FINAL MINUTES

UK CLINICAL RESEARCH COLLABORATION
BOARD MEETING 16 May 2013

Minutes of the meeting held on 16 May 2013, Rooms 1&2, 13th Floor, MRC,
One Kemble Street, London WC2B 4TS

Present

Members

Professor Dame Sally Davies – Department of Health, England (Chair/DH)
Sir John Savill – Medical Research Council (MRC, Chair - item 17 onwards)
Dr Bina Rawal – The Association of the British Pharmaceutical Industry (ABPI)
Dr Helen Bodmer – Department for Business, Innovation and Skills (BIS)
Sharmila Nebhrajani - Association of Medical Research Charities (AMRC)
Dr Russell Hamilton – Department of Health, England (DH)
Kate Law – Cancer Research UK (CRUK)
Dr David Lynn – Wellcome Trust
Mike Stevens – Scottish Government Health Directorates
Professor Bernie Hannigan – Health & Social Care R&D, Northern Ireland
Steve Bates – BioIndustry Association (BIA)
Carys Thomas – National Institute for Social Care and Health Research, Welsh Assembly
Government (NISCHR)
John Hughes - Patient/Public Member
Andrew Russell – Patient/Public Member
Sir Nick Partridge – Patient/Public Member (Deputy Chair)
Professor David Adams – Academy of Medical Sciences (AMS)
Sarah Garner – National Clinical Institute for Health and Clinical Excellence (NICE)
Sir Gordon Duff - Medicines and Healthcare products Regulatory Agency (MHRA)
Dr Martyn Ward - Medicines and Healthcare products Regulatory Agency (MHRA)
Dr Steven Hill – Higher Education Funding Councils (HEFC)
Professor Adrian Clark – Universities Representative
Dr Tim Cave – Senior Representative from the Pharmaceutical Industry
Adrian Alsop – Economic and Social Research Council (ESRC)
Dr Janet Wisely – Health Research Authority (HRA)
Professor Keith Willetts - NHS England

In attendance

Bill Davidson – Department of Health, England (DH)
Peter Knight – Department of Health, England (DH)
Dr Louise Wood – Department of Health (DH)
Sarah Qureshi – Partnership Manager, UKCRC

Observers

Dr Liz Mears – Chief Executive, The Walton Centre NHS Foundation Trust
Dr David Cox – Department of Health, England (DH)
Dr Helen Campbell – Department of Health, England (DH)
Announcements and Apologies

Apologies

Dr Richard Tiner – Academy of Medical Royal Colleges (AOMRC)
Sir Ron Kerr – NHS Confederation
Caroline Shaw - The Association of University Hospitals UK
Phil Brown – Association of British Healthcare Industries (ABHI)
Simon Denegri – INVOLVE

Announcements

The Board noted that:

- This was the first meeting that two new Partners of the UKCRC; NHS England and the HRA were represented. Keith Willett and Janet Wisely were warmly welcomed to the Board.
- With the re-structuring of the NHS, SHAs would no longer be represented on the Board. Candy Morris was warmly thanked for her hard work.

Other Announcements

The Board congratulated:

- John Savill on the award of his Fellowship of the Royal Society.
- Jeremy Farrar on his appointment as the new Director of the Wellcome Trust. He takes up his appointment on the 1st October 2013.

Any Other Business

International Clinical Trials day (20th May) was raised as any other business.

1. Minutes of the twenty-fifth UKCRC Board Meeting UKCRC/13/01

The Board approved the minutes of the last meeting subject to two changes:

- Item 12, Life Sciences Strategy, the first bullet point should state that ‘The first 10 million of the Biomedical Catalyst fund has been awarded.’
- Item 17, Recent critique of UK Research Regulation, third bullet point should read ‘The ABPI is signed up to international standards such as the joint positions of international trade bodies’.

2. Matters arising Oral

The Board was informed that all matters arising are covered in the agenda.

One action point from the last meeting remained. Dr Richard Tiner was going to circulate his review of ‘Bad Pharma’ by Dr Ben Goldacre. The Chair wrote to Dr Tiner who stated that his article promoting the book was not published and therefore not appropriate to circulate. In addition, the Faculty of Pharmaceutical Medicine was considering a complete analysis of the book if a second edition was published.
Policy Update

3. **UKCRC Partnership Manager’s Report**  UKCRC/13/02

Sarah Qureshi referred the Board to the paper and highlighted the following:

- The expenditure for the UKCRC running costs in 2012/2013 were on target.
- The Board were reminded that the MRC hosts the UKCRC free of charge and employs the sole member of staff, the Partnership Manager.
- DH England agrees to undertake the UKCRC running costs. This includes staffing and meeting costs. Accordingly, the MRC invoices DH England for these costs one quarter in arrears.
- The budget for the UKCRC costs in 2013/2014 demonstrated an uplift. This was mainly due to an increase in salary costs following a staff pay restructure at the MRC.

The Board noted the position.

4. **Public Health Centres of Excellence**  UKCRC/13/03

John Savill reported that the five public health centres of excellence established in 2008 had now been reviewed and the funders had agreed their commitment to the second round of funding for these centres. Due to the close similarities between them and the Scottish Collaboration for Public Health and Policy centre, this centre was included in the process. In total the funders had committed 16 million.

The Board noted the position.

5. **Clinical Trials Units Network**  UKCRC/13/04

Sarah Qureshi referred the Board to the paper and highlighted the following:

- Final interim reviews were taking place in September. Potential for the withdrawal of registration status for some units therefore remained.
- The Network was introducing an annual self-sign off to capture key changes at the units.
- The next call for registration was being planned for 2015. The funding model to be used has not yet been discussed but is likely to follow the same structure as previously with funders underwriting the process.

The Board noted the position.

Reports from Subgroups and Fora

6. **Research Regulation and Governance**  UKCRC/13/05

Bill Davidson referred the Board to the paper and highlighted that the HRA would be taking forward the possible review of the non-commercial clinical trial agreement.

During discussion it was raised that, if it were to be implemented in its current form, the impact of the EU Data Protection Regulation on research would be dramatic. The Board noted that the Ministry of Justice is negotiating on behalf of the UK in this issue.
7. **Public Awareness**

Kate Law reported that at their last meeting this group discussed that CPRD would be happy to re-distribute the ‘Your health record saves lives’ leaflet. This would entail the introduction of their logo and a relevant case study. The group was keen to retain editorial control. The Board expressed their thanks that another Partner has been found to help take forward this work.

The group were in the process of updating their remit, which would be presented at the next Board meeting.

8. **Experimental Medicine Funders Group**

John Savill reported that there were major investments in support of experimental medicine and highlighted the following:

- The MRC are leading on producing a report for OSCHR on Molecular Pathology regarding how the NHS would be best placed to take advantage of advances in stratified medicine.
- A business case will be developed by the MRC for this group to discuss regarding coordination and harmonisation on the Tissue Banking and STRATUM project.
- The NIHR are taking the lead on rare diseases regarding linking genetic and phenotypic data and a coordinated database for clinical records.

The Board noted the position.

Activities

9. **Promoting Research in the NHS**

Developments in Northern Ireland (NI) included:

- In January this year the new Molecular Pathology Laboratory was opened in Belfast. This facility is a partnership between Cancer Research and Cell Biology in Queen’s University and the Belfast Trust and is integrated with NI Biobank.
- A Task & Finish Group has presented its report on opportunities for Jobs and Economic Development through ‘Connected Health’, i.e. the deployment of digital capabilities within services. It will be important to benefit from research opportunities facilitated by this initiative.
- A new partnership in dementia care research is being established with The Atlantic Philanthropies. This work will assist with implementation of the NI Dementia Strategy. NI is in a unique position of having an excess of 30 year history of integrated health and social care services so this work should create models relevant to other regions.

Developments in Scotland included:

- CSO, the Scottish Funding Council and others have pledged up to £4.5 million over 5 years to establish a Centre of Excellence in Improvement Science, with the aim of putting evidence at the heart of quality improvement.
- An Informatics Centre is to be established in Edinburgh as part of a wider UK Network.
- Three innovation centres have recently been announced by the Scottish Funding Council. One in stratified medicine, one in sensors and one in digital health. All will be funded over the next five years to build collaborations with industry.
Developments in Wales included:

- Wales has a new Minister for Health and Social Services, Mark Drakeford. The new Head of NISCHR has also been appointed, Professor Jonathan Bisson.
- A Health, Wellbeing, Best Practice and Innovation Board has been established by the Minister to improve the acceleration of innovation and best practice in NHS and social care environment.
- Health Research Wales was launched in March. It is designed to be a one-stop source of information and support for companies wishing to undertake clinical research in Wales. For example, advice and support in contract negotiation and feasibility.
- NISCHR has issued a press release regarding International clinical trials day and will use the opportunity to raise profile in Wales on Public engagement in R&D. This will be featured in the main Welsh newspaper, the Western Mail.
- A NISCHR Informatics vision and plan will be published shortly and highlights the importance NISCHR is placing on strengthening informatics and bioinformatics in Wales. This will be followed by a range of initiatives, including a mapping exercise of existing datasets and increasing data capture on the SAIL database.
- Following a senior faculty competition, 23 Fellows have been appointed.

Developments in England included:

- Keith Willett has been appointed to the role of Director for Acute Episodes of Care, he is one of the two Directors appointed at this stage. Further staff are to be appointed shortly.
- The research strategy for NHS England is to be produced by the end of this year.
- The need for research in contracts is recognised. Consideration is also being given of research incentives in tariffs.
- Following the application process, 15 applications for AHSNs were received with contracts yet to be agreed. An announcement will be made by the end of June.
- NIHR budget remains as it was originally, with the Department of Health.
- NHS England will be working closely with the Department of Health.

During discussion the AMRC was highly commended on its vision for research in the NHS. This was developed from input from their members and consisted of 3 main themes; access to patients, help identify staff confident about research, and systems process and education.

The Board noted progress in these areas.

Reports from Subgroups and Fora

10. **Health Research Analysis Forum**

Ian Viney reported that the second analysis of research spend in the UK (2009-2010) had been completed, this group was now looking at the third analysis and what would be expected. During discussion the following was raised:
• The second analysis had revealed some interesting facts, was proving helpful and had given leverage to the Treasury discussions regarding the spending review.
• Some Partners felt the second analysis was not as useful as the first.
• There was the potential for more in depth analysis in the third analysis e.g. dementia care could be incorporated.
• Researchfish (an easy-to-use research outcomes system for researchers and funding organisations) has been adopted by the AMRC (65 organisations) and NIHR. This effectively allows for the portfolio data to be in an electronic format, allowing the analysis to be undertaken more efficiently for the third analysis.
• The analysis requires classification but can help decide on the best return on investment.
• The analysis was a tool that allowed organisations to prioritise research better.

The group was asked to put together a proposal for the undertaking of the third analysis including the costs involved and present it to the Board.

Activities

11. Open session of new research initiatives (Regulation Partners) Oral

Regulation Partners (NICE & MHRA) were invited to give an update on research initiatives that they were involved in under this item. Among the items highlighted were:

• The scientific advice programme at NICE is working with companies to ensure that the development pathway takes into account the needs of the NHS and HTA agencies. Joint advice with the EMA and MHRA is being given.
• The NICE med tech programme is working with companies to facilitate the development of the evidence base to support applications.
• MHRA are putting together a licensing framework for early access.
• CPRD can be used proactively in pharmacovigilance, potentially giving near real time comparisons and data on adverse effects.
• The MHRA is very active in vaccine work, among those being considered are HPV and anti-shingles.

The Board noted progress in these areas.

For discussion

Policy

12. Health Research Authority Oral

Janet Wisely highlighted the following developments at the HRA:

• GTAC time lines for approval have significantly improved. The latest gene therapy advisory committee approval was given in 40 days.
• The HRA has taken on responsibility for section 251 review function of the NHS Act 2006. This allows the common law duty of confidentiality to be set aside in specific circumstances where anonymised information is not sufficient and where patient consent is not practical.
• The Over-volunteering Prevention System (TOPS) database function has come into the remit of the HRA. It is designed to prevent participants from taking part too often in trials of new medicines. It is now a standard condition of ethics approval as well as MHRA accreditation that all studies register research participants into TOPS.
The HRA have taken a lead role in promoting transparency. Partners were reminded that this remains a global issue. Registration within an agreed time frame will become a condition of REC approval from September 2013. The HRA will develop simple mechanisms to monitor compliance with NRES taking on the lead role.

The HRA feasibility study for HRA assessment to support approval of research in the NHS is in its testing phase. It will now be taken to the HRA Board in June. The HRA is also looking at proposals to reduce the burden with approval of amendments.

During discussion the following was raised:

- Partners supported the HRA’s aspirations.
- The HRA operates directly in England only, but had good working arrangements in other nations.
- The HFEA regulates human embryo research. The HFEA and the HTA research applications will be integrated into IRAS. This will allow streamlining of working arrangements.
- Legislation for the HRA to become a NDPB is proceeding.

The Board noted progress in these areas.

13. **Life Sciences Strategy**  

Helen Bodmer reported that Sir John O’Reilly had now become the Director General for Knowledge and Innovation at BIS. Since the launch of the UK Life Sciences, a report on the progress made one year on had been produced in December. She highlighted the following:

- The government’s commitment to sequencing of 100,000 whole genomes from NHS patients over the next 3‐5 years. A Genomics Strategy Board has now been established, chaired by Professor Malcolm Grant.
- The MRC collaboration with AstraZeneca regarding making 22 compounds available to academic researchers has won a best partnership award.
- The Health and Social Care Information Centre (HSCIC) has signed a memorandum of understanding with AstraZeneca to develop understanding about the role medicines play in helping patients with chronic diseases.
- £20 million is being distributed by the Technology Strategy Board as research partnership development funds for SME’s.
- A newsletter was now being circulated to update on the strategy.

The Board noted progress in these areas.

**Collaboration**

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

John Savill reported that OSCHR Board last met on the 1st May. The Board was reminded that OSCHR consists of the public funders of research in the UK and included three non-executive members. Discussion at this meeting centred upon:

- The life sciences strategy road map.
- Consistent messages regarding the spending review.
- Development of e-Health Informatics Centres of Excellence.
- Activity on anti-microbial resistance.
The Board noted progress in these areas.

15. **EU Clinical Trials Regulation - Update**  
Presentation

Martyn Ward presented to the Board the current situation regarding the implementation of the amended EU Clinical Trials Directive. The following was highlighted:

- It would be in the form of a regulation.
- It would introduce a simplified approval procedure.
- It would increase transparency via registry, trial activity and results.
- The introduction of a national indemnification mechanism.

In discussion the following were raised:

- Partners paid tribute to the MHRA for taking this work forward.
- The number of amendments requested was far more than expected.
- The timelines suggested maybe ambitious.

The Board noted progress in this area.

16. **Caldicott Review into sharing of health information**  
Oral

Nick Partridge presented the outcomes of The Information Governance Review chaired by Dame Fiona Caldicott. He highlighted the following:

- Patients expected to be asked before their data is used.
- Training is required for professionals in this area and could take the form of revalidation.
- Ambiguity still remained regarding potentially identifiable data.

In discussion the following were raised:

- The report was very useful, particularly in regard to data processing from a legal perspective.
- Multiple approvals remained problematic. A pilot was currently taking place in Scotland regarding this, in which two guardians decide and their decision is accepted by others.
- That the agenda on transparency had changed with the Alltrials register, Science and Technology Select Committee (Commons) evidence on clinical trials, the HRA promoting transparency and pharma such as GlaxoSmithKline taking initiatives in making data available. The issue had now become how to best to manage this data.
- Nick Partridge had been appointed as a non-executive member of the Health and Social Care Information Centre.

The Board noted progress in this area.

**General/Discussion**

17. **Spending Review**  
Oral

The Chair described the process for the spending review. The following points were made in discussion:
• The main reasons for the ring fencing of the science budget were: leverage for the economy, failure to invest and regional effects.
• Any future cuts would affect work now.
• Third party endorsement from stakeholders such as ABPI, AMRC, OSCHR, BIS etc was crucial.
• Consistent messages are paramount.

The Board noted progress in this area.

18. Patients, Clinical Trials; access and transparency  Oral

The Board acknowledged that a welcome shift had taken place regarding transparency (item 16). They went onto discuss the following remaining issues:

• Implementation of the Caldicott Review was important to the debate.
• The Clinical Trials Gateway is the main vehicle for patients to access clinical trials. This needs to be publicised further and changes that have been identified made.
• Funders had various policies regarding publication of results. The monitoring and enforcement of these was now paramount.
• Regulators may need to ensure implementation of their requirements via incentives.
• Partners had experienced little resistance in their membership to transparency and established various working groups/meetings to explore the issues further.
• Partners were beginning to understand their roles better in this agenda.
• The specific issues with older trials still require to be addressed. For example, cost and use.
• PPI members were confident that to avoid publication bias, regulators would enforce summary publication of commercial clinical trial results. The Deputy Chair believed that co-operation with industry was preferable to regulation.
• Intellectual property strategies needed to be addressed in light of developments.
• Now that the data was being made available, how it was being used and the cost of this needs to be considered.

The Board agreed to continue to keep this item on their agenda.

19. Any Other Business

International Clinical Trials Day  Oral

The date that James Lind performed the first clinical trial, 20th May is recognised as International Clinical Trials day. The NIHR have a range of activities to celebrate and are launching the ‘OK to ask’ campaign. This is a call to arms for patients to enquire about clinical research in their health condition(s). Partners were encouraged to take part and publicise as widely as possible.

Next meeting is on 3 October 2013 from 2pm-5pm. Rooms 1&2, 13th Floor, MRC, One Kemble Street, London WC2B 4TS.