

Enpr-EMA Nurse - Coordinator Working Group



**Enabling
Clinical
Trials for
Children**



What's been achieved up until now?

- Chair **Gareth Veal** (Professor of Cancer Pharmacology -Newcastle University) coordinated the following:
 - Accumulated a list of interested parties/ members across Europe (circa 20-25)
 - Designated roles within that group based on their interests and findings of survey
 - Released a survey to identify key areas/aspects that Nurses see as areas for improvement
 - Findings published BMJ Paediatrics Open 2017 “Investigating the roles and training of paediatric research nurses working across Europe: a questionnaire-based survey”

What's been achieved up until now?

- Survey concluded that:

“Enpr-EMA should look to enhance the design of the European paediatric research nurse core curriculum, together with relevant European Nursing Associations, which could be then adopted across EU countries. Increased collaboration and discussion between key stakeholders will help to harmonise approaches to training and standardise the way that paediatric clinical trials are conducted across Europe, promoting improved ethical and clinical standards and the generation of robust results from clinical trials.”

Plan Moving Forward

1. Transition of Chair from **Gareth Veal** to **Vincent O'Mahony**.

- Vincent O'Mahony:
 - Registered Nurse – Nursing and Midwifery Board Ireland
 - Clinical Research Operations Manager & (Acting) Programme Manager
 - National Children's Research Centre, Ireland.

Plan Moving Forward

2. Implement recommendations from survey:

- **Training - Determine feasibility of:**

- Online training portal – Portal could include orientation templates, various work packages to aid a nurse/coordinators role in Clinical Research e.g Study set-up, initiation, recruitment aids, budgeting, study intensity tools, Emergency Scenario training, how to prepare for a regulatory inspection etc.
- Face-to-face training and workshops
- Annual EU Research Nurse/Coordinator Conference
- Teleconferences or Webinars

Plan Moving Forward

2. Implement recommendations from survey:

- **Standardisation of Role:**

- Determine feasibility of standardised Job Descriptions – A template for individual countries to base their Job descriptions from
- Promote role of Clinical Research Nurse/Coordinators in countries where the role is still being developed
- Speak with Industry to determine their expectation of Nurse/Coordinators at site to aid standardisation across the continent.

Plan Moving Forward

2. Implement recommendations from survey:

- **Peer Support:**

- Implementation of a forum for peer-to-peer communication.
- As previously mentioned can take the form of face-to-face meetings/conferences/workshops/online
- Build relationship and collaborate with **C4C Network**

- **Increase Membership:**

- Spread the word!

Plan Moving Forward

3. Challenges and Opportunities:

- **Funding and Resourcing**

- Determine possible funding streams
- Determine host website
- Determine physical and web space to host meetings/webinars/conferences

- **Role of the EMA as a host to support and encourage growth**

- Ensure Feedback to Enpr-EMA Coordinating Group

- **Identify working group member to drive vision forward**

- Arrange call with current working group members to relay proposed plan going forward

Vincent O'Mahony

vincent.omahony@ncrc.ie



NATIONAL
CHILDREN'S
RESEARCH
CENTRE



Enabling
Clinical
Trials for
Children

