Board members are asked to:

i) Agree the minutes of the last meeting

Annexes

Annex 1 Draft Minutes of the last UKCRC Board Meeting (3 October 2013)
Annex 1

DRAFT MINUTES

UK CLINICAL RESEARCH COLLABORATION
BOARD MEETING 3 October 2013

Minutes of the meeting held on 3 October 2013, Rooms 1&2, 13th Floor, MRC, One Kemble Street, London WC2B 4TS

Present

Members

Sir John Savill – Medical Research Council (MRC, Chair)
Dr Louise Leong – 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)
Simon Denegri – INVOLVE
Harpal Kumar – Cancer Research UK (CRUK)
Nicola Perrin – Wellcome Trust
Mike Stevens – Scottish Government Health Directorates
Professor Bernie Hannigan – Health & Social Care R&D, Northern Ireland
Steve Bates – BioIndustry Association (BIA)
Professor Jon Bisson – 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)
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 Richard Trembath – 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)
Katie Petty-Saphon - The Association of University Hospitals UK

In attendance

Sir John Tooke – Academy of Medical Sciences (items 1-3 only)
Dr Rachel Quinn – Academy of medical Sciences (items 1-3 only)
Peter Knight – Department of Health, England (DH)
Sarah Qureshi – Partnership Manager, UKCRC

Observers

Simone Bayes – Department of Health, England (DH)
Dr Helen Campbell – Department of Health, England (DH)
Announcements and Apologies

Apologies

Professor Dame Sally Davies – Department of Health, England (Chair/DH)
Simon Pleydell – NHS Confederation
Dr Russell Hamilton – Department of Health, England (DH)
Dr Tim Cave – Senior Representative from the Pharmaceutical Industry
Steve Fairman – NHS England

Announcements

The Board noted that:

- This is the first meeting for David Haslam since being appointed as Chair of NICE and Jon Bisson as head of NISCHR. Both were welcomed.
- The ABHI requested to become a corresponding Partner of the UKCRC, allowing them to attend when appropriate. The Board granted this request.

1. Minutes of the twenty-sixth UKCRC Board Meeting UKCRC/13/09

The Board approved the minutes of the last meeting.

2. Matters arising Oral

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

The Board was asked to note that the Health Research Analysis Forum would now report to the next UKCRC Board meeting on the 28th May 2014 and that the OSCHR Update had been taken off the agenda as it had not met since the last UKCRC Board meeting (16th May).

Discussion

3. Team Science UKCRC/13/10

Sir John Tooke presented the Team Science (inter-disciplinary collaboration) approach and the progress of this AMS initiative. In discussion the following was raised:

- This approach should be seen as an opportunity.
- This approach places the emphasis on collaboration and not the individual.
- The Wellcome Trust has a working group looking at how to describe the roles of authors in papers. Eleven categories have been developed; these are currently being trialled with publishers and positive feedback received.
- Different disciplines have different languages and cultures, integration of these requires cross learning which could be achieved via appropriate courses to help develop a common language.
- Development of such organisations as The Francis Crick Institute encourages this approach.
- Universities were the place to encourage his approach with funders playing an important role.
- Funders were already rewarding those with a team approach via different types of awards.
• A transition stage can be observed as transdisciplinary applications are already being received by funders.
• Patient and public involvement would greatly enhance the process and is of prime importance.
• The NIHR leadership course was highlighted.
• Career progression and capacity within PhD and Post-docs posts needs to be enhanced.
• Medical schools may be the best place to take a lead in promotion discussions.
• The approach of e-health can be considered a success in this area.
• The Research Excellence Framework may change academic culture towards a more collaborative approach.

The Board noted progress in this area.

Activities

3. Promoting Research in the NHS Oral

Developments in Northern Ireland (NI) included:
• The two major investments, totalling some £30 million, in stratified medicine. These are in areas of strength that previously received Technology Strategy Board funding.
• A new regional office opened by GlaxoSmithKline who had also increased sponsorship of clinical trials in the region.
• The theme of the annual Science and Stormont conference was ‘Health and Innovation’.
• A current call for proposals to evaluate the impact of PPI in health and social care services (not just in research).

Developments in Scotland included:
• Following a positive consultation now moving to a re-structuring of the networks and speciality groups.
• Pushing forward to conclude the work of the Health Informatics Research Advisory Group, focusing on five main areas – federal network of safe havens, clear point of access to the service, proportionate and efficient governance, improved quality and accessibility of datasets and engagement with patients and public. A draft report is expected by the end of the year.
• The annual NHS Research Scotland (NRS) conference will take place at the end of October.
• This will also celebrate the 40th anniversary of the Chief Scientist Office.

Developments in Wales included:
• The second year of Primary Care Incentivisation Scheme has been launched, this will allow the number of practices participating from around 15 to 30.
• A further Clinical Research Time Competition is about to be launched. To allow NHS staff to have being ring-fenced time for research. This, as with other schemes, is being monitored through outcome metrics.
• A data linkage initiative aims to increase the number of General Practices in Wales linked to the SAIL dataset, held in Swansea, to over 70%.
• A work review of patient and public involvement is taking place.
• A discussion paper for the review and re-structuring of NISCHR funded infrastructure and programmes is inviting views on initial proposals/options. This will affect funding from March 2015 onwards. Members of the UKCRC Board are invited to respond.
The Chair apologised for the absence of an update from England due to unforeseen circumstances.

The Board noted progress in these areas.

**Activities**

4. **Open session of new research initiatives (Other Partners)**

Partners (AMS, AUKUH, HEFCE & AoMRC) were invited to give an update on research initiatives that they were involved in under this item. Among the items highlighted were:

- The AMS offers starter grants up to 30k for research active Clinical Lecturers to pursue research work and gather preliminary data to strengthen their applications for longer-term fellowships and funding. A review of the scheme has been conducted with the Wellcome Trust. The quality of the applications has been found to be very high. This grant does not cover salary costs.
- The AMS Clinical Scientist Fellowship allows enables talented clinicians to pursue academic research alongside their clinical practice in order to make long-term improvements in healthcare and focuses on translational research. The programme includes five years of funding to cover personal salary.
- The AMS mentoring programme has been extended to non-clinician scientists.
- The AUKUH runs a lively R&D Directors group. It is currently facilitating a consensus on Good Clinical Practice training which varies widely from Trust to Trust.
- The four UK higher education funding bodies are currently consulting on proposals for the implementation of an open-access requirement in the post-2014 Research Excellence Framework.
- £200 million capital funding will be invested in higher education science and engineering teaching facilities by HEFCE in 2015-2016. The first two rounds will launch in one month.
- Birmingham University and the Academy of Royal Colleges are about to start a 3 year NIHR-funded programme in high intensity care.
- The agenda of the Academy of Royal Colleges has been dominated by the 24 hour care, seven days a week government NHS initiative and the potential impact of the impending Greenaway report on the Shape of Thinking.
- Pathology in the UK has lost 60% of its academic posts in the last 10 years. In an effort to redress this to support stratified medicine, the college is in discussion with research funding bodies.

The Board noted progress in these areas.

**General**

5. **Patients, Clinical Trials; access and transparency**

Andrew Russell reminded the Board that this item was introduced a year ago following the publication of Ben Goldacre's book, Bad Pharma. The book reflected on the bias of clinical trial results and a lack of proper regulation. Progress was being made in securing a commitment from stakeholders to greater transparency. Both the MHRA and the HRA had a part to play in leading change. The House of Commons Science and Technology Select Committee recently published their report on this topic, stating that too many trials remained unregistered and unpublished. The Select Committee stressed that more effective regulation and a change in culture were needed.

John Hughes reported that the availability of GSK data was a positive step forward but that this was a system that primarily was directed towards researchers and statisticians. There was still a need to increase wider transparency. He is a member of the GSK independent
review panel which Roche hoped to converge with. The quality of lay reviews is important within the GSK application system and is considered by all panel members. GSK has reported that data sets available have increased from 200 to 400 which includes those where negative outcomes are being reported. It now remains to be seen how other pharmaceutical companies wish to proceed.

The ABPI reported that there was greater convergence on the disclosure of trial data, the limitations on the data and the release via safe havens requires further negotiation. The Board were reminded that this is a global industry with international standards. An ABPI toolkit has been produced instilling best practice and guidelines and a balance was required so that industry standards were not too much of a burden for competition. The issuing of industry guidelines is evidence of an upward trend.

The HRA reported that from the 30th September it is a condition of research ethics approval that the trial has been registered. Registration is required within 6 weeks of the recruitment of the first patient. An extension can be requested and in this situation the reason for an extension is given on the website.

The Board noted that progress continued to be made in this area.

Collaboration

6. EU Clinical Trials Regulation

Sir Gordon Duff reported that this regulation was now in the final stages of text agreement between the Council of Ministers and the European Parliament. The Board was reminded that Glynis Wilmott MEP was the rapporteur (lead legislator) for this regulation and is a member of the environment, health and food safety committee (ENVI). UK is in favour of most, but not all, suggested amendments.

The aim of the new Clinical Trials Regulation is to create a better environment for clinical trials in Europe and to address some recognised deficiencies in the 2004 directive.

Main items include, harmonisation of implementation, transparency, and risk-proportionate regulation.

During discussion the following was raised:
- The introduction of a harmonised authorisation dossier with a single submission to the National Competent Authority and the Ethics Committee(s) and a single decision.
- A single EU portal for all clinical trials applications in the EU (including single state trials). The main concern for this is whether the IT infrastructure required is in place. An assessment of IT requirements may be undertaken and linked to implementation timelines.
- The introduction of a flexible system of joint assessment of multi-state clinical trials without creating a centralised bureaucracy.
- A national indemnification system in each member state. This arises from an impact assessment that suggested an 8-fold increase in premiums. However, survey work by MHRA found no large impact on insurance availability or cost in the UK.
- Planning was being undertaken to help with the challenges raised for small companies.
- Realistically agreement needed to be reached before the Christmas break, if agreement could not be reached by the end of the parliamentary term in May 2014, the process would begin again after the European elections.
- The UK welcomes the European Commission’s proposal for a Clinical Trials Regulation and has been very active in promoting and supporting most aspects. It is believed that the proposal has the potential to create a more favourable environment for the conduct of clinical trials in the European Union by making it easier to conduct trials in
multiple Member States and introducing a proportionate and risk-adapted approach to clinical trials.

The Board noted progress in this area.

General

7. **Patient Access to NHS research**

Simon Denegri presented the changes made to how patients access research in the NHS. He highlighted:

- Changes in culture to involve patients and the public, delivering patient insight and experience to improve and deliver quality research leading to 345 studies with public involvement.
- The shortfall in the current patient experience and the public appetite for participation. Bridging the gap of a patient from a willing to active research participant.
- The ‘Ok to ask’ campaign launched on clinical trials day (21 May 2013) encouraging patients to ask about clinical research and the positive feedback received from it.
- Future developments include the continuation of the ‘Ok to ask’ campaign, information and tools for health professionals to support patient conversations, redevelopment of the UKCTG and formal measurement of changes in perceptions and attitudes.
- That Professor Til Wykes, Director of MHRN had provided evidence that patient involvement was linked to recruitment target and therefore study success.

The Board noted progress in this area.

Reports from Subgroups and Fora

7. **Public Awareness**

Simon Denegri reported that following consultation with the Partner members it was decided to dissolve this sub-group. The sub-group had produced the popular ‘Your health record saves lives’ leaflet, however the opportunity was lost for another edition and the costs of re-distribution were prohibitive. It was noted that other organisations were taking up the mantle of raising public awareness. The remaining budget of £3,457 remains with the AMRC, which the Chair of the sub-group (John Williams) and Simon Denegri will make arrangements for.

The Board thanked the Chair and its members for their hard work.

UKCRC General

8. **UKCRC Partnership Manager’s Report**

The Board noted the position in the paper.

9. **Translational Infection Research Initiative Phase 1 review**

The Board noted the position in the paper.
Reports from Subgroups and Fora

10. **Experimental Medicine Funders Group** Oral

Catherine Elliott reported that the EMFG had not met since the last UKCRC Board meeting and highlighted the following:

- Following agreement a business case for Human Tissue banking had been put together and would be taken forward.
- The group will be considering molecular pathology in rare diseases, this work will be co-ordinated via OSCHR.
- The National Phenome Centre was now up and running with a second call for projects underway.
- Options for staff deployment across experimental medicine projects in commercial and non-commercial projects will be considered at the next meeting.

The Board noted the position.

Collaboration

11. **EU Data Protection Regulation** Oral

Catherine Elliott reported that this regulation has caused a lot of concern within research as it would affect how patient data can be used. In particular it would severely restrict the use of personal data for scientific research purposes without consent. It was highlighted that this regulation would be become UK law instantaneously and that research data was just a small part of the whole regulation.

During discussion the following was raised:

- There are over 3000 amendments to be discussed, this had led to the postponement of a vote on the regulation twice already.
- The regulation would cover anonyomised data. The best outcome would be an opt out for medical research.
- If agreement cannot be reached before the end of the parliamentary term in May 2014, the process would begin anew following the EU elections.
- The involvement and awareness of patient groups will be increased via organisations such as the Science Media Centre and NHS England to this regulation.

The Board noted progress in this area.

General

12. **Spending Review** Oral

Helen Bodmer reported that on the 26th June the settlement for science and innovation for the 2015-2016 spending review was announced by the Chancellor. The following was highlighted:

- An increase capital in real terms from £0.6billion in 2012-13 to £1.1 billion in 2015-16 and grows in line with inflation each year to 2020-21.
- Extension of the Research Partnership Investment Fund (RPIF) to 2016-17 making available at least £100 million each year of match-funding to leverage private investment in science infrastructure.
• £150 million from the Department of Health in 2015-16 to fund work on dementia, genomics and imaging.
• £185 million additional resource for the TSB to give a total budget of £477 million in 2015-16 including new catapult centres, SME support, new innovation platforms and the Biomedical Catalyst.
• It is anticipated that the allocation process will be completed by the end of the year.

Partners were thanked and congratulated on their work in this area.

Policy

13. **Life Sciences Strategy**

Helen Bodmer reported that the life sciences strategy had become part of the wider government industrial strategy. As such there were no plans to specifically produce a ‘two years on’ document. An industrial strategy update would be provided in the spring of next year. She highlighted the following:

- NHS England will be refreshing their ‘innovation health and wealth’ measures. This aims to include the changes in the NHS landscape.
- The NIHR has announced 13 new CLAHRCs (Collaborations for Leadership in Applied Health Research and Care). These are 13 teams which will work on current issues in healthcare, with an emphasis on long-term conditions such as dementia.
- NICE is set to produce a new product called ‘Medtech Innovation Briefings’, which will summarise published evidence on new technologies to save individual organisations from doing it separately.
- The TSB is developing a new ‘Diagnostics for Stratified Medicine’ Catapult, launching in April 2014.
- The next newsletter would be circulated to Partners.

The Board noted progress in these areas.

Policy

14. **Health Research Authority**

Janet Wisely highlighted the following developments at the HRA:

- A business case for assessment and approval has been approved by the HRA Board.
- Following consultation, they have revised their information sheet guidance.
- Their new website will launch on Monday 7th October. It will contain a new and improved search function.

The Board noted progress in these areas.

Collaboration

15. **Caldicott Review into sharing of health information**

Nick Partridge presented the Government response to the Caldicott Review and the Health and Social Care Information Centre (HSCIC) Guide to Confidentiality in Health and Social Care. He highlighted the following:
• Chapter six of the Government Response to the Caldicott Review is dedicated to Research.
• Rule 4 of the HSCIC guide to Confidentiality in Health and Social Care states that ‘An individual's right to the sharing of confidential information about them should be respected’.

In discussion the following were raised:

• DH support for the Caldicott principals was welcomed.
• Patient groups are crucial to the success of the implementation of the Caldicott principals.
• It was clarified that a patient’s right to object to their data being used can take place at two points. The first is when the information is leaving the GP surgery, the second is at the time of forward transmission e.g. at the information centre.
• Rule 4 inspires public confidence.
• Safe havens and how they are to accredited now needs to be addressed.
• The proportion of objections from recent data indicates this to be less than 1%. This needs to be kept in proportion to the work required in this area.
• A patient’s objection may be reversed.
• Patient data from GP’s surgery has already been used in the past and takes place currently.
• NHS England are implementing a public awareness strategy in this area.
• What need to be achieved is a balance of public confidence and an understanding of how the health service works.
• Appropriate training of staff is crucial in the implementation of Rule 4.

The Board noted progress in this area.

Other

16. Any Other Business

No other business was declared.

Next meeting is on 28th May 2014 from 2pm-5pm. Rooms 1&2, 13th Floor, MRC, One Kemble Street, London WC2B 4TS.