Joint Clinical Research Board

Friday 15th September 2023
MS Teams

Present:

Amrita Ahluwalia
William Ajala
Adeeba Ashghar
Bryony Butland (BB)
Mark Caulfield (MC)
Stuart Chandler (SC)
Alistair Chesser (Chair) (AC)
Mary Collins
Hortensia Gimeno
Francesca Gliubich
Nick Good (NG)
Ginette Hoare (GH)
Richard Hooper
Bryan Leventis (BL)
Nick Lemoine (NL)
Jo Martin
Jo Morgan (JM)
Steven Newhouse (SN)
Rupert Pearse (RP)
Caspar Ridley
Manish Saxena
Klaus Schmierer (KS)
Ajay Sinha (AS)
Imogen Skene
Beth Stuart
Sophie Welch

Apologies:

Sharon Barrett
Sven Bunn
Nikos Donos
Panos Deloukas
Steve Ford
Rhian Gabe
Xavier Griffin
Mays Jawad (MJ)
Hemant Kocher
Gerry Leonard
Kieran McCafferty (KM)
Neeta Patel
Mauro Perretti
Julie Sanders
Fiona Walter

Agenda Item	Action
1. Minutes and Actions from the last meeting. AC welcomed everyone. The draft minutes of the last meeting in June were agreed and apologies for this meeting noted. Actions from the last meeting were noted as follows: (i) NG to put non-recruitment to commercial studies on the September JCRB Agenda. *On the agenda.* (ii) NG to note Precision Medicine/ data core update to JCRB as a possible September meeting item. *On the agenda.* (iii) NG to ensure a CRF progress update returns to JCRB in due course in consultation with KM – a possible September agenda item. *On the agenda.* (iv) JP to take the agreed Research Misconduct Policy forward for agreement by both QM and BH.	

NG reported that this is proceeding through the QM structure and once agreed (probably in October) it will be put to the Trust Policy Committee. RP asked if there had been any changes. NG said none so far and RP said that if there were changes it would need to return to the JCRB. He looked forward to positive news at the next JCRB. (v) RP to meet with Trust finance officers and others to review what practical measures can take place to move away from the short-term employment culture. RP said that various discussions had taken place but that this was long-term work in progress. (vi) Once the Oversight Committee for the Distribution of CRN Funds pilot is established and operational it is to report back to JCRB. RP reported that this was now operational (just) and would report to the next JCRB. **ACTION**: NG to put an update regarding the CRN Funding Oversight Committee on the next JCRB agenda.	**NG**
2. Precision Medicine: data core SN gave a presentation updating the JCRB on developments in the last six months. An additional £5m funding from Barts charity is now in place to support growth up to July 2027. The main actions now are assembling a team and developing the evolving process. Alongside this work is ongoing to identify and accommodate related approvals that take place in other parts of the Trust and to work with those teams, including JRMO and IG. The new data environment will be operational in 2024. It allows for proportionate reviews that will depend on data usage and the data itself. Further work will take place to identify users. Current thinking is that there are five main user groups: (i) Informatics (ii) Inquirers (iii) Clinicians (iv) Administrators (v) Governance/ oversight Capability summaries for each group are being developed linked to the uses they have for data and related activities. They are looking to procure software expertise that will create a secure environment complementary to NHS England's and other similar London developments. The focus will then be on Trust-wide training around accessing this and similar facilities. MC asked for confirmation that the data will be stored in Azure Cloud and what is the approach to scoping changes and future storage increases. He said it would also be useful to know about charging ASAP to head off any issues.	

SN confirmed it will be hosted in Azure. The thinking is that the cost will cover cloud usage plus administrative costs/ overheads reacting to applications. BL asked where any IP around this data would rest. SN said patient data within the system would be accessible on a reading library basis and could only be viewed within the environment. IP for other data developed will depend and the contracts team will be involved in any such agreements. It may be that we do not release any IP, just enter into licensing etc. agreements. AC asked if IP-related decisions would come to the IP Oversight Group and SN confirmed that would still be the case. BB asked how this connects to the bid for 'red funds'. SN was unsure what that was but said it would create an environment for sharing data. MC said that Sophie (Williams?) is involved in both projects and issues will need to be articulated as they develop. He also suggested that issues around IP should be kept as simple as possible – that is the lesson to be learnt from Genomics England whose delays led to disincentivising that system, whereas Biobank UK has been more open and so more successful. AS asked about ongoing costs where access relates to core Trust business. SN suggested that where activity was part of the Trust's business, for example, audits, the Trust may cover those costs. He said that this is under present consideration. KS asked if there was any overlap with existing application processes and forms. SN said that at present there is a Word application form which will go online. Work is ongoing to capture as much relevant information upfront as possible but that is all subject to further review as the project progresses. AC thanked SN for the update. **ACTION:** SN to send NG his Precision Medicine presentation and NG to circulate that.	**SN/ NG**
3. Pharmacy update SC began by saying he was very happy to report that the research pharmacy service is now business as normal. He would not give a presentation today but would just run through some updates. The teams at all sites have worked hard. Processes have all been updated and documented and there is no outstanding amendment backlog. There has been a major recruitment drive and new staff are bedding in; the SBH team is much happier and there have been no staff changes in 18 months at RLH. Negative feedback is now minimal. SC asked that any specific issues be directed to him and asked if there were any questions. RP said that it was great to hear such good news and congratulated the teams on their hard work to achieve this. He said that as we are now getting more ambitious, we will be focussing on bringing the Whipps Cross and Newham pharmacies up to par. He anticipated some growing pains on those sites.	

AC asked if there were any other questions. There were not so he thanked SC for his work on this.	
4. NIHR Barts CRF JM sent KM's apologies and said she would go through the report circulated. Key aims for the CRF include: • Having appropriately trained staff to deliver early phase trials and provide support before the facility opening; • Continuing to grow the portfolio of studies, with the early phase experimental research opening in July 2024; • Supporting the development of the new CRF at the Royal London Hospital by advising the design, specification and operational management arrangements and advising the CRF leadership team on the vision scoping and prioritisation of studies; • ensuring patients and the public are involved in planning, designing, running, and disseminating research activity, to develop a rolling programme of projects and activities that align with the overall aims and objectives. Be responsive to the changing needs and priorities of patients and the public. Build capacity, including training and support for researchers and public contributors who are involved; • communicating the ability to deliver research from early to late phase in a dedicated inpatient unit to our research delivery community, stakeholders and commercial/non-commercial sponsors; • having appropriate IT systems to facilitate the operations within the unit; and • Working with the NIHR to deliver joint BRC/CRF EDI/PPIE strategies. Work is proceeding on all these fronts. NL expressed his congratulations to KM for receiving the Royal Colleague of Physician's NIHR CRN Consultant Award for Research. He said we all need to keep spreading the word about what is and will be available in terms of facilities. RP said that JM and KM have been doing an outstanding job getting the CRF up to speed. He was proud of the ongoing activity and excited that it all remains to target. AC said this was exceptional work and congratulated the team as well.	
5. Recruitment to commercial studies GH went through a presentation to update JCRB on the position. It is one year on from our initial consideration, when we were at 63% of 2017/18 activity. We are now up to 77% of activity and the recruitment of participants is back up to 2017/18 levels. Barts' relative position is also up and better than in recent years, although we still have a lot of non-recruiting studies. We still appear to be taking on studies with low recruitment targets which needs investigation and the spread of this activity is still heavily towards SBH and RLH. Our commercial CTIMPS are ahead of all other Trusts and her overall number of commercial studies is high but again, the volumes are small. NL commented that total recruitment is disappointing but more meaningful is the number of studies recruiting to time and target. He asked if that data was available. GH said that	

these targets often depend on how sponsors feel about recruitment, but NL said that going forward it would be helpful to know how on-track recruitment is. GH said that time to target data would be available every quarter; this is work in hand. RP agreed that useful data is vital, as is live data as that can help focus delivery resources and identify problems to fix. He said that GH's role will be to produce data that supports and informs decision-making. Real-time data can be misleading, so we need teams to keep their data up to date. N: agreed that complexities in the portfolio need to be realised, and we need good data to incentivise and reward as appropriate. BL suggested that GH attend a Commercial Directorate meeting, which she said she was happy to do so they will liaise offline. He asked if there was a single biggest barrier to this activity. RP said that getting staff to deliver was something we needed to work on with the CRNs through training and development. Investing in new PIs is also an issue we are focussing on but such staff changes only have an impact around three to five years down the road. AC welcomed these improvements in useful data presentation as evidence of further progress. NL asked if we have a grasp of the impact the junior doctors' strike is having on research. GH said that anecdotally it has had an impact on all Trusts but assessing the local impact needs further work and she is happy to take that offline with NL. JM reported that the impact in the CRF has been offset by some staff working through difficult times. **ACTION**: NG to circulate GH's recruitment to commercial studies presentation.	**NG**
6. MHRA inspection RP reported that there is very little to report. The Dossier was sent to the MHRA on time and the team is not waiting to hear back. This could well take months, quite possibly into 2024. We are guessing that databases and their functionality will be a focus, also around four Queen Mary-sponsored CTIMPs will be chosen and there are likely to be findings of some sort. Teams should continue to keep their records up to date and tidy, and any matters identified in the initial review by the JRMO need to be addressed. **ACTION**: As soon as we hear from the MHRA about an inspection there will be general and specific communications from the JRMO.	**MJ/ RP**
7. 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.	

8. A.O.B. (i) **Issues for future JCRB meeting** – RP asked for any ideas for topics for future JCRB meetings to be sent to NG. **ACTION:** All to send ideas for future JCRB discussion topics to NG. AC thanked everyone for attending and said it was heartening to hear so much good and positive news for a change.	**All**
9. Next JCRB meeting: 18th December.	
10. Summary of forward Actions (i) NG to put an update regarding the CRN Funding Oversight Committee on the next JCRB agenda. (ii) SN to send NG his Precision Medicine presentation and NG to circulate that. (iii) NG to circulate GH's recruitment to commercial studies presentation. (iv) As soon as we hear from the MHRA about an inspection there will be general and specific communications from the JRMO. (v) All to send ideas for future JCRB discussion topics to NG.	**NG** **SN/ NG** **NG** **RP/ MJ** **All**

NG
20th September 2023