MINUTES
UK CLINICAL RESEARCH COLLABORATION (UKCRC)
BOARD MEETING 12 May 2016

Minutes of the meeting held on 12 May 2016, Rooms 1&2, 13th Floor, MRC,
One Kemble Street, London WC2B 4TS

Present

Members

Chris Whitty – Department of Health, England; Chair
Mike Thompson – The Association of the British Pharmaceutical Industry (ABPI)
Sharon Ellis – Department for Business, Innovation and Skills (BIS)
Aisling Burnard - Association of Medical Research Charities (AMRC)
Zoe Gray – INVOLVE
Pamela Kearns – Cancer Research UK (CRUK)
Nicola Perrin – Wellcome Trust
Mike Stevens – Scottish Government Health Directorates
Steve Bates – BioIndustry Association (BIA)
Jon Bisson – Health and Care Research, Wales
Naho Yamazaki – Academy of Medical Sciences (AMS)
Carole Longson – National Clinical Institute for Health and Care Excellence (NICE)
Michael Rawlins - Medicines and Healthcare products Regulatory Agency (MHRA)
Steven Hill – Higher Education Funding Councils (HEFC)
Salim Kakhoo – Universities Representative
Joy Todd – Economic and Social Research Council (ESRC)
Janet Wisely – Health Research Authority (HRA)
Jonathan Weber - The Association of UK University Hospitals (AUKUH)
Phil McCarvill – NHS Confederation
Alan Chant – Patient/Public Involvement (PPI) Member
Tim Cave – Senior Representative from the Pharmaceutical Industry
John Savill – Medical Research Council (MRC, Deputy Chair)
Nick Partridge – Independent (Deputy Chair)
Ian Young – Health & Social Care, Northern Ireland
Louise Wood – Department of Health, England (DH)

In attendance

Sarah Qureshi – Partnership Manager, UKCRC
Eve Roodhouse – Health and Social Care Information Centre (HSCIC, item 3 only)
Ronan O’Connor – NHS England (item 3 only)
Peter Knight – Department of Health, England (DH, item 3 only)

Observer

Helen Campbell – Department of Health, England (DH)
**Apologies and Announcements**

**Apologies**

- Simon Wessely (Academy of Medical Royal Colleges)
- Harpreet Sood (NHS England)

**Announcements**

The Board welcomed the Chair to his first meeting.

The Board noted that John Hughes had stepped down from the Board. He was thanked for his valuable contribution to the Board.

The Chair welcomed Ian Young and Mike Thompson to their first meeting.

1. **Minutes of the thirty-first UKCRC Board Meeting**

   UKCRC/16/01

   The Board approved the minutes of the last meeting.

2. **Matters arising**

   Oral

   The Board were informed that an update on Accelerated Access Review (AAR) would be planned once the final report is published. At the next Board meeting on the 6th October Dave Jones (Dean for Trainees) has been invited to lead a discussion on academic trainees and John Watson (Deputy Chief Medical Officer) would update on AntiMicrobial Resistance (AMR).

   All other matters arising were covered in the agenda.

**Discussion**

3. **Patient Data and Research**

   Oral

   John Savill introduced this topic by reminding the Board that this was about access to patient data for research via a framework. Partners had invested vast amounts of money in the area including into the Farr Institute of Health Informatics Research. HSCIC have established a Research Advisory group, co-chaired by Dame Sally Davies; Chief Medical Officer for England and himself. He reminded the Board of one study that although consent for access to data has been granted by patients, 3.5 years on, no data has been able to be obtained from the HSCIC. A third Caldicott report on data sharing was in progress and would make recommendations on opt-out processes.

   Ronan O’Connor explained that care.data (plan to join up patient information to improve health outcomes) comes under the remit of NHS England and aims to connect information from GP systems to hospital data collected by the HSCIC. Both organisations share the objectives and interest of the Board in the matter. Because of the national referendum regarding Britain remaining in the EU, publication of the Caldicott report would be delayed. He anticipated that when the third Caldicott report is published that events will move very swiftly. He reassured the Board that NHS England and HSCIC shared the frustrations of the group.
Eve Roodhouse updated the Board on the current status of care.data. She assured the Board that NHS England and HSCIC had worked tirelessly since the pause in care.data in 2014. The pathfinder areas (Blackburn with Darwen, Leeds, Somerset and West Hampshire) had played an important role. The programme was unable to proceed with plans to test communications in pathfinder areas due to the announcement of the Caldicott Report but had progressed engagement with stakeholders on GP data. Eve also advised that other data sets (maternity, child health and mental health) are now flowing to the HSCIC and that work had started to establish a community data set. Peter Knight highlighted that policy directors had worked to reduce the steps to access data significantly. HSCIC had learnt lessons from the past and currently there was a hiatus.

Nicola Perrin further explained that the Wellcome Trust’s commissioned report on ‘Public Attitudes to Commercial Access to Health Data’ highlighted that transparency and clear communication was paramount. This report demonstrated the complex views held and a low awareness of how data is used by the public. Over 2000 people were surveyed with emphasis found to be on the ‘Why’ and ‘Who’ would access the data and not so much as on the ‘How’. Overwhelmingly, the public did not agree to the insurance industry being permitted access. These views were highlighted in the recent partnership of Royal Free NHS Foundation Trust and Google DeepMind in developing an app aimed at improving the identification and treatment of patients at risk of acute kidney injury and the publicity surrounding it.

The Wellcome Trust is now considering setting-up a group based via a mechanism on the O’Neill Review of AMR, which has the support of government, but is independent from it. This would have a task force role and the UKCRC may be a useful umbrella to help coordinate activities. It was envisaged that the group would complete their objectives in two years and require a small secretariat independent of the Wellcome Trust. Partners suggested that the scope of activities should include use of patient data for delivery of care, as well as research, and data available via apps and “wearables”.

Mike Rawlins reported on the success of the Clinical Practice Research Datalink (CPRD, formally General Practice Research Database), a service providing primary care records for public health research based at the MHRA. The concern was now that an opt-in consent procedure would make it unworkable. The Board was reminded that the alleged link between autism and MMR was investigated using CPRD data. Access to the data is via very strict rules and is highly anonymised e.g. year of birth only.

In discussion the following was raised:

- As public understanding of terms used is at a low base (e.g. anonymisation) that some kind of education programme may be required.
- The successful implementation of care.data will be determined by the Government understanding of this work especially via the Secretary of State.
- The length of time taken so far is worrying long and has not yet included the further time required for care.data to be fully established.
- This work required a lot of joined up coordination.
- The creation of a social movement in the area with patient benefit the driving force would be beneficial.
- Lessons could be learnt from other health sectors e.g. the soft opt out used for organ donation in Wales had increased the number of transplants.
- The Board needed to be aware of international competition in the area with Sweden currently leading the way.
- New formats of data capture are constantly being developed e.g. fitbits.

The Board expressed their frustration and fear that there were still serious barriers to overcome. The Board was reassured that when the Caldicott review was published that
NHS England and HSCIC could move quickly. The Board reinforced their support and welcomed the proposal from the Wellcome Trust.

Activities

4. Update from Health Departments

Developments in Scotland included:
- Launch of Scottish Government Health and Social Care Research Strategy in November. The focus of which is where new investments will have biggest impact and review of existing investments. The link between research and adoption was also a theme with the Chief Scientist Office expanding its remit by taking on the responsibility for Health Innovation.
- A record year for NHS Research Scotland activity with a record number of patients being recruited to non-commercial studies. The contract value of new commercial studies in 2015-2016 reaching £19 million and current studies £38 million.
- Global data indicating that Scotland is second only to the Ukraine is its start-up times for trials. Therefore concern in HRA approval on performance, particularly different processes UK wide. Following a discussion with DH, the planned return to standardised forms across the UK is welcomed.
- Strategic partner in AstraZeneca Global genomics initiative.

Developments in Wales included:
- New infrastructure with the establishment of Health and Care Research Wales.
- The outcome of a flat-line budget for financial year 2016-17.
- No appointment of First Minister to date.
- Launch of Social Care Wales in April 2017.
- Lessons to be learnt from the introduction of the UK-wide HRA approvals system.
- Statement of Intent on genomic and precision medicine.

Developments in Northern Ireland (NI) included:
- The appointment of new ministers.
- Creation of the NI Department of Health.
- Strategy launched in February with five main objectives focussing on strength, economic devolution and an implementing plan.
- Extended funding in the NI biobank with a focus on cancer and molecular testing.
- Involvement in the 100,000 genome project via the creation of the Northern Ireland Genomic Medicine Centre with a £3.3 million investment which includes the MRC. Recruitment has now begun.

Developments in England included:
- The Comprehensive Spending Review (CSR) settlement of £1.078 billion for DH R&D, representing a flat cash settlement in a difficult environment. In addition, government had allocated the Department a further £400.5 million of Official Development Assistance (ODA) funding over the next five years to support research to benefit developing countries. The Board were thanked for their submissions on the subject and assured that they had made a difference.
- Target of April 2017 for research strategy of the NHS England Mental Health Task force.
- Dementia remaining a key priority for the government with real progress being made. 17,000 patients are now registered on Join Dementia Research, a service run by NIHR, Alzheimer’s Society and Alzheimer’s Research UK, to enable people to register their wish to be contacted about participating in research. Further drives are still required.
• Further strengthening infrastructure via the launch of new open competition call for Biomedical Research Centres (BRC) designation for the next five years (2017-2022). Consideration is by an international selection panel.
• Shortlisting of round 6 of the National Institute for Health Research (NIHR) Research Professorships, with interviews to take place next month.
• The 10th anniversary of the NIHR, giving a chance to celebrate and reflect on achievements and consider the future.

Sharon Ellis informed the Board that the capital invested in science is growing each year. £1.5 billion had been given to the Global Challenges Research Fund (GCRF), this spend over the next five years is to ensure that UK research takes a leading role in problems faced by developing countries and is part of ODA. Allocation will be via Research Councils in future calls. An increase in the Newton Fund was also announced.

John Savill confirmed that a Director for the Dementia Research Institute was being recruited. This is government initiative with an £150 million investment with the Alzheimer’s Society and Alzheimer’s Research UK committing a further £50 million each over seven years and led by the MRC. It will operate very much like the Turing Institute and it is anticipated that up to 500 scientists will be working under the Director.

It was noted that although better than expected settlements were achieved following the CSR that the Biomedical Catalyst had not been re-funded. This brought into question what to expect in the future. Innovate UK’s budget for this scheme has been halted and it would switch from giving grants to granting loans in future.

6. Update from NHS England  
Oral

The Chair reported that due to his ill health Harpreet Sood was unable to attend and had suggested that in this circumstance his presentation be circulated to the Board. The Board agreed, however requested that future updates be given in person so that Partners had an opportunity to question and comment directly on initiatives being taken.

7. Update from Health Research Authority  
Oral

Janet Wisely reported that the completed roll out took place as planned at the end of March to introduce a UK compatible approval system. Problems have arisen with compatibility with devolved nations mainly due to the fact that interim cross border arrangements were agreed too late in the process. Approximately 1000 applications have been received with 120 with sites outside England and 36 led by a devolved nation. Data will be published in the May newsletter which will include performance indicators.

The biggest issue that has arisen is the extraordinary amount of substantial amendments requested. This highlights the disproportionate approach to amendments. She encouraged feedback.

During discussion it was highlighted that the Registered Clinical Trial Unit Network was collating questions for the HRA as it was understood that the high number of amendments was due to misunderstandings of transition. It was also questioned whether NHS Trusts understood the requirements.

The Board noted progress in these areas.

8. Open session of new research initiatives (Others)  
Oral

Two Partners (AMS & ESRC) were invited to given an update on research initiatives that they are involved in.
Naho Yamazaki (AMS) reported that:
- Commencement of the one year pilot of SUSTAIN; a programme allowing female early career researchers to thrive. This includes interactive career development workshops, peer to peer support network and mentoring.
- Springboard awards for non-clinical researchers in collaboration with the Wellcome Trust. This is an annual call for researchers who have not received substantial funding within three years of appointment in a two year package.
- Publication of the Team Science project report in March. The key finding was the lack of recognition to researchers. Other recommendations focussed on communication, networking and project management. Recommendations would now be addressed.

Joy Todd (ESRC) reported that:
- Mental health is now a strategic priority. A Leadership Fellow will be appointed who will have a championing role and a beacon research project. They will work across existing social science projects in mental health.
- Routine reviews of funding of longitudinal cohort studies are taking place.
- Behaviour impacts on antimicrobial resistance relevant to humans and animals. This will include smaller prime pumping grants as well as larger collaborative research grants and includes research relevant to the UK or global landscape and research of specific benefit to ODA countries.

During discussion it was stated that the Dementia Funders Forum will also look at similar areas to the Leadership Fellow in mental health.

The Board noted progress in these areas.

9. Patients and Public in Research

Zoe Gray reminded the Board that INVOLVE was an internationally respected national advisory group to advance public and patient involvement in health and social care research and part of the NIHR. The new contract for INVOLVE, won by Southampton University Wessex Institute began in February. They were recruiting new staff and changing the model to reflect both the expansion and progress of PPI across the NIHR system and beyond and the Going the Extra Mile strategy. INVOLVE had been concentrating on recruiting the team, developing the partnership model and maintaining core business (e.g. guidance for the research system on involving patients and public). Moving forward, INVOLVE would provide system leadership and be the catalyst for progress in public and patient involvement through three main priority areas: equality and diversity, learning and development community, partnership and networks.

The Board was reminded that International Clinical Trials Day on 20th May with continuation of the ‘Okay to Ask about Clinical Research’ campaign.

The Board requested to be kept up to date with developments.

10. Clinical Data Sharing

Nicola Perrin reported to the Board that the Clinical Data Request Panel originally set up by GlaxoSmithKline now had more than 13 sponsor companies with the Wellcome Trust providing the secretariat. The system was working well with over 200 applications reviewed. There was work to be done to raise its awareness and they were considering a broader global platform.

Currently, a test case was being heard regarding the PACE trial (a large scale trial to test and compare the effects of four main treatments for chronic fatigue syndrome run by Queen Mary, University of London). Following a Freedom of Information request from a member of the public for individual patient level data, Queen Mary refused the request on the basis that
the consent forms stated that data would not be released beyond the research team. The Information Commissioners Office permitted disclosure, following an appeal of the decision by Queen Mary the request is being considered by an Information Tribunal. The outcome is awaited particularly due to possible repercussions.

The Board requested to be kept up to date with developments.

Reports from Subgroups and Fora

11. Experimental Medicine Funders Group
John Savill reported that this group last met in April, the main highlights of the last meeting were:
- Examination of the Clinical Pharmacology Skills Gap. The MRC has funded 30 such posts over the next five years. Funders were now considering further training routes, opportunities and a landscape map/career path.
- A halt of the re-development of the UKCRC Experimental Medicine Resource Finder (maintained by the NIHR Office of Clinical Research Infrastructure, NOCRI) following a survey with industry; instead the capture of the top 10 selling points for UK experimental medicine had been proposed.
- Update on the UKCRC Tissue Directory and Coordination Centre. 55 Biobanks have now registered and evaluation criteria are now being established.

The Board noted progress in this area.

Collaboration

12. Office for Strategic Co-ordination of Health Research (OSCHR)
John Savill reported that Chris Whitty and Ian Johnson attended their first OSCHR Board meeting in January. Items discussed included:
- The outcome of the CSR (at the time details of allocations were not known).
- The Biomedical catalyst and the bid for more funding to BIS.
- The establishment of an Informatics subgroup, specifically its remit and governance.
- Attendance of George Freeman MP, Minister for Life Sciences to discuss progress on AAR. The final report should be expected in the summer.

The Board noted progress in this area.

13. Nurse Review of Research Councils
John Savill reported that the Board could expect a White paper on the government’s implementation of the review in the near future. The review aimed to increase strategic thinking and stated that the research councils would remain as research councils but come under the umbrella of one non-departmental public body; Research UK (including Innovate UK).

The Board requested a further update at the next Board meeting.
UKCRC General

14. UKCRC Partnership Manager’s Report UKCRC/16/03

Sarah Qureshi referred to the paper and reported that there were no significant variances to the UKCRC’s spend from budget in 2015-2016.

The Board noted the budget for UKCRC’s running costs in 2016-2017.

Other

15. Any Other Business

Transparency
Mike Thompson informed the Board that the ABPI would from 1 July 2016, publish via a publicly available and searchable database, payments made from the pharmaceutical industry to individual health care professionals and healthcare organisations. This information was being released as part of transparency in the EU and would likely attract publicity. It was suggested that Partners prepare for the impact.

Research in Europe
The Board noted that the EU spend on research in the UK was in the region of 8 billion euros (as of September 2015) which is a disproportionately high amount for the UK, recognising the excellence of UK science.

Next meeting is on 6th October 2016 from 2pm-5pm. Rooms 1&2, 13th Floor, MRC, One Kemble Street, London WC2B 4TS.