Minutes of the meeting held on 9 October 2014, Rooms 1&2, 13th Floor, MRC, One Kemble Street, London WC2B 4TS

Present

Members

Sir John Savill – Medical Research Council (Chair)
Dr Bina Rawal – The Association of the British Pharmaceutical Industry (ABPI)
Dr Helen Bodmer – Department for Business, Innovation and Skills (BIS)
Aisling Burnand - Association of Medical Research Charities (AMRC)
Simon Denegri – INVOLVE
Dr Ian Walker – Cancer Research UK (CRUK)
Dr John Williams – Wellcome Trust
Mike Stevens – Scottish Government Health Directorates
Dr Janice Ballie – Health & Social Care R&D, Northern Ireland
Steve Bates – BiIndustry Association (BIA)
Professor Jon Bisson – National Institute for Social Care and Health Research, Welsh Assembly Government (NISCHR)
John Hughes - Patient/Public Member
Sir Nick Partridge – Independent (Deputy Chair)
Dr Rachel Quinn – Academy of Medical Sciences (AMS)
Professor David Haslam – National Clinical Institute for Health and Care Excellence (NICE)
Sir Gordon Duff - Medicines and Healthcare products Regulatory Agency (MHRA)
Dr Steven Hill – Higher Education Funding Councils (HEFC)
Professor Adrian Clark – Universities Representative
Adrian Alsop – Economic and Social Research Council (ESRC)
Dr Janet Wisely – Health Research Authority (HRA)
Dr Archie Prentice – Academy of Medical Royal Colleges (AoMRC)
Professor David Wynick - The Association of UK University Hospitals (AUKUH)
Dr Russell Hamilton – Department of Health, England (DH)
Dr Jon Fistein – Medical Research Council (MRC)
Valerie Shanks-Pepper – NHS England
Michael Wood – NHS Confederation
Alan Chant – Patient/Public Member

In attendance

Dr Louise Wood - Department of Health, England (DH)
Sarah Qureshi – Partnership Manager, UKCRC
Dr Ian Viney - Medical Research Council (MRC)

Observers

Dr Helen Campbell – Department of Health, England (DH)
John Wilkinson - Department of Health, England (DH)
Dr Jim Carter - Medical Research Council (MRC)
**Apologies and Announcements**

### Apologies

- Professor Dame Sally Davies – Department of Health, England (UKCRC Chair)
- Dr Tim Cave – Senior Representative from the Pharmaceutical Industry

### Announcements

The Board noted that:

- Alan Chant had been appointed as a PPI member of the Board via open competition. Alan was warmly welcomed to his first Board meeting.

1. **Minutes of the twenty-eighth UKCRC Board Meeting**  
   **UKCRC/14/07**

   Gordon Duff clarified that the penultimate sentence of item 13 EU Clinical Trials Regulation, should read ‘All trial summaries are required to be published within a year and the clinical study report within 30 days of the regulatory decision’ (not clinical decision). He also clarified that he has been asked to remain as Chair of the MHRA until the end of this year (item 19).

   Subject to these changes the minutes were agreed.

2. **EU Clinical Trials Regulation**  
   **Oral**

   Gordon Duff informed the Board that the MHRA and the HRA are working in close collaboration regarding the implementation of the regulation that will deliver a streamlined and simplified process for authorisation of a clinical trial. The regulation will apply from 2016 at the earliest.

   Some limited national legislation will be required to support its functioning and to make use of the flexibilities, for example regarding ethics committees. Before the regulation can be introduced the single portal and database for applications must be established. The introduction of the regulation can be delayed if the Information Technology (IT) underpinning this is not fully functional. The MHRA is one of the seven member states working with the European Medicines Agency (EMA) to agree the functionality of the IT. Tighter regulations regarding transparency are included in the regulation.

   Michael Wood informed the Board that the NHS European Office of the NHS Confederation had produced a helpful briefing on the impact of the new EU Clinical Trials Regulation on the NHS. This along with a written brief from the MHRA would be circulated to the Board.

3. **Matters arising**  
   **Oral**

   The Board was informed that Tim Kelsey would be invited to a future meeting in 2015 to update the Board on care.data.

   All other matters arising were covered in the agenda.
Discussion

3. **Genomics England**

The Chair introduced Mark Caulfield who presented the mission of Genomics England. The programme consists of the 100,000 whole genome sequences in patients of rare inherited diseases, cancer and infection to generate health and wealth; build a legacy of infrastructure and allow them to become world leaders in the application of genomic medicine to healthcare. He highlighted that rare inherited diseases affects about 3 million people in the UK of which 7000 are rare disorders, whole genome sequencing will increase discovery by about 25%.

Regarding specifically cancer (a disease of disordered genomes where over 200 drivers are known) Genomics England is part of the International Cancer Genomes Consortium and the Cancer Genome Atlas. They have established an ethics advisory group has been established with support from the HRA and they are now working towards NHS Genomic Medicine Consent. Genomics England is currently in the establishment phase of their main programme. This involves the founding of NHS Genome Sequencing Centre, UK Data Infrastructure for Genomic Medicine and Genomics Medicine Centres.

A Genomics England Clinical Interpretation Partnership has also been established combining researchers, the NHS and trainees. All the data generated contributes to the Genomics England Dataset and are available to all. Feedback to the NHS will be simple, accessible and meaningful for patients, focus on disease and have a systematic approach to validation. The need for specialised scientific training in the area has been addressed with fellowships introduced in molecular pathology, genetics/genomics and bioinformatics along with an MSc in Genomic Medicine and CPD access for specialist practitioners.

Genomics England is aware of the challenges that they face and aim to leave a legacy by the end of 2017.

In discussion the following was raised:

- All the devolved nations have been invited to participate.
- A progression of consent process has been developed with patients, for example patients in the first instance are given a patient information leaflet and a further more detailed booklet a month later. Research Ethics Committees (REC) were included in developing the process and patients tested included teenagers and children.
- The intellectual property and data will all be owned by Genomics England and licensed back for use. Rates have not been set. It is expected that the rates would favourable and scaled, for example with pharmaceutical companies paying the most.
- It was noted that the capacity was for 150,000 genomes to be identified although 100,000 were initially being classified.
- No profit would be made from the data. Any gains would be returned to the government or reinvested back. Funders would not be asked to pay twice for the data that they had already invested in.
- The prospect of a skills gap had been also been addressed by the introduction of secondments.

Mark Caulfield ended by thanking the Partners and acknowledging that the funders were represented on the Board. In particular, he wished to thank them all for creating the infrastructure in the UK for projects like these to have the correct environment to develop.

The Board requested future updates in the area.
4. **Dementia**

Martin Rosser presented the current situation in dementia care and research in the UK. He outlined the Prime Minister's Challenge on Dementia launched in March 2012 and the G8 Dementia Summit Declaration, highlighting some of the commitments made. In particular, the commitment to increase the number of people involved in clinical trials and studies on dementia to 10% by 2017. Currently, 4.5% of people with dementia are engaged in research (increased from 3.7% in 2012/2013).

To improve recruitment to dementia studies by developing ‘ready’ cohorts of patients consenting to be approached about research, ‘Join Dementia Research’ was launched by the NIHR, Alzheimer’s society and Alzheimer’s Research UK. The Research Capacity in Dementia Care Pilot Programme is being delivered through the NIHR Collaborations for Leadership in Applied Health Research and Care (CLARHRCs) and Enabling Research in Care Homes (ENRICH) has increased the number of care homes in the research network.

In discussion the following was raised:
- Genome sequencing would greatly assist in this area particularly for rare dementias.
- The UK biobank (funded by MRC/DH and British Heart Foundation) includes brain scans. It is anticipated that further investment in the improvement of scanning will take place.
- 2 million patients are at risk of dementia.
- Early presentation (short term memory loss) requires further attention.
- 20 million pounds had been invested in this area in the biggest social care programme by the National Institute of Health Research (NIHR) and the ESRC. Details are to follow next year.
- Training is required at the boundary of social and clinical care. Engagement of ethnic minorities’ would also need attention.
- The consent issues in this area are very different as there is a big community of carers.

The Board were reminded that change in the UK research landscape over the last 10 years had allowed Partners to come together in various collaborations and partnerships to allow incentives such as this to develop.

The Board asked to be kept informed of developments in this area.

**Activities**

5. **Promoting Research in the NHS**

The main development in Scotland was the support for the recommendations set out in the draft Research Strategy, including:
- Ethics and R&D are to be integrated by early next year;
- Refocusing of the CSO grants programme as part of a strategic review, and
- New stratified medicine and informatics grants to support NHS adoption of these technologies.

The revised Scottish Government Research Strategy will now be finalised and published in the New Year.
Developments in Wales included:
• External panel review of applications to become NISCHR Centres and Units
• Planned independent review of genomics in Wales and future needs in this area
• Re-commissioning of elements of infrastructure to support research excellence.

Developments in Northern Ireland included:
• Vacancy for the position of Director of Research & Development for the HSC & Chief Scientific Advisor to the CMO, as Bernie Hannigan moves to Head of R&D at PH England.
• Mr Jim Wells (MLA) has taken up post as Minister of Health, Social Services & Public Safety in Northern Ireland, replacing Mr Edwin Poots (MLA), and has launched a consultation on the new HSC R&D Strategy, which is due to run until 2nd January 2015. The headline themes include data accessibility & the research for health & wealth agenda.
• DHSSPS has just completed consultation on a proposal to introduce primary legislation for the use of service user identifiable information for secondary purposes in controlled circumstances. This would address a long-standing disparity between legislation in Northern Ireland and the rest of the UK.
• An event in Belfast in September, co-hosted by HSC R&D Division & ABPI, attracted 19 ABPI member companies, and resulted in excellent feedback and a number of new leads for clinical trials in Northern Ireland.
• HSC R&D Division will welcome Dr Janet Wisely to a workshop in Northern Ireland on 14 October to present developments on the work of HRA.
• The £2 million joint call (HSC R&D Division with The Atlantic Philanthropies) has now completed evaluation and has invested in 7 new projects in dementia care.

Developments in England included:
• NIHR research network reporting that 99% of NHS Trusts have patients in clinical trials and 85% in commercial trials. This suggests that the breadth of NHS involvement in research has been achieved and that the need now is to concentrate on the depth of involvement.
• The introduction of awards such as; HSJ Clinical Research Impact award and the Nursing Times, Clinical Research Nursing award.
• Publishing of the NIHR metrics (70 day benchmark) on their website.
• The refresh of the Mandate between DH and NHS England which sets out accountability.

NHS England reported the following:
• Its research strategy becoming more focussed, for example becoming more closely aligned with Clinical Practice Research Datalink (CPRD). The strategy is designed to bring together the commissioning groups and building capability in the area.
• Development of a suite of tools such as the innovation compass diagnostic tool, allowing the commissioning community to better engage in research.
• The research section in the standard NHS contract becoming more ambitious.
• A focus on excess treatment costs.
• The development of a single operating model for honorary research contracts moving the establishment of them from the organisation to researcher and thereby increasing patient recruitment by 13% (pilot study). This will now be rolled out across England.

In discussion it was raised that the draft standard operating procedure produced by NHS England for excess treatment costs had raised concerns with some Partners. These were recognised and it was acknowledged that the issues may need to be addressed more locally rather than a one-size fits all policy.
6. Life Sciences Strategy

Louise Wood reported that during the cabinet reshuffle George Freeman had been appointed to the newly created Minister of Life Sciences post. This post would work across DH and BIS sending a clear signal regarding the importance given to life sciences by the government. His passion is for enabling earlier access to medicines, with a focus on deployment of genomic and health record data, and better engagement with medical research charities. Senior officials are meeting with him on a weekly basis.

The cabinet reshuffle has also resulted in Greg Clark being appointed Minister for Universities, Science and Cities. In addition, John Jeans has been appointed a Life Sciences Champion and the Technology Strategy Board will now operate as Innovate UK. It was agreed that the Strategy for UK Life Sciences recent newsletters (from August and October) would be circulated to the Board.

It was discussed that the Life Sciences Champions would have specific areas of expertise for example, John Jeans would champion Medical Technology. The aim was to put together a group of advisors representing difference areas.

7. UKCRC Partnership Manager’s Report

Sarah Qureshi reported that over 50 applications had been received for the position of PPI Board member and that the appointments panel was chaired by Simon Denegri.

In accordance with cost cutting procedures the UKCRC website had now been moved to the INVOLVE server holding the People in Research website.

The Board noted the position.

8. Health Research Analysis Forum

Ian Viney reported that the next analysis due for publication in June 2015 detailing all spend in 2014 was underway. This encompassed a wider range of funders than the previous analysis from 2009/2010. To ensure that there was no repeat of the delays in publishing the previous report a Project Manager, Jim Carter has been appointed.

To increase the capacity and give the support required to the Health Research Classification System underpinning the analysis, training of a new set of coders would take place at the end of the month.

During discussion it was raised that the analysis of the Research Excellence Framework were due to be publically available in March 2015. A link between these two data sets would be invaluable as the Research Excellence Framework data displayed the health related entries of research in UK higher education institutions. In addition, Greg Clark MP has asked each Dean at an upcoming Medical Schools Council meeting to highlight their favourite impact study.
9. **Experimental Medicine Funders Group**  

John Savill reported to the Board that the UKCRC Tissue Directory and Coordination Centre had been awarded to a multi-institutional centre at UCL and Nottingham. The Centre will draw on expertise from NCRI (Anne Carter) and other institutions which submitted applications will also be involved (e.g. Bristol, Manchester and Newcastle). Work will begin by November.

The Board noted progress in this area.

10. **R&G Forum**  

The Board noted this paper for information.

**Collaboration**

11. **Office for Strategic Co-ordination of Health Research (OSCHR)**  

John Savill reported that the main topics for discussion at the last OSCHR meeting in June were:

- The Ministerial Industry Strategy Group (MISG) Task and Finish Group on the R&D Environment. Further work on the vision had taken place and OSCHR will continue to take this forward with greater interaction and ambition.
- Cross funder activity in Antimicrobial Resistance acknowledging the long-term commitment, stability and innovation required in this area.
- The Life Science Strategy, in particular sustaining development.

It was discussed that a recent article in the Financial Times (6 October) highlighted the upward trend in venture capital in the UK Life Sciences following the introduction of the policies in the Life Science Strategy. The article along with the Ernst & Young (EY) and BIA State of the Nation 2014 (Fundamentals Strengths of the UK Ecosystem) report is to be circulated to the Board.

12. **Open session of new research initiatives (Regulatory Partners)**  

Regulatory Partners (HRA & NICE) were invited to given an update on research initiatives that they are involved in.

David Haslam reported that the appointment of George Freeman as Minister for Life Sciences was a welcome outcome for NICE as the post straddles across BIS and DH in a similar fashion to NICE. He highlighted that:

- The NICE remit now includes social care, this challenging particularly due to the lack of research in this area.
- NICE research is conducted through national processes with research funders and academics. As a result research activity is secondary and guidance produced from this.
- NICE’s citizen’s council is engaging in the debate regarding data.
- NICE’s medical technology programme aims to identify interventions that are a step change as medical technologies go through a different route to pharmaceutical regulation and therefore require the right evidence at launch.
During discussion it was clarified that NICE and the MHRA are also leading on Promising Innovative Medicine (PIM). The NICE written brief would be circulated to the Board.

Janet Wisely presented an update on the HRA Approval Programme and on research transparency. The aim of the Approval Programme is to have one application, one assessment and one approval for research in the NHS. She highlighted that recruitment to the Approval Programme is now complete and successful delivery feasible but requires management attention. At a recent gateway review the status given was ‘amber’. UK wide compatibility via the Integrated Research Application System (IRAS) and the HRA ethics database (HARP) are to be updated to provide the required UK wide platform. Roll out is on a study type basis, for example experimental cancer medicine centre network including the single pharmacy technical assurance (provided by the NHS) has been through the first phase of roll out, in partnership with CRUK. The ambition is that for all study types the Approval Programme is in place by the end of 2015.

She confirmed that transparency sits at the heart of the role of the HRA and that the HRA welcomes its responsibilities and duties in this area provided to it via the Care Act. From the 30th September 2013 it has been a condition of the REC opinion that registration of the clinical trial has taken place before the first participant is recruited. Failure to do within 6 weeks of the first UK participant is recruited is a breach of the favourable ethical opinion unless a notice to defer registration has been granted by the HRA. Publishers of key journals such as the British Medical Journal (BMJ) require registration and the HRA has updated the declaration the sponsor makes on a new application to a REC from September 2014. In April 2015 the HRA will extend registration requirements to all trials in active recruitment in the UK.

During discussion it was raised that the rates for registration were over 100 between 2009-2013. An audit on the degree of compliance would be required and that before EU Clinical Trials Regulation comes into effect the transparency tool kit would need to be updated. The HRA were congratulated on progress made in these areas.

Other

13. Any Other Business

Ian Walker reported that following the launch of the new CRUK strategy four new funding schemes had since been launched. The new funding streams are; cancer immunology awards, programme foundation awards, multidisciplinary cancer awards and biotherapeutic programme and project awards. In addition to these new awards, CRUK has also committed to future funding of the National Awareness and Early Diagnosis Initiative (NAEDI) research stream, given the emphasis on early diagnosis in the new research strategy.

Bina Rawal reported that the ABPI R&D conference on 20 November would be on Stratified Medicine (Discovery to Patient - Mind the Gap) and that the ABPI skills survey has now been completed. The results from the manufacturing section of the skills survey had been analysed and revealed areas of skills shortages which will be addressed through the Science Industry Partnership. Collaboration with the Farr institute continues with a joint meeting planned on 16th December, at which the development of an MOU between ABPI and the Farr Institute would be announced.

Next meeting is on 14th May 2015 from 2pm-5pm. Rooms 1&2, 13th Floor, MRC, One Kemble Street, London WC2B 4TS.