

## MINUTES

### UK CLINICAL RESEARCH COLLABORATION BOARD MEETING 10 April 2008

Minutes of the meeting held on 10th April 2008, Himsworth and Fletcher Rooms,  
UKCRC, 20 Park Crescent, London, W1B 1AL

#### Present

#### Members

Professor Sally Davies – Department of Health (DH) (Chair)  
Professor Sir Alasdair Breckenridge - Medicines and Healthcare products Regulatory Agency (MHRA)  
Simon Denegri – Association of Medical Research Charities (AMRC)  
Dr Sue Denman – Welsh Assembly Government  
Dr Russell Hamilton – Department of Health (DH)  
Paul Hubbard – Higher Education Funding Councils (HEFCE)  
Harpal Kumar – Cancer Research UK (CRUK)  
Professor Peter Littlejohns – National Institute for Health and Clinical Excellence (NICE)  
Dr David Lynn – Wellcome Trust (WT)  
Jenny McKibben - Patient/Public Member  
Dr Declan Mulkeen – Medical Research Council (MRC)  
John Neilson – Department for Innovation, Universities and Skills (DIUS)  
Dr Liam O'Toole – UK Clinical Research Collaboration (UKCRC)  
Nick Partridge – INVOLVE  
Dr John Patterson – Senior Representative from the Pharmaceutical Industry  
Professor Bob Souhami – The Academy of Medical Sciences (AMS)  
Dr Alison Spaul – Scottish Executive Health Department  
Dr Richard Tiner – The Association of the British Pharmaceutical Industry (ABPI)

#### Observers/Invited

Professor Janet Darbyshire – UK Clinical Research Network (UKCRN)  
Catherine Johns – Department of Health R&D (DH)  
Marc Taylor – Department of Health (DH)

#### UKCRC Secretariat

Dr Janet Valentine  
Dr Sue Bourne  
Dr Andrew Speakman  
Philippa Yeeles  
Dr Rebecca Hodges  
Ngozi Okwudili-Ince

Dr Matthew Hallsworth  
Sarah Harrop  
Samia Majid  
Dominique Capostagno  
Katie Gale

## **Announcements and Apologies**

### **Apologies**

Glyn Edwards, BIA

Professor Bernie Hannigan, Research and Development Department for the Northern Ireland Health and Personal Social Services. Bob Stout has now retired and Board members expressed their thanks

Ron Kerr, NHS Confederation

Professor Peter Kopelman, Universities Representative

Candy Morris, SHAs

Professor Adrian Newland, AOMRC

John Wilkinson, ABHI

### **Announcements**

The Chair welcomed everyone to the fourteenth meeting of the UKCRC Board.

Attending the UKCRC Board for the first time were:

- John Patterson, Executive Director AstraZeneca
- Sue Denman in her capacity as Deputy Director of the Wales Office of Research & Development for Health & Social Care (WORD). John Williams' secondment to WORD had come to an end and Board members expressed their thanks for his contribution to UKCRC.
- Bob Souhami, who had been appointed by the Academy of Medical Sciences as the successor to Patrick Maxwell

## **1. Minutes of the Thirteenth UKCRC Board Meeting**

**UKCRC/07/38**

The Board approved the minutes of the last meeting.

## **UKCRC General**

## **2. Chief Executive's Report**

**UKCRC/08/01**

Liam O'Toole highlighted a number of elements of the UKCRC Workplan that had been delivered since the last UKCRC Board Meeting. The Board noted that where feasible, metrics have been embedded in UKCRC initiatives or a formal evaluation has been agreed. The Board was reminded that the role of the UKCRC was to bring these metrics together rather than create new ones and an overview of available performance measures relating to UKCRC activities would be presented at the next Board meeting.

The Board noted that Diana Dunstan had retired and Simon Denegri, Chief Executive of the Association of Medical Research Charities, had replaced her as Chair of the Research Funders Liaison Group.

Following on from the 2004-2006 Progress Report, the UKCRC Secretariat had commenced work on the 2006-2008 UKCRC Progress Report and would be approaching Board members for their input over the coming months.

A summary of the UK Trade and Investment Clinical Trials Mission to the USA was provided and the importance of promoting the positive changes in the UK clinical research environment to international pharmaceutical biotech and healthcare industries was emphasised.

### **3. UKCRC 2008/09 Workplan**

**UKCRC/08/02**

The Chair reminded the Board that due to the cancellation of the December 2007 Board meeting, the 2008/09 Workplan had been circulated to the Board via email for comment prior to the Board meeting. As no substantial changes were requested by the Board, the Workplan had been approved by Chairman's action.

Liam O'Toole reviewed the main themes of the 2008/09 UKCRC Workplan. The focus of the fourth year of operations will be delivery and communication. The Workplan was largely a continuation of work in progress, with two areas of enhanced activity. These areas - patient and public involvement and raising patient and public awareness of the benefits of clinical research, were identified by the Board in September 2007 as part of the discussion of the future of the UKCRC.

Dr O'Toole reminded the Board that at the September 2007 meeting it was agreed that the work set out by the Research for Patient Benefit Working Party had yet to be completed and that although the UKCRC had begun to affect cultural change this process was not complete. It was agreed that the next review of the long term role of UKCRC would take place in Autumn 2009.

In their discussion of the Workplan the Board noted that many of the changes and initiatives being implemented would need to continue for a number of years. The importance of the continued commitment from the UKCRC Partners was stressed to ensure that momentum was maintained throughout these developments.

### **4. UKCRC Budget 2008/09**

**UKCRC/08/03**

#### **4.1 2007/08 Quarter 3 Report**

Nick Partridge, Chair of the UKCRC Budget Committee, summarised the key points of the Quarter 3 financial report for 2007/08. The 2007/08 budget reforecast showed a revised projected spend for the 2007/08 financial year of 22% less than the approved budget leaving a surplus available at the end of the financial year.

#### **4.2 UKCRC Budget 2008/09**

Nick Partridge reminded members that it was established practice for the Board to consider the UKCRC draft budget for the coming financial year at their December meeting. However as the December 2007 meeting was cancelled and the Board was not due to meet again until after the start of the next financial year, the Board had devolved responsibility for reviewing the draft UKCRC 2008/09 Budget to the Budget Committee.

The Budget Committee met in January 2008 to review the draft 2008/09 Budget based on the draft 2007/08 Workplan. The resulting draft budget with the accompanying draft 2008/09 Workplan were circulated to Board members prior to the April Board meeting for comment. The 2007/08 Workplan and Budget were subsequently approved by Chairman's action.

The Chair of the Budget Committee highlighted that, in accordance with the long term plan to reduce UKCRC Secretariat costs, the 2007/08 budget represented a decrease in real terms from the previous 2007/08 financial year.

#### 4.3 Use of 2007/08 surplus

The Budget Committee had been asked by the Board to consider options for the use of the projected 2007/08 surplus. The Board were reminded that DH had underwritten the Secretariat for the first 6 months and had contributed 50% of costs for the past 3 years on the understanding that this amount would decrease over time. The Budget Committee had therefore proposed that half of the surplus be used to reduce the DH contribution to the Secretariat costs for 2008/09. It was also proposed that the remaining half of the surplus be used as programmatic funding to support a new joint approach to raising public awareness of the benefits of clinical research as outlined in the 2008/09 Workplan. MRC and the Wellcome Trust commented that they were happy with the proposed approach, subject to a satisfactory business case being made for the work on public awareness

The Board agreed this approach in principle with the caveat that any partner organisation that also wished for a reduction in their 2008/09 contribution could write to the Chairman of the Budget Committee. Any reduction would then result in a lower budget for the public awareness work. It was noted that with the exception of DH, Partner contributions would therefore remain at a similar level as for 2007/08 unless otherwise decided.

### 5. Update on OSCHR and new MRC and NIHR activities

**UKCRC/08/04**

Board members noted progress in OSCHR and related MRC and NIHR activities. The OSCHR Board had now been established with three non-executive members recruited through the Appointments Commission. In addition, Scotland and Wales had joined the OSCHR Board as full members.

NIHR and MRC had been developing joint plans under the oversight of the OSCHR Board in the following areas:

- Translational Medicine Research – from discovery and experimental medicine to clinical trials and evaluation
- Public Health Research
- E-Health Research
- Methodology Research

A number of key milestones have been implemented to date in Translational Medicine and Methodology. It was noted that a document summarising the strategy in the above areas was planned for publication in Summer 2008.

### 6. NHS IT Systems – Update

**oral**

Professor Ian Diamond, Chair of the External Reference Group (ERG) to the NHS CfH Research Capability Programme (RCP), updated the Board on developments in NHS IT systems since publication of the UKCRC R&D Advisory Group report on research simulations in June 2007. Sir Alex Markham had been appointed as Senior Responsible Officer/Chair for the RCP and the Programme Director, Peter Knight had been recruited as Director of the RCP by NHS CfH with funding from the NIHR. The ERG had representation

from a range of stakeholder communities including academia, patient representatives, industry, funders and technical experts.

The aim of embedding the RCP as an NHS CfH programme was to ensure that research remained a priority within NHS CfH. The RCP was currently in its enabling phase and working towards development of a Full Business Case (FBC). The FBC would outline the required architecture, functional scope, safety and ethical issues. Information governance would fall within the remit of the National Information Governance Board, however where relevant these issues would also be addressed as part of the FBC. Following production of the FBC, the RCP would move to a full programme and commission the architecture for research. DH, England confirmed that substantial funding had been allocated in preparation for this next phase.

The ERG also had a further role functioning as the OSCHR E-Health Records Research Board. Within this role, the group were currently focusing on a programme of work to map the E-health research landscape in the UK.

## **7. National Information Governance Board update**

**UKCRC/08/05**

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 for Health and Social Care (NIGB), which had taken over the role of the Care Records Development Board. A progress update on the establishment of the NIGB had now been provided to the Board summarising the role, membership and terms of reference of the NIGB.

In discussion the Board noted that Patient Information Advisory Group (PIAG) would be subsumed into NIGB's function. The opportunity for the research community to influence secondary legislation before it was finalised in Autumn of 2008 was also highlighted. The Board agreed to invite Harry Cayton to attend the next Board meeting to provide a further progress update.

Following on from these discussions David Lynn updated the Board on Mark Walport's behalf on progress of the Ministry of Justice *Data Sharing Review*. In excess of 230 responses to the consultation paper on the use and sharing of personal information had been received. A significant number of these had come from the research community. A number of workshops and meetings had been held with representatives from various groups in the public and private sectors. A data sharing review report would be published by the Ministry of Justice in June 2008.

## **8. UKCRC Brain Bank update**

**oral**

Declan Mulkeen informed the Board that the UKCRC Brain Bank Committee was making good progress. The main concepts had been agreed and a report from the Committee would be presented at the July Board meeting.

## **Activities**

## **9. Building up the Infrastructure for Research in the NHS**

### **a) UKCRN – Update paper**

**UKCRC/08/06**

The Board noted the update from the UKCRC Board Subgroup for the UKCRN which summarised progress.

Russell Hamilton reported that members of the Board Subgroup wished to refer the issue of engagement of the NHS with the networks and promotion of clinical research in the NHS in general to the Board for consideration. The Board discussion of this issue is covered under item 15 – Developing Incentives for Research in the NHS.

Professor Janet Darbyshire informed the Board that in recognition of the expanding nature of UKCRN Mr Andrew Riley, a NHS Trust Chief Executive, had been appointed as Managing Director of the UKCRN Co-ordinating Centre. Mr Riley will become the most senior manager of UKCRN CC and report to the joint directors. His role will include strengthening relationships between NHS Trusts and the UKCRN.

Professor Sally Davies reported that the NIHR Coordinated System for gaining NHS Permission (NIHR CSP) that was originally scheduled for implementation in April 2008 has been postponed until later in 2008. NIHR CSP will provide a streamlined process for gaining permission to conduct clinical research in the NHS and was being led by the UKCRN, working closely with staff in Comprehensive Local Research Networks across England. The later implementation would allow for the Integrated Research Application System (IRAS) to interface with NIHR CSP. Professor Davies noted that the decision to postpone implementation of NIHR CSP until later in 2008 will provide enough time for key staff to be put in place, trained and familiar with the systems and software to be fully tested. This approach will ensure a smoother transition for both the research and research management communities and in the longer term deliver a more robust and effective system.

Richard Tiner noted that NIHR CSP was viewed by industry as a key development to improve trial start up times and it was important that this process was implemented as soon as possible.

Professor Janet Darbyshire informed the Board that the International Review Committee that assessed the applications for UKCRC Registered Clinical Trials Units (CTUs) agreed that the data management systems in many of the CTUs were suboptimal. The UKCRC CTU Oversight Group recently discussed the need for a coordinated approach to developing standard data management systems to support trials run through CTUs. The group agreed that this work should be taken forward by a team of CTU directors and IS staff and led by the NIHR Information Systems team. The project would be overseen by the CTU Oversight Group on behalf of the UKCRC Board. The Board endorsed this approach and agreed that the CTU Oversight Group should provide regular progress reports to the Board.

### **b) Experimental Medicine – Update paper**

**UKCRC/08/07**

The Board noted the progress on Experimental Medicine reported in the update paper.

Janet Valentine reported that a proposal to map the UK Experimental Medicine infrastructure and capacity was considered at the recent meeting of the Experimental Medicine Database Management Group. The Group agreed that this was a worthwhile exercise, building on the work to develop the Experimental Medicine Resources Website, provided it focused on the strategic needs of the UKCRC Partners. The Board discussed the proposal and agreed that the mapping exercise would be of value and worth doing. It was agreed that the scope of the project would need to be clearly defined and a business

case would need to be developed by UKCRN in close collaboration with the funders. The Experimental Medicine Database Management Group should take strategic oversight of this work on behalf of the Board.

**c) Experimental Medicine Resources website**

**presentation**

Professor William Rosenberg, UKCRN Director for Experimental Medicine, gave a presentation of the UKCRC Experimental Resources website that was launched in January 2008. The website contains information resources and expertise available in the major experimental medicine facilities funded by the UKCRC Partners including the CRFs funded under the Clinical Research Infrastructure Initiative, NIHR Biomedical Research Centres, Experimental Cancer Medicine Centres and MRC Translational Medicine Centres.

Professor Rosenberg demonstrated the search functions on the site and the range of information available. The presentation also outlined the maintenance process to ensure the website was update to date and the future development plans for the site.

The Board enquired about potential inclusion of other experimental medicine facilities. Professor Rosenberg reported that the Management Group was establishing a process for assessment and inclusion of additional facilities that were comparable with those currently on the site.

The Board agreed that the website was a valuable resource for UK experimental medicine and congratulated Professor Rosenberg and his team. The importance of raising awareness and publicising the site was highlighted and it was agreed that metrics to measure the impact and use of the site should be collected.

**10. Patient and Public Involvement**

**UKCRC/08/08**

**a) Update paper**

The Board noted progress reported in the update paper.

**b) PPI Strategy**

**presentation**

Simon Denegri, Chair of the Strategy Development Group, presented the UKCRC's Patient and Public Involvement Strategic Plan 2008-2011. The Board was reminded of the consultative process through which the plan had been developed. The focus of both the strategy and the implementation plan would be on areas of patient and public involvement in research where the UKCRC partnership could add value and that could not easily be addressed by a single organisation.

The Board agreed to establish a UKCRC Board Subgroup for Patient and Public Involvement. The Subgroup would be responsible for finalising the Implementation Plan 08/09, overseeing the implementation of the Strategic Plan and regularly reporting on progress to the UKCRC Board. The Subgroup would take on the role and broad membership of the UKCRC Patient and Public Involvement Project Group, which would cease to function. Partner organisations that were not currently represented on the Project Group will be encouraged to join the Subgroup. The Board supported the nomination of Sarah Buckland (Director of INVOLVE) to chair the Subgroup.

The presentation summarised the key elements of the draft implementation plan including three activities that would be undertaken in the current year:

- ▶ UKCRC Board Subgroup for Patient and Public Involvement to coordinate the development of a panel of patients and members of the public to contribute to the work of the UKCRC and UKCRC Partner organisations
- ▶ Work with the UKCRC Board Subgroup for Public Awareness on the use of patient data for research purposes
- ▶ Collaborate with the NHS Centre for Involvement ([www.nhscentreforinvolvement.nhs.uk](http://www.nhscentreforinvolvement.nhs.uk)) and the School of Health and Social Sciences at Warwick University to undertake a structured review of evidence on the conceptualisation, measurement, impact and outcomes of patient and public involvement in research

The Subgroup would finalise the implementation plan when it first meets in June 2008 and the Board agreed that work on key areas of the draft implementation plan should begin ahead of the first meeting.

The Board thanked Simon Denegri for his leadership of the strategy development process.

## **11. Public Awareness – Update paper**

**UKCRC/08/09**

The Board was reminded that at the last meeting in September 2007 there was strong support for developing a coordinated approach across the Partnership to raising public awareness of clinical research. The Board had asked Nick Partridge to lead on developing a potential way forward in this area.

Nick Partridge outlined a proposal that had evolved from discussions with a number of UKCRC Partner organisations to establish a UKCRC Board Subgroup on public awareness. Using the combined experience and backing of the Partners, the role of the Subgroup would be to develop and oversee the implementation of a programme of activities designed to make a substantial impact in raising public awareness of the benefits of clinical research. Membership would be drawn from across the Partnership and the Subgroup would regularly report progress to the Board. In preliminary discussions with the Partners there had been strong support for the Subgroup to initially focus on use of patient data.

The Board raised a number of points in discussion including:

- Increased public awareness of the importance of clinical research was another potentially important route to help incentivise research in the NHS.
- It would be important to link with the work of the NHS Connecting for Health Research Capability Programme. The Research Capability Programme was about to undertake a consultation with professionals and patients and to probe public attitudes towards the use of medical information for research purposes.
- Cancer Research UK would also wish to be part of the Subgroup.

The Board agreed the establishment of a Board Subgroup to undertake and oversee this work and endorsed the nomination of Professor John Williams as chair of the Subgroup.

The Board agreed to use half of the surplus from the 2007/08 UKCRC budget as initial programmatic funding to support joint activity undertaken by the Subgroup.

## **12. Streamlining the Regulatory and Governance Environment**

### **a) Streamlining the Regulatory and Governance Environment – Update paper**

**UKCRC/08/10**

The Board noted that significant progress had been made in the Regulatory and Governance workstream since the last Board meeting, in particular the successful delivery of three key objectives:

- The Contract Research Organisation version of the model Clinical Trial Agreement
- The launch of the Research Passport
- The Integrated Research Application System.

Janet Valentine highlighted that the Contract Research Organisation version of the model Clinical Trial Agreement, CRO mCTA, was launched in October 2007 for use throughout the UK. The CRO mCTA was based on the bipartite mCTA and had been developed collaboratively by a group representing DH, NHS and Industry.

Marc Taylor, Chair of the Research Passport Working Group, presented the final report from the Working Group. The Research Passport was launched at an event in October 2007 and the four Health Departments were leading on rolling out the Research Passport across the UK. As use of the Passport was not mandatory, the Board was asked to agree a statement of endorsement for its use. The Board supported the proposed UKCRC Partners' Statement of Endorsement for the Research Passport.

#### **b) IRAS demonstration**

#### **presentation**

Dr Janet Wisely, Director of the National Research Ethics Service (NRES), gave a presentation on the Integrated Research Application System (IRAS). The Board noted that:

- The development of IRAS was initiated by a UKCRC Working Group, chaired by Sir John Lilleyman, that had achieved stakeholder buy-in before tasking NRES to lead the project on behalf of the UKCRC culminating in the development of IRAS
- IRAS was a web-based system that would streamline the research application process by reducing administrative duplication
- IRAS was launched on 29 January 2008 for use and consultation. Consultation questions focused on dataset content and delivery mechanism (IT platform)
- Feedback has so far been very positive and focus of communications will now move to strongly recommending the use of IRAS
- Next steps were to include the development of web-based training, inclusion of EudraCT functionality and the establishment of an IRAS Management Board

The Board agreed that IRAS was a very successful development and an excellent example of partnership working. The project had involved virtually every UKCRC partner organisation, including patients and other stakeholder groups. The Board congratulated Dr Wisely and the IRAS Project Team on significant progress made to date. The addition of EudraCT functionality due in Summer 2008, would be a major step forward and it was recommended that communication about the system and its development should be sustained.

#### **13. Building up the Research Workforce – Update Paper**

**UKCRC/08/11**

The Board noted the progress update on academic fellowships and lectureships in England.

#### **14. Coordinating Research Funding – Update paper**

**UKCRC/08/12**

The Board noted progress on activities reported in the Coordinating Research Funding update paper. Janet Valentine highlighted the successful launch of the two major initiatives in Public Health and Microbiology and Infectious Diseases Research resulting from the

respective Strategic Planning Groups (SPGs). It was also noted that the reports from both planning groups were being finalised and would be published shortly and circulated to Board members.

The Board thanked the Chairs and members of both SPGs for their work and agreed that the SPG process was a successful model for joint strategic planning which had delivered a number of multi-funder initiatives.

## **15. Developing Incentives for Research in the NHS**

**UKCRC/08/13**

The Board noted a paper outlining the progress made in Wales and Scotland to incentivise research in the NHS. In Wales good progress was being made in communicating with local Health Boards and in Scotland there was ministerial interest in this area following input from the wider industry forum via the Economic Development Agency.

The Board noted ongoing activity to incentivise and raise the profile of research in the NHS in England:

- NIHR was bringing together 40 chief executives from NHS Trusts with biomedical centres or units to discuss research and the use of patient data
- There was an opportunity to discuss the possibility of including research as a key component of an NHS constitution. This opportunity would be open for the next few months
- In England, NIHR had held a seminar for chief executives from a number of NHS organisations to explore incentives for both individuals and NHS organisations to do research. The Workshop was hosted by the Nuffield Trust, with the AMS in attendance and discussion was led by Tom Ling of RAND Europe. Topics of discussion included the importance of recognition for research, reputation enhancement opportunities, financial awards as well as standards assessments as research incentives
- In England, DH had responded to the latest consultation on healthcare assessment standards

Catherine Johns updated the Board on the progress of discussions about Quality and Outcome Framework (QOF) points. Following discussion in January 2008 between the DH in England, PCRN and QOF representatives, it was agreed that the use of QOF points would not be an appropriate method of incentivising research in primary care.

Members discussed possible further actions to raise the profile of research amongst chief executives of NHS organisations including the feasibility of a UKCRC led coordinated initiative on incentivising research in the NHS. Harpal Kumar proposed that a joint letter from UKCRC Partners should be sent to ministers emphasising the importance of this area and the Board were supportive of CRUK leading this activity on behalf of the Partnership. The Board agreed that individual organisations should also continue to highlight the importance of research in the NHS to the Government.

Board members expressed their disappointment that there was no representation from the NHS at the Board meeting.

## **Other**

## **16. Any Other Business**

- 16.1 The Chair reminded the Board that initially the UKCRC Board had two Deputy Chairs, Nick Partridge and John Bell. As John Bell was no longer a member of the Board, a replacement deputy chair would need to be appointed. The Chair advised the Board that the UKCRC would follow the process that was used last time and the Chair would write to members asking for nominations. If there was a contest the Chair would ask members to vote.
- 16.2 The Chair also noted that there were currently 3 Board meetings arranged for 2008 (April, July, and October). Board Members were asked how many meetings should be arranged in 2009. Given the amount of business to be discussed at each meeting, it was agreed that 3 meetings a year were still necessary.

**Next meeting: 14.00 –17.00, 10 July 2008, UKCRC, Himsworth and Fletcher Rooms, 20 Park Crescent, London, W1B 1AL**