

Working Group 3:

**How to establish communication
between Enpr-EMA networks and
industry**

Working Group 5:

**Sharing Good Practice within Enpr-EMA
and with Industry Partners**

Susan Tansey

Chair WG 3 and WG 5

Enpr-EMA WGs 3 and 5

Role:

Develop recommendations for how Enpr-EMA can:

- facilitate communication between industry and networks including
 - provide industry with easy access about individual Enpr-EMA networks
 - make contact with a range of industry partners
- Gather examples of good practice from both Networks and industry colleagues working with Enpr-EMA networks
- Develop proposals to disseminate examples of good practice to Enpr-EMA members and industry partners.

Enpr-EMA WG 3 and WG 5

Industry members:

Ron Portman

Charles A Thompson

Matthew McClure

Martine Dehlinger-Kremer

Klaus Hartmann

Lynda Wight

Network members:

Susan Tansey (Acting Chair)

Pirkko Lepola (Steering group)

Jenny Preston (Steering group)

Pamela Dicks (Steering group)

Nicola Ruperto

Andy Pearson

Christina Peters

Richard Trompeter

Enpr-EMA WGs 3 and 5

Key Tasks, Timeframes and Outputs (1)

Progress so far

Draft questions for a survey monkey style questionnaire to collect good practice examples from both network members and Industry colleagues. Actual date: 9th December 2013

Finalise survey monkey questionnaire and distribute.

Actual date: 18th December 2013

Deadline for responses.

Actual date: 13th January 2014

Extended date: 14th February 2014

Send draft report of survey monkey to Enpr-EMA and WGs.

Actual date: ? June 2014

Enpr-EMA WGs 3 and 5

Key Tasks, Timeframes and Outputs (2)

Next steps

To incorporate comments from EnprEMA and the WGs 3 and 5 and finalise the report for wider dissemination

Planned date: August 2014

Develop a dissemination strategy to distribute and share good practice. Some ideas would include distributing via newsletters, EnprEMA website, Meeting Presentations, Webinars.

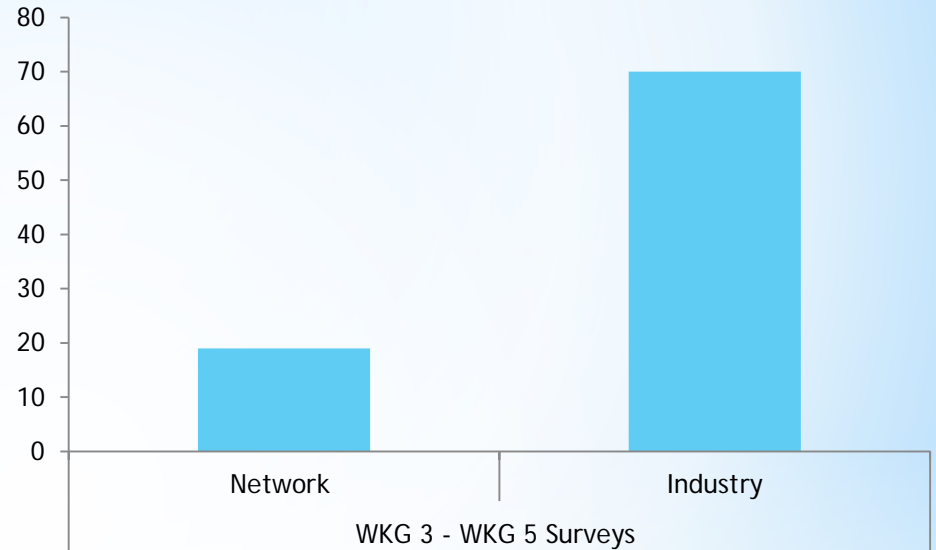
Planned date: August 2014

Initial results of Industry and Network surveys

Responses received: Total 89

Network responses 19

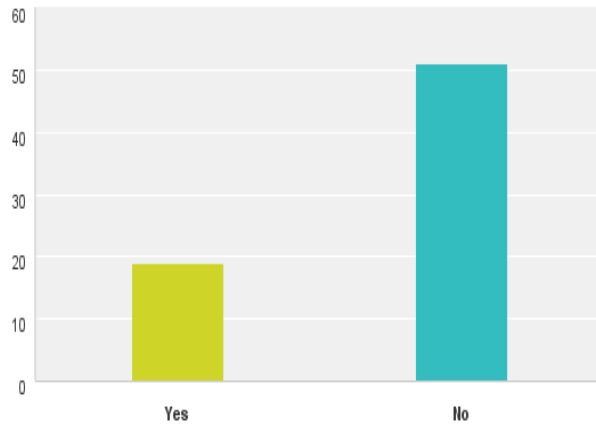
Industry responses 70



Results of Industry survey

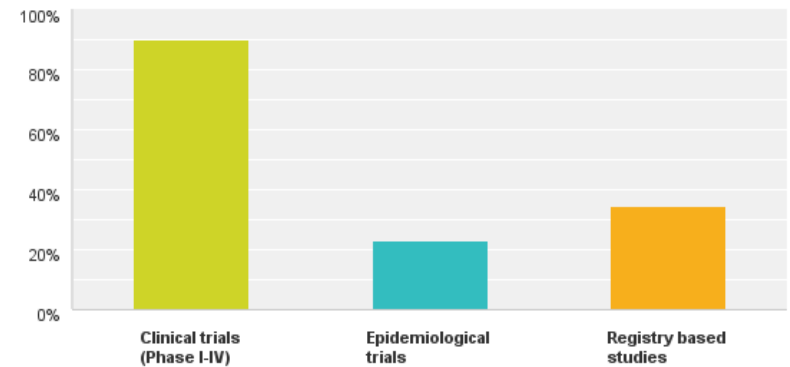
Does your company have a paediatric council/committee?

Answered: 70 Skipped: 0



Does your company have experience of trials in children?

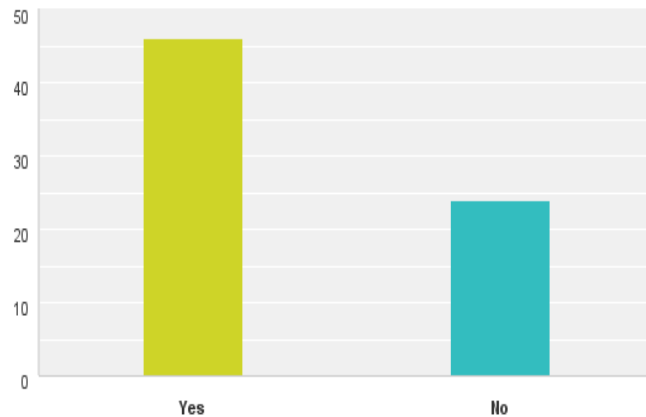
Answered: 70 Skipped: 0



Results of Industry survey

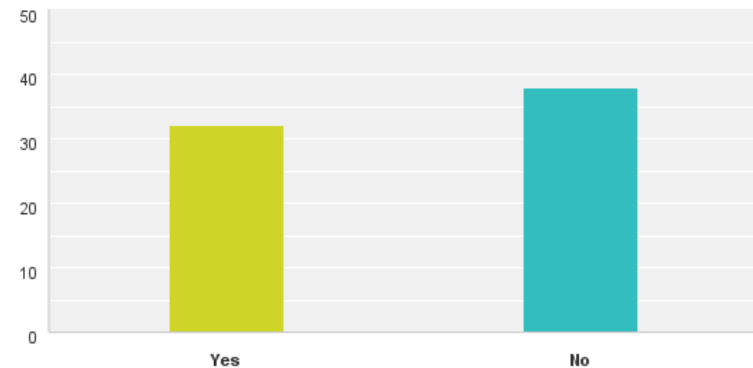
**Are you aware of the European Network
Paediatric Research Networks within the
EMA (Enpr-EMA)?**

Answered: 70 Skipped: 0

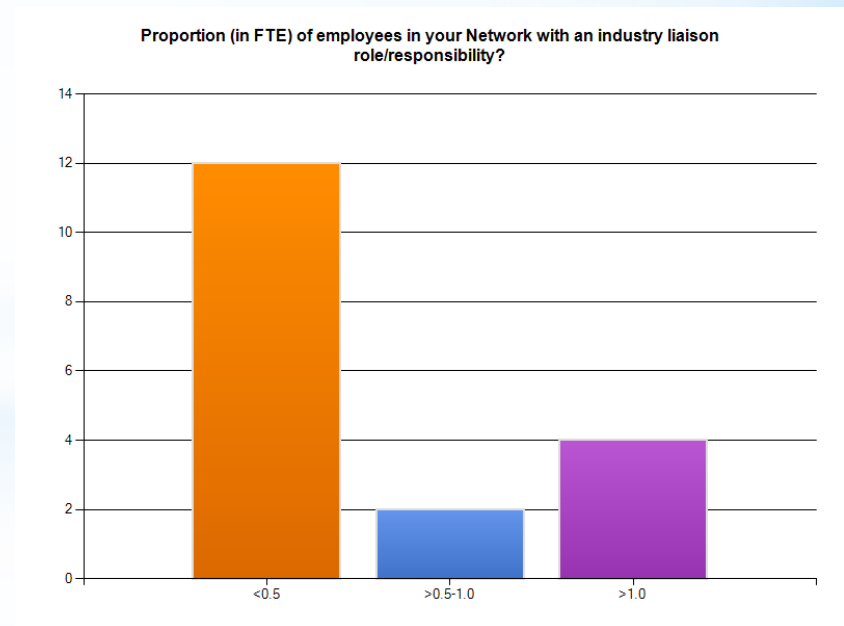
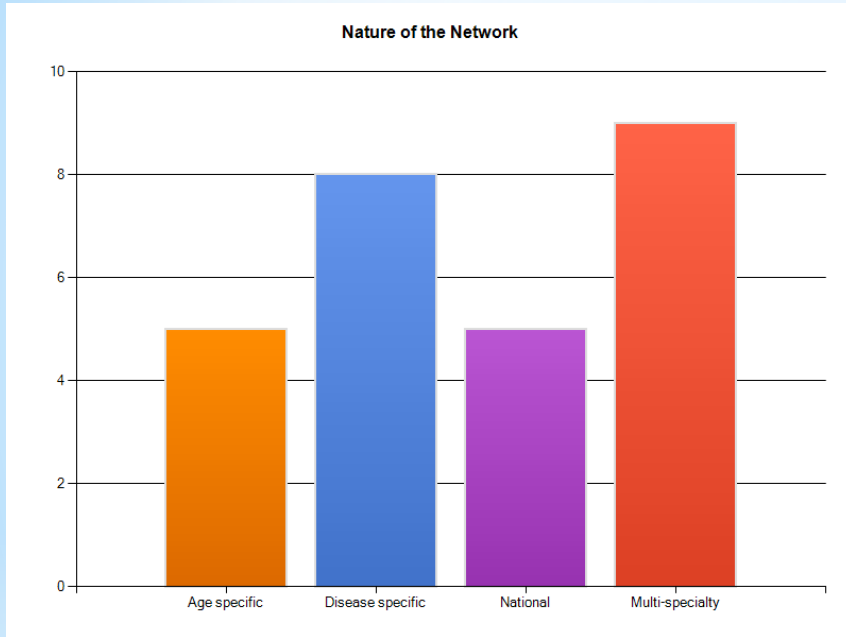


**Have you, or your company worked with
a research network (Enpr-EMA) or other
network in the development and/or
implementation of clinical trials with
children?**

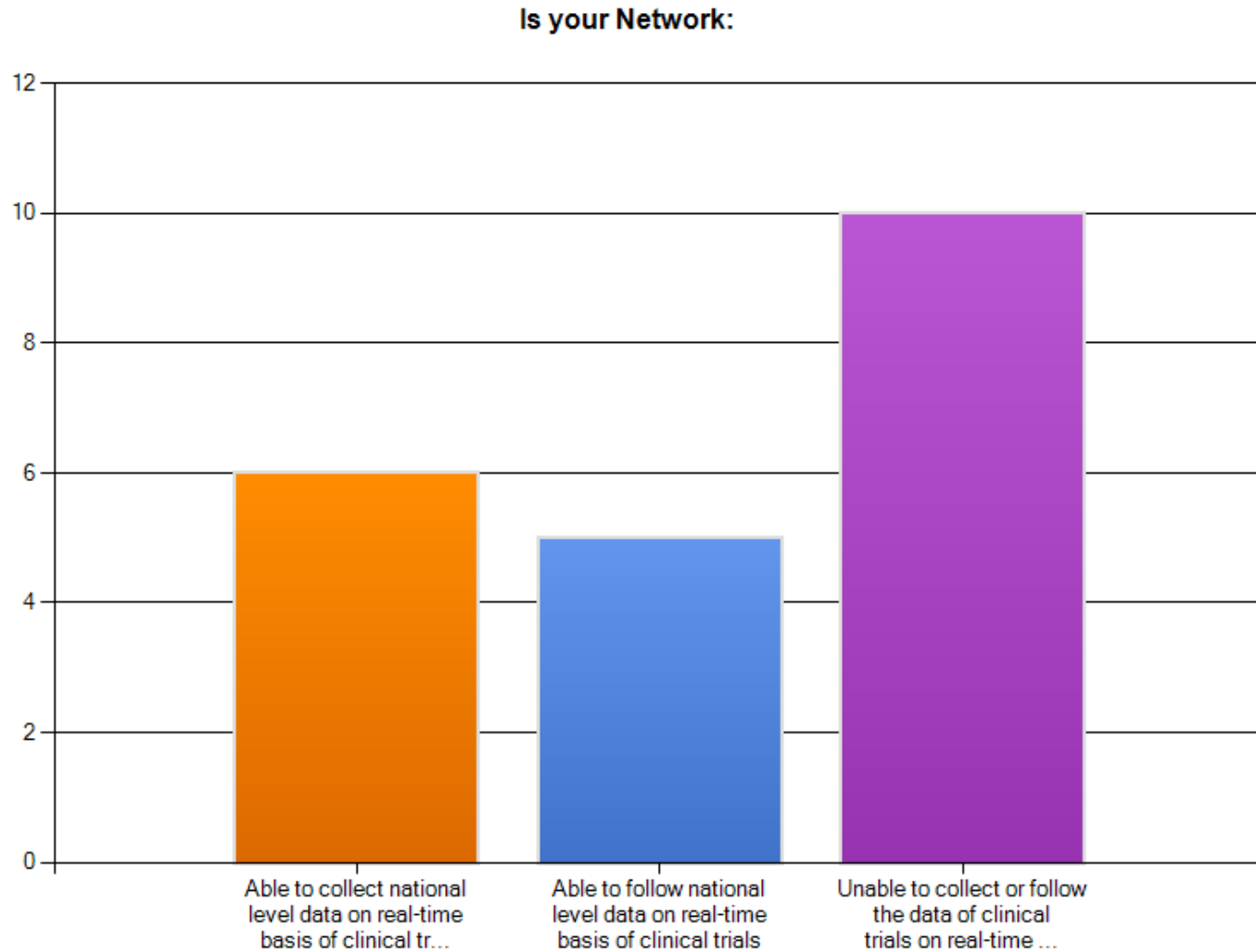
Answered: 70 Skipped: 0



Results of Network survey

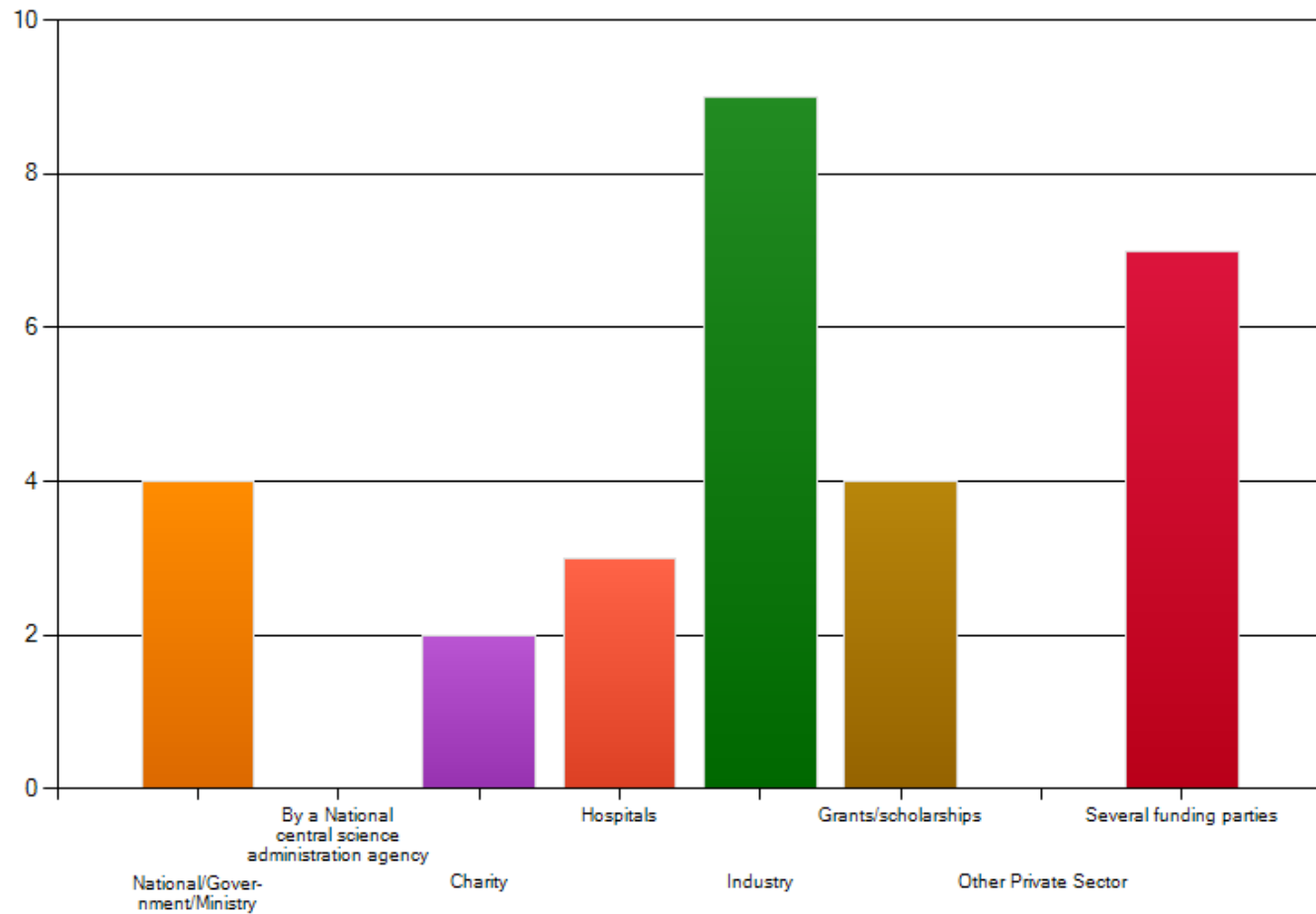


Initial results of Network survey



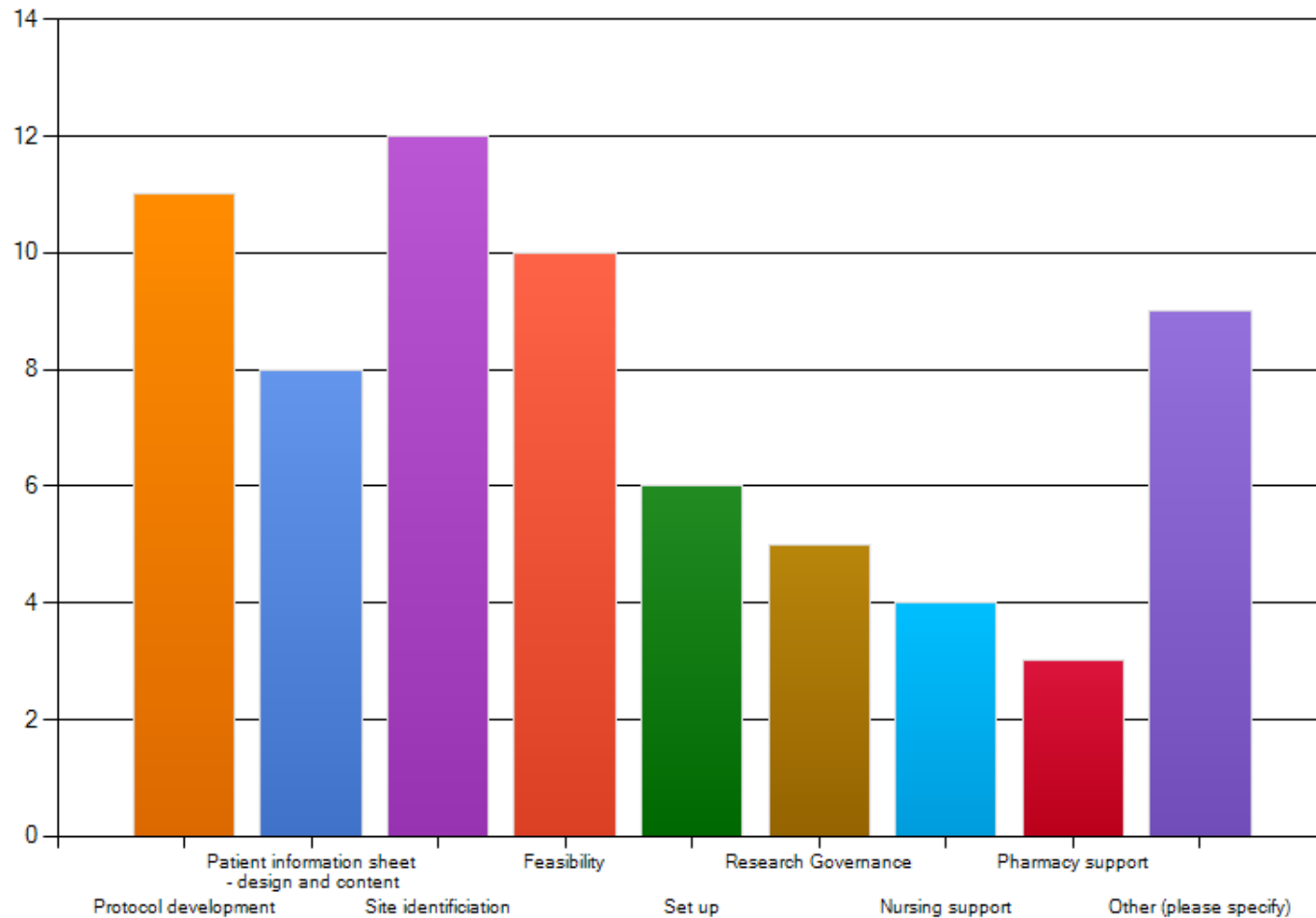
Results of Network survey

How is your network financed?



Results of Network survey

What services do your network provide to industry?



Industry survey- Benefits of Networks

- Assistance with protocol design and PIPs
- Rapid feasibility/site selection
- Links with families and children
- Review of patient information/documents
- Access to key opinion leaders/scientific advice
- Assistance with approvals and training

Network survey- Benefits of Working with Industry

- Industry considers proposals made by the Networks (including patients and families) resulting in more feasible protocols
- Access to new medicinal products
- Well resourced studies/financial aspects
- Staff gain experience in different types of studies
- Advice/input from Industry experts

Industry survey- Challenges when working with Networks

- Timelines are prolonged
- Differing priorities :scientific interest vs commercial
- Contracts can be difficult to negotiate e.g not centralized process
- Resources may be limited
- Global links may be difficult to establish

Network survey- Challenges of Working with Industry

- Not involved early enough in protocol development or PIPs
- Protocols with unrealistic schedules/ expectations of participants and parents
- CROs- can cause confusion and complexity when decisions are required or problems arise
- Unrealistic timelines for feasibility
- Lack of communication e.g feedback to sites not selected
- Lack of paediatric input - knowledge of working with families and children

Solutions !

- Guidelines for new Networks setting up
 - The Ideal network!
- Database of Networks - now set-up on EMA website/Enpr-EMA page
- Improve access to information about the Networks
- CDA's in place- open dialogue - same objectives to recruit to trials on time
- Early involvement of Networks in Clinical Development Programmes

Dissemination strategy

- Detailed (final) report to EnprEMA and WG members
- Post executive summaries on EnprEMA webpage (no details of companies/individuals)
- Contact those who responded to the survey with link to reports
- Utilise results to develop guidelines for new networks and make recommendations to current networks
- Repeat the survey in 12 months