Minutes of the meeting held on 11 October 2012, Room 1, 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 (Deputy Chair/MRC)
Bina Rawal – The Association of the British Pharmaceutical Industry (ABPI)
Dr Helen Bodmer – Department for Business, Innovation and Skills (BIS)
Sarah Buckland – INVOLVE
Sharmila Nebhrajani - Association of Medical Research Charities (AMRC)
Dr Russell Hamilton – Department of Health, England (DH)
Harpal Kumar – Cancer Research UK (CRUK)
Dr Richard Tiner – Academy of Medical Royal Colleges (AOMRC)
Beth Thompson – Wellcome Trust
Mike Stevens – Scottish Government Health Directorates
Professor Bernie Hannigan – Health & Social Care R&D, Northern Ireland
Steve Bates – BioIndustry Association (BIA)
Michael Bowdery – National Institute for Social Care and Health Research, Welsh Assembly Government (NISCHR)
John Hughes - Patient/Public Member
Andrew Russell – Patient/Public Member
Sir Ron Kerr – NHS Confederation
Sir Nick Partridge – Patient/Public Member (Deputy Chair)
David Adams – Academy of Medical Sciences (AMS)
Professor Carole Longson – National Clinical Institute for Health and Clinical Excellence (NICE)
Andy French - Medicines and Healthcare products Regulatory Agency (MHRA)
Caroline Shaw - The Association of University Hospitals UK
Paul Hubbard – Higher Education Funding Councils (HEFC)
Professor Iain Cameron – Universities Representative
Oliver Wells – Association of British Healthcare Industries (ABHI)

In attendance

Simone Bayes – Department of Health, England (DH)
Tony Soteriou – Department of Health, England (DH)
Peter Knight – Department of Health, England (DH)
David Cox – Department of Health, England (DH)
Sarah Qureshi – Partnership Manager, UKCRC
Jane Belfourd - Office of Life Sciences
**Announcements and Apologies**

**Apologies**

Dr Tim Cave – Senior Representative from the Pharmaceutical Industry  
Joy Todd – Economic and Social Research Council (ESRC)  
Janet Wisely – Health Research Authority (HRA)  
Sir Bruce Keogh – NHS Commissioning Board

**Announcements**

The Board noted that:

- Both the HRA and NHS Commissioning Board have accepted invitations to join the UKCRC Board. Unfortunately, both were unable to send representation to this meeting.
- This would be Richard Tiner’s last meeting. The Board thanked him for his contributions and dedication. He will be succeeded by Dr Archie Prentice from the Academy.
- The UKCRC was acknowledged at yesterday’s Dementia research showcase event, organised as part of the Prime Minister’s Challenge on Dementia.

1. **Minutes of the twenty-third UKCRC Board Meeting**  
   UKCRC/12/09

   The Board approved the minutes of the last meeting.

**Policy Update**

2. **UKCRC Partnership Manager’s Report**  
   UKCRC/12/10

   The Partnership Manager, Sarah Qureshi referred the Board to the paper detailing her activities since the last Board meeting and the financial position of the UKCRC. The Board were reminded that the running costs of the UKCRC were met by DH England and that the UKCRC is hosted by the MRC.

   The Board noted the position.

3. **Public Health Centres of Excellence**  
   Oral

   John Savill informed the Board that seven of the eight original funders had now committed funds of approximately 16 million for the second phase of the funding of these centres over the next five years. At the final funders meeting under ESRC management the annual reports of the centres were reviewed and no significant concerns were found. The MRC would now manage the competition for the second phase of funding.

   The MRC were thanked for taking over the management of these centres from the ESRC.
4. **CTU Registration**

Julia Brown, Director of the Registered UKCRC CTU Network presented this paper. The 2012 call for registration was led by the Working Group and took place at the University of Leeds, Clinical Trials Research Unit. The following was highlighted:

- 55 applications were received and a total of 46 successfully granted registration.
- The International review panel met in July and were impressed with the standards shown in the units.
- Some units had shared their resources as previously recommended.
- Funders were invited to observe the process and had given positive feedback.
- A self-funding financial model via a registration fee was used which was underwritten by the 5 main funders. At this point it was unlikely that the funders would need to contribute via the underwriting.
- The next CTU directors meeting would take place in November.
- The next call for registration would be in January 2015. Consideration of how this was to be funded would now be given.

Julia Brown and colleagues were thanked for their hard work in bringing together a successful programme and achieving harmonisation across units. Funders had shown their value of the scheme by only funding trials whose CTUs are accredited. The brand is very much valued and international interest in the standards and methodology has been received. The development of any international models could not be financed by the UKCRC.

**Reports for Subgroups and Fora**

5. **Research Regulation and Governance**

Simone Bayes reported that this group serves as a useful exchange for consulting and co-ordination for Partners. It was highlighted that:

- The Health Related Findings public engagement is joint research by the Wellcome Trust and the MRC. This was not a public consultation as it is principled based and looking at the evidence gap. A summary would be circulated to Partners in due course.
- The MHRA was co-ordinating the UK’s standpoint on the EU Clinical Trials Directive review. A public consultation would take place in mid-October. Glynis Willmott is the rapporteur (led MEP) for the Directive and Christiane Abouzeid (BIA) Chair of the EuropaBio group looking at its revision. Implementation would be in 2016 at the earliest. The MHRA agreed to provide an update at the next UKCRC Board meeting.

The Board noted progress in these areas.

6. **Health Research Analysis Report**

John Savill reminded the Board that the original valuable analysis of UK spend on research was completed in 2006, this second report was displaying how the landscape has changed 5 years on. The report was due to be released imminently and would be displayed on the UKCRC and MRC website.

The Board stated how useful this work was, especially in light of the Spending Review. Partners agreed to make the appropriate links to the report when released. The MRC was thanked for its management of this work.
7. **Public Awareness**

Peter Knight referred the Board to the tabled paper. Three main avenues for dissemination of the booklet have been identified:

- Via the ABPI, a survey of the companies likely to participate was being investigated whilst final sign-off of the accompanying letters takes place.
- Via existing NHS networks currently being exploited.
- Exploring the option of the NHS Commissioning Board adopting the booklet as part of its remit to promote research and streamline it into mainstream NHS publications.

This sub-group was also now looking to expand its remit as it considers its role in the ‘Patient Choice’ agenda.

The Board continued to encourage dissemination of the booklet as widely as possible by Partners.

8. **Experimental Medicine Funders Group**

John Savill referred the Board to the paper and highlighted the following recent developments:

- The MRC-NIHR Phenome Centre, this is part of the Olympic legacy and would entail tissue banking.
- NIHR Translational Research collaboration in rare diseases.
- The feasibility of portfolio and output metrics via health research classification and publication metrics.

Russell Hamilton commented that the distinction between TRPs and TRCs was not quite right in the paper and explained the differences. NOCRI will provide amended text to the group.

The Board sought reassurance that the metrics on output would not include patient recruitment. PPI members of the Board were encouraged to find that the group was considering the issue of reporting negative results.

**For discussion**

**Policy**

9. **Health Research Authority**

Russell Hamilton highlighted the following developments at the HRA:

- Chair (Jonathan Montgomery) has been appointed, two non-executive directors and a substantive Chief Executive (Janet Wisely). Next full Board meeting is October.
- The National Research Ethics Advisors Panel terms of reference have been updated and new appointments made.
- Establishment of a UK-wide steering group for projects, remit includes guidance on training requirements for researchers, including GCP, requirements for local signatures on the site assessment for and early use of the IRAS project reference to ensure accurate identification of studies.
- The National Research Ethics Service is conducting a pilot of an ethics officer function from September.
• The Patient and Public involvement working group is currently preparing proposals the appointment of an engagement manager is expected soon.
• The UK Ethics Committee Authority (UKECA) now chaired by the HRA Chief Executive and has proved to be a helpful forum.
• The National Information Governance Board closes in March 2013, advice functions on use of data will transfer to the HRA.
• Development of an advisory service.

The Board noted that the next Health and Social Care Bill would include provision for the establishment of the HRA as a NDPB.

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

Nick Partridge reminded the Board that the aim of the review was to achieve a balance of protecting and sharing health information. A consent model was being developed. The Review had received 150 written submissions and was due to be published next year.

The Board noted progress in this area.

11. **Consultation on NHS Constitution** Oral

Peter Knight reminded the Board that the NHS Future Forum has recommended a Review of the NHS Constitution. It was found that 20% of patients are aware of the Constitution and that very positive about research with research considered an important activity. NHS Future Forum would now give advice to the Secretary of State and are therefore awaiting direction from the Minister.

The Board noted progress in this area.

12. **Life Sciences Strategy** Oral

Jane Belfourd reported that David Willetts had released a letter regarding an update on the Life Sciences initiatives in the summer (available on BIS website). She and Tony Soteriou highlighted the following:

• The first 10 million of the Biomedical Catalyst fund has been awarded.
• John Brown has been appointed Chair of the Cell Therapy Catapult.
• The Society of Biology has launched their undergraduate degree accreditation programme.
• An update on ‘Innovation Health and Wealth’ by David Nicholson was expected in December.
• The establishment of Academic Health Science Networks is ongoing.
• The BIS mori poll on the public attitudes towards the transport of animals for research will be released shortly. This demonstrated that the majority of public supports animals and research. Encouragingly, 75% of participants wanted to know more about research.

The Board noted that funds from the Biomedical Catalysts were targeted to SMEs and expansion to larger companies was not possible.
13. **Mandate to NHS Commissioning Board** Oral

Russell Hamilton reported that it was the duty of the NHS Commissioning Board to promote research, and the main vehicle for the Secretary of State to communicate to the NHS Commissioning Board about this was through the mandate. The consultation on the mandate closed last month and the outcomes are expected to be reported within the next two months. Research is also included in the Choice Framework.

The Board noted progress in this area.

**Collaboration**

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

John Savill reported that OSCHR Board meeting in May was its 21st meeting. John Bell has been invited by Ministers to continue as Chair for a further 3 years and Mark Walport will continue as an independent Board member until December 2013. The Board was reminded that life sciences strategy was devised at OSCHR and that the TSB, BIS, HEFEC, MRC and the Devolved Nations were represented at this Board. Discussion at this meeting centred upon:

- The development of a national narrative in preparation for the Future Spending Review
- A short OSCHR progress report in the form of a letter to Ministers with an annex detailing OSCHR’s achievements will be produced as an impact statement for the partnership.
- Development of the knowledge base within UKTI.

The Board noted progress in these areas.

**Activities**

15. **Promoting Research in the NHS** Oral

Developments in Wales included:

- A new NHS focused Research for Patient and Public Benefit (RfPPB) scheme that will launch in November 2012.
- New awards under an NHS-focused ‘proof of concept’ scheme called INVENT. Applications from NHS with emphasis on industry collaboration/commercialisation potential.
- Ongoing implementation of an Activity Based Funding model for NHS R&D allocations.
- New Clinical Research Time competition awards, within the Welsh Academic Health Science Collaboration.
- Recent publication of an NHS-relevant Industry Plan.

Developments in Scotland included:

- A new Minister has been appointed who is very enthusiastic for research and informatics.
- The inaugural NHS Research Scotland (NRS) Conference on 1 October.
- Launch of the Scottish Health Research Register (SHARE).
- A Health Science Scotland bid for Stratified Medicine.
Developments in Northern Ireland included:

- External evaluation of the impact of HSC R&D noted in particular that 20% of funded projects impacted on policy or practice while also creating employment and career progression. For each £1 allocated, over £4 additional funding was attracted to NI.
- The evaluation also noted concerns around the inability to apply for NIHR funding. Health Minister agreed to provide funding to support NETS studies alongside UK partners.
- Joint working with economic development agency (InvestNI).
- Extension of the NI UKCRC Public Health Centre of Excellence through a Public Health Research Network that also involves the regional Public Health Agency with its community and voluntary partners.

Developments in England included:

- The 70 days benchmark from application validation to patient recruitment has been established. Data has now been collected from the first quarter and is being checked for completeness and quality.
- The AUHUK has established a Research Director Group, one area they are considering is understanding data issues.
- Regional events have been taking place between NIHR R&D managers & Chief Executives of NHS Trusts. This has been very successful due to shared learning.
- Work towards a single sign-off within an AHSN wide system. Clarity on what is required is needed.

The Board noted progress in these areas.

16. Open session of new research initiatives (Charity Partners)  Oral

Charity Partners (AMRC, CRUK & Wellcome Trust) were invited to give an update on research initiatives that they were involved in under this item. Among the items highlighted were:

- The AMRC has been undertaking a strategic review with its key themes being “support, influence and connect”.
- Collaboration is a key theme, two workshops one on innovative mechanisms of IP and the other on charity-industry collaboration are being produced which will take a case study approach. Case-studies will be examined.
- The charity sector welcomed AcoRD implementation in all four nations which was a great help in supporting charity funding research in the NHS.
- The AMRC are also looking extending the work done in MRC and elsewhere on impact and evaluation sector wide with an especial focus on mid-sized and smaller charities.
- CRUK has a £30 million call for awards for new imaging centres. Part of the funding will be provided by the EPSRC.
- CRUK has been piloting a stratified medicine programme for cancer patients. The NHS, TSB, Pfizer and AstraZeneca are partners. This programme is working very well.
- CRUK is a partner in two of the projects which recently received funding through the HEFCE capital project research fund. The largest is in Oxford and will cover therapeutic strategy for early stage cancers.
- CRUK is a Partner in the Francis Crick institute, the development of which is on target.
- CRUK are proposing to engage the public more directly in research projects. A pilot activity, termed Citizen Science, will place data on unsolved problems in cancer on the web for the public to get involved.
- Innovative Engineering for Health is a new £30 million partnership between the Wellcome Trust and the EPSRC. This is aimed at innovative, multidisciplinary projects addressing any unmet needs in medicine or public health.
• The Wellcome Trust has established Pathfinder Awards to provide pilot funding (less than £100,000) for academic-industry partnerships to develop early-stage applied research and development projects in orphan and neglected disease areas.

The Board noted progress in these areas.

General

17. Recent critique of UK Research Regulation  Oral

PPI members of the Board raised the issue of the suppression of data of clinical trials where the results are unflattering or show undesirable outcomes. These comments were centred on the book published by Ben Goldacre called ‘Bad Pharma’, in which he states that this gives rise to an overly positive outcome of systematic review and meta-analyses of such drugs, leading to their acceptance for prescription in the NHS. The regulatory authorities were accused by the book of complacency or even complicity in this process. An article in the Guardian today announced that GlaxoSmithKline would publish all the data from its clinical trials. PPI members questioned how robust the UK regulatory system is in ensuring maximum information for the benefit of the public. During discussion the following was raised:

• Richard Tiner who was undertaking a book review on behalf of the BMJ said that the book lacked the details of the progress made in this area, specifically that fact that all clinical trials must be registered and the data published at the end of the trial. Partners were encouraged to send their views for possible inclusion.
• The ABPI has issued a statement regarding the main allegations made, available on its website.
• The ABPI is signed up to international standards such as the joint positions of international trade bodies.
• The book called for the retrospective publishing of trials data to avoid positive bias in systematic reviews. However, it was asserted by some Partners that whilst the data of early trials has not been published, the landscape had now changed.
• The MHRA requires a signed declaration for each trial. The omitting of data in the requirement to publish results is a criminal offence.
• The publishing of fraudulent data is the real concern.
• Adverse incidents may not become apparent until a drug is released into the wider population.
• The new HRA does not have the remit of total governance of UK medical research.
• The MHRA is currently consulting widely on its strategic aims.
• Partners concurred that any suppression of trials data was a serious matter, but felt that progress was being made towards greater transparency.

The PPI members asked that at future meetings reports should be made detailing these measures and progress made. Richard Tiner would advise Partners when his comprehensive review was on the website. INVOLVE were asked to consider the issue and keep a watching brief.

The Board concluded that many Partners had already endorsed the fact that all results from clinical trials should be published including negative results. The Board was not able to police this area but could have a very useful role in encouraging and co-ordinating work in this progressive area.
18. Any Other Business

Preparation for the Spending Review  Oral

Helen Bodmer reported that there had been good engagement in building the evidence base for the next spending review. The press indications have been that the Spending Review would not take place before the next general election in 2014. Partners were encouraged to continue to gather the evidence required and focus on research impact e.g. via collaborations.

Mark Walport appointed to UK Chief Scientific Adviser  Oral

The Board were informed that Mark Walport had been appointed as the UK’s Chief Scientific Adviser. He would take up his post in April 2013. He is currently Director at the Wellcome Trust and will step down as Director at the same time.

Next meeting is on 16 May 2013 from 2pm-5pm. Room 2, 13th Floor, MRC, One Kemble Street, London WC2B 4TS.