



Joint Clinical Research Board

Thursday 6th June 2024 - MS Teams

Present:

Leanne Aitken (left early)

Amrita Ahluwalia (AA) (left early)

Kieran McCafferty (KM)

Sharon Barrett (SB)

Jackie Buck

Bryony Butland

Anthony Mathur

Jo Morgan (JM)

Neeta Patel

Alistair Chesser (Chair) (AC)

Mary Collins

Nikos Donos

Lauren Ellis (LE)

Ginette Hoare (GH)

Rupert Pearse (RP)

Jenny Rivers (JR)

Manish Saxena (MS)

Imogen Skene (IS)

Fiona Walter (left early)

Mays Jawad (MJ) Sophie Welch (SW Jamila Kassam

Apologies:

Sven Bunn Xavier Griffin Mark Caulfield Jo Martin

Steve Ford Klaus Schmierer

Nick Good (NG)

Agenda Item		Action
1. Minut	es and Actions from the last meeting.	
AC welcomed everyone. The draft minutes of the last meeting in March were agreed and apologies for this meeting noted (as above). Actions from the last meeting were as follows:		
(i)	NG and LE to remain in touch about updates regarding the Academic Centre for Healthy Ageing to JCRB as appropriate. Ongoing.	
(ii)	NG and SN to liaise and SN to probably return with an update on the Precision Medicine: Data Core for the September JCRB. Ongoing.	
(iii)	SB and NG to liaise on SB returning to the JCRB to discuss the Research and Clinical Trials workstream in due course. Ongoing	
(iv)	CR (TM) to inform NG of any changes to the IP Policy or IP website information so that the JRMO website can be updated accordingly. Ongoing.	
1. Joint Clinical Director's update		
RP opene	d by discussing the membership of the JCRB which has evolved over a long	

period. He suggested that he and NG or the JCRB itself decide who are the right people to attend the meeting.

AC said it would be helpful if a small group of people brought back a proposal at the next meeting and reviewed the TOR. RP will lead on this.

RP said the Senior Team is in place now, having taken a long time to get the right people in the right roles. JR is now seen as the key person to go to within the Trust. We are moving into the next phase of the opening of the CRF, as we start to think about the work we are going to do in the CRF which JR is leading on. We are also looking at how the CRF can be part of a partnership with neighbours around East London. We are bidding for funding which will support us being a hub where sites like BHR or Homerton can deliver trials without that they would not have otherwise been able to deliver without the support of the CRF.

The updated MHRA Inspection report was frustrating which upgraded two major findings to critical findings. We feel it is harsh, but there are some important lessons learnt across both organisations to work on. The biggest lesson learnt is that we were not told anything was wrong that we did not already know was wrong; in effect, there were no new lessons to be learnt by MJ and her team. What we now need is for researchers to listen a bit more carefully to the JRMO's Governance Team and make sure that they follow that advice. That way we will be able to do things more effectively and avoid future findings.

RP reported that we have appointed a great senior team for the RRDN to work with Sharon Barrett. It includes Kieran McCafferty as Medical Senior Leader within the team. The main things holding us back are being decided at a national level and Jenny has been leading the feedback to the DHSC and the co-ordinating centre for not just our area but other parts of the country too, which allows us to get more airtime. There is anxiety within the Researcher community about the funding for their research delivery teams and we have not yet been told how that will work.

RP gave an update on the work being carried out to represent diversity and inclusion following a proposal from the NIHR for all BRCs and CRFs to collect data on diversity for researchers, participants and staff. Rather than focus on the activity of the CRF and BRC we decided to do something for the whole of QMUL and the Trust that covers all Health Science research.

RP thanked MJ and Michael Garvey-Eckett for the work they have done in how the patient information is logged on Edge which will enable us to capture aggregate data on protected characteristics. Michael is going to do a proof of concept run to see if we can generate a draft list. This will establish rules about the number of individual patients in each group and will need to think carefully about how we report on that. BB has confirmed that her plan has been signed off by QM HR to capture the data. We hope to be able to release a report in October. It won't have the full data for all of the staff and patients, but it will show that we can achieve, and it will give a clear statement that we think working on the inclusion for both patients and researchers

is important. A lot of organisations have gone back to the NIHR and said it is impossible to do. This is therefore a great moment to show what Barts Health and QMUL can deliver as a partnership and to be identified as organisations that see these things as really important and are seen as a role model that can demonstrate that difficult things can be done if you try hard enough.

AH said that at Barts CVCTU the Data Manager has created a version of the Diversity and Inclusion Survey (DAISY) guidance in REDCAP and it will be implemented for all of the trials that we adopt within Barts CVCTU. The form has been shared and is being reviewed by QM HR. RP said it has been an amazing team effort.

AC said it speaks volumes for the leadership you provide and asked if there were any other questions. There were no other questions.

ACTION: RP to liaise with JCRB members and prepare a revised membership list to present at the next meeting.

RP

2. Research and Newham Hospital

SW presented an update on developing the research at Newham Hospital. The presentation had been circulated in advance. SW thanked the team for their hard work in particular Dr Liat Sarner, Tom Ellis, Nayna and the support received from JR, RRP, JM and GH. Newham had an established research portfolio, particularly in children's and public health, but the model was not sustainable. With the commitment and drive of the leadership team, and group level support we are now looking at developing the research infrastructure. Looking particularly at space, staff, pharmacy, and pathology. The award for the MRI scanner is fantastic which will grow activity. A research lead has been appointed and five PIs based at Newham who are growing their portfolios covering a broad range of areas including Gastro, Anaesthetics, Diabetes ED and Critical Care. We are not looking at developing a core group of research delivery staff and have recently had approval of new office space which will be dedicated for research in the modular build.

SW congratulated NP on successfully being awarded a Barts Charity to grow the research engagement team which is a key enabler to grow research activity.

SW said that research-active specialties have grown significantly, which is excellent. Moving forward to the next financial year is to build on expanding the research capability and infrastructure. We are currently drafting a research strategy and looking at an implementation plan which looks at 5 key strategic objectives.

SW gave a brief overview of the research delivery staff.

AC thanked SW for the update and said it is fantastic progress and thanked everyone involved. There is a lot more to do but there are some solid foundations at Newham now which were not there in the past. AC asked if there were any questions or comments.

KM agreed that the transformation at Newham was amazing and that this is a fantastic model to take to other sites and congratulated everyone involved.

LA asked how much success has there been getting into diverse professions across the institution and whether there is the same level of interest across all the professions; are there pockets that are not working?

SW thanked LA for the questions and said that for now the core team is made up of Research nurses, but we do want to expand that to AHPs and CRPs which is key and is an important drive, in terms of the CRN as well. We will be looking at for future posts and joint job descriptions. We are also looking at clinical academia and supporting maps in terms of developing careers. LA to contact SW separately to discuss this further.

AC said please tell us what you need. There is a good working team with site leadership at Newham and the feedback from colleagues at Newham is nothing but positive. Thank you very much on behalf of them as well as myself.

SW ended by thanking all the team and in particular JM and GH for all their hard work.

3. CRN funding committee progress

SW delivered a presentation on the progress of the CRN funding committee which was set up in August 2023. The presentation had been circulated in advance. SW thanked IS, JM, GH, the Deputy Clinical Directors and Maria.

SW said that the scope of the committee has grown significantly and has become a lot more work going forward. It is now focusing on streamlining this, increasing access to alternative funding streams and looking at where CRN funding is, so even if we are not able to support new funding, we may be able to help teams in other ways. We are promoting collaboration and cross-site working. This includes supporting the submission of business cases to the CRN if we are unable to provide support for new funding, as well as managing the CRN contingency funding. We are also looking at the funding review in terms of the annual financial plan, how core staff are funded and where they are based. There is a significant variation across teams in terms of infrastructure, but we are now building a better idea and mapping the research delivery workforce which will be important going forward when the new CRF opens. SW provided an overview of the applications received, what applications have been approved and declined and the timelines.

IS provided an update on the key learning and explained the growing complexity of applications. The application form is being revised and we now have a finance office sitting on the committee, to raise awareness of the application. The applicants are given a lead person within the committee who liaises with them, clarifies any additional details needed and streamlines the response times. We are asking for

local organograms to be supplied with future applications so we can get a better idea of the team line management and support within the applications.

SW said that sometimes it is about supporting the teams so they understand their finances better, how staff are funded and look at sustainability of short-term funding.

AC thanked SW for the update and said it was good to see all this fantastic work. AC asked if there were any questions.

SB said this has been a very efficient way of working with the site from a CRN point and it is great to see this model and the successes it has had to date. In her view, this put QM-BH one step ahead in terms of what comes to us in the new RDN world (the CRN contract will come to an end in September).

AA asked when studies are newly adopted onto the network, is it the same application process?

SW said that information should come through to the committee so it can be reviewed and then we could support in terms of going forward directly to the CRN for additional funding if that is what is required. SW acknowledged that the generic application form is not right for every application which is why we are tailoring it to make it easier for teams to know which one to complete and be more efficient.

IS said people should just send an email to the funding committee inbox as we may be able to point them in the direction of someone already in post within the Trust who's able to support them or fill in and submit the form.

There were no further questions.

4. MHRA inspection final report

MJ reported that the inspection finding report was received on the 9th May and to our surprise, as Rupert alluded to, two of our major findings were upgraded to critical, which in our opinion is unfair as well as unexpected. One of the findings has been disputed, formerly in our response to them making it very clear to them that we do not agree with that finding. MJ said that she will need to work with Institute directors to see how we can support how the study teams will include any disclaimers in publications going forward and how the JRMO has oversight of the publications. The response has been submitted for the critical findings. MJ provided an update on the two major findings and advised that the JRMO are currently drafting the corrective and preventative actions which must be submitted to the MHRA by the 4th of July but hoping to submit this by the end of June.

MJ said that, as Rupert mentioned, we already have processes and procedures in place so it is not difficult to address a lot of the findings. We have also delivered two training sessions on lessons learnt which were very well received.

AC said that the fact that it is comparatively easy to address these issues speaks volumes of the quality of the Governance team and said no one should beat themselves up about this although it is important to pay attention and get things right. AC thanked MJ and her team for what they have been doing and asked if there were any questions. There were no questions.

ACTION: MJ to liaise with Institute Directors on how to better support them with MHRA requests for disclaimers to be added in publications and how the JRMO has oversight on publications.

MJ

5. CRF update

JM provided an update on the CRF the presentation had been circulated in advance. JM advised that the enabling works started last week and will take approximately four weeks to complete. There are still some outstanding legal issues which need to be signed off due to the building works. The new design which will take 12-16 weeks before that's confirmed, which has led to a slight delay in the formal approval of the deed of amendment. If this is not signed off within 12-16 weeks and if anything is raised, we will have to wait another 12-16 weeks before the approval can be given. That is a potential risk to the building work starting. But if everything goes to plan the work will begin in October which would be in line with the CRF opening June-July 2025.

The CRF workforce workshop took place last week and will be meeting monthly. JM gave an update on the development of the portfolio. Ongoing work continues with the community advisory group and the scientific advisory group as well as the development of the CRF identity. As the pace is now picking up, we are looking at the promotion of the CRF and site governance.

KM said we have been invited to join the London Advanced Therapies ATEMP active researchers across London and they are sharing their governance and SOPs with us which will save a lot of time.

AC said it was wonderful to see the progress and thanked everyone involved.

Action: JM to continue to update JCRB on the progress of the CRF.

JM

6. RRDN progress

JR said there is still a lot of work to be done. We are expecting some reassurance from the DOH soon about the next financial year's funding allocation. We are working closely with the DOH and Social Care, co-ordinating centre and other hosts.

Barts has a strong leadership role in place. We are behind where we needed to be in terms of implementing the change for 1st of October and that's largely based on the

amount of complexity across the 15 different local CRNs and the agile workforce in primary care.

We recognise that there will be a period of extended transition that we will have to balance. We are due to update the final organogram and the structure of the RRDN by the 17th of June.

Governance has not yet been set nationally, particularly in terms of decision making and it is very clear that this is a national network. We are expecting some of the decisions to be made by the board where Sharon will be our key representative but there will be some local things that we want.

The speciality leads and setting leads have now been appointed. One of Kieran's first jobs will be to appoint the regional speciality leads. Do think about colleagues working in areas that you know who may want to take a regional role.

We are working as quickly as we can when we get the right information.

AC thanked Jenny for the update and extended his personal thanks to JR and SB for working through this long and difficult process.

SB thanked JR, RP and GH for their support over the past few months. Whilst this is a national network it should not stop us from driving some of the strategy, and whilst we will be told about governance structures we will need in place, it does not stop us from having other groups as well.

AC thanked SB and said it is both a responsibility and a privilege to host the RRDN. There is a lot to learn on the way, and he said he had every confidence that we are doing extremely well. He paid tribute to how the relationships with the other partners across the two CRNs have been handled and said that he is getting very positive feedback from them.

7. Sponsored Oversight Group (SOG) minutes

MJ asked those present to confirm that they read the circulated SOG minutes. There was no dissent or comments and the SOG minutes were therefore agreed.

8. A.O.B.

KM advised we received £3.5 million from the NIHR to increase research MRI capacity and Newham was chosen as the site. We have now established the funding from the NIHR and NHSE to deliver the MRI scanner with a mixed research and clinical role. An MRI project board has been set up chaired by John Middleton the new Deputy CEO and workstreams are in place to deliver the project, a workforce research group which KM chairs, and a finance workstream led by Jo. This is on course to deliver the new MRI scanner by March 2025.

get the mo imaging st the Hamil	to drum up support for more imaging capacity across sites and we need to essage out to PIs that we have this new opportunity to take in-house any cudies that we previously would have outsourced. We have engaged with ton who use MRI scanners privately to deliver their work and they are keen ith us and move these to Newham MRI capacity.	
AC thanke	ed Keiran for the very good news story.	
	d that the HPN inspection which is taking place at Charter House Square is l. AC thanked HK for the update.	
9. Next J	CRB meeting	
MR said th	nat the next meeting was arranged for Thursday 26 th September.	
10. Summ	ary of Forward Actions	
(i)	RP to liaise with JCRB members and prepare a revised membership list to present at the next meeting.	RP
(ii)	MJ to liaise with Institute Directors on how to better support them with MHRA requests for disclaimers to be added in publications and how the JRMO has oversight on publications.	МЈ
(iii)	JM to continue to update provide update on the progress of the CRF.	JM

MR

7th June 2024