

Joint Research Boards

A meeting of the Joint Clinical Research Board and the Barts Health Research Board

Wednesday 8th July 2020

MS Teams

Members present:

Amrita Ahluwalia (AA)
 Karim Brohi (KB)
 Sven Bunn (SB)
 Sir Mark Caulfield (MC)
 Alistair Chesser (AC)
 Coleen Colechin (CC)
 Sandra Eldridge (SE)
 Rhian Gabe (RG)
 Deanna Gibbs (DG)
 Charlotte Hopkins (CH)

Stamatina Iliodromiti (SI)
 Hemant Kocher (HK)
 Gerry Leonard (GL)
 Kieran McCafferty (KM)
 Vivienne Monk (VM)
 Rupert Pearse (RP), Chair
 Mauro Perretti (MP)
 Steffen Petersen (SP)
 Julie Sanders (JS)
 Tim Warner (TW)

In attendance:

Nick Good (NG)
 Mays Jawad (MJ)
 Jo Morgan (JM)

Chloe Orkin (CO)
 Neeta Patel (NP)

Apologies:

Sharon Ellis
 Jo Martin

Anthony Warrens

Agenda Item	Action
<p>1. Minutes and Actions from the last meetings</p> <p>RP thanked everyone for attending this unusual joint meeting. He explained that this meeting would focus primarily on COVID-19 and related matters. Matters would, he anticipated, return to something closer to normality in the autumn</p> <p>The minutes of the last meetings of both the Joint Clinical Research Board (9th March 2020) and the Barts Health Research Board (13th February) were agreed. Actions were noted as completed.</p>	
<p>1. COVID -19 Research</p> <p>RP thanked CO and MC for attending to talk through some key points of their activity on COVID-19 (C-19) research.</p> <p>CO, Clinical Lead for C-19 research, thanked RP for inviting her to attend this meeting. She began by setting out some figures of numbers recruited to C-19 Research which were 3,135 to date overall, 1,883 of which are NHS patients. At the point where the temporary Nightingale Hospital closed, all its patients had enrolled in research trials. She reported that there are around 40 research staff members who have developed excellent cross-disciplinary</p>	

and cross-site working. We need to maintain this capacity and develop into effective prevention and better treatment, working now in PEP and PrEP.

Vaccine trials were now coming through the pipeline: 12 trials are anticipated overall, with an anticipated enrolment of around 30,000. Barts Health will now be a hub; it was not going to be a hub, but this decision has been based on both our successes at the Nightingale Hospital and our BAME-related work. CO said that we could get to work on 4 or 5 vaccine trials, but it is a competitive process. The first trial is now in the feasibility phase, but it is only looking to enrol 125 participants.

CO reported that it took UCL 120 staff to recruit 750 participants in 14 days, so this work is going to be very labour-intensive. To take part in vaccine trialling will mean redeploying staff, setting up a call-centre, using existing volunteers and finding a suitable venue. The larger the trial, the more challenging this all becomes. All pre-consented patients will need to be contacted and in such a way that is consistent with the aims of other work being undertaken re 'Black Lives Matter' and BAME in general.

RP thanked CO and asked if the latest accrual figures could be circulated to all.

ACTION: MJ to send NG the latest C-19 patient accrual figures that he will then circulate.

NJ/ NG

HK asked if the Tissue Bank could be of help? CO said yes if staff in the Tissue Bank have permission to contact those who have supplied samples regarding other research work.

SE asked if there was a lead being taken to address BAME-related issues at a strategic level rather than this just being left to teams. CO said this was a live issue, and that a lot of thought is going into how to address apparent inequalities to both access and medical outcomes. NP agreed that a lot of work is now going into this and urged people to view the useful videos that Barts Health (BH) has put online and to attend the related training. NG said that this work would be featured, with links, in the forthcoming R&D News Bulletin.

RP thanked CO again and handed over to MC who has been leading on C-19 research delivery across BH hospitals. MC began by thanking all those who have been part of the fantastic team effort to both set up and then manage successful research delivery at all BH sites. Our figures around recruitment stand up well against all other organisations. E-consenting was a success and. He was particularly pleased with the 9 language-specific videos that were prepared very quickly and which have been a great help to recruitment and outreach work. Both the public and patients have been involved, alongside clinical teams, in the daily 6 pm meetings; this has been of great help with various challenging issues that have arisen from time to time.

Preparation is now beginning for both a potential second wave of C-19 and vaccine trials. MC agreed with CO that it was our work to date, plus lobbying, that has got us a vaccine hub. Our East London hub is geographically wide-ranging and should enable a considerable reach for potential vaccines across our diverse population.

RP thanked MC and said he did not have much to add but was very gratified to see the response from all those involved. He particularly thanked the JRMO which has had to manage both the existing portfolio and the new, C-19 trials through a challenging period. Existing work had to be shut-down in an orderly manner, and that is now being reopened in a similarly planned way. New processes have been developed which in many cases have been adopted elsewhere too. He recognised that there have been tensions between establishing new trials

<p>and existing work, but these have worked through consistently.</p> <p>We established an expedited C-19 review process; the new C-19 Clinical Research Review Committee has now met 14 times (over 14 weeks), reviewing 269 proposals, 139 of which amounted to potential research studies. Barts Life Sciences set up an additional board to review data research as this presents a massive information governance challenge.</p> <p>It has also been interesting to observe people working outside their normal areas of expertise. That has, at times, been challenging and has led to questions arising over processes where reviews are now needed. Statmand training is needed on the ethics appraisal process.</p> <p>MP asked what the cost implications of C-19 research have been. RP said that, in terms of delivery, much of the research has been for social good rather than profit. Having said that, he felt that a failure to rise to these challenges would have been a mark against the Trust with regards to future centrally awarded funding, so there was very little choice. Being involved was of strategic importance.</p> <p>MP asked if the vaccine trials were likely to generate any income. MC said that these concerns around income are valid, but it is also important to realise that we have now developed a sound data platform that will bring in future income; that should be seen as an investment, not just as an outgoing. Additionally, we have gained a great deal of eternal goodwill and internal experience. He added that vaccine trials are much more likely to be undertaken on a commercial basis; these projects are now being fully costed.</p> <p>SI asked how the redeployment of CRN staff to C-19 work will sit with CRN funding and, in particular, RCF. RP suggested this led into the next item and handed over to GL.</p>	
<p>2. Research Capability Funding (RCF)</p> <p>GL said that the C-19 pandemic has had a massive impact on research finances and future budgets are likely to change as a result of this. In particular, there will be an impact on the CRN funding model, which has, over two years resulted in a reduction of some £900 to the Trust's allocation. However, because of the C-19 impact on NIHR portfolio studies, most of which have been suspended, the NIHR position appears to be that it will not punish trusts for unavoidable drops in recruitment. Rather than cut staff funded from the NIHR budget, some posts have been moved over to the RCF budget, but it will be the case that Internal decisions will eventually be needed to establish a mechanism for reducing our research staff.</p> <p>On the specifics of research capability funding, GL reported that the issue is the same as it always is; yet another reduction overall, but a slight increase in BH allocation because of an increase in NIHR awards. He had circulated a paper which set out that our workforce has, so far, been maintained by using RCF as an interim measure to fund staff removed from the Network budget until those between grants can be funded from alternative sources. He reported that all R&D Directors are lobbying for more support and so far he is aware of no further cuts to RCF for next year.</p>	
<p>3. PI scheme</p> <p>GL then moved to the PI-PA scheme that was launched in 2019. Like so many other things, he said that this was affected significantly by the C-19 outbreak. A proper review of performance needs to take place as some awarded PIs became involved in unplanned C-19, whilst others</p>	

<p>simply returned to C-19 clinical activity. This may mean extending some awards and cancelling others. There remains considerable interest in the scheme and, with awards only lasting for a maximum of 2 years, new recipients will emerge.</p>	
<p>4. JRMO audit</p> <p>MJ had circulated a copy of the Barts Health audit team’s review of some JRMO processes against performance and the UK RMG framework. Overall performance was marked ‘Reasonable’. It was reasonable across all items. Items included:</p> <ul style="list-style-type: none"> (i) R&D Joint Policies. A full review of these is overdue but was delayed due to Brexit. It is now agreed that these will be reviewed in 2021. (ii) Governance processes. This included end-study audits not always being done which is now being reviewed. (iii) Escalation of compliance issues. This includes a clarification of BHRB TORs and accountability to BHRB and/or JCRB by JRMO & investigators. <p>AC thanked MJ and the team for their hard work and said that ‘reasonable’ is a lot more impressive than it sounded.</p> <p>RP commented that the impact of Brexit on all sorts of legal-based issues remained a significant question-mark for organisations.</p>	
<p>5. JRMO move</p> <p>CC reported that as previously announced, the JRMO is moving to Empire House, across the road from the current office. The C-19 situation has both delayed the move and meant that a move to new clean offices is essential as a basis of some degree of normality resuming. The original plan was for the move to take place in May, but it is now firming up to take place in early August. Staff will continue remote working through this period with planned access to enable packing up and filing reviews. The hope is that following a full risk review, covering suitable distancing measures and some shift working, staff will be present in Empire House from September.</p> <p>CC said that the next stage – a move to ‘Dept W’ – is currently on hold due to cost pressures within Queen Mary. This delays the problem of the CRC being homeless, but it does not make it go away altogether.</p> <p>RP asked CC or Sharon Ellis (SE) to return to the JCRB next time to provide a further update.</p> <p>ACTION: CC or SE to return with an update on the JRMO move(s). NG to add this to the agenda.</p>	<p>CC/SE & NG</p>
<p>6. Matters arising</p> <ul style="list-style-type: none"> (i) NG said that a matter arising from the JRMO audit was that the Barts Health Research Board’s Terms of Reference (BHRB TORs) needed reviewing. He asked if it would be acceptable for him to send these round, with some comments, for a paper review by committee members. AC agreed this should be done. 	

<p>ACTION: NG to circulate BHRB TORs for review.</p> <p>(ii) RP asked if there were any comments on the JRMO activity reports that were circulated. There were none.</p>	<p>NG</p>
<p>7. AOB</p> <p>(i) AA said that there appeared to be a growing issue around the capacity of the Trust for undertaking research-related scans. She agreed that clinical work was the immediate priority but if patients were happy to come in for funded research work this should not be blocked. RP agreed that the clinical activity backlog does present the Trust with difficulties. He understood that research imaging is a national challenge now and is aware that we are being asked to help out other sites too.</p> <p>AC said he was sorry this was taking time, but it is all a question of priorities being considered carefully and then agreed. AA asked if there was guidance on how priorities are to be assessed and if decisions were being taken centrally. AC said there is no specific process as yet but he recognises that there cannot be a generic response. As of now all we can do is work individually to overcome individual blockages.</p> <p>RP suggested that if anyone experiences what seems to be an unreasonable imaging-related block, they should contact him.</p>	
<p>8. Next meetings</p> <p>The BHRB is due to meet next on 19th November.</p> <p>The JCRB is due to meet in late autumn/ early winter (date TBC).</p>	
<p>9. Summary of forward Actions</p> <p>(i) Mays Jawad to send Nick Good the latest C-19 patient accrual figures that he will then circulate.</p> <p>(ii) Coleen Colechin or Sharon Ellis to return to JCRB with an update on the JRMO move(s). Nick Good to add this to the agenda.</p> <p>(iii) Nick Good to circulate BHRB TORs to BHRB members for review.</p>	<p>MJ/ NG</p> <p>CC/SE & NG</p> <p>NG</p>

NG
14th July 2020