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-Grafe - 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…**

◆ AL Delbecq, AH van De Ven, DH Gustafson: *Group Technique for Program Planning. A guide to nominal group technique and Delphi process.* Glenview, Illinois. Scott, Foresman and Company, 1975

◆ Ruperto et al for PRINTO. Consensus procedures and their role in paediatric rheumatology. Current Rheumatology Reports 2008, 10:142-146.
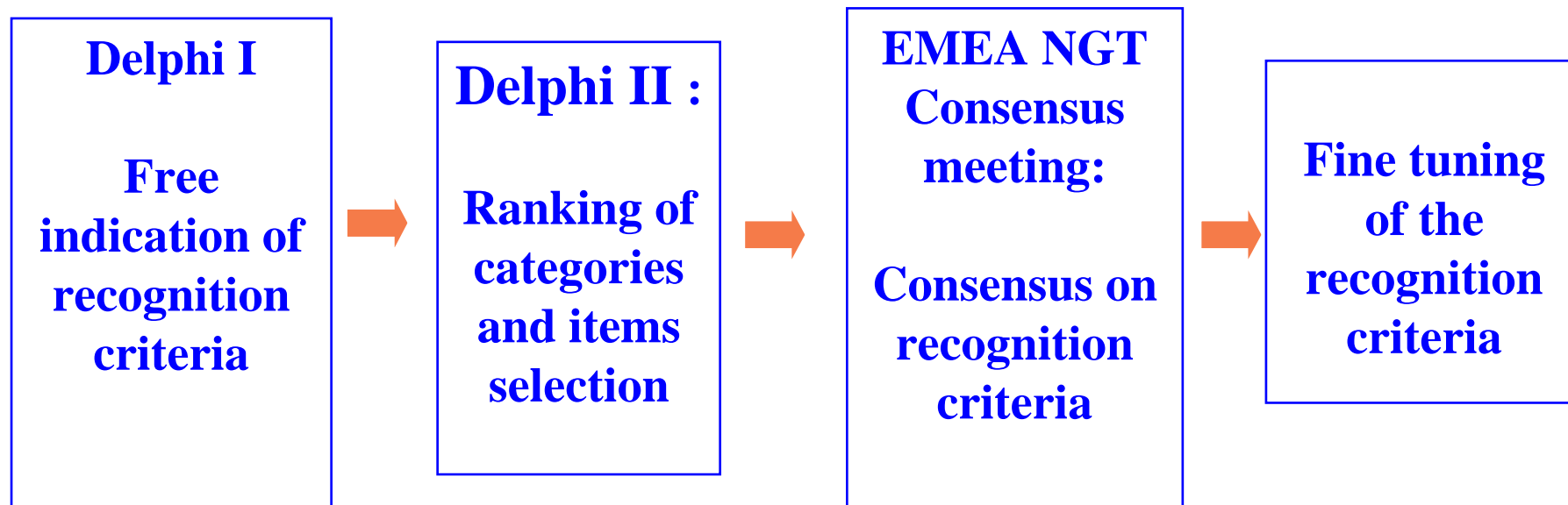
Consensus techniques

◆ **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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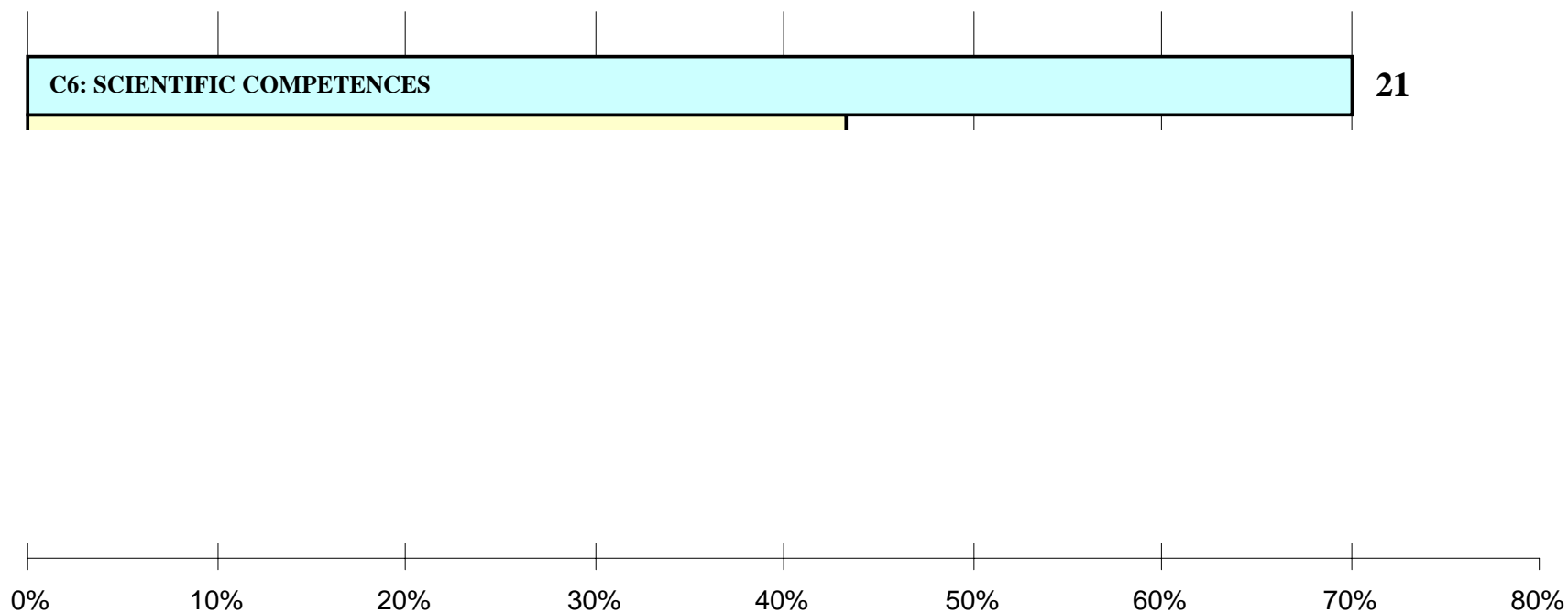**Update your contact details**

See Delphi I

Delphi survey 1: results

◆ 30 surveys over <u>62 networks</u> (48%)

◆ 335 lines of reply grouped into

– 8 categories and 69 items

Delphi survey 1: categories

C6: SCIENTIFIC COMPETENCES — 21

0% 10% 20% 30% 40% 50% 60% 70% 80%

Numbers of repliers (over a total of 30) that indicated the category as important.
The bars are proportional to percentages.

Delphi survey 2

- 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

| Rank assigning 8 to the most important category and 1 to the least important (1-8) ☐	ACQUIRED EXPERIENCE AND RESEARCH ABILITY OF THE NETWORK (REFER TO THE LAST 5 YEARS)	
	Items	Please select the essential items (from a minimum of 1 to n items)
	Year of network foundation	☐
	Industry sponsored trials:	
	Number of paediatric conditions (e.g. diseases) covered by paediatric trials	☐
	Number of trials supervised or co-ordinated	☐

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

C1: ACQUIRED EXPERIENCE AND RESEARCH ABILITY OF THE NETWORK (REFER TO THE LAST 5 YEARS) **247**

Percentages of the maximum achievable sum of ranks

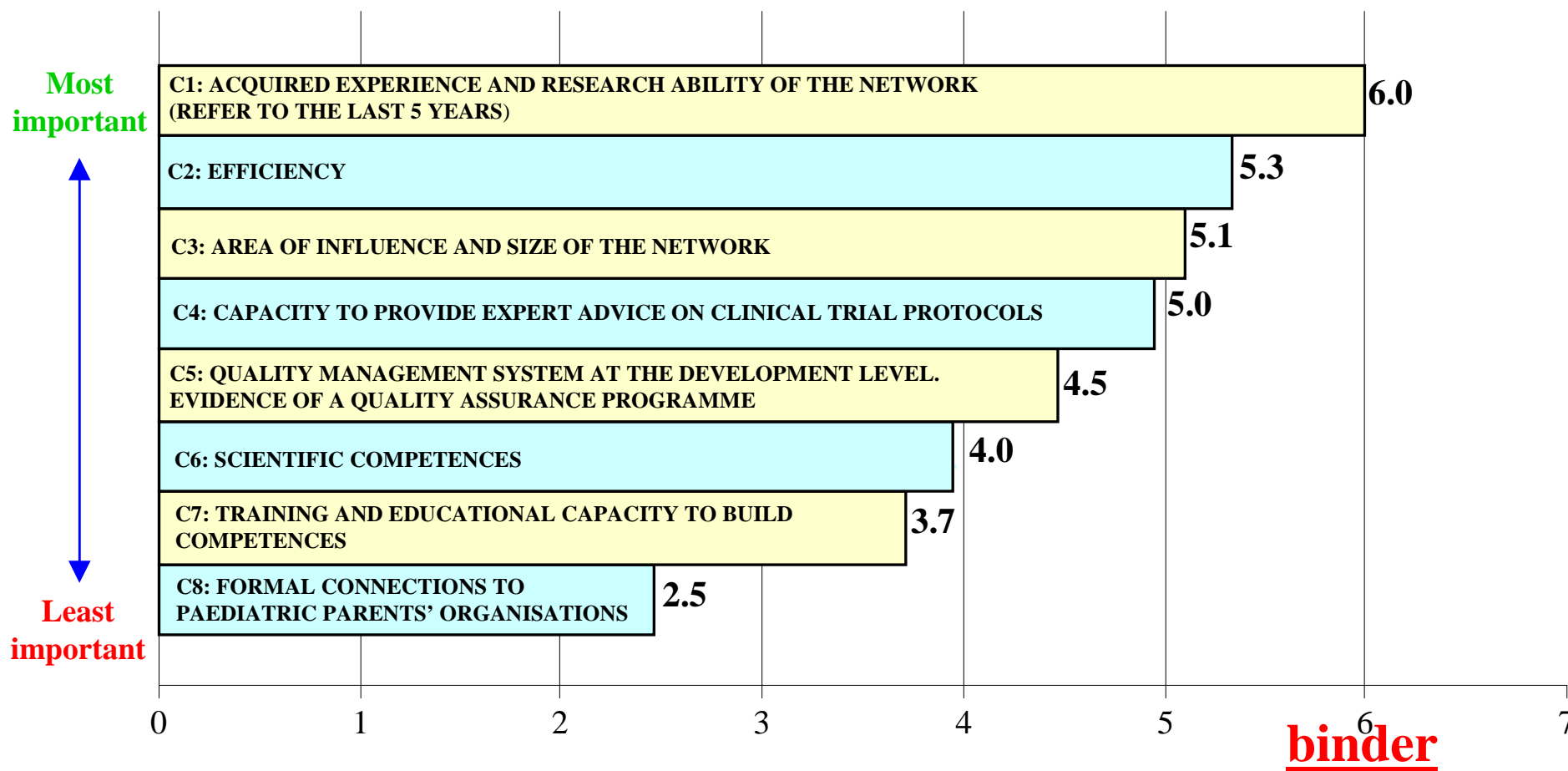0   10   20   30   40   50   60   70   80 %
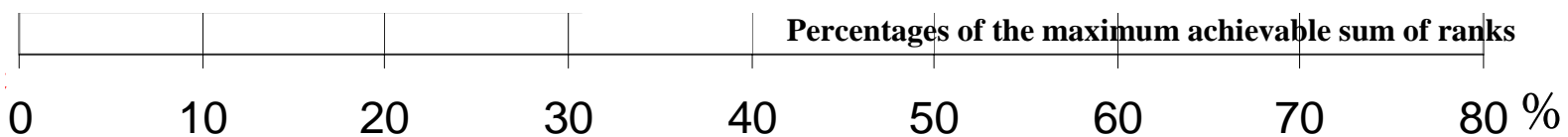
41 is the minimum possible sum of ranks for a category (every replier ranks it at the last place, there are 41 respondent)

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

Categories: means of the ranks

Most important

Category	Value
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

Least important

0   1   2   3   4   5   6   7

binder

Categories: individual ranks

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

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)

Category	%
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

0 10 20 30 40 50 60 70 80 90 %

binder

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

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

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

◆ <u>Criteria</u>

– 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