

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

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

Chair: Gareth Veal

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

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



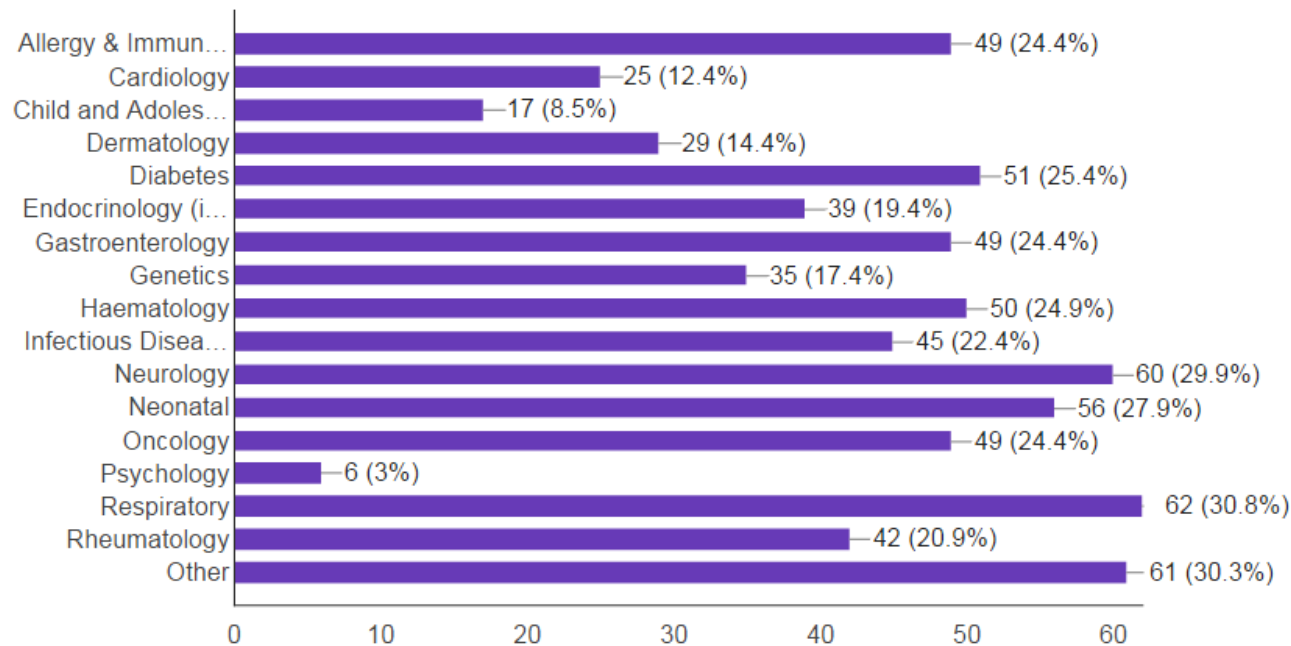
Summary of data obtained:

- Total of 28 organisations identified for circulation of questionnaire study
- Countries: UK, Ireland, France, Switzerland, Finland, Norway, Sweden, Denmark, Netherlands, Spain, Germany, Italy
- Specialties: Oncology, haematology, neonatal (majority 'multiple')
- Link to questionnaires sent to points of contact for each organisation between 12-13th April, 2016.
- Translation of questionnaire into French for organisations in France
- Completed questionnaires received to date: 201

Paediatric Specialties

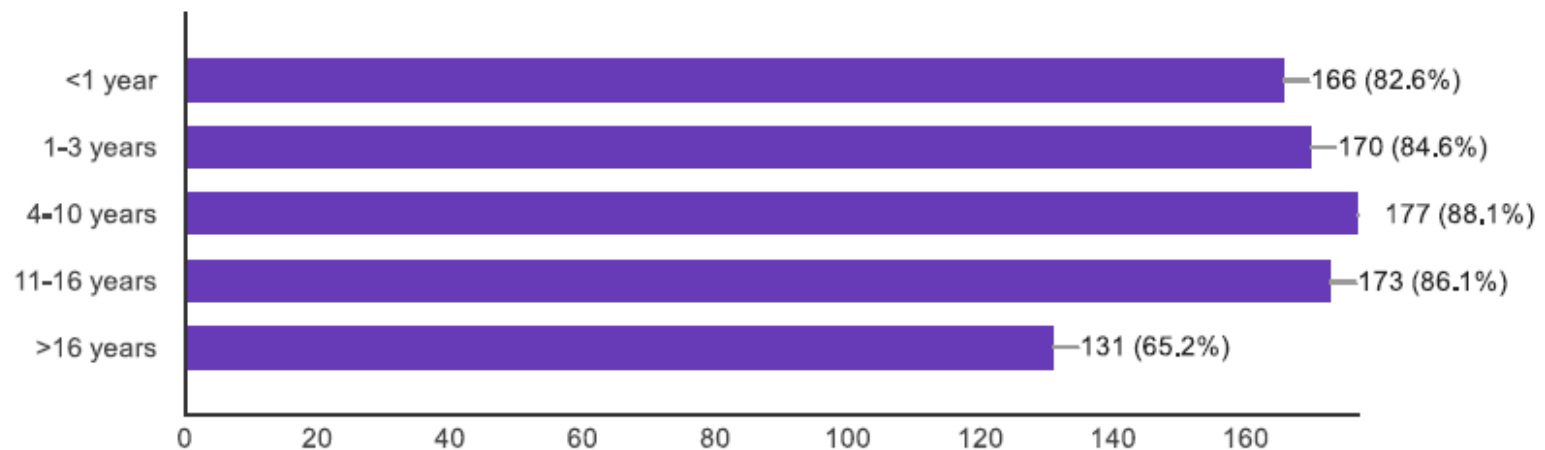
1. Across what specialties do you work in paediatrics? (select all that apply)

(201 responses)



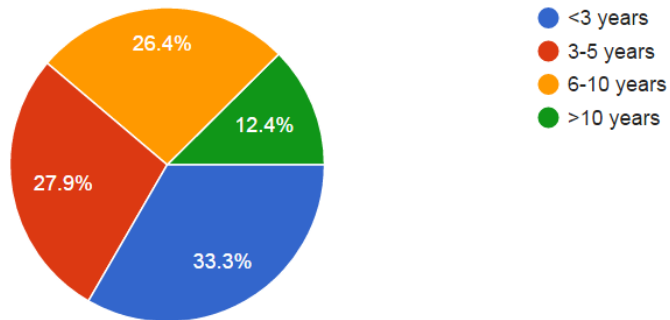
Age of Children

2. What age of children do you work with? (select all that apply) (201 responses)

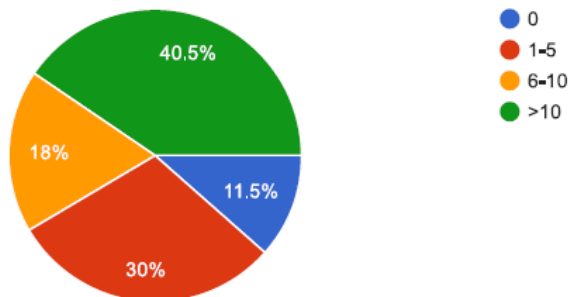


Research Nurse Experience

3. How long have you worked as a research nurse? (201 responses)



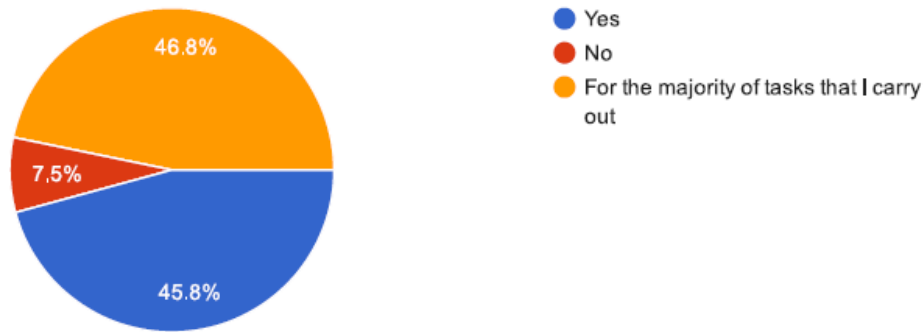
4. How many Phase I, II, III or IV clinical trials have you participated in?
(200 responses)



Level of Training Received

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

(201 responses)



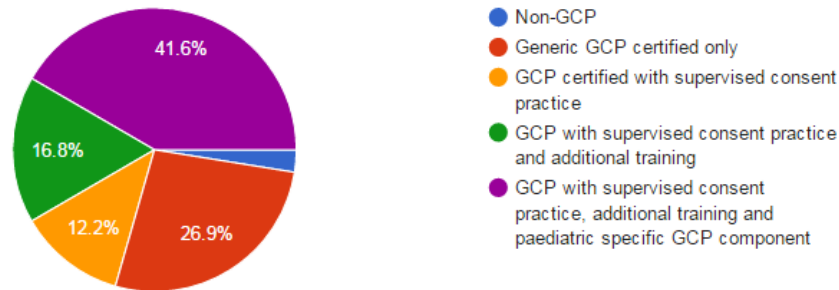
1/3 research nurses felt that they would benefit from additional training. Specific areas of need identified:

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

Specifics of Training Received

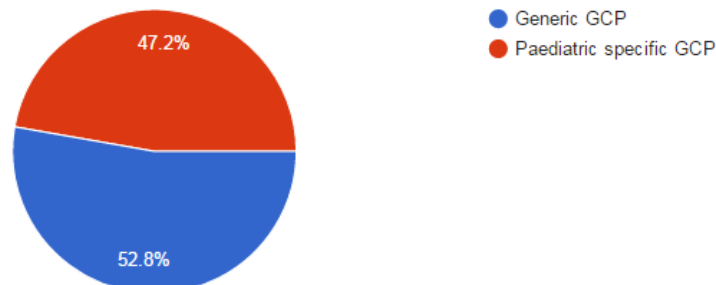
7. How would you best describe the training that you have received for your role (select one)?

(197 responses)



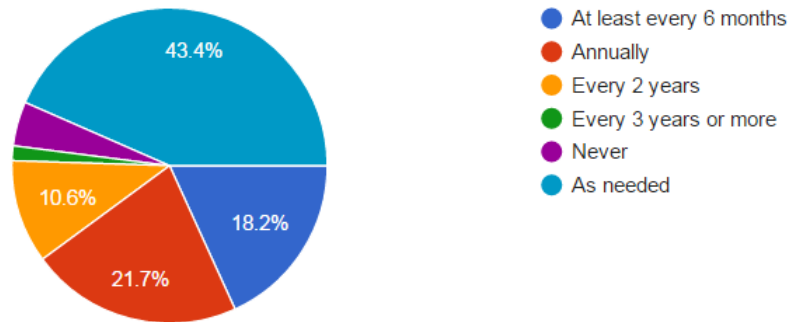
8. If you have received GCP training has this been generic GCP training or paediatric specific GCP training?

(199 responses)

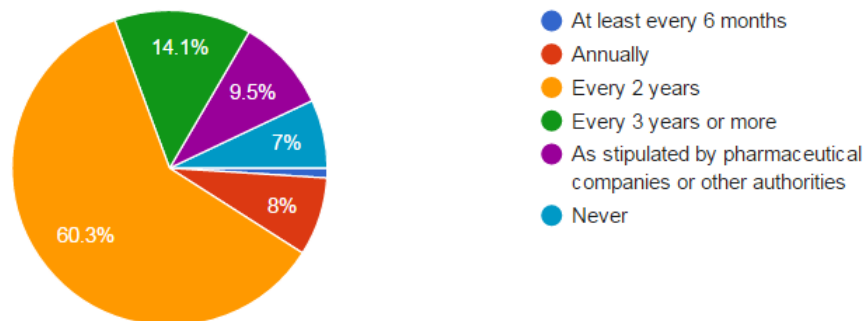


Frequency of Training Received

10. How frequently do you receive training in your current job? (198 responses)



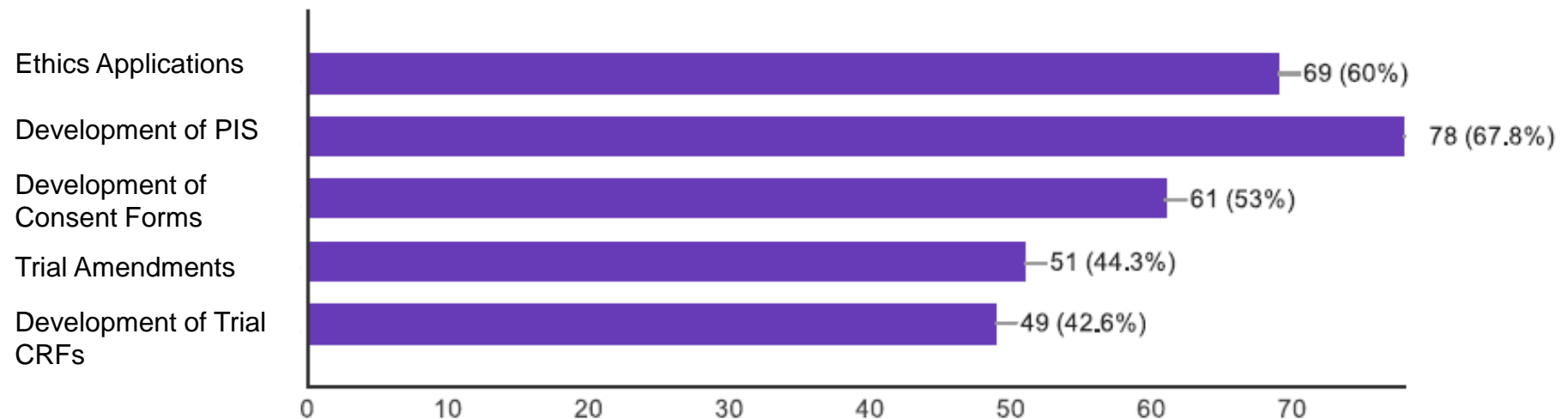
11. How frequently do you receive GCP certified training within your role? (199 responses)



Research Nurse Activities

14. Which of the following activities do you have experience of actively participating in?

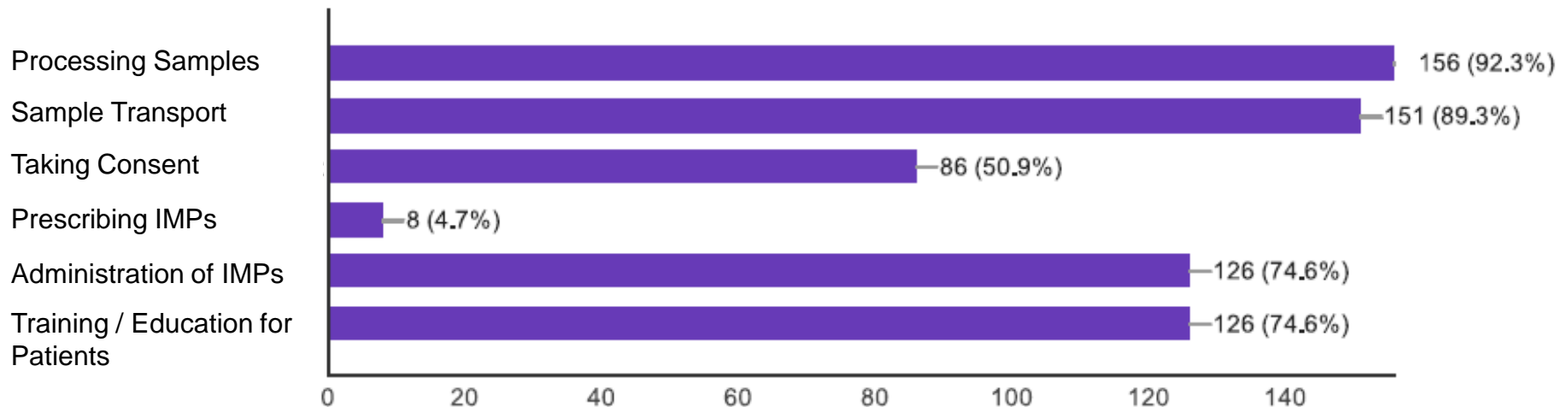
(115 responses)



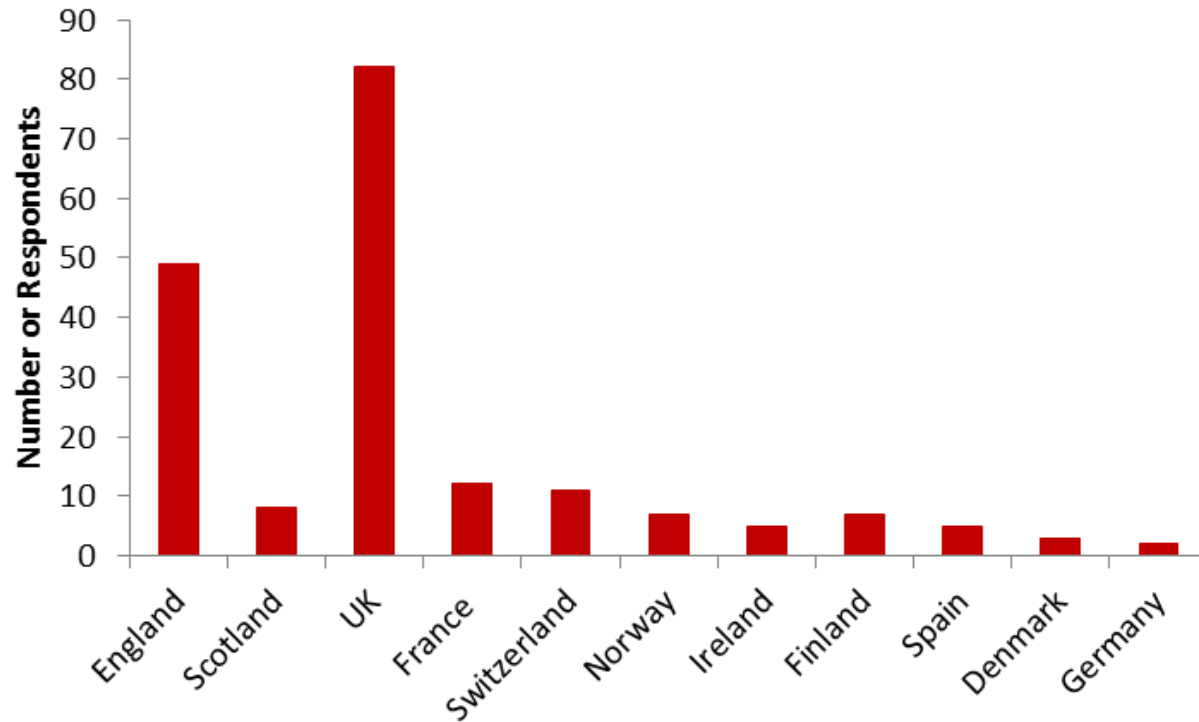
Participation in CTIMPs

- 84% of research nurses completing questionnaire participate in CTIMPs
- 57% of research nurses participate in Phase I/II trials

16. If yes, which of the following roles do you perform? (169 responses)



Questionnaire Responses by Country



Immediate and Future Plans:

- Identification of organisations for circulation of questionnaire study in countries currently under-represented in dataset obtained
- Analysis of data obtained
- Publication of study data in appropriate journal with data summary and link to publication through EnprEMA website
- Potential impact of findings on future research nurse training