

Joint Clinical Research Board

Monday 19th December 2016
BCI Boardroom, Charterhouse Square

Present: Sally Burtles (SB), Mike Curtis (MC), Sandra Eldridge (SE), Khalid Khan (KK), Gerry Leonard (GL), Jo Martin (JM) (Chair), Jonathan Morgan (JMO), Mauro Perretti (MP), Anju Sahdev (AS), Peter Sasieni (PS)

By telephone: Nick Croft (NC), Shakila Thangaratinam (ST)

In attendance: Sharon Barrett (SBA), Elizabeth Clough (EC), Nick Good (NG), Jo Morgan (JMR), Neeta Patel (NP)

Apologies: Deanna Gibbs, Graham Hitman, Nick Lemoine, Steffen Petersen, Costantino Pitzalis, Steve Thornton

Agenda Item	Action
<p>1. Minutes and actions from the last meeting</p> <p>JM opened the meeting. The minutes were agreed and actions are up to date. Actions discussed were:</p> <ul style="list-style-type: none"> • Trial portfolio: SBA agreed to take up JL action to look into available comparative data across the LCRN: a new Action. • Funding for Cancer site staff: JM reported that she had discussed this with NL and JM3 but that this remains works in progress. • Study metric split on site/ CAG basis: This is also work in progress. • Reporting to JCRB by CAGs and Institutes. NG reported a very poor response; all the reports he has received are via JRMO attendees at meetings. There was discussion about escalating this and how papers that are sent through should be disseminated: <p>Action: MC and JM will raise this issue at VP-RAG</p> <p>Action: NG to circulate reports gathered together, prior to next JCRB, via email.</p>	<p>SBA</p> <p>MC + JM</p> <p>NG</p>
<p>2. Trial portfolio</p> <p>EC presented a first attempt to capture the joint trial portfolio. The aim will be to break this down by Site, CAG, Institute and/or clinical areas in the future. She said that the usefulness of those options is open to discussion either at the Board or offline.</p>	

<p>JM said that this was very helpful and, subject to comments, should be presented every 6 months.</p> <p>SE asked whether a breakdown of data could be provided. EC said yes; the categories as presented accord with IRAS. It was agreed that this data could very usefully inform discussion about where internal investment could be targeted to produce best results.</p> <p>PS asked whether this could be linked to patient recruitment and assessments of research impact. SB said that recruitment data was covered in the study metric report but that JRMO is not best placed to provide assessments of research impact. MC said that any comments on impact should rightly come from CAGs or Institutes – preferably in their annual reports to JCRB.</p> <p>Action: Any additional comments on this report to EC.</p> <p>Action: EC to prepare this report again for the June 2017 JRCB.</p> <p>MP commented that the structure of research capture on QM side is improving.</p> <p>Action: MP to share QM research reports with NG prior to next JCRB (and routinely)</p>	<p>All</p> <p>EC</p> <p>MP</p>
<p>3. Study metrics</p> <p>This report had been circulated. JM commented that the number of NIHR projects had fallen. GL said that this was due to a fall in the overall number of projects with old ones closing and fewer new awards being received. SE agreed that there is a rolling cycle of NIHR awards and we need to view applications strategically; the NIHR budget has remained stable but fewer calls are coming through as applications improve in terms of quality.</p> <p>It was agreed that there was a need to bring on a new generation of researchers who could grow with additional support.</p> <p>GL said that success seems to be in pockets and we ought to encourage use of project development grants.</p> <p>SB said that a lesson from T&F Group work is that researchers should use CTUs and other embedded resource wherever possible.</p> <p>JM said that it was good to see that we were still on target re recruitment even excluding ‘Genes and Health’.</p>	
<p>4. LCRN report</p> <p>JM welcomed SBA for the LCRN, she will be attending these meetings to represent the Network for the immediate future. S</p> <p>BA presented a report that had been sent through with tables of data broken down into research by sites and specialisms. There was discussion around the Trust’s overall performance and the clear variance re CV research. On the latter, EC said there are reasons</p>	

<p>for this, specifically a suspension of research after UCLH team move to Barts but lost all their research nurses. GL said that the problem is being worked through and the lesson from Cancer is that with sufficient focus it is soluble.</p> <p>PS asked how the targets were set and SBA said these are a combination of local aspiration and central parameters from NIHR-CCF. There was discussion on the extent to which the variant CV data was based on past BH or UCLH research.</p> <p>JM commented that there is clearly headroom overall. Future targets ought to take account of strategic planning within CAGs although SE commented that, whilst the overall figures were predictable year on year, the detail in each specialism was too small to be directly anticipated.</p> <p>PS suggested splitting targets between ongoing and newly opened studies within any given period. SBA said that could be done but the unknown remains unpredictable.</p> <p>ST asked whether the Women’s and Children’s data could be split. SBA said that new targets were being generated in January so that could be taken into account then. JMR commented that it should be feasible as it had been done last year.</p> <p>JM said that there was a need to link these targets in with research strategy development, research capacity and site planning.</p> <p>PS said that there is an eighteen month lag between initials plans to undertake research and recruiting the first patient. JM agreed and said this is a factor in strategic planning.</p> <p>Finally SBA reminded the Board that the LCRN is hosting a meeting on 1st February with researchers to discuss better feasibility assessment and how to better meet targets.</p>	
<p>5. Sponsor oversight group report</p> <p>Minutes of last week’s meeting had been circulated. SB talked through the paper; there are currently no significant or unusual concerns. Audits are ongoing and there is an agreed schedule stretching into next year. The number of live studies on the dossier is stable at around 60. Imminent inspections are highlighted in the report although no major Trust-/QM-wide inspection had been notified.</p> <p>AS raised an ongoing concern that trial lab manuals are not being sent through, so Labs do not know how to correctly process samples. This can look like labs holding up trials. EC agreed and wondered if the Network could assist. SBA said she would look into this.</p>	
<p>6. JRMO report</p> <p>SB had circulated a report. As the first report of this type it gave a lot of background but in the future it would focus on activity reporting. Bullets on page 2 of the report highlighted that in 2015-16, Research Services:</p> <ul style="list-style-type: none"> • Carried out 2584 costings • Processed 1,292 grant applications 	

<ul style="list-style-type: none"> • Supported 6 large strategic bids of which 5 were successful • Negotiated and concluded 1,036 contracts • Produced monthly, quarterly and ad hoc reports for researchers, schools, institutes, faculties, QMUL and Barts Health • Managed 2,300 grants and an income of around £90M (QMUL) and £46M (BHT) • Processed and issued 2,681 invoices and claims • Hosted 19 successful funder audits, including RCUK and EU audits • Gave approvals for 376 clinical trials and studies, including 8 CTIMPs and 78 interventional Non-CTIMPs • Over the last 9 months reviewed 746 study amendments, including 252 CTIMP amendments • Supported QMERC to review and approve 78 projects • Undertook expedited review of about 300 low risk projects for QMERC • Conducted 13 Clinical Audits • Delivered 28 training courses • Conducted 51 Clinical trials through the CRC and CRU • Supported 131 funding proposals through Business Development, of which 48 were successful (36%) and worth £21.5M • Organised >40 company visits for researchers to facilitate the development of new collaborations • Issued 110 letters of access or hon research contracts <p>SB suggested that future reporting should be a slimmer quarterly format. JM agreed.</p> <p>There was discussion around progress on CRF development within RLH in light of the failure to secure addition NIHR funding. MP felt it could be useful to focus on what the message from NIHR had been so we could work towards future calls.</p> <p>Action: CRF planning to feature in next JCRB Agenda.</p>	<p>NG</p>
<p>7. Task and Finish Joint Implementation Group (TFJIG)</p> <p>MC presented a paper put together by SB, including outcomes on the various recommendations. Of the 5 original recommendations, made by the original post-MHRA Inspection T&F Group in 2015, the TFJIG had now considered 4, with the 5th due for consideration in January. The 4 recommendations with action plans or where actions had been implemented are:</p> <ul style="list-style-type: none"> (i) To establish formal governance arrangements for joint oversight of clinical trials through a Joint Clinical Research /R&D Board – this has been completed and JCRB exists. (ii) That Institutes, Clinical Academic Groups (CAGs) and Trust Site Teams should have clearly delegated responsibility for trials undertaken under their auspices – reviews are underway to improve the strategic fit of research; peer review; protocol review ; resource and capacity review; and ongoing oversight throughout the trial. (iii) To clarify the role of the JRMO acting on behalf of QMUL and BHT as sponsor of clinical trials by, in part, creating academic lead Clinical Directors to advise the JRMO. (iv) To increase the breadth of Clinical Trials Unit (CTU) provision and CTU support. 	

<p>JMO asked when we know whether CAGs and Institutes were complying with the proposals. There was discussion in particular of CAG and Insitute reporting to JCRB, the need to embed the idea of reporting and highlight tensions (including re Sites and CAGs).</p> <p>MC said that it would be useful if JCRB could review this in a year's time. It was agreed that CAG and Institute reporting to JCRB should be on an exception basis and not onerous.</p> <p>Action: A review of CAG and Institute compliance with recommendations, including reporting to JCRB, would be undertaken by JRMO in Autumn of 2017 and brought to the December 2017 meeting for consideration.</p>	<p>NG and others</p>
<p>8. CAG and Insitute updates</p> <p>JM asked for a brief highlights from those CAGs and Institutes represented at JRCB:</p> <ul style="list-style-type: none"> • CSS: AS highlighted ongoing tensions between the Imaging and Pathology parts of CSS. Lack of scanning capacity had been raised as a Risk on DATIX and that will need additional investment • Children's Health: NC reported issues re lack of suitable accommodation for children's research at Whipps Cross. JMR reported that she is developing a plan for this with local leads. NC said that he is considering approaching Barts Charity re developing the research facilities further at RLH. <p>Action: NC to send a draft proposal for Barts Charity to KK and JM for review before submitting to the Charity.</p> <ul style="list-style-type: none"> • Women's Health: ST reported that staffing is stable Newham continues to pose problems space-wise. JM asked for a couple of paragraphs to be sent to herself and KK on this so it can be raised with Site Board. NP commented that office space seems safe now but there are significant issues re clinical space; it would be useful to consider this alongside the Children's Health issues. 	<p>NC</p>
<p>9. AOB</p> <ul style="list-style-type: none"> • GL raised a significant draft Ashridge report he had seen on R&D Managers' experiences. He could not circulate this at present as it was confidential but would do so as soon as he had an approved format. He will advise NG on this and as to whether the timing is right for it to become a JCRB Agenda item. • PS reported that the Royal College of Surgeons are looking into how they might co-fund Academic Chairs, this could be of interest and he will forward further details in due course. <p>JM thanked those who had attended these meetings over the last year and wished everyone a good Christmas and happy New Year.</p>	
<p>10. Next meeting:</p>	

20 th March 2017, Whitechapel	
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NG
21st December 2016