Commercial Clinical Operations Group (cCOG) Meeting Minutes

Date: Wednesday 6th March 2019
Time: 10:30 – 16:15
Location: Covance, Osprey House, Westacott Way, Maidenhead, SL6 3QH
Chair: Lynette Okello (Gilead)
Minutes: Eduardo Chicote (Novartis)
# Agenda - morning

<table>
<thead>
<tr>
<th>Time</th>
<th>Item</th>
<th>Topic details</th>
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<tbody>
<tr>
<td>10:15</td>
<td>Coffee available</td>
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| 10:30  | Welcome                       | • Agenda overview  
• Introductions                                                                   | Lynette/All                  |
| 10:40  | Health and Care Research Wales| • Update from Health and Care Research Wales                                 | Lydia Vitolo                 |
| 10:55  | HRA                           | • Update from HRA                                                           | Alastair Nicholson           |
| 11:55  | NIHR News                     | • Research Activity - monthly recruitment data  
• Commercial Contract Single Review Process  
• National Improvement Project Plan  
  o Stakeholder engagement  
  o Effective study set-up  
  o Performance monitoring  
• Research Targeting Tool  
• Training & Information Resources  
• Contact details                                                                 | Lorraine Fincham             |
<p>| 12:25  | NHS Research Scotland Updates | • Update from NRS                                                            | Lynette on behalf of Charles Weller |</p>
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<thead>
<tr>
<th>Time</th>
<th>Session/Topics</th>
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<tr>
<td>13.15</td>
<td><strong>cCOG team charter</strong></td>
<td>Lynette on behalf of Sarah Durston</td>
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<td><strong>2019 review</strong></td>
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<td>• Are updates required or a fresh approach?</td>
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<td>13.30</td>
<td><strong>Member group updates</strong></td>
<td>Member group representatives</td>
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<td>• R&amp;D forum</td>
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<td>• Road Map</td>
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<td>• CREN</td>
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<td>• Costing Group</td>
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<td>14:00</td>
<td><strong>Points for Discussion/Hot Topics</strong></td>
<td>All</td>
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<td>Topics:</td>
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<td></td>
<td>• Patient review groups (Marianna)</td>
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<td>• Pharmacy review (Charlotte)</td>
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<td>• UAT for costing tool (Natasha)</td>
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<td>• Meeting locations 2019</td>
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<td>- Wednesday 5th June: Novo Nordisk, Gatwick</td>
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<td>- Boehringer Ingelheim, Bracknell</td>
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<td>• Confirm 2019 meeting dates</td>
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<td>• Volunteer to manage member companies list and prepare website postings after each meeting</td>
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<td>• Round table topics/issues</td>
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<td>15.00</td>
<td><strong>Meeting Checks</strong></td>
<td>Lynette</td>
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<td>• Industry Website posting consent</td>
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<td>• Distribution list updates</td>
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<td>• Chair (GSK/ICON back-up?) and minute taker (Novo Nordisk/Pfizer back-up?) for Q2 2019 meeting</td>
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<td>15.30</td>
<td><strong>Meeting close</strong></td>
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Update from Health and Care Research Wales
Presenter: Lydia Vitolo (LV)

- No slides.
- **Site identification and setup in Wales**
  - The Welsh site identification service continues to link with the UK-wide service and good progress has been made in terms of Expressions of Interest that have been received from potential PIs.
  - Feedback from Wales was that they would like to see more timely responses from Sponsors and CROs about whether sites have been selected and when sites have not been selected, feedback on why would be helpful.
  - A new process is being trialled in Wales, whereby the Support and Delivery Centre will approach potential PIs directly (where possible). This should mean that site identification can be done more directly and within better timelines. Although please note that R&D departments will still lead on the approval of Capability & Capacity.
  - Responses from Wales will aim to provide an increased number of patients by encouraging working across Health Boards with a hub and spoke model. The process will also be enhanced by using a one cost one contract approach to setup.
- Please contact Lydia.Vitolo@wales.nhs.uk for further information
Implementation of new UK Local Information Pack

- To be Introduced on 5th of June 2019. (transition late March/early April)
- A new **Organisation Information Document (available from April)** will replace the current **Statement of Activities** used in England and Wales and the **Site Specific Information form**, used in Northern Ireland and Scotland.
- Consistent package to support study set-up and delivery across the UK.
- Background/Rationale:
  - Initially planned in IRAS. But delays – Technical/new regulations so decided to continue w LIP as in Eng and Wales but applicable for all 4 nations (no more SSI in Scot/NI)
  - Implement a new document to serve as main identity of study across all systems (.doc). Shorter and standardised for commercial and non commercial studies.
  - Prepare for new electronic process
HRA Updates
Presenter: Alastair Nicholson (AN)

Master Indemnity Agreement
- Background: DHSC approached HRA to address ongoing issues or questions from sites/sponsors.
  - When is it needed? Who should it be the signatories?
  - Led to Proposal by DHSC for not using MIA in research context
    - Push back from NHS sites as sponsors/mCTA do not offer full product liability but only personal indemnity
    - DHSC expect Sponsors to provide solutions to sites through mCTA or MIAs with sponsor or vendors directly.
- An issue is raised with eRT where vendor is not willing to sign MIA. DHSC planning to order to force the call off of all agreements between NHS and eRT. Alastair requested support from cCOG to assess the extend of the issue and clarify any potential misunderstanding.
  - DHSC open to discuss with the view that sponsor should cover and not vendor as they supply the sponsor. However questions were raised by NHS sites about who is the real supplier.
  - Global Vendors raised the question why this is only required in UK; and this makes difficult for sponsors to negotiate a position only for UK
  - More clarification is required who need to sign those MIAs
  - Alastair will send the exact questions to answer after the meeting
HRA Updates
Presenter: Alastair Nicholson (AN)

Other questions from cCOG group

ARSAC

- HRA CEO had a meeting with ARSAC on 11 Jan 2019.
- High level discussion and positive response from Public Health England
- HRA requested to take into account the political context and requested solutions. This has triggered conversations at high level (not much details about this)
- PHE was not aware of the issue
- Actions:
  - Activate complaint procedure directly with the PHE – AN to send the link
  - Operational measures
    - How can information be better provided to ARSAC
    - Improve the communication between the different parties
    - Better Resourcing – currently only 2 people - not immediate
  - Keep ongoing the high level conversations on the agenda
HRA Updates
Presenter: Alastair Nicholson (AN)

Other questions from cCOG group
Update on new version of mCTA the include the GDPR
- Not major updates
- There are currently issues with the transfer clauses but if no agreement, it will be published anyway without those transfer clauses.
- Not date for now but it should be out in a matter of weeks.

Is HRA participating on the Shared Investigator Platform (transcelerate initiative)
- HRA not participating. cCOG to provide information to AN.
- NIHR aware and it is working on it as it is related on the delivery of studies.

Is there updates on the CWOW?
- No major changes are planned. There will be some minor tweaks on the assessment elements and how they work to help the devolved administrations (ie Scotland).
- IRAS being developed to cope with any scenario and interface with the new MHRA portal as necessary
- Working to improve the actual turn around timelines but will not be a change on the maximum allocance
- Pharmacy manual/laboratory manuals will still be optional documents. However having those may avoid question from the central reviewers. Conversation ongoing to filter what exactly reviewers need from those manuals.
NIHR update

Lorraine Fincham
NIHR updates

Research Activity - monthly recruitment data

Commercial Contract Single Review Process

National Improvement Project Plan
  • Stakeholder engagement
  • Effective study set-up
  • Performance monitoring

Research Targeting Tool

Training & Information Resources

Contact details
Monthly recruitment updates are a pre-requisite for a study to be included onto the NIHR CRN Portfolio - a key to our performance monitoring activity will be replaced by Research Activity after May 2019 (date TBC)

RA Videoscribe

Used to generate a suite of reports that allow us to closely monitor the up to date performance of the study nationally and locally.

Designated team that uploads the data once received and provides support
Logging On

Current users log in as normal, new users to use the “Create account” link
Supporting These Changes

- Please update your teams on the upcoming changes
  - Rather than a provision of a monthly recruitment spreadsheet, we require the Company Representative to log into CPMS and confirm the data provided by the site delivery staff in LPMS
- Please complete the online training when this is made available
- How can the NIHR communicate these CPMS changes and accompanying training throughout the ‘Industry’ community?
Commercial Contract Single Review Process

Commercial Contract Single Review Process

- Costing template and contract use
- Single review process
- Online costing template

Accessing the online template via existing CPMS entry point - independent to and separate from existing CRN feasibility services

- independent of CRN portfolio eligibility (open access i.e. not restricted to being on portfolio)

- anyone can set-up an account to access the template (i.e. maintain the open access that current excel version has)
Commercial Contract Single Review Process Continued...

This includes:

- a document that outlines the principles of the work that will be taken forward

- a timeline of the online UK wide costing template that will underpin this process

- a statement about what came into force on 10/10/2018 via the NHSE standard contract
National Improvement Project Plan:

Workstreams

- Performance Monitoring
- Effective study set-up
- Optimising delivery
- Site ID
- Early Feedback
- Early contact and engagement

Out of scope:
Development of new services
Removal of existing services
Improvement Plan For Delivery Of Commercial Studies

The three priority areas identified are:

1) **Stakeholder engagement**
   Specifically, ensuring our customers understand what we offer & ensuring our customers know what we need from them

2) **Effective study set-up**
   Specifically, sharing set-up intelligence

3) **Target setting and performance monitoring**
   Specifically, roles and responsibilities and target setting
National Improvement Plan

Workstream 1

Stakeholder Engagement

• Communication Agreement: final version and to present at relevant meetings

• Industry guide (written by industry)

• Interactive Route map: - now live and will be reviewed after 3 months

• NIHR Champions programme - Bi-monthly Webinar & updates
Workstream 6: Effective study set-up

• Expand the CPMS Feasibility questions:
  • SPOC for companies
  • Standardised liaison point with the Network
  • Enhance Network Feasibility
  • Provides national consistency

• Offer of a call with the Lead Network to discuss any known/expected challenges to study set-up, standardised offering across all Local Clinical Research Networks
Workstream 7:

Performance monitoring

Updated Performance Monitoring process providing:
● clarification of roles and responsibilities of Performance Lead
● Clear, defined customer contact points and cross-network communication channels

2) Revised Study Milestone Schedule
● Excel format
● Useful document to support Sponsor/Site/CRN staff
● Start completion as early as possible (start up) and update and share on a continual basis

3) Share Open Data Platform (ODP) report of study progress for Sponsor/CRO/Study team to check and verify as part of schedule reviews
NIHR updates

Research Targeting Tool - ‘bubblemaps’
Training & Information Resources

Study Support Service (Youtube)

NIHR Youtube channel

NIHR Life Sciences Industry newsletter

- Stay informed about the work the NIHR is doing to support the delivery of commercial clinical research in the NHS  Sign up
# Contacts

<table>
<thead>
<tr>
<th>NIHR CRN Industry Information Centre</th>
<th>The National NIHR CRN Industry Team for feasibility, Start up and Performance Monitoring can be contacted at:</th>
</tr>
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<tbody>
<tr>
<td>Phone: +44 113 34 34 555</td>
<td><a href="mailto:crncc.support@nihr.ac.uk">crncc.support@nihr.ac.uk</a></td>
</tr>
<tr>
<td>Email: <a href="mailto:supportmystudy@nihr.ac.uk">supportmystudy@nihr.ac.uk</a></td>
<td>Site &amp; local teams can be contacted at:</td>
</tr>
<tr>
<td>Web: <a href="http://www.supportmystudy.nihr.ac.uk">www.supportmystudy.nihr.ac.uk</a></td>
<td>Industry Operations Managers contact details</td>
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Web [NIHR CRN Life Sciences](#)
Update from NHS Research Scotland

Presenter: Lynette Okello, content provided by Charles Weller

- Feeding into a number of ongoing UK-wide changes: CWOW, Local Information Pack, ICT
- From a Scottish perspective, we are engaging with these to ensure that the UK process is compatible, although we will retain Scottish systems where we consider these to deliver efficiencies locally. One example is that we plan to distribute the Local Information Pack to Scottish sites when it is implemented in the summer, which is different from the other UK nations, where the sponsor will have to do this.

- Under development:
  - Industry development plan
  - Scottish Operational Vision - intended to review more widely some the key principles underpinning how we handle research approvals and support
Member Updates

- R&D forum – See slides
- Road Map
- CREN
- Costing Group
• Published a written response to the DHSC: In support of the Life Sciences Sector Deal: Plans for establishing 5 commercial centres for late phase commercial research

Summary of our response

1. The 5 centres have the potential to increase overall UK clinical trial capacity and on this basis they are to be welcomed. It is recognised that the existing NIHR infrastructure has a well-developed approach to delivering commercial research and there would be a synergy if the centres were fully integrated, operating in a way that complements the existing practice and process.

2. There is the potential for unintended consequences if the centres introduce additional bureaucracy, if they disrupt NIHR funding arrangements, promote more competition or silo working, or if they make it difficult for patients with the highest clinical need to access research. There is a risk that the centres draw from rather than increase commercial research to Providers and we should mitigate this risk as commercial research income maintains important R&D infrastructure and supports a wider R&D activity with all the associated benefits to patient care and professional development of clinicians.

3. We propose a framework of principles that we believe should underpin the development of the centres, to minimize the risk described and to ensure the delivery of their full potential.

4. There is an opportunity in the design of these centres to develop acute, community and primary care partnerships that support improved collaborative working for research with public involvement at the core. A systems change that enables full recognition of all contributions to the research journey would facilitate this further and at pace.

5. If partnerships can ensure facilities also reach out to communities in addition to providing extra physical capacity and infrastructure we will move closer towards our aim of bringing research to those who need it most in line with the NHS England Long Term Plan.
Principles

Through this paper we aim to help shape the development of the 5 centres and how they optimally deliver benefit for all stakeholders. Each heading represents a principle we believe should form the set-up of the centres with some practical considerations and solutions.

- **Principle 1:** The centres should add value to the research patient pathway. They should learn from and compliment existing NIHR clinical research infrastructure, and be fully embedded in the NHS.

- **Principle 2:** The centres should be a catalyst for true primary, community and secondary care partnerships with a role to extend the reach of our research and enabling more patients to benefit from opportunities. To align with the Long Term Plan, the partnerships underpinning the design of the centres should aim to enable research to go out to patients wherever possible as well as providing extra physical clinic space.

- **Principle 3:** Development of the NIHR portfolio activity recognition methodology should be considered in conjunction with the establishment of the centres in order to recognise and reward all organisational contributions to the research journey and facilitate better partnerships working across boundaries. This includes all participation in research in addition to participant identification.
Relevant Work Areas

- Attended DHSC workshop to contribute to the skills training for Sponsors and R&D departments for delivery trials with novel methods.
- Supporting the implementation of the Clinical Commercial Research work led by NHSE and NIHR CRN.
- Recent drive to ensure the Forum Directory of R&D office contacts is up to date
- Supported circulation of Brexit related information from DHSC to R&D Offices
NEXT COURSES OPEN

1st April, London. http://www.rdforum.nhs.uk/content/nhs-rd-forum-event-detail/?id=2730
June 13th, London. Relevant to NHS and Industry – understand how the NHS works at set up
June 24th, London. Relevant to NHS and Industry – understand how the NHS works at set up
Annual Conference

BOOKINGS OPEN:
https://www.annualrdforum.org.uk/

Sunday Night Networking
Academi Wales: Applied Positive Psychology
Finding Happiness in the Workplace.

Special Plenary
Dame Fiona Caldicott & Prof Jonathan Montgomery

Keynote speakers
Prof Philip Darbyshire
Dr Louise Wood
Teresa Allen

PLEASE LOG ON & VIEW THE PROGRAMME
How do we work on areas better together?
What are the key things to work on together?

Sign up to receive monthly news
http://www.rdforum.nhs.uk/content/membership/

http://www.rdforum.nhs.uk
@NHSRDFORUM

Thank you.
Member Updates

- R&D forum
- Road Map – Sarah Durston
  - Not present – Feedback next meeting
- CREN
  - Discussion on the planning of activities for 2019
  - How to coordinate all groups
- Costing Group – Natasha Boddy
  - Planning how the new group will be represented. Two cCOG representative are allowed.
  - New costing review will not be until Q3/Q4.
  - New costing template still planned to be launched in April 1st.
    - cCOG requested LF to review the date to avoid risks of delaying significantly study startups at the same time with BREXIT
Points for Discussion / Hot Topics
Presenter: All

- UAT for costing tool (Natasha) – See previous slide
- Patient review groups (Marianna)
  - Often REC requests about ICF being reviewed by patient’s organization –
    - How sponsors need to address this?
    - What to do with conflicting comments from those groups
    - NIHR pilot for patient’s engagement projects (ie ICF review, etc.)
- Pharmacy review (Charlotte)
  - By choosing the central pharmacy review in IRAS, it is expected that protocols should be reviewed by pharmacist within 5 days.
  - However multiple questions are raised which required back and forth with the central reviewer. What information can it be sent in advance to avoid this delay
  - For complex protocols, the local pharmacy will still require to review it. What is the benefit of the central review?
- Indemnification of equipment (Natasha) – Discussed on HRA section
  - Additional question about the use of DocSign
    - Some resistance at the beginning and required explaining well the advantages
    - Most sites are OK but some still refuse. Also used for CDAs.
    - It was really easy for the sites.
- cCOG charter (Lynette on behalf of Sarah Durston) – 2019 review
  - cCOG members to send comments to Lynette within the next 2/3 weeks
AOB

- 2019 Meeting Locations
  - Wednesday 5th June: Novo Nordisk, Gatwick
  - Boehringer Ingelheim, Bracknell
  - Astrazeneca, Luton, Q3/Q4
  - PRA, Green Park, Q3/Q4
- Volunteer to manage member companies list and prepare website postings after each meeting
AOB

Industry Website Posting – ???

Next Meeting:

Date: 5 June 2019
Time: 10:30 – 15:30
Location: Novo Nordisk, Gatwick
Chair: 
Minutes:

MEETING CLOSED