nhsa
Northern Health Science Alliance

NIHR | Clinical Research Network Greater Manchester

Clinical Research Network Collaboration

Gastroenterology Clinical Trials: Lessons Learned Workshop

The Nowgen Centre, Manchester

Workshop Report

MANCHESTER 1824

Contents

Section One: Background and Attendees

Over recent months, the NHSA has been working with the four Northern LCRNs (Greater Manchester CRN, North West Coast CRN, Yorkshire and Humber CRN and North East CRN); acting as a broker to develop new ways of working that would help secure more commercially sponsored and funded studies in the North of England. It was agreed that a Network Collaborative Framework should be drawn up by the four LCRNs that could be shared with respective partners to secure agreement and buy-in, whereby establishing a framework for increasing the number of commercial trials with research sites in the North. The purpose and objectives of the Network Collaborative Framework are defined as:

- To identify ways of measuring effectively increased commercial research activity within the four Northern LCRNs as a direct result from working collaboratively across LCRN network boundaries T
- To undertake a mapping exercise of commercial research strengths across all four LCRNs, to identify gaps and opportunities
- To undertake to share information about performance across the four LCRN networks with respect to commercial research activity
- To engage with new Principal Investigators and Partner Organisations as a direct result from cross-network working activities
- To open at least one multi-site study in more than one LCRN region within 12 months

This agreement has now been signed by all LCRNs and the NHSA.

Gastro Collaboration Meeting 8th February 2017

During the negotiation and signing process, the first opportunity for trans-regional collaboration was identified within the theme of Gastro-Intestinal medicine. The NHSA attended the above meeting where colleagues from the Greater Manchester CRN and North East North Cost CRN met to discuss and share best practice for managing commercially led Gastroenterology clinical trials.

Section One: Background and Attendees

Opportunities for further Engagement

Discussions during the meeting on the 8th February between NHSA representatives and Professor John McLaughlin led to exploring the opportunity to engage with key research professionals in the GM Gastro arena to learn from past and current experiences in carrying out commercial clinical trials, particularly from the frontline.

The NHSA along with Professor McLaughlin, would like to lead on facilitating group workshops/focus groups to consider what the issues are and how we can learn from colleagues.

A half-day workshop was proposed, with attendance from the following groups: research delivery managers, research nurses, principal investigators, pharmacists and radiographers. The results of the workshop will be written up into a formal report for dissemination amongst relevant stakeholders.

Attendees

The workshop was attended by representatives across the Greater Manchester region and included:

- Research Nurses
- Research Managers
- Specialist Nurses
- Charity Representatives
- Industry Representatives
- Clinicians
- Academics

Section Two: What took place?

9.30 – 10.00	Coffee & Registration
10.00 – 10.10	Welcome and aims of the Day, Shirley Hannan & John McLaughlin Melanie Taylor, Senior Research Nurse
10.10 – 10.45	Interactive session: understanding researchers experiences, clinical and industry perspectives
10.45 – 11.30	Group work
11.30 – 11.45	Break with Coffee
11.45 – 12.15	Feedback on Group Work: lessons learned
12.15 – 12.30	Agreed Actions and Recommendations
12.30 – 1.00	Lunch and Networking

Section Two: What took place?

Welcome and Aims of the Day – Professor John McLaughlin

- To understand what works well and what does not in clinical trials
- To consider
  - Ethical issues
  - Practical issues
- To share and learn from each other
- To identify lessons and ways ahead
- To offer something different and better?

Melanie Taylor – Assessing clinical staff perceptions of barriers in recruiting to Randomised Control Trials

Presented the results of a small survey of clinicians in NW England experienced in IBD clinical trials involving placebo –controlled methodology, including where commercial alternatives are available. It was acknowledged that randomised control trials are important and effective. However 72% of clinicians would have ethical concerns about recruiting patients in these circumstance. To improve recruitment and retention to clinical trials 71% felt that less restrictive criteria more reflective of the “real world” with active control as comparator would be beneficial.

Section Two: What took place?

Interactive Session and Group Work

The attendees were asked to consider the following questions, highlighting not only the issues but also possible solutions

Understanding Experiences

- What issues are research professionals facing when carrying out commercial clinical trials?
- How do these issues compare to those faced carrying out Academic-Led clinical trials?
- How can the Gastro CRN input into Industry led clinical trial design?
- How can we learn best from what hasn't worked?
- What are some of the biggest lessons learned from when studies stall or fail?

Solutions to Issues

- Of the issues identified, how can these issues be resolved practically?
- How can we implement changes to improve the effectiveness of clinical trial management?
- How best can what we know from lessons learned be created into a message for industry?

Section Three: Group Work Notes

Table 1: Facilitator Sarah Fallon

Issues:

- Placebo
- Washout
- Disease advancement
- Inclusive/exclusion criteria
- Equipment e.g. wearables; types of equipment, compliance, access, problems with technical support, no paper
- Relationships with KoL
- Company contacts
- Moral with current issues – affect future recruitment
- Closing sites – lack of agreement between clinical teams
- Vendors for studies don't coordinate
- Co-morbidities – working populations
- Payment for patients, credit cards; vulnerable groups; ID requirements, ethics of when to pay; tax
- Cluster randomisation issues

Section Three: Group Work Notes

Table 1: Facilitator Sarah Fallon

Solutions:

- Placebo design studies – flag early feedback, alternatives
- Speak to as many of the clinical team as possible (including specialist nurses)
- Screening log (high level review)
- Northern approach pre-screening
- Sharing information about studies – helping each other – perhaps newsletters?
- Targets/Contracts: wider discussions/sharing across sites
- Escalations/Feedback to CRN (CRA/MSL etc)
- CDA trustwide – beneficial to have conversations across sites
- Caution using recruitment companies

Section Three: Group Work Notes

Table Two: Facilitator Dayle Roberts

- Early opportunity to feed into protocol design
- Acknowledgement of sheer amount of background work required to deliver a study – no true reflection of costs
- Trust focus on infrastructure needed – Trust/CRN focus on numbers but no space to deliver
- More CRN engagement to Trust to inform about new studies
- More time to review feasibility would enable larger engagement
- Patient Identification Costs – costing template
- More time for feasibility
- Engagement Trusts/Teams at an earlier point for delivery feedback
- More clarification on Research Team experience – understanding experience of teams, Industry tick box, 'computer says no'
- More robust feasibility, discuss previous issues
- Take feedback from all involved
- Lessons learning statement from all sites (set up & delivery)
- Forced, rushed feasibility leads to bad results
- Utilise the expert knowledge available at local sites
- Delivery staff deliver research so they will know what will work – involve them as early as possible

Section Three: Group Work Notes

Table Three: Facilitator Shirley Hannan

Issues:

- Screening period vs real world
- Protocols don't allow for real world
- Severe disease doesn't align with placebo trials
- Pressure from government for targets/numbers
- The timescale of turning round feasibility – need realistic timelines
- CROs can cause issues with timelines when competing CROs
- How do we get DGHs involved – teaching hospitals need to collaborate more with DGHs but PICs get very little funding
- Competing against other Trusts for numbers – how can we feed that back to the national bodies
- Reporting on patient activity is conducive to competition amongst Trusts
- Early feedback (expert review) is done at the same time as early identification and it shouldn't be
- No PPI in protocol development
- Aligning scientific validity with patient expectation particularly in early phase
- Type of CRO used e.g. large vs. small
- Gastro – low number of biomarkers available
- Cross network patient referral – the current funding mechanism not conducive to collaborative working

Section Three: Group Work Notes

Table Three: Facilitator Shirley Hannan

Solutions:

- In order to get our Academics to input early into protocol development need to raise the profile to be internationally recognised specialists/clinicians/professionals
- We need to have unified voice to approach the issues
- There needs to be honest feasibility nationally and locally
- There needs to be a coordinated approach to feedback changes
- Is there the potential for UK addendums to protocols
- Need the national network to give a rationale for longer time for feasibility
- The reporting needs to be done on the right metrics to encourage collaboration
- Feasibility needs to have input from the coalface. The specialist nurses know their patients.
- Companies need to get involved with specialist frontline staff and recognise the importance of these groups
- Protocol development need representation from patient groups; clinicians; specialist nurses
- Adaptive Trial Design
- The role of the speciality lead could be added to to give more than one perspective, e.g. more than one type of professional in the role

Section Four: Recommendations and Next Steps

- Ensure meaningful consultation with relevant specialist colleagues and at an early stage in protocol development
- Utilise local leadership assets to work with Industry to improve the quality of our clinical research studies
- Drive transformation for wider patient access into clinical research studies across the North of England
- Explore how the North of England can become a test bed for real world clinical trials

Next Steps

We propose taking this work forward by engaging with patient groups and Industry across the region to gain a further understanding of the patient perspective.

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