Working Group 6: Educational Training of Research Staff Involved in Paediatric Clinical Trials / GCP Training across multispecialty and countries

May, 2017

Working Group 6 : GCP Training Across Multi-specialties and Countries

Chair: Gareth Veal

Membership: Salma Malik, Mary Costello, Susan Macfarlane, Pirkko Lepola, Adriana Ceci

Objectives: Training of research nurses who conduct clinical trials: models, needs and current gaps across different specialties and countries

Purpose: To review the current requirements, level and consistency of training received by research nurses involved in paediatric clinical trials across different European countries. What does this training involve and how frequently is it provided? To identify potential gaps in training and the purported needs of research nurses currently involved in paediatric trials. How might these gaps be filled through the development of optimal research nurse training models? To assess variation in the role and scope of research nurse activities across European countries and specialties. What level of responsibility is given in terms of taking consent, prescribing drugs for CTIMPs, etc.?

Key Tasks, Timeframes and Outputs

- To design a questionnaire-based study to allow the generation of information on what research nurse training models currently exist, what training is currently given and what gaps there may be in training across different specialties and countries.

- An initial draft of the questionnaire will be developed and finalised by the working group by the end of November, 2015.

- The initial draft will be circulated to Enpr-EMA networks for comments in December, 2015.

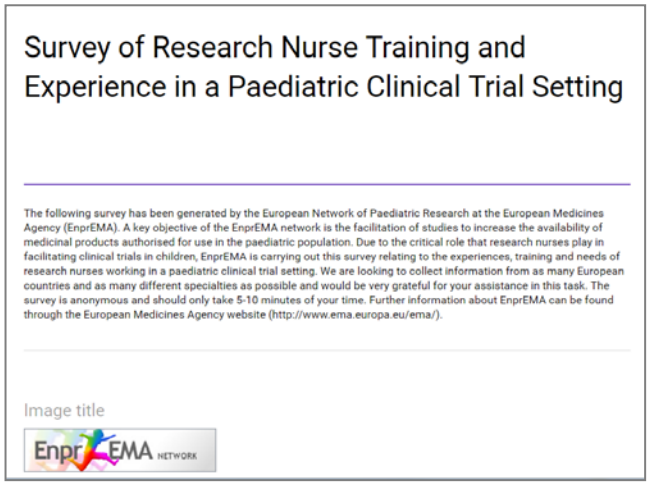
- To assemble a list of research nurse groups/networks and contact details covering a wide range of European countries and specialties.

- To assess the most effective method of carrying out the questionnaire-based survey across the groups defined above.

- To obtain and collate the information received, share the data with the Enpr-EMA networks (May, 2016) and review the potential for publication.

Areas of focus for questionnaire:

- Area of work (specialties, age range, etc)
- Level of experience
- Training received and frequency
- Additional training requirements?
- Form of training received
- GCP certified training?
- Roles of research nurse (clinical trial-related)


Survey of Research Nurse Training and Experience in a Paediatric Clinical Trial Setting

The following survey has been generated by the European Network of Paediatric Research at the European Medicines Agency (EnprEMA). A key objective of the EnprEMA network is the facilitation of studies to increase the availability of medicinal products authorised for use in the paediatric population. Due to the critical role that research nurses play in facilitating clinical trials in children, EnprEMA is carrying out this survey relating to the experiences, training and needs of research nurses working in a paediatric clinical trial setting. We are looking to collect information from as many European countries and as many different specialties as possible and would be very grateful for your assistance in this task. The survey is anonymous and should only take 5-10 minutes of your time. Further information about EnprEMA can be found through the European Medicines Agency website (http://www.ema.europa.eu/ema/).

Image title

EnprEMA NETWORK

EnprEMA

European Network of Paediatric Research at the European Medicines Agency

Summary of data obtained:

• Total of 75 organisations from 15 countries identified for circulation of questionnaire study

• Countries: UK, Ireland, France, Switzerland, Finland, Norway, Sweden, Denmark, Netherlands, Spain, Germany, Italy, Belgium, Hungary, Albania

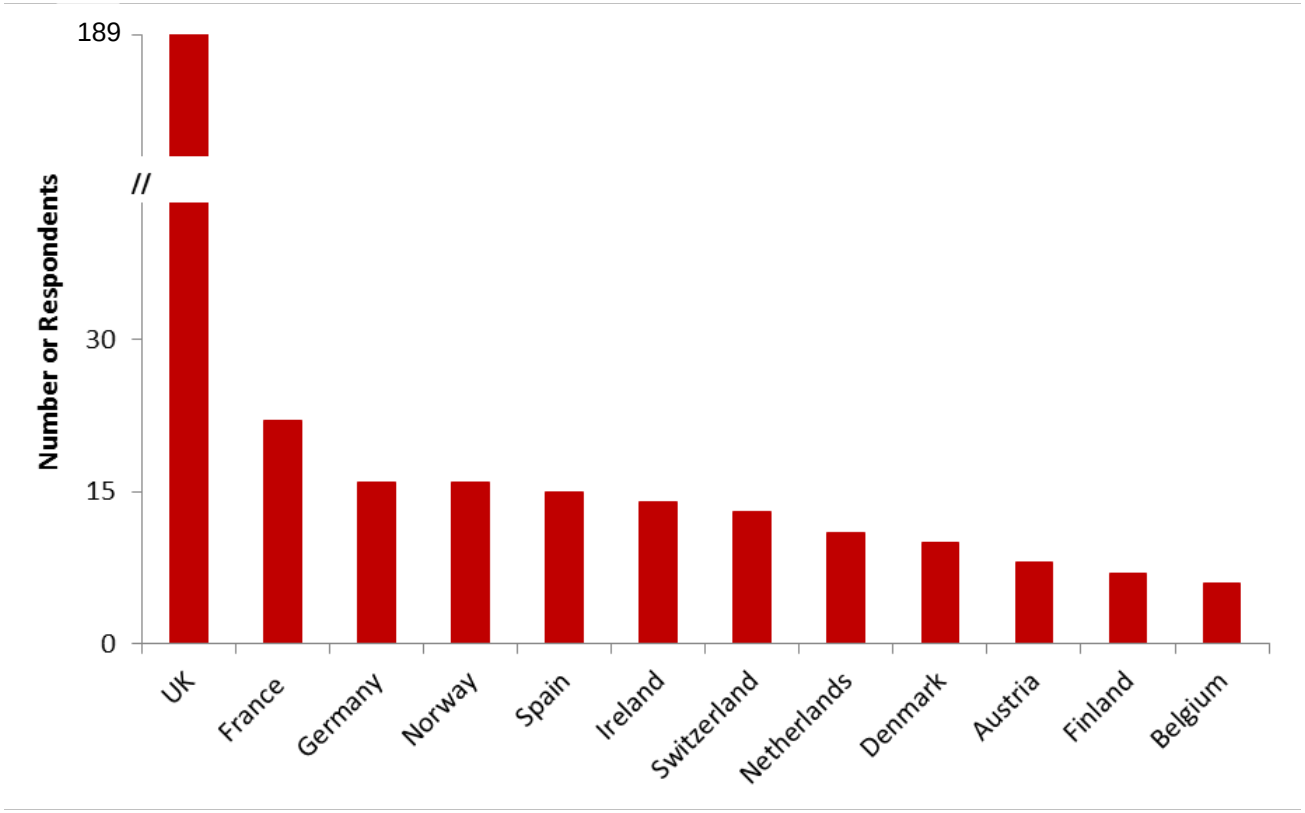
• Specialties: Respiratory, oncology, neonatal (majority 'multiple')

• Link to questionnaires sent to points of contact for each organisation between April-December, 2016.

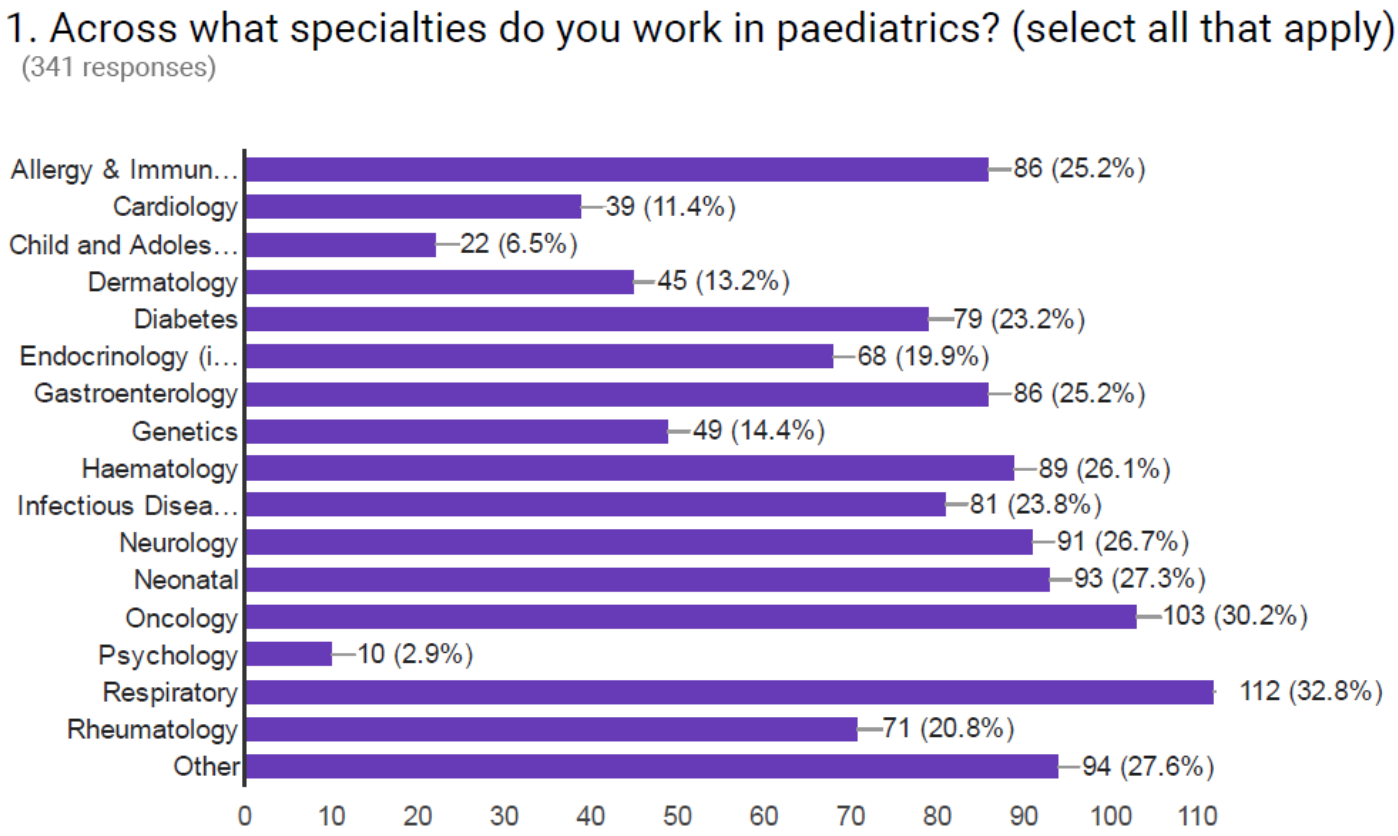
• Translation of questionnaire into French for organisations in France

• Completed questionnaires received: 343

Questionnaire Responses by Country

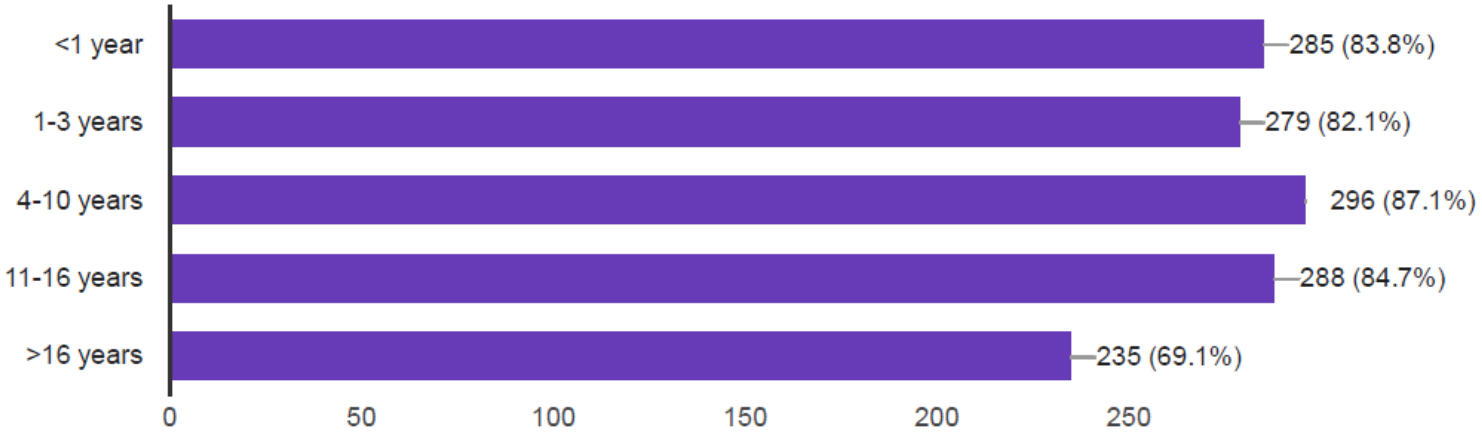


Paediatric Specialties



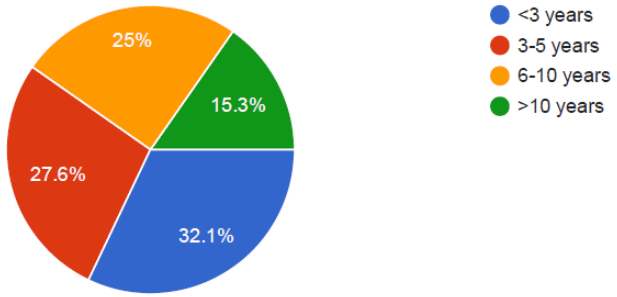
Age of Children

2. What age of children do you work with? (select all that apply) (340 responses)

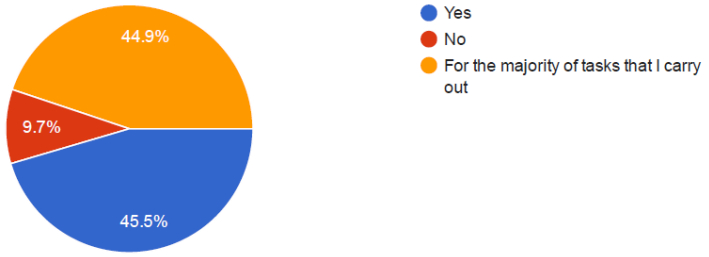


Research Nurse Experience / Training

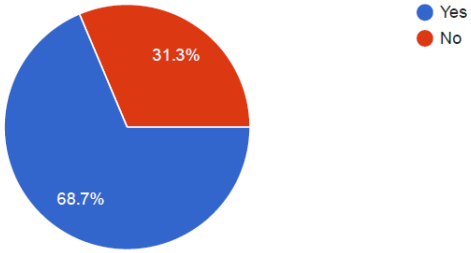
3. How long have you worked as a research nurse? (340 responses)



5. Do you feel that you have received appropriate training for the role(s) you carry out in your position?
(341 responses)



6. Do you feel that you would benefit from additional training in some aspects of your job?
(335 responses)

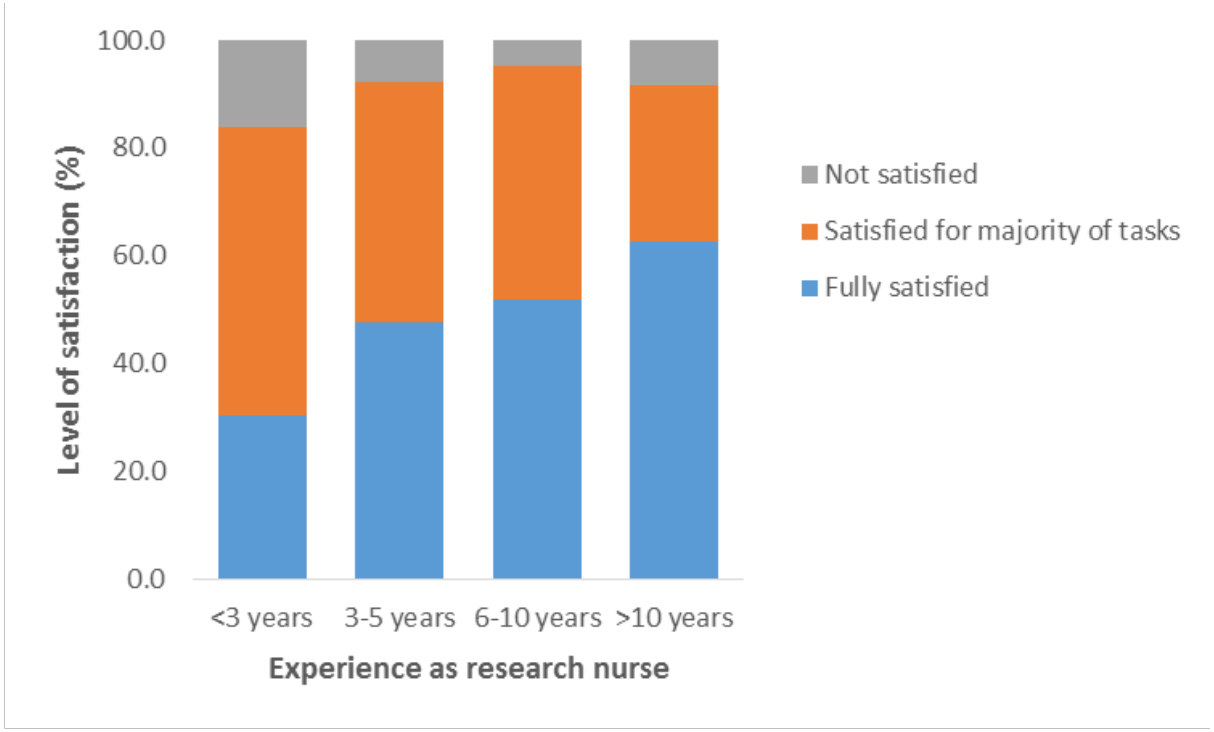


1/3 research nurses felt that they would benefit from additional training. Specific areas of need identified:

- *IT training / clinical trial setup / specialist skills for clinical trials / sample handling / finance / research governance*

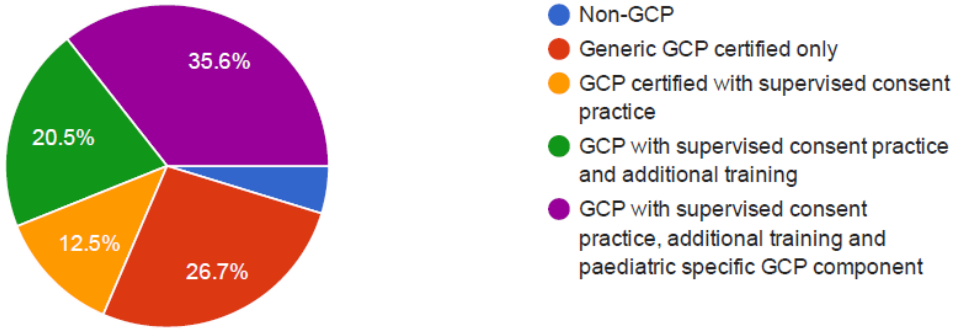
- Higher levels of dissatisfaction with training in Norway (25%) and Denmark (20%)

Level of Satisfaction vs Experience

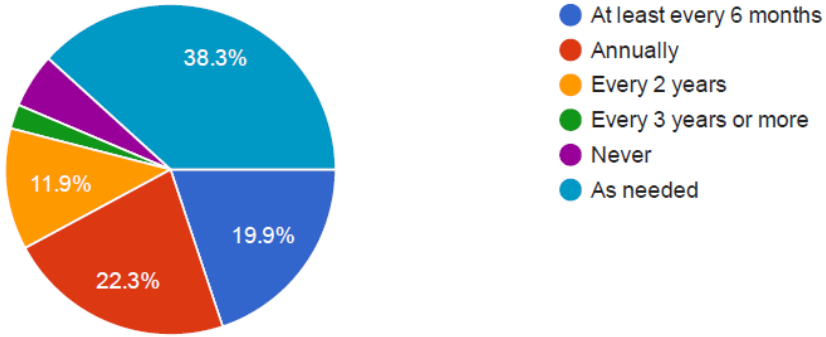


Specifics of Training Received

7. How would you best describe the training that you have received for your role (select one)?
(337 responses)

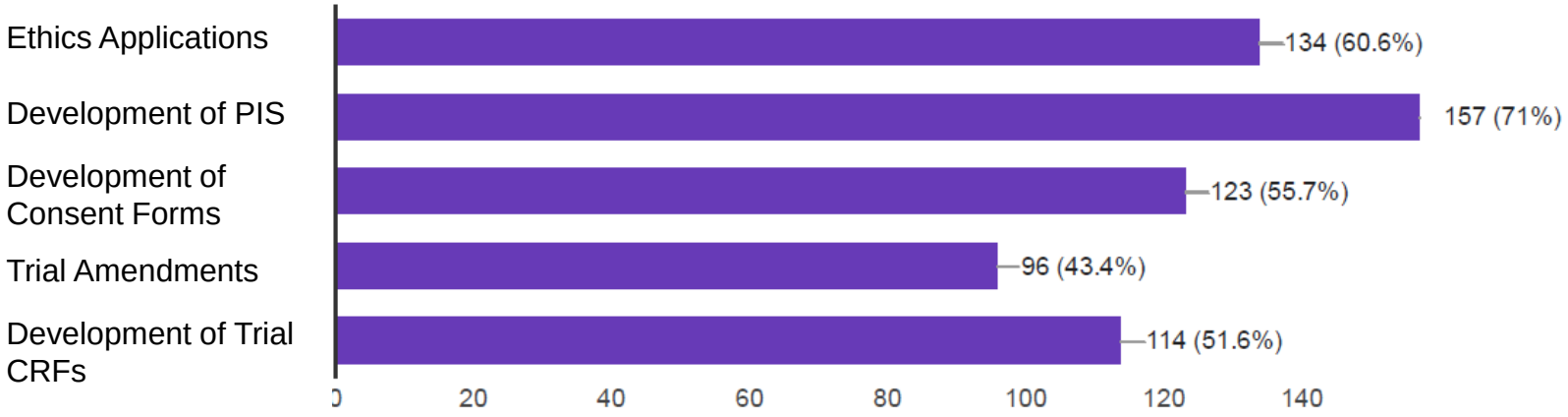


10. How frequently do you receive training in your current job? (337 responses)



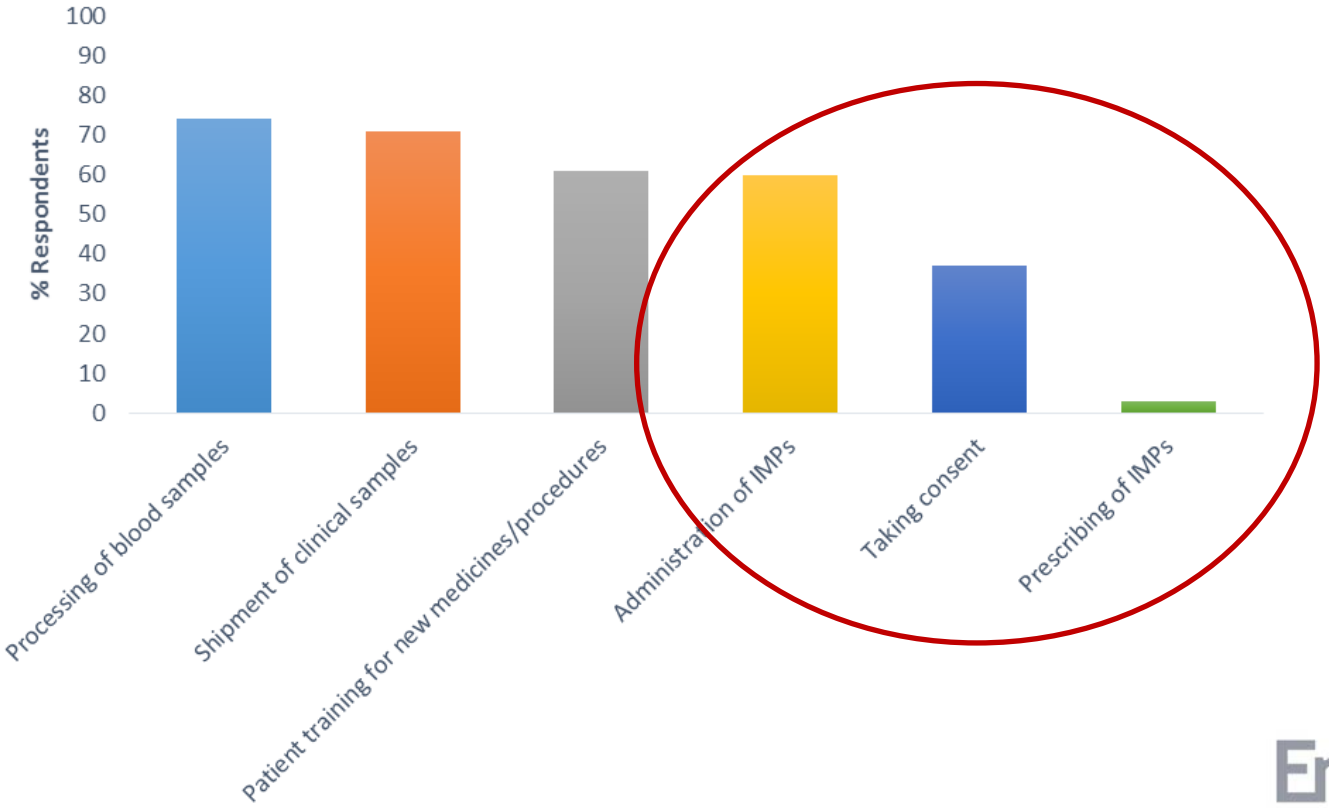
• Higher percentage of respondents who received self-funded training in mainland Europe (15-20% in Germany, Norway, Switzerland, Denmark) versus <1% in UK

Research Nurse Activities



Participation in CTIMPs

- >80% of research nurses completing questionnaire participate in CTIMPs
- >60% of research nurses participate in Phase I/II trials



Data analysis and publication:

• Analysis of data complete / manuscript drafted / comments received from WG members

• Interesting points for discussion:

- *method of obtaining training (67% receive training updates online)*
- *potential benefits of increased training opportunities when first in post*
- *availability of training programs? Self-funded training in some countries*
- *benefits of increasing numbers of nurses able to prescribe IMPs?*
- *why are <50% research nurses taking patient consent?*
- *research nurse roles / differences between countries*

• Review of manuscript by wider EnprEMA networks

• Publication of study data in appropriate journal with data summary and link to publication through EnprEMA website

• Potential impact on future research nurse training