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## MINUTES

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

Minutes of the meeting held on 10th July 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)  
Malcolm Carlisle – Association of British Healthcare Industries (ABHI)  
Dr Mike Davies – Department for Innovation, Universities and Skills (DIUS)  
Simon Denegri – Association of Medical Research Charities (AMRC)  
Dr Sue Denman – Welsh Assembly Government  
Glyn Edwards – Bio-Industry Association (BIA)  
Dr Sarah Garner- 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  
Professor Peter Johnson – Cancer Research UK (CRUK)  
Ron Kerr – NHS Confederation  
Professor Peter Kopelman - Universities Representative  
John Williams – 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 Adrian Newland – Academy of Medical Royal Colleges (AOMRC)  
Dr Liam O'Toole – UK Clinical Research Collaboration (UKCRC)  
Nick Partridge – INVOLVE  
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)  
Dr Helen Campbell – Department of Health (DH)  
Andrew Riley – UK Clinical Research Network (UKCRN)  
Louise Wood – Department of Health (DH)  
Professor Jonathan Montgomery – University of Southampton (Item 6)  
Professor Fran Balkwill – Centre of the Cell (Item 9b)  
Nicola Jagger – Centre of the Cell (Item 9b)  
Dr Mark Lewis – Health Management and Clinical Research Consultant (Item 10b)

## UKCRC Secretariat

Dr Janet Valentine  
Dr Sue Bourne  
Dr Andrew Speakman  
Philippa Yeeles  
Dr Rebecca Hodges

Dr Matthew Hallsworth  
Sarah Harrop  
Samia Majid  
Hannah Brown  
Katie Gale

## **Announcements and Apologies**

### Apologies

David Eastwood – Higher Education Funding Councils (HEFCE)

Professor Adrian Newland – Academy of Medical Royal Colleges (AoMRC)

### Announcements

The Chair welcomed everyone to the fifteenth meeting of the UKCRC Board and announced that:

- Dr Richard Barker, ABPI, had accepted the vacant position of the second Deputy Chair on the Board.
- ESRC had accepted the invitation to join the UKCRC partnership. She welcomed Professor Ian Diamond to his first Board meeting as a Board member.

Attending the UKCRC Board for the first time were:

- Professor Bernadette Hannigan, the new Director of HSC R&D Office NI who has replaced Bob Stout
- Professor Peter Kopelman, Principal at St George's, University of London who has replaced Sir John Tooke as the Universities representative on the Board
- Malcolm Carlisle, has been appointed by ABHI as the successor to Peter Arnold
- Dr Clive Morris, Late Development Director for Oncology, the new Alternate member for Astra Zeneca
- Professor Peter Johnson, Chief Clinician, the new Alternate member for CRUK
- Dr Mike Davies attending on behalf of DIUS
- Dr Sarah Garner on behalf of NICE, as an observer and
- Andrew Riley, the new Managing Director of UKCRN, as an observer

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

**UKCRC/08/14**

The Board approved the minutes of the last meeting.

## **UKCRC General**

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

**UKCRC/08/15**

### Four Year Progress Report

The Board was reminded that the UKCRC Secretariat was currently working on a Four Year Progress Report. This will follow the structure and sign-off process used for the last Progress Report, the only difference will be the inclusion of more case studies and

examples of what has been delivered. All 23 Partner organisations will have the opportunity to comment on the draft and the plan was to publish the Report in November.

#### Staff Departures

The Board noted that it had agreed that the size of the UKCRC Secretariat should decrease over the next year as key elements of the Workplan were completed. This process was being overseen by the Budget Committee on behalf of the Board. In keeping with this, it was reported that Ngozi Okwudili-Ince has moved on at the end of her contract. It was also noted that Janet Valentine will be leaving the UKCRC in September to take on a permanent post at the MRC. The Board thanked Ngozi and Janet for their work and in particular noted the major contribution Janet had made to the work of the UKCRC.

#### UKCRC Budget Report

The Board noted that in keeping with agreed practice, the Secretariat had provided the Budget Committee with a financial report detailing spending in the final quarter of 2007/08, the final 2007/08 budget figures and the revised 2008/09 budget approved by the UKCRC Board in April 2008.

Nick Partridge, Chair of the Budget Committee, summarised the key points from the report. The overall final expenditure for the financial year 2007/08 was £968k. The UKCRC Secretariat had total funds available for 2007/08 of £1.497 million. Therefore the surplus at the end of the financial year 2007/08 was £529.3k. The Board was reminded that it was agreed at the April Board meeting that half of the 2007/08 surplus would be used to reduce the Department of Health's contribution to the Secretariat costs for 2008/09 and the remaining surplus would be used for activities to be overseen by the UKCRC Board Subgroup for Public Awareness.

The Board noted that the issue of Partner contributions for 2008/09 has been resolved. It was reported that there will be sufficient funds to deliver the 2008/09 Workplan activities.

### **3. UKCRC Performance Measures**

**UKCRC/08/16**

Liam O'Toole reminded the Board that in 2005 RAND Europe had been commissioned to develop an evaluation framework for the UKCRC. Following discussion, the Board had agreed that to avoid duplication of effort no new metrics should be developed by UKCRC however, performance measures and metrics being collected by UKCRC Partners would be brought together annually. The Board noted that very little reliable historic data existed for baseline activity.

The paper before the Board summarised the measures that have been put in place to evaluate activities carried out under the umbrella of the UKCRC and highlighted their stage of development.

Janet Valentine presented the findings from a recent survey to evaluate the use and impact of the Health Research Classification System (HRCS) and the health research analyses. The survey showed that the analysis reports have been widely distributed and that they have been used by the 29 survey respondents to inform their strategic discussions. It was noted that 76% of the survey respondents were using or intended to use the HRCS and that 79% were undertaking an analysis or would do so in the future with some help. The Board members agreed that the results of the survey were a strong and positive message that the analyses and the HRCS had been very useful initiatives.

The Board discussed the research network metrics presented in the UKCRN Update Paper (UKCRC/08/19). Janet Darbyshire highlighted that the UKCRN Coordinating Centre

(UKCRN CC) was now able to collect good data on studies conducted through the Topic specific Clinical Trial Networks (TCRNs). These metrics and data will inform the three year reviews of the TCRNs which will all be conducted in 2009. UKCRN CC on behalf of NIHR will make these data available to the Board in 2009.

The Board noted that there were currently 99 industry trials adopted into the networks and the rate of accrual into these studies was similar to non-commercial studies. The Board requested in future clarification on the number of industry device trials ongoing in the networks and the speed of recruitment. The Board noted the possibility of gathering data on studies conducted outside the networks. Richard Tiner informed the Board that the ABPI annual data collection will include data on trials outside the networks.

**4. Update on OSCHR and new MRC and NIHR activities UKCRC/08/17**

The Chair presented this paper to the Board for information and asked members to direct any questions or comments to either Liam O'Toole, Russell Hamilton or Declan Mulkeen outside the Board meeting.

**5. NHS IT Systems Update oral**

Professor Ian Diamond as Chair of the Research Capability Programme External Reference Group updated the Board on progress. The RCP has great potential to create a system that will have a real impact on research. The External Reference Group has had a large amount of work to do over the past four months, reading and commenting on documents often of high technical complexity. He also discussed work under the auspices of the OSCHR E-health Records Research Board, including a mapping exercise to plot the many ongoing initiatives in E-health research across the UK. A funders group had been established to discuss coordination of activities to complement the RCP.

The Board noted that whilst many Trusts agreed with the ambition of the programme, more effort should be made to highlight its benefits and encourage understanding of why it is important. The Board were also informed that the report of the Health Informatics Review was now available on the Department of Health's website at:  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_086073](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_086073)

**6. Development of a UK Brain Banking Framework UKCRC/08/18**

Professor Jonathan Montgomery, Professor of Healthcare Law at the University of Southampton, Chairman of Hampshire Primary Trust and Chair of the Brain Bank Strategy Advisory Committee (SAC) gave a presentation on the proposed strategy for UK coordination for brain banking for medical research. The Board noted that:

- The SAC was established by the MRC on behalf of the funders in March 2007 following an MRC Workshop in October 2006. It had been agreed that the development of a national strategy was important and should best be taken forward in partnership.
- The SAC has made two main short term recommendations as part of its strategy:
  - i) Commission a Director to drive forward the coordination and implementation of brain banking;
  - ii) Extend one of the existing brain banks to collect controls proactively through medico-legal autopsies via a call for proposals from established partnerships.

- A successful brain banking system was already in place in Edinburgh and lessons could be learned from this.

The Board noted that further debate with potential funders was required to ensure long-term support for this initiative. MRC would lead on this and discuss with other funders.

## **Activities**

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

#### **a) Engagement with the NHS**

Russell Hamilton, as Chair of the Board Subgroup for the UKCRN, reported on a very good discussion at its last meeting in June on engagement with the NHS. Ron Kerr had led the discussions which brought a senior NHS perspective to the debate. The Board Subgroup noted that there was no single strategy for engaging the NHS, however much could be achieved through a range of measures provided activities were coordinated.

The majority of effort should be directed at communicating with Chief Executives of Trusts that already had an existing interest in research. In smaller non-research active Trusts, it may be more beneficial to ensure each Trust identified a contact on the Trust Board with a responsibility for research.

Dr Hamilton reported that a paper will go to the next Board Subgroup meeting summarising all of the current NHS engagement activities and the Subgroup would then consider whether this issue should become a standing item on its agenda.

The Board strongly supported the proposed approach and agreed that there was no single answer in how to engage with the NHS. It was noted that the inclusion of research in Lord Darzi's Next Stage Review and the draft NHS Constitution will also provide an important opportunity to emphasise to Chief Executives the importance of research in the NHS.

#### **b) UKCRN Update paper**

**UKCRC/08/19**

Janet Darbyshire explained that the implementation of the NIHR Coordinated System for Gaining NHS Permission (NIHR CSP) was moving forward with a new management team and project plan. UKCRN CC plan to begin implementation of NIHR CSP later in 2008.

Alison Spaul reported that the Dementia Network in Scotland has been approved and will be formally launched in September.

Sue Denman informed the Board that the CRC Cymru networks continued to work well and were linked with others across the UK. A Stroke Research Interest Group has been formed with the Older People and Aging Network (OPAN).

Bernie Hannigan explained that a structural review of Health and Social Care (HSC) had hindered the appointment of key posts within the Northern Ireland Clinical Research Network (NICRN). NICRN hope to report shortly about progress and activity within the network.

Janet Valentine informed the Board that the UKCRN, on behalf of the UKCRC CTU Oversight Group, were developing the UKCRC Registered CTUs website which will give funders and researchers access to the expertise of the Registered CTUs. The website will be modelled on the Experimental Medicine Resources Website and launched before the

next UKCRC Board meeting.

The UKCRN Clinical Trials Team was also conducting a CTU Capacity Mapping project on behalf of the Oversight Group. This will assess the current CTU core capacity in the UK and the potential future funding requirements needed to sustain core resources. This project will be presented to the Board at the next meeting.

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

**UKCRC/08/20**

The Board received a report from Janet Valentine on the latest meeting of the Experimental Medicine Database Management Group (EMDMG). Board members were reminded that they had delegated authority to the EMDMG to consider a business case for a project to map out the UK's experimental medicine infrastructure and capacity in key areas of strategic interest. The EMDMG members (comprising representatives from MRC, CRUK, Wellcome Trust and NIHR) had reviewed the business case for the exercise and agreed that mapping should begin in three focussed and strategically important areas:

- Imaging, which would build on recent existing reviews of PET imaging.
- Methodology support in biostatistics and epidemiology
- “Omics platforms” was agreed as a key third area to map. However taking into account the breadth of this field, the recommended approach was to bring together a group of experts to define potential scope and feasibility issues before proceeding.

The Board noted that the EMDMG had asked the UKCRN Experimental Medicine Team to start the work and that options for a project plan would be considered at the next EMDMG meeting.

### **8. Patient and Public Involvement – Update paper**

**UKCRC/08/21**

The UKCRC Board Subgroup for PPI had been established by the UKCRC Board to oversee and monitor the implementation of the UKCRC's PPI Strategic Plan 08-11. It held its first meeting on 6<sup>th</sup> June. Richard Tiner, a member of the Subgroup, spoke to the update paper and emphasised the degree to which partnership working would be required to deliver the implementation plan. The Board noted progress in this area.

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

**UKCRC/08/22**

The Board noted progress in establishing the UKCRC Board Subgroup on Public Awareness. Members welcomed the fact that Professor John Williams had agreed to chair the group.

In addition Professor Fran Balkwill, Director of the Centre of the Cell, attended the Board meeting to give a presentation on progress in developing educational materials on clinical research to support the National Curriculum for Science.

The Board welcomed the update and agreed that it was an excellent piece of work. In discussion the Board made suggestions on useful links that could be made with other organisations and initiatives.

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

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

**UKCRC/08/23**

The Board noted the continued progress that had been made in the Regulatory and Governance workstream since the last Board meeting. Dr Janet Valentine, Chair of the UKCRC Regulatory and Governance Working Group, highlighted two specific developments:

- The introduction of the first phase of EudraCT functionality to the Integrated Research Application System (IRAS). This meant that information on Investigation Medicinal Products was included in the system and applications could be made to the Medicines Sector of the Medicines and Healthcare products Regulatory Agency (MHRA).
- Introduction of an online system for submission of queries to the UKCRC Regulatory and Governance Advice Service; this replaced the original email based system

Dr Richard Tiner welcomed the introduction of additional functionality to IRAS but said that it was too early to assess use of IRAS by the pharmaceutical sector.

**b) Model Agreements**

**presentation**

Dr Mark Lewis, Health Management and Clinical Research Consultant, gave a presentation on the progress that has been made with the development of the model commercial trial agreements. The Board noted that:

- Work to develop model commercial agreements arose as a response to the Pharmaceutical Industry Competiveness Task Force (PICTF) Report, 2001.
- The first model agreement for pharmaceutical clinical trials (mCTA) was negotiated by DH and the ABPI/pharmaceutical companies and published for use in February 2003. However, although it was adopted it was routinely heavily amended by both companies and Trusts.
- The second version (2006) of the mCTA resulted from wide consultation and contained important changes relating to the registration and publication of trials, a requirement to consult university partners, liabilities and Freedom of Information Act. This version has been widely endorsed by the UKCRC Partners. It has been almost universally adopted with only one company known not to use it and in Scotland data suggests that its use halves time to negotiate contracts and initiate trials
- A tripartite version of the mCTA was launched in 2007 containing provisions allocating responsibilities between the sponsor, CRO and Trust
- An agreement for medical device investigations (mCIA) is under negotiation and although it is very similar to the mCTAs it is being drafted to take into account differences in the handling of registration and publication with respect to the device development cycle. The launch of this agreement is projected for September 2008
- In the future, agreements will be developed for CRO managed medical device clinical investigations and primary care versions of the mCTAs.
- These agreements were complementary to the other strands of work in research management and governance

In discussion the Board recognised that insurance for research remains an issue particularly for smaller companies. The Chair thanked Mark Lewis for his presentation and for the many years of work that he has contributed to ensure the successful development of these agreements. She also acknowledged Louise Wood (DH) and Richard Tiner (ABPI) for their contributions.

## **11. Building up the Research Workforce – Update paper**

**UKCRC/08/24**

Sally Davies provided an update on the implementation of the Integrated Academic Training Programme (IAT). A consultant has been commissioned by NIHR to review the current system and consider the model of allocating the numbers of fellowships. NIHR will shortly write to the Medical School Council with proposals for change.

Russell Hamilton updated the Board on the implementation of the recommendations made in the UKCRC report *Developing the best Research Professionals*. Money has been agreed from the Workforce Directorate in the Department of Health, England to implement the recommendations in England for nurses, midwives, allied health professionals (AHPs) and healthcare scientists.

A programme parallel to the IAT for doctors and dentists will be established for nurses, midwives and AHPs. This will be managed by the National Coordinating Centre for Research Capacity Development (NCCRCD) on behalf of NIHR and an implementation group will be formed shortly. Sue Hill, the Chief Scientific Officer, will be developing a more focussed programme for healthcare scientists to support career development. Despite the funding for these projects being outside NIHR, both schemes will be managed by NCCRCD and trainees will be badged as NIHR Faculty Trainees.

It was noted that the health departments in Wales and Northern Ireland were in discussion with the Chief Nursing Officers to develop an approach to nursing careers in each country. Scotland initiated training schemes before the publication of the report.

The Board agreed that there were potential synergies with medical trainees and potential existed to improve the baseline quality of nursing research. The inclusion of a broad Masters degree in clinical research would help this.

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

**UKCRC/08/25**

The Board received a verbal report from Janet Valentine which highlighted three key areas:

- An online version of the Health Research Classification System was being prepared for release and there was significant international interest in the system (including from Hong Kong and Singapore).
- The report of the Public Health Research Strategic Planning Group has recently been published summarising the work of the group and the earlier successful launch of five Public Health Centres of Excellence.
- The announcement of £9m joint funding for two successful Translational Infection Research Consortia based in Oxford and London was planned for 16<sup>th</sup> July. The Consortia were part of the first round of funding of the UKCRC Translational Infection Research Initiative which came out of the Strategic Planning Group on Microbiology and Infectious Diseases Research.

The Board noted the activities reported in the Coordinating Research Funding update paper.

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

**oral**

Russell Hamilton reported on two current activities to incentivise and raise the profile of research in the NHS in England:

- NIHR was arranging a meeting of Chief Executives of NHS Trusts with an existing interest in research, including those with an existing NIHR Biomedical Research Centre or Unit.
- The Government's commitment to research was mentioned in the first page of the draft NHS Constitution. It was noted that the Constitution was accompanied by a handbook which made patients aware of the benefits of research and provided reassurance around the confidentiality of patient data used in research. The Constitution was currently out for consultation and members were urged to take the opportunity and respond positively to this.

## **Other**

### **14. Any Other Business**

- 14.1 The Chair referred Board members to the GMC confidentiality consultation and encouraged members to respond. The Chair also drew the Boards attention to the NHS Constitution and again urged members to submit a response to the consultation.
- 14.2 The Chair informed the Board that the Prime Ministers Health Research Summit in April this year was successful and that funding for the MRC Laboratory of Molecular Biology in Cambridge had been announced at the Summit. The overall sense was that public awareness had been raised in the main areas of clinical trials and CfH (Patient Data).
- 14.3 The Board noted with approval that many of the items in papers UKCRC/08/23, UKCRC/08/24 and UKCRC/08/25 had been completed. However, they agreed that it would be helpful if the Secretariat could provide more detail on timelines and milestones for delivery or completion of ongoing work.

**Next meeting: 14.00 –17.00, 30 October 2008, UKCRC, Himsworth and Fletcher Rooms, 20 Park Crescent, London, W1B 1AL**