



Joint Clinical Research Board

Monday 18th December 2023 MS Teams

Sophie Welch

Present:

Leanne Aitken Kieran McCafferty (KM)

William Ajala Jo Martin
Sharon Barrett (SB) Jo Morgan
Bryony Butland Neeta Patel

Sven Bunn (SvB) James Patterson (JP) Mark Caulfield (Chair) (MC) Rupert Pearse (RP) Mary Collins (MAC) Caspar Ridley **Nikos Donos** Jenny Rivers (JR) Rhian Gabe **Julie Sanders** Deanna Gibbs Manish Saxena Hortensia Gimeno Klaus Schmierer (KS) Francesca Gliubich (FG) Ajay Sinha (AS) Nick Good (NG) Imogen Skene (IS) Fiona Walter Ginette Hoare (GH)

Apologies:

Mays Jawad (MJ)

Alistair Chesser Hemant Kocher
Coleen Colechin Nick Lemoine

Steve Ford Arunthathi Mahendran

Xavier GriffinMauro PerrettiJamilla KassamBeth Stuart

Agenda Item		Action
1. Minu	ites and Actions from the last meeting.	
	omed everyone. The draft minutes of the last meeting in September were agreed ogies for this meeting noted (as above).	
Actions f	rom the last meeting were as follows:	
(i)	NG to put an update regarding the CRN Funding Oversight Committee on the next JCRB agenda.	
	NG confirmed this was in this agenda.	
(ii)	SN to send NG his Precision Medicine presentation and NG to circulate that, and	
(iii)	NG to circulate GH's recruitment to commercial studies presentation. NG confirmed that both documents had been circulated after the last meeting.	
(iv)	As soon as we hear from the MHRA about an inspection there will be general and specific communications from the JRMO.	
	NG confirmed this was in this agenda.	
(v)	All to send ideas for future JCRB discussion topics to NG. NG reported none received. MC asked that people continue to bear this in mine.	

2. MHRA inspection and JRMO Governance activity update

MJ reported that a five-day MHRA inspection had begun on 17th November. It went well as there were no critical findings. There was one major findings, one potential major finding and eight other findings, and the inspectors are due back for site visits in early February, but the feedback has been very positive about lessons having been learnt since the 2014 inspection.

MC said he was very grateful to MJ and her team in the JRMO. This has been a very good outcome but those involved need to maintain their vigilance at the site visits.

RP added his congratulations to MJ and her team. This success is due to long team planning and preparation, including the internal auditing of studies. The MHRA made it clear that our processes are consistent and timely and not reactive to the MHRA inspection itself.

MJ said that the inspection shows that our oversight processes work. She further reported that she is now recruiting a new GCP manager.

Moving on, MJ said that further activity reports had been circulated. She asked for any feedback on the usefulness of this data and the format of presentation. Since a new data and AI person had been recruited to the governance team, we are reviewing what useful reports could be produced to assist in management oversight of JRMO and R&D activity. The main theme of the data appears to be that we are on track and have recovered up from the pandemic; overall the volume of open studies is down, but that is consistent with other major recruiting Trusts and due largely to our proactively closing old/ non-recruiting studies.

MC asked if there were any questions for MJ. There were not bit he asked how often these data sets wee being produced. MJ confirmed this would be quarterly for the JCRB.

ACTION: MJ to continue to produce quarterly reporting data for the JCRB, along the lines of the reports submitted to this meeting, subject to any further views expressed.

MJ

3. RRDN update

MC welcomed JR to the JCRB. JR said she had received a warm welcome and thanked those she had already met for their time. She reported that Barts Health would be hosting the new NIHR Regional Research Delivery Network (RRDN) for North London from October 2024. Its Director has down been appointed (SB), congratulations to her. We look forward to working with SB in her new post from April '24. Two more senior posts are due to go out to advert very soon with interviewing planned for the end of January. Then clinical leads will be appointed and that will make up the RRDN's senior management team.

As the geography of the new network will be different, we are working closely with Imperial Healthcare on staffing issues. That is going well but naturally there is some anxiety amongst existing staff about what the transition might mean for them. The service specification is the next thing that needs to be agreed with NIHR and DHSC. A high-level agreement is expected by the end of January with more details to be agreed by the end of March.

JR reported that Barts has also been asked to host a parallel NIHR Regional Research Leadership Office (RRLO) that is intended to focus on the clinical academic community and

the development of NMAHP researchers. It has now been confirmed that Barts will host both networks.

MC asked if all the new RRDN staff would be Barts Health employees. JR confirmed this would be the case, so any currently employed by Imperial Healthcare who get jobs in the new RRDN would need to transfer across.

MC asked if there were any concerns around taking on the new RRLO. JR said that the team is mindful that this is an area where we clearly need to work with partners to develop, much of its activity falls outside the areas of Barts' traditional strength.

RP said that this was all part of an effort by DHSC and NIHR to create a more nationally coordinated approach to research delivery; it is not just a re-brand. It is good that we are going to be at the heart of these changes.

MC thanked JR and said he looked forward to hearing mire on this in due course.

4. Research Misconduct policy

JP reported that the new Policy, discussed at the June JCRB, was due to go to SET in October. However, concerns have been raised over institutional autonomy (investigating matters independently from partner organisations) so further drafting work is being undertaken. He hoped that a further draft can be circulated early in 2024.

MC thanked JP for his work on this and agreed it was right to get this agreed so that we have a policy that lasts.

5. CRN update

SB reported that Barts has a healthy level of study recruitment, although it is consistent with recruitment across our area in having seen a general reduction.

In relation to the transition to the RRDN, she reported that meetings involving both the North Thames and Northwest London CRN teams are taking place. There are concerns about the pace being driven.

The next financial year's funding will be split in two, to be managed by the CRN and then the RRDN. The CRN's funding working group is proposing a rollover of the existing funding model.

MC congratulated SB on her new role.

KS asked if we were losing any high-recruitment sites through the network boundary changes. SB confirmed that those sites being lost in Essex have lower recruitment levels, so that will have little overall impact.

6. CRN Funding Oversight Committee

IS reported that the funding pilot, agreed earlier in the year, had now been operational since September. Applications to the committee were growing month on month. There had been 14 so far and most had been approved. Requests need to be submitted at least one week

before meetings and the turnaround has been good. The plan is to continue the pilot, fully review it and then report back to the JCRB.

RP said that he wanted to thank IS and GH. This has been a difficult piece of work, tackling sensitive issues around funding allocation. The committee's turnaround times and working transparency are impressive.

MC said that he echoed that. He said that we now have a system with a clear audit trail, and he is receiving fewer complaints which cannot be bad.

7. Clinical Director's report

RP started by thanking MJ and the governance team for their work on the MHRA inspection and welcoming JR to her first JCRB. He also congratulated SB on her appointment to the RRDN and offered any help towards that transition.

He reported that the new CRF has hit a delicate contractual issue, but hopefully this will not impact on the overall timeline.

The NHS partners strategy is being reviewed to take account of RRDN changes. Primary care working will now be a focus to make the partnerships work better, building new relationships and reviewing opportunities.

There are a lot of exciting research developments at Newham, there is senior support for research and a site research lead has now been appointed with an ongoing integration of various resources. RP said that Newham is much the same size as Barts so should support similar amounts of research activity. KM has been working to establish an MRI scanner at Newham to assist with research activity and it looks like it is now a matter of the size of the scanner rather than whether one can be purchased or not.

The Inclusivity metrics group has been working to develop meaningful metrics to measure the diversity of research participants and research staff. There will be a rollout of communications on this topic in the first quarter of 2024 to explain this work and involve teams.

The PI scheme has been progressing well but is still in the set-up phase. We will need to develop metrics to demonstrate its success in due course.

KS asked when there might be another call for applications for this and MAC wondered whether there could be value in working up clusters of activity n this area, maybe in partnership with QM, to increase impact.

RP said that it may be five years before we can be sure about the success of the scheme, but it appears to show that there is hidden talent. If only one in ten of staff supported become major researchers that is an excellent result. There will need to a business case made for any further awards. He said he had concerns that certain areas were probably at the ceiling for research volumes and there were areas (location and specialism) where the Trust wished to grow research activity.

SB noted that some pharma companies are keen to help support new clinical researchers; this is clearly an area for potential growth.

AS asked if the PI scheme could support researchers generating their own ideas. RP said it could but only if they were also involved in research delivery for portfolio studies; that was the main point of the scheme. He added that there are MRC and NIHR fellowships available to support own initiative research.			
MC said that it will take some years to see the effectiveness of the scheme, but we clearly need to foster new talent. Research delivery is a Trust issue so that is quite correctly the focus of its scheme.			
RP said that JCRB membership needs to be reviewed as there have been so many changes.			
ACTION : RP will work with NG to review membership of the JCRB before the next meeting in March.			
RP suggested that a report from the Academic Centre for Healthy Ageing could usefully be made to the next JCRB.			
ACTION : NG to establish with RP who would be best to speak about the Academic Centre for Healthy Ageing and place this on the JCRB Agenda for March.			
8. Sponsorship Oversight Group (SOG) minutes			
NG asked those present to confirm they had read the circulated SOG minutes. There was no dissent or comments and the SOG minutes were therefore agreed.			
9. A.O.B.			
CRN North Thames Research Awards – SB reported that this new scheme had just been launched with a closing date on 31sty January. RP said that we would circulate details of this around our researcher teams.			
BCI safe haven – KS asked if there was an update on this. MJ said that the issue was subject to round-the-clock activity within the JRMO and QM IT. Activity had ceased and the attempted intrusion isolated; the MHRA had been kept fully informed. She hoped that it would be resolved by New Year; the good news was that no patient data was compromised. FG added that the attempt had failed and that systems remained locked down for security reasons. RP suggested that there be a report on this incident to the next JCRB.			
ACTION : NG to work with MJ on a report covering the IT issues around the BCI safe haven outage.	NG & MJ		
Research and Clinical Trials workstream of the Acute Provider Collaborative – SvB suggested that he make a report to the next JCRB on this group's activities. This was agreed.			
ACTION : NG to liaise with SVB and get a report re the Research and Clinical Trials workstream of the Acute Provider Collaborative on the next JCRB agenda.	NG & SVB		

10.	10. Next JCRB meeting				
	MC thanked everyone for their hard work over the last year, wished them a happy and restful Christmas break. He hoped they would return refreshed for 2024.				
	NG said	d that the next meeting was arranged for Wednesday 13 th March.			
11.	11. Summary of forward Actions				
	(i)	MJ to continue to produce quarterly reporting data for the JCRB, along the lines of the reports submitted to this meeting, subject to any further views expressed.	МЈ		
	(ii)	RP will work with NG to review membership of the JCRB before the next meeting in March.	RP & NG		
	(iii)	NG to establish with RP who would be best to speak about the Academic Centre for Healthy Ageing and place this on the JCRB Agenda for March.	NG& RP		
	(iv)	NG to work with MJ on a report covering the IT issues around the BCI safe haven outage.	NG & MJ		
	(v)	NG to liaise with SvB and get a report re the Research and Clinical Trials workstream of the Acute Provider Collaborative on the next JCRB agenda.	NG & SvB		

NG

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