

Joint Clinical Research Board

1.30 pm, Tuesday 29th November 2022

MS Teams

Present:

Sharon Barrett (SB)
 Bryony Butland (BB)
 Mark Caulfield (MC) - Chair
 Stuart Chandler (SC)
 Alistair Chesser (AC)
 David Collier
 Mary Collins (MC)
 Panagiotis Deloukas (PD)
 Stephen Ford (SF)
 Nick Good (NG)
 Ginette Hoare (GH)
 Richard Hooper
 Mays Jawad (MJ)
 Jamila Kassam
 Hemant Kocher (HK)

Gerry Leonard (GL)
 Nick Lemoine
 Anthony Mathur
 Kieran McCafferty
 Vickie McDonald (VM)
 Joanne Martin
 Jo Morgan
 Neeta Patel (NP)
 Rupert Pearse (RP)
 Mauro Perretti
 Julie Sanders (JS)
 Manish Saxena
 Klaus Schmierer (KS)
 Ajay Sinha
 Imogen Skene (IS)

Apologies:

Melissa Anderson
 Rob Bennett
 Sven Bunn
 Nikos Danos
 Rhian Gabe
 Deanna Gibbs

Xavier Griffin
 Stephen Kelly
 Nick Lemoine (from 2 pm)
 Aranthathi Mahendran
 Beth Stuart

Agenda Item	Action
<p>1. Minutes and Actions from the last meeting.</p> <p>MC welcomed everyone, particularly newcomers. The draft minutes of the last meeting in September were agreed and apologies were noted. Actions from the last meeting were noted as follows:</p> <p>(i) CC to keep NG updated on the progress of the Joint Policies so that records can be updated as soon as possible.</p> <p>NG reported that the joint policies had been passed by Queen Mary Senate and reconfirmed for the Barts Health Executive in October. All the policies are now published on the JRMO website, as a set and individually, see: http://www.irmo.org.uk/about-us/research-policies/ and this will be announced in the forthcoming R&D News Bulletin.</p> <p>(ii) NG to circulate a copy of SN's presentation on the Precision Medicine project. Completed.</p>	

<p>(iii) NG to continue to assist JP in progressing the Research Misconduct policy through the Trust’s approval structure.</p> <p>NG reported that whilst QM had passed the policy as presented in September, the Trust felt that it contained details that were not appropriate to its workings which may be better covered by an accompanying (different) process document. Discussions around this were ongoing. GL said that the issue was the governance interfaces and SF agreed that this needed further review.</p> <p>MC said that we need to allow for local differences whilst developing an overarching policy that both organisations could agree to - avoiding uncertainty and loopholes was crucial. AC agreed and said that a high-level policy with separate but compatible processes should be achievable and present a way forward.</p> <p>ACTION: SF, GL, RP and BB to meet and discuss ways forward for the research misconduct policy and related QM/BH processes.</p> <p>(iv) NG to put the CRN restructuring (RRDNs) back on the agenda for the next JCRB. This is on the agenda (item 7).</p>	<p>SF, GL, RP & BB</p>
<p>2. Pharmacy update</p> <p>MC thanked SC for coming along to deliver a presentation. SC said he was very happy to be here and take the Board through developments over the last 3 years, since his last report, pre-pandemic.</p> <p>He reported that a huge amount of work had been undertaken and key financial issues had now been sorted out, with bad debts now effectively cleared and stabilised at a low level. Set-up times had improved dramatically with there now being no limit on the number of set-ups the team could undertake each month. Governance processes had been overhauled and a lot of work has been put into challenging bad habits and poor performance. Staff now have a clear vision to work to and training and objectives are in line with that.</p> <p>Pharmacy is proud of its contribution to Covid research and that contributed to maintaining income levels. They are also very pleased to have been involved in the development of the new CRF from the start. Pharmacist prescription is another exciting area soon to be trialled.</p> <p>Current challenges were explained. Pharmacy provision at Newham and Whipps Cross is challenging. There has been a lot of work with JRMO on set-up processes which should shortly deliver a much earlier pharmacy approval and so address concerns. There are still issues around the aseptic pharmacy and the WHRI agreement to be resolved.</p> <p>RP thanked SC for his hard work and a good presentation. He was pleased that the CRF work has gone so well and sets a good precedent for the future. There was discussion around the importance of sustaining a presence at all sites, especially with the CRF consolidating sites.</p> <p>SB thanked SC for his support of CRN research and she was keen to help further. They will discuss that offline.</p>	

<p>HK asked if new processes were now in place to correct past errors by staff. SC said he was aware of previous issues around processes, and they had been taken into account when new processes and training were being developed.</p> <p>MC thanked SC for his presentation and said it was good to meet him. He said there is a chance to run gene therapy trials at the Royal London and it would be excellent if there was a qualified gene therapy pharmacist there. She hoped this could be built into future plans so the team could move away from using Royal Free pharmacy services.</p> <p>SC said that he was keen to expand services in this direction but, being realistic, that would involve licensing as well as an additional pharmacist. He said there were other providers, and he is happy to take that offline with MC.</p> <p>RP thanked him and said advanced therapy trials were a key part of the CRF strategic agenda. MC agreed that there is an exciting opportunity here we cannot afford to lose.</p> <p>MC asked if there were any further questions.</p> <p>PD offered to assist with the WHRI agreement.</p> <p>IS asked if there was any development on e-prescription for IMP from a patient safety perspective. SC said there is a Trust-wide system and there had been trials, but clinical trials presented additional challenges.</p> <p>MC thanked SC and asked if he could return to the next JCRB with an update on the progress of the various challenges he had identified.</p> <p>ACTION: NG to add a Pharmacy Challenges update to the agenda for the March JCRB and SC to attend to present on that.</p>	<p>NG & SC</p>
<p>3. Clinical Director's report</p> <p>RP said there were many issues he could cover but, given time constraints, he would focus on a few highlights.</p> <p>A full clinical director team is now in place and is working through a 'to-do' list with the JRMO, mainly focussing on governance issues.</p> <p>The new CRF was approved by the Trust Board two weeks ago and returns to the Barts Charity Board this week. Negotiations with a commercial partner are ongoing with the aim of not only securing funding and expertise but also work; so far this is all very positive.</p> <p>IS is working to create support and infrastructure for NMAHP research comparable to the support that exists for doctors. IS and VM are reviewing CRN funding distribution. Work around community engagement, outside the usual disease-specific, is beginning with some gap analysis by NP. MJ is presenting some early work on governance processes later (item 5) and GH is working on ideas around keeping research moving (item 6).</p> <p>The precision medicine data core is progressing and will become a key part of the future Barts research delivery offer. The Research Infrastructure Board will launch soon having</p>	

<p>now been agreed upon. In addition, the team is working actively with BHRUT to support research activity there.</p> <p>MC thanked RP and asked if the NIHR capital monies bidding is sorted out yet. RP said we are moving ahead on this but some details are yet to be agreed. MC said that impacts from this need to be felt across the area and time limits taken into account. GL said that the focus of this NIHR call is equipment (of £5k plus) and any location investment/ refit only comes out of that. MC agreed and said that CRN partner access to new equipment is important.</p> <p>JS said that she is delighted to see a stronger focus on supporting NMAHP researchers, this will help her and Deanna Gibbs' work.</p> <p>ACTION: RP to return to JCRB with further Clinical Director updates as necessary.</p>	RP
<p>4. CRN North Thames update</p> <p>MC said that we had fallen behind on the agenda, so asked speakers to keep to a higher level.</p> <p>SB introduced the report she had circulated and said she would focus on highlights.</p> <p>CRN NT has the highest number of portfolio studies and achieved the highest level of recruitment. In terms of performance GP reach-out was doing well with 35.9% of our GP Practices recruiting into portfolio studies, the second-highest number of practices participating nationally. Quarterly high-level objectives pose challenges. The LCRN funding model is being reviewed by a working group, but it is likely changes in this last LCRN year will be minimal.</p> <p>MC thanked SB and said these were an impressive set of metrics. He asked if there were any questions.</p> <p>In response to a question from KS, there was a discussion about inflation concerning network research funding. SB said that in addition to 2% for inflation we may get an additional 5%, but this remains unconfirmed.</p>	
<p>5. Research Governance Section development plan</p> <p>MC thanked MJ for her report. MJ said that she had met with many in our community now as part of a process and procedures review. Overall this is a 12-month project, but some early deliverables are planned. A key one is a pilot project for the new year, empowering more experienced teams to set up their own hosted studies. The report circulated sets out metrics and the JRMO is working with pharmacy and other key stakeholders to improve set-up times.</p> <p>MC asked what KPIs there are on set-up and what would be a meaningful target for this. Adding that additional resources can be made available if that would help.</p> <p>MJ said that a major issue is outside of the JRMO and that needs to be unpicked. This is the work underway and will be the focus of the pilot. So far working with stakeholders has been very positive so thinking about additional JRMO staffing may be unnecessary.</p>	

<p>MC said that he and AC are happy to help if resourcing is the issue and we should be aiming to be competitive but not necessarily number one. AC agreed and asked that the ongoing work break down where the problems arise and focus on what we need to do about that.</p> <p>MC suggested that MJ should work further with RP, SF, BB, GL and the Clinical Directors and she will report back to JCRN on progress both with the pilot and other developments proposed.</p> <p>ACTION: MJ is to return to JCRB with further updates around the JRMO governance development projects as necessary.</p>	<p>MJ</p>
<p>6. Commercial Research Activity at Barts Health</p> <p>GH had submitted a paper outlining her review of an apparent fall in commercial research volumes, to understand whether the trends reported nationally are mirrored in our organisation and if so what the cause of this decline in commercial research activity might be and how we can address it.</p> <p>Barts has always had a large number of commercial trials but that had dropped – 63% down in 2021 from the 2017 level. However, in the financial year 22-23 to date, we have had 96 commercial studies approved which would indicate a yearly figure of c140 which would amount to a return to pre-pandemic levels. In addition, the trend appears to be to complexity, rather than simple volume recruitment, which offers a higher return.</p> <p>The other issue is that there are still a lot of approved studies not recruiting or under-recruiting. GH suggested that we undertake feasibility work to monitor non-recruitment and inform future decision-making.</p> <p>RP said this was an excellent report and puts a spotlight on the real issues around commercial research. He suggested that GH work with Stephen Kelly (SK) to develop a strategy for what we could do to mitigate matters.</p> <p>MC agreed and said that if there are repeat offenders, costing large amounts of money undertaking set-up but not then delivering income through recruitment, we need to know who they are as part of working out what to do about it.</p> <p>GL said that he had been involved in a national NIHR working group and that group's work suggested that new trails are now coming through across the country, so there would appear to be a post-pandemic return to normal commercial activity. NIHR metrics on recruitment are however being challenged and we need to take into account whether delivery targets are part of the picture blocking recruitment.</p> <p>ACTION: GH to work with GL and SK on non-recruitment to approved commercial studies and return to the next JCRB with some suggestions.</p>	<p>GH, GL & SK</p>
<p>7. North London RRDN application</p> <p>GL explained that the NIHR is restructuring its LCRNs from 15 to 12 and ours will be split up with the London area part of it joined to NW London to form a new North London area. They are also being renamed Reginal Research Delivery Networks (RRDN). Barts Health has submitted an initial expression of interest and he is working on a substantive bid to be</p>	

<p>submitted on 6th December. It looks almost certain that the bid will be unopposed from within our area with Imperial, the current NW London host, not applying. Partner engagement activity is ongoing to build both relationships with our partners and strengths in our hosting, and foster greater transparency and openness. But it appears we may not hear back until the spring which seems odd if Barts is the only applicant and will delay transition planning.</p> <p>MC asked if the application included metrics and performance data. GL said that the form was all about demonstrating host infrastructure and experience, rather than undertaking the business of an actual LCRN/ RRDN.</p> <p>There was a discussion around Imperial’s possible thinking in not applying (if that is what they are doing).</p> <p>MC asked if letters of support were needed and RP said no, other than one from the Trust’s executive that AC can sign and that is in hand.</p> <p>SB said that in terms of cash flow the new network would be larger than the current one but not massively so: it would be approximately £42m against CRN-NT’s £31m budget.</p>	
<p>8. A.O.B.</p> <p>MC asked if there was any other business but there was none.</p>	
<p>9. Next JCRB meeting: 7th March 2023</p>	
<p>10. Summary of forward Actions</p> <ul style="list-style-type: none"> (i) SF, GL, RP and BB to meet and discuss ways forward for the research misconduct policy and related QM/BH processes. SF, GL, RP & BB (ii) NG to add a Pharmacy Challenges update to the agenda for the March JCRB and SC to attend to present on that. NG & SC (iii) RP is to return to JCRB with further Clinical Director updates as necessary. RP (iv) MJ to return to JCRB with further updates around the JRMO governance development projects as necessary. MJ (v) GH to work with GL and SK on non-recruitment to approved commercial studies and return to the next JCRB with some suggestions. GH, GL & SK 	

NG
1st December 2022