MINUTES

UK CLINICAL RESEARCH COLLABORATION
BOARD MEETING 30 October 2008

Minutes of the meeting held on 30th October 2008, Himsworth and Fletcher Rooms, UKCRC, 20 Park Crescent, London, W1B 1AL

Present

Members

Nick Partridge – INVOLVE Chair
Adrian Alsop – Economic and Social Research Council (ESRC)
Dr Richard Barker – The Association of the British Pharmaceutical Industry (ABPI)
Professor Sir Alasdair Breckenridge - Medicines and Healthcare Products Regulatory Agency (MHRA)
Dr Mike Davies – Department for Innovation, Universities and Skills (DIUS)
Simon Denegri – Association of Medical Research Charities (AMRC)
Glyn Edwards – Bio-Industry Association (BIA)
Peter Littlejohns - National Institute for Health and Clinical Excellence (NICE)
Dr Russell Hamilton – Department of Health (DH)
Professor Bernie Hannigan – Health & Social Care R&D Office, Northern Ireland
Harpal Kumar – Cancer Research UK (CRUK)
Jane Austin – NHS Confederation
Professor Peter Kopelman - Universities Representative
Dr Mark Walport – Wellcome Trust (WT)
Jenny McKibben - Patient/Public Member
Candy Morris – Strategic Health Authorities (SHAs)
Dr Clive Morris – Senior Representative from the Pharmaceutical Industry
Dr Declan Mulkeen – Medical Research Council (MRC)
Professor Alan Maryon-Davis – Academy of Medical Royal Colleges (AOMRC)
Dr Liam O’Toole – UK Clinical Research Collaboration (UKCRC)
Professor Ian Lauder – The Academy of Medical Sciences (AMS)
Dr Alison Spaull – Scottish Executive Health Department

Observers/Invited

Professor Janet Darbyshire – NIHR Clinical Research Network Coordinating Centre (NIHR CRN CC)
Catherine Johns – Department of Health (DH)
Marc Taylor – Department of Health (DH)
Dr Louise Wood – Department of Health (DH)
Dr David Cox – Department of Health (DH)
Dr David Lynn – Wellcome Trust (WT)
Dr Richard Tiner - The Association of the British Pharmaceutical Industry (ABPI)
Harry Cayton – National Information Governance Board (NIGB) (Item 4)
Ian Johnstone – National Information Governance Board (NIGB) (Item 4)
Dr Helen Howard- NIHR Clinical Research Network Coordinating Centre (NIHR CRN CC) (Item 5)
UKCRC Secretariat

Dr Matthew Hallsworth        Samia Majid
Dr Sue Bourne               Hannah Brown
Dr Rebecca Hodges           Dominique Capostagno
Philippa Yeeles             Katie Gale

Announcements and Apologies

Apologies
Professor Sally Davies – Department of Health (DH)
Malcolm Carlisle – Association of British Healthcare Industries (ABHI)
Dr Sue Denman – Welsh Assembly Government
David Eastwood – Higher Education Funding Councils (HEFCE)

Announcements
The Chair welcomed everyone to the sixteenth meeting of the UKCRC Board. Attending the
UKCRC Board for the first time were:

- Professor Alan Maryon-Davis, President of the Faculty of Public Health
  Medicine, as the new Alternate member for AOMRC
- Professor Ian Lauder, Academy of Medical Sciences Treasurer and recently
  retired as Dean of the Leicester Medical School, as the new AMS Alternate
  member
- Adrian Alsop, Director for Research at ESRC, as the new ESRC Alternate
  member
- Dr David Cox, Deputy Director of Research Faculty in the Department of Health,
  who will attend UKCRC Board meetings as an Observer

The Chair announced that this was Jenny McKibben’s last Board meeting and that Andrew
Russell would be attending the next meeting of the Board in his role as the Alternate
Patient/Public member on the Board. The Board thanked Jenny for her contribution towards
the UKCRC.

1. Minutes of the Fifteenth UKCRC Board Meeting

The Board approved the minutes of the last meeting.

UKCRC General

2. Chief Executive’s Report

Staff Departures
In keeping with the planned reduction of the UKCRC Secretariat, Sarah Harrop (Science
Writer) and Katie Gale (PA to Chief Executive) have left the UKCRC to take up permanent
posts within the MRC. Both Sarah and Katie were on fixed-term contracts, which would
have ended during 2009, however both have elected to leave early.

The Board thanked Sarah and Katie for their contribution to the work of the UKCRC.
Progress Report
The 2006 – 2008 UKCRC Progress Report was now published and copies were tabled at the meeting. The Board, and all who were involved, were thanked for their contributions and efforts in enabling the report to be produced on time.

Budget
The Board noted that in keeping with agreed practice, the Secretariat had provided the Budget Committee with financial reports detailing spending in the first and second quarters of 2008/09 and a 2008/09 budget reforecast.

Nick Partridge, Chair of the Budget Committee, summarised the key points from both the reports. It was noted that the final expenditures for Quarter 1 and Quarter 2 of the financial year 2008/09 were respectively, 0.5% and 12.5% less than had been estimated in the 2008/09 approved budget. This underspend could mainly be accounted for by the unexpected reduction in staff costs and planned activities now taking place later in the year.

The October reforecast showed a revised projected spend for 2008/09 financial year of 1.4% less than the approved 2008/09 budget.


The Chair reminded the Board that it has been 4 years since the start of the UKCRC. The Progress Report highlighted the enormous amount that had been achieved in this time. This was a tribute to the UKCRC Partners, stakeholders and Secretariat. The Board considered the tasks that needed completion during 2009/10 and then discussed the longer-term future of the UKCRC.

2009/10 Workplan

The Board agreed that the role for the UKCRC during 2009/10 should be to ensure that work already started was to be completed. This included those tasks laid out in Annex 1 of the paper (UKCRC/08/28). The Board acknowledged that progress has been made in the area of regulation and governance but that the full impact of change has not yet taken effect. This should remain the highest priority for the 2009/10 Workplan. Members agreed that any work on incentives for research in the NHS should continue to be led by the Health Departments and noted the offer of industry to help on this issue.

The Board agreed that the UKCRC Secretariat should draft the Workplan on the basis of the Board discussion. In keeping with normal practice the Budget Committee will meet in November 2008 to agree on the draft budget to deliver the draft Workplan. These draft documents would then be circulated to the Board for comment and approval prior to the February 2009 Board meeting. The Board noted that the resources required to complete the 2009/10 Workplan would be considerably less than the 2008/09 budget.

Longer-term future of UKCRC

The Board turned to a discussion of the longer-term future of UKCRC. Members agreed the following:

- There was a continued need for the UKCRC to continue as a forum to jointly monitor the UK health research environment, identify emerging issues that need addressing and agree action.
• There was a need for a major evolution in the way that the collaboration worked. The role of any secretariat in future should be very different. Its role would be to work closely with the UKCRC partners to identify extant and emerging issues that need addressing and draw them together for annual discussion. The UKCRC Partners would then agree amongst themselves how and by whom these issues should be addressed.

• The “UKCRC way of working”, particularly the transparency and accountability should be sustained. The principles that have been successfully applied to joint working should be clearly defined and treated as responsibilities of those leading on joint projects in the future.

• There was a need to agree a “transition plan” to ensure that activities where there was continued need for joint action had a “home” or lead organisation to keep them going outside the secretariat.

The Board asked the CEO, Dr Liam O’Toole, to put together a paper, with help from UKCRC Partners, mapping out the future of the UKCRC based on the above points. The paper should include the following: 1) a Statement of the UKCRC vision; 2) the principles of working in collaboration; 3) a Strategic Framework (priority is R&G) for activities; and 4) the Transition Plan. This would be circulated and finalised at the February 2009 Board meeting. The Chair thanked the Board members for their input.

4. National Information Governance Board update

The Chair reminded members that in March 2007 Harry Cayton, then National Director for Patients and the Public at Department of Health, had been invited to the Board to present an update on the Information Governance Review. Harry Cayton had subsequently been appointed Chair of the National Information Governance Board (NIGB), which had taken over the role of the Care Records Development Board. A written update on the establishment of the NIGB had been provided to the Board in April 2008.

Harry Cayton informed the Board that, following legislation, the NIGB would be established as a statutory body in December 2008 and that from January 2009 it would subsume the statutory functions of the Patient Information Advisory Group (PIAG), which was abolished. The NIGB would comprise a Chair appointed by the Appointments Commission, 10 public members and 10 representative members from health and social care organisations. It was noted that Carol Dezateux, representing the AMS, was a representative member of the Board. The Chair of the statutory NIGB would be announced by the Appointments Commission in the coming week.

The Board were reminded that the NIGB is an advisory body reporting to the Secretary of State for Health. Its remit includes all uses of data derived from patient information including NHS funded research. Its statutory functions include issuing advice to organisations and individuals to promote improvements on information governance matters across health and social care. These bodies were required to have regard to the advice, and if requested, to provide information to the NIGB showing how they had regard to such advice.

The NIGB has submitted a response to the consultation on the draft NHS Constitution i) supporting the importance of research in the NHS and ii) expressing concern that the draft Handbook appears to suggest that researchers could access patient information/care records, without consent, in order to identify suitable patients for clinical trials. The view of the NIGB was that this was in conflict with the NHS Care Record Guarantee.

The Board discussed the NIGB’s view, and whether patients should expect the NHS to identify them confidentially so that they could then be asked for consent to participate in
Harry Cayton commented that the NHS Constitution placed too much emphasis on confidentiality and not enough on consent. Asked whether the NIGB would recommend amending the NHS Care Record Guarantee, he said it would do so if the Government changed the law. He noted that the NHS Constitution was a declarative document, not legislative. Asked whether the NIGB would consider a class exemption in this area, he said that no exemption had been proposed to it. He recognised the issue and said he was confident it could be resolved in some way.

Harry Cayton further highlighted the following:
- The NIGB had been running in a non-statutory form for a year now and an annual report was in preparation. He encouraged members to attend the first annual public meeting of the NIGB on 6 November 2008.
- The NIGB proposed to form a sub-committee that would take on PIAG’s statutory role. The administrative functions supporting PIAG had been merged with the office supporting the NIGB. Ian Johnstone, Interim Head of Office for the NIGB, had ordered a review to ensure applications were processed efficiently, and would set up an appeal mechanism.
- The wider remit of the NIGB included providing advice and guidance in areas relating to the governance of data derived from patient information but not involving research, such as advice on Children’s Summary Care Records, approval of the Social Care Record Guarantee and a report on ‘Honest Brokers’ and ‘Safe Havens’
- NIGB Board papers were publicly available on the NIGB website [http://www.connectingforhealth.nhs.uk/nigb](http://www.connectingforhealth.nhs.uk/nigb)

The Chair thanked Harry Cayton for his attendance and agreed that he should be invited to attend an appropriate Board meeting in the future to provide a further update.

5. Review of Core Capacity of UKCRC Registered Clinical Trials Units and Future Funding Requirements for the development and delivery of academic-led, late phase, randomised controlled trials across the UK

Janet Darbyshire outlined the recently completed review of core capacity in UKCRC registered Clinical Trials Units. The project aimed to assess current capacity in terms of geographical distribution and areas of health and disease.

In summary the review showed that:
- There was a good geographical distribution of registered units
- All key health/disease research areas were covered
- Over 500 core posts were currently supported, but at least 25% of these were likely to have expired by 2012
- There was a need to increase the capacity of clinical trials units to meet the increase in translational and clinical research activity.

The next step was that the full report will be reviewed by the UKCRC Research Funders Liaison Group and they will consider what actions are required in response to the report.

In discussion the Board raised a number of points for consideration, including:
- The modelling carried out in the course of the review was based on the projections of funding bodies for increases in the number of clinical trials that were likely to be carried out in the UK. These projections were high and should be carefully checked before discussion by the Funders Liaison Group.
- Details should be provided to the Research Funders Liaison Group on how the review questions had been framed in order to fully inform their discussions.
• The Board agreed that it was probably the case that trials run through a CTU were of better quality and were more likely to complete to task than those not run through a unit. This was borne out by the experience in cancer trials. Getting the balance right between core staff and staff supported on a project basis was key to appropriate resolution of the capacity issue.

6. **UK-wide Working within UKCRC Activities**  

The paper presented to the Board summarised the results of a mapping exercise to identify the differences and similarities between the four UK nations with respect to UKCRC activities. This project had been initiated by the UKCRC Secretariat to help them in their work and it was intended that the paper would be shared with operational staff within Partner organisations and other interested stakeholders.

The Board welcomed the document as an extremely useful resource and it was agreed to make it publicly available on the main part of the UKCRC website, after consulting with the Health Departments that there is no information included which should not be made public.

Action: Secretariat to liaise with Health Departments before publishing the document on the UKCRC website.

**Activities**

7. **Summary of Current Activities**  

Following discussions at the last Board meeting on the way updates on the UKCRC activities were provided to the Board, the Secretariat have revised the format and compiled this information into one document. Board members should refer to this paper for updates on the UKCRC activities (items 8b – 13). The Board welcomed this revised format.

8. **Building up the Infrastructure for Research in the NHS**

a) **UKCRN Update paper**

Janet Darbyshire presented the update paper. The Board welcomed the new format of the UKCRN Update paper and agreed that it was clearer in presenting the progress made by the UKCRN since the last meeting.

The Board noted that Jenny McKibben had requested that the Subgroup highlight to the Board the sense of achievement in developing the research infrastructure for conducting clinical studies throughout the UK, and the speed at which these achievements have been realised. This received widespread support from the other Subgroup and Board members.

There were now 132 industry-sponsored studies in the network, and five device studies. The Subgroup wished to highlight Figure 1 in Annex 2 of the paper which provided data on the first 14 industry-sponsored studies to be conducted from start to finish through the networks. The figure showed percentage accrual against UK target, split by studies pre-opened at adoption and those opened to accrual following adoption. It was hoped that such data would build industry’s confidence that the networks can deliver their aims.

Glyn Edwards and Richard Tiner from BIA and ABPI welcomed the data. Richard Tiner commented that these data were the first set of metrics available on the performance of industry-sponsored trials run through the networks. He noted that out of those studies
opened after adoption into the networks, 80% reached their projected sample size within the target time and 4 out of the 6 studies achieved over 100% of their accrual target.

The Board noted that following a two week pilot of the NIHR Coordinated System for gaining NHS Permissions (NIHR CSP), the System was due to ‘go live’ on 18th November 2008. The NIHR Clinical Research Network Coordinating Centre (NIHR CRN CC) were now focusing their efforts on training, communications and fixing the glitches identified in the pilot. The aim was that all NIHR Portfolio studies will go through NIHR CSP by April 2009, and industry sponsored studies after that time.

The other priority for the NIHR CRN CC is the NIHR Comprehensive Research Network (CCRN). Professor Stephen Smye has been appointed Director for the CCRN and was working with the Department of Health England on developing activity-based funding.

The Board noted progress in this area.

**b) Experimental Medicine**

The Board noted progress in this area. Seven additional facilities had been recommended and agreed for inclusion in the Experimental Medicine Resources’ website. In addition, an approach to the mapping exercise to identify infrastructure and capacity in experimental medicine had been agreed.

**9. Patient and Public Involvement**

The Board noted progress with the implementation of the PPI Strategy. Since the last Board meeting the main focus of activity had been on establishing the following projects:

- An evaluation of the process and impact of patient and public involvement in the UKCRC advisory groups
- An evaluation of the People in Research web-based resource
- A structured review of evidence on the conceptualisation, measurement, impact and outcomes of patient and public involvement in research.

**10. Public Awareness**

The Board noted progress made since the last Board meeting. The UKCRC Board Subgroup on Public Awareness had now been established. It held its first meeting on 4th August and the terms of reference had been agreed. Two areas of potential activity had been identified and currently project plans were being developed to take these forward. In addition it was noted that work with the Centre of the Cell was now coming to fruition with the imminent launch of a suite of education materials and classroom resources on clinical research to support the science curricula across the UK.

**11. Streamlining the Regulatory and Governance Environment**

The Board noted the continued progress that had been made in the Regulatory and Governance workstream since the last Board meeting. Three specific developments were highlighted:

- The model agreement for industry sponsored clinical investigations of medical devices (mCIA) will be launched in the coming week.
- Usage of the Integrated Research Application System (IRAS) was steadily increasing. Over 50% of ethics applications were now being made through IRAS even though the system was not yet mandatory.
Discussions between the four Health Departments on harmonising NHS approvals across the UK have continued. This was being facilitated by work to link national NHS permissions systems into IRAS.

12. **Building up the Research Workforce**

12.1 The Board noted the progress made in England. In particular it was noted that the NIHR and Chief Nursing Officer for England had announced the launch of a major new Clinical Academic Training pathway for nurses, midwives and allied health professionals (AHPs). An implementation group had been established to develop the application processes for the schemes. It was anticipated that successful candidates would take up their posts in September 2009.

12.2 The supplementary paper provided a progress report on the HEFCE Clinical Senior Lectureship Awards, the Scottish Senior Clinical Fellowships and an update on building up the research workforce in Northern Ireland from the HSC R&D Office.

13. **Coordinating Research Funding**

The Board noted progress in this area. Four key achievements since the last Board meeting were highlighted:

- Completion of a new joint analysis of stem cell research awards.
- Arrangement of an international workshop on the Health Research Classification System to be held in January 2009.
- Agreement with 3 major Industry partners on the scope for an analysis of their 2007 clinical trial data and initial data collection.
- Further development of the prototype website for the Health Research Classification System.

14. **Developing Incentives for Research in the NHS**

There were no specific updates to report from the Health Departments. ABPI offered to work with the Health Department leads in the area of Incentives.

Other

15. **UK Clinical Trials Gateway**

Marc Taylor, DH, informed the Board of progress being made in exploring the need for and feasibility of a UK Clinical Trials Gateway (UKCTG). He explained that the UKCTG would be a publicly available and searchable web-based portal enabling quick and easy access to information about trials with sites in the UK. It would not be a primary register of trials but an easy route to view records from existing public registers via a single entry point.

It was noted that Professor Sir Iain Chalmers had chaired a meeting in May 2007 between interested parties who supported the establishment of a UKCTG. One of the outcomes of the meeting was that the DH had funded the development of a prototype Gateway (http://www.controlled-trials.com/ukctr/). The next step for DH would be to commission the full UKCTG and a further meeting had been arranged in November 2008 to consider this. Board members were being invited to consider how they could support this development.
Board members welcomed this initiative to implement a UKCTG. Declan Mulkeen reported that the MRC wished to actively support the UKCTG and would welcome a discussion of further MRC involvement with Marc Taylor.

Members from industry also welcomed UKCTG as an additional resource to increase transparency about clinical trials being undertaken in the UK.

During discussion, it was also noted that the World Health Organisation (WHO) was working to establish standards for reporting the results of trials which could then be made publicly available on registers.

16. **Any Other Business**

16.1 Louise Wood gave an update to the Board on the BIGT Refresh. A mid-term review led by Sir David Cooksey in collaboration with Industry and other members of the research community will produce a report that would be released in January 2009. The report will assess how far the previous recommendations had been realised and propose new recommendations for the future.

16.2 Liam O'Toole informed the Board that the OSCHR Progress Report on its first year of operation was due for publication in early November.

16.3 Mark Walport updated the Board on the Walport/Thomas report on data sharing. The response from the Government on the data review was imminent.

16.4 The Board noted that UKCRC Board minutes were posted on the public section of the UKCRC website once they'd been approved. It was agreed that in future Board papers could also be made available to the public once considered by the Board. Members would have the opportunity to flag up any confidential issues.

**Next meeting:** 14.00 – 17.00, 26 February 2009, UKCRC, Himsworth and Fletcher Rooms, 20 Park Crescent, London, W1B 1AL