investigator’s) initiated studies (e.g. studies conducted independently from pharmaceutical companies)

- Number of trials supervised or co-ordinated: 82.93%
- Number of ongoing trials (phase I to IV): 73.17%
- Number of paediatric conditions covered by paediatric trials: 65.85%
- Number of other ongoing research program: 63.41%
- Number of patients registered per year: 51.22%
- Number of paediatric patients eligible per year: 48.78%
- Public funding capabilities (%): 36.59%
EMA CONSENSUS MEETING

London December 3, 2009

Participants:
- Klaus Hartmann
- Lars Hjorth
- Pirkko Lepola
- Christina Peters
- Vanessa Poustie
- Monika Seibert-Grafe
- Hannah Dijkhuis Ruedisueli (replacing Alfarez)
- Adolfo Valls-i-Soler
- Gilles Vassal
- William Van't Hoff
- Irmgard Eichler
- Ralf Herold
- Agnès Saint Raymond
NGT questions

1. How many categories in the final list?
2. How many items within each category?
3. Do we need a core of categories/items to apply to the net of nets?
4. Should we regroup the order of categories/items?
5. Publication plan?
6. Other questions?
NGT: Description of the process

1) Silent evaluation of results (5 minutes)

2) Recording of responses by NGT moderator (consensus reached if agreement ≥ 80%) (2 minutes)

3) Round robin discussion of items for which consensus is NOT achieved (<80%), second evaluation and second vote (5-10 minutes)
Results of the consensus meeting

<table>
<thead>
<tr>
<th>FINAL %</th>
<th>Categories/items POST</th>
</tr>
</thead>
<tbody>
<tr>
<td>90,9</td>
<td>C1: ACQUIRED EXPERIENCE AND RESEARCH ABILITY OF THE NETWORK (REFER TO THE LAST 5 YEARS)</td>
</tr>
<tr>
<td>100,0</td>
<td>C2: EFFICIENCY</td>
</tr>
<tr>
<td>81,8</td>
<td>C3: AREA, SCOPE AND SIZE</td>
</tr>
<tr>
<td>100,0</td>
<td>C4: CAPACITY TO PROVIDE EXPERT ADVICE ON CLINICAL TRIAL PROTOCOLS</td>
</tr>
<tr>
<td>100,0</td>
<td>C5: QUALITY MANAGEMENT</td>
</tr>
<tr>
<td>90,9</td>
<td>C6: SCIENTIFIC COMPETENCES</td>
</tr>
<tr>
<td>100,0</td>
<td>C7: TRAINING AND EDUCATIONAL CAPACITY TO BUILD COMPETENCES</td>
</tr>
<tr>
<td>81,8</td>
<td>C8: EVIDENCE OF INVOLVEMENT OF PARENTS’ ORGANISATIONS</td>
</tr>
</tbody>
</table>
Fine tuning post consensus

- Preparation of the glossary
- Layout formatting
- Testing
- Version 29/1/2010
- European Network of Paediatric Research at the European Medicines Agency (ENPREMA)
ENPREMA survey content

- Network identification and description
- Criteria
  - 1: Research experience and ability
  - 2: Efficiency requirements
  - 3: Scientific competencies and capacity to provide expert advice
  - 4: Quality management
  - 5: Training and educational capacity to build competences
  - 6: Public involvement
Future plans

- Publication
- Final survey data collection