



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EnprEMA Recognition Criteria

Minimum <quality> requirements

EnprEMA – Workshop of the European Network of Paediatric Research at the European Medicines Agency



Criteria background – EnprEMA

- Networks should be ,recognised' by quality of paediatric research
- (Minimum) level of QUALITY should be defined
- By design, may be different between organisations
- How to measure quality? (reference systems)
- Intention to be inclusive for new organisations

Recognition criteria – overview

- Refinement process
- Piloting and commenting
- Domains (# of items)
 - Research experience and ability (13)
 - Network organisation and processes (10)
 - Scientific competencies and expert capacity (7)
 - Quality management (7)
 - Training and educational capacity to build (5)
 - Public involvement (3)

Suggested approaches

- In each domain at least n item(s), or specific?
- Networks in construction:
 - Define individually n years for setting up
 - Increase by x/n over the years
- Intra-organisational progress tracking
- Criteria review frequency (and publication)?

Proposed Minimum Criteria (for CT network) 1/2

- At least 1 ongoing/completed trial
- Identified contact person
- External or internal Advisory Board
- Patient database / log
- Individual data protection, data security
- Access to experts/expert groups
- Capacity to answer scientific questions

Proposed Minimum Criteria (for CT network) 2/2

- **Compliance with GCP**
- **Compliance with Ethical Considerations**
- Monitoring Capacity (internal or external)
- Quality control
- Awareness of regulatory requirements on medicines development
- Training received/given
- Involvement of patients in design, or information, or priorities (at least 1)



Conclusion

- Need for different criteria for networks that are not performing trials (e.g. Priomed, Teddy, EUPFI)
- Other (better?) ways of capturing 'quality' of research?
- Testing the system with existing networks