R48- **Clinical trials methodology: key issues for successful study design and conduct - a focussed workshop for Academic Clinical Trainees**
1 January 2014- 30 September 2014 (workshop date 14-15 July 2014 London)
Prof Jane Blazeby (PI), Prof Mike Clarke, Prof Jane Armitage, Dr Emma Tomlinson, Ms Colby Benari, Prof Alan Montgomery. Prof Tony Marson was also part of the Expert Panel, and a workshop convenor and presenter.

Original objectives The main objective was to provide a 2-day workshop giving a focussed introduction to the development and conduct of clinical trials for early-career clinical academic researchers. The focus of this workshop was on the methodology involved in trials, ensuring a distinction between this workshop and other courses aimed at trial managers. The course fits an identified niche in the development of academic clinicians, which is a capacity gap recognised by funders and the NHS.

The workshop was funded by the Network and offered free to delegates (including both lunches and the conference drinks and light meal reception on the evening of the first day). The workshop also received supportive funding from the ConDucT II Hub to provide costs for organiser travel. The Academy of Medical Sciences were co-applicants on this initiative, providing the venue at a discounted rate, and promotion of the workshop to their distribution lists.

What was achieved? The workshop was advertised for two weeks in spring 2014, and places filled up rapidly. Initial capacity was for 30 delegates, and 31 applicants were offered a place. A brief shortlisting process reviewed the applications to ensure eligibility criteria were met. As we were not oversubscribed all eligible candidates were invited. The majority of delegates were NIHR Academic Clinical Lecturers (ACLs). There were two delegates currently working as allied health professionals. Most delegates had minimal experience of trials. Some had previously obtaining funding for short feasibility studies within their NIHR Fellowships. 26 delegates attended on the day[, and 19 provided feedback following the course[. We intend to contact all delegates 12 months after the course to determine whether this has impacted on their clinical practise or research.

All the presentations during the workshop were rated by the majority as good/excellent. Some of the talks incorporated discussions between the session Chair and another Panel member, and delegates reported that they found it interesting to hear the expert opinion and discussion of ideas.

Feedback overall was extremely positive. One delegate provided negative feedbackon the meeting, but his expectations of the workshop appeared to have been for more detailed methodology training (e.g. an opportunity to learn about non-inferiority design).

The two day workshop also encompassed a "Dragons Den" type workshop, where participants were split into groups (mixed on location and specialty) and developed a trial proposal over the two days. The Panel set a different hypothetical trial idea for each group. These examples involved conditions that the clinicians were not specialists in. This was to ensure the groups focussed on the trial design and methodology, and were not biased by their pre-existing clinical knowledge. There was some contribution from the Expert Panel members, each being assigned a team to work with, this included provision of general advice, statistical information about sample size and a listening ear at the rehearsal stage. The groups presented their trial proposals to the organisers (the Dragons) and the rest of the delegate group on the second day. They were questioned on their proposal, and the development

process followed. One team was chosen as the winner, and prizes were issued. There was also a prize for the best question from a delegate.

The Dragons Den workshop sessions provoked interesting discussion within the groups, some of which reflected conscious decisions that had been taken in setting up the groups and selecting the topics. Delegates were placed in mixed groups and given an example trial question to work on. There was limited time with one of the Expert Panel members to assist with specific trial development issues. The intention of these workshops was to allow delegates to focus on the principles of good trial design, without necessarily knowing the background to the trial area they were given to study. For many of the delegates this was a controversial challenge that they were outside their specialty comfort zone. However, all five groups presented competent trial designs and made proficient presentations to the Dragons.

Feedback on the Dragons Den was largely positive, despite initial scepticism from some delegates at the close of day one . For example,

"*Initially I thought this might not be very useful but actually really good to focus on trial of something no have no vested interest/prior knowledge of*"

"*This was one of the most useful aspects of the workshop as we worked collaboratively. We learnt and complemented each-others knowledge, and we had a shot at asking. More of this please if possible (depending on mix of delegates (streamlining this to fit participant- e.g. surgeon designing a surgical trial*"

Prof Tom Walley closed the meeting, representing the NIHR, and it was beneficial for the delegates to be able to ask questions of a senior funder. Tom provided advice on which schemes at the HTA might be more suited to a developing researcher, and offered advice on working with other CTU and trial CIs to gain experience in the trials arena, noting that there is no easy route into obtaining trials funding.

The next steps We consider this workshop to have been successful, and several of the attendees were interested in attending subsequent workshops targeted at NIHR ACLs. The Academy of Medical Sciences was supportive of the workshop, but unable to offer any financial support for this or future events.
Should further funding be sought, we would review the feedback from delegates in developing the programme, and would consider working with a Royal for this event. There could be an option for groups to design their own trial, related to their clinical practice; but this would shift the focus of the Dragons Den workshop away from its intended purpose of realising trial management and planning methodologies in the context of a trial that one doesn't "own". We could develop this workshop further by working with the NIHR on developing a larger workshop, if matched funding could be provided, or continue to run this event for groups of 15-30 participants.

We could also tailor the workshop and target it at different subgroups of the clinical trials community, for example allied health professionals and nurses, who have different challenges in obtaining funding for trials research; or look at offering the workshop in a different location in the UK.