MINUTES

UK CLINICAL RESEARCH COLLABORATION (UKCRC)
BOARD MEETING 8 DECEMBER 2005

Minutes of the meeting held on Thursday 8 December 2005, The Darwin Room, The Wellcome Trust, 215 Euston Road, London, NW1 2BE

Present

Members
Professor Sally Davies – Department of Health (DH) (Chair)
Professor John Bell – The Academy of Medical Sciences (AMS)
Dr Diana Dunstan – Medical Research Council (MRC)
Professor Sir Alasdair Breckenridge – Medicines and Healthcare Products Regulatory Agency (MHRA)
Mr Glyn Edwards – BioIndustry Association (BIA)
Dr Alison Austin – Office of Science and Technology (OST) / Department of Trade and Industry (DTI)
Richard Tiner – The Association of the British Pharmaceutical Industry (ABPI)
Sir Jonathan Michael – NHS Confederation
Nick Partridge – INVOLVE
Dr Neil Goodwin – Strategic Health Authorities (SHAs)
Dr Alison Spaull – Scottish Executive Health Department
Professor Bob Stout – Research and Development Department for the Northern Ireland Health and Personal Social Services
Dr Mark Walport – The Wellcome Trust
Professor John Williams – Welsh Assembly Government
Paul Hubbard – UK Higher Education Funding Councils
Dr Russell Hamilton – Department of Health (DH)
Dr Liam O’Toole – UK Clinical Research Collaboration (UKCRC)

Observers/Invited
Chris Watkins – Medical Research Council
Noreen Caine – Department of Health (DH)
Marc Taylor – Department of Health (DH)
Dr Helen Campbell – Department of Health (DH)
Dr Janet Derbyshire – UK Clinical Research Network (UKCRN)
Tom Ling – RAND Europe
Professor Bob Souhami – Cancer Research UK (CR UK)

UKCRC Secretariat
Dr Matthew Hallsworth
Dr Sue Bourne
Dr Janet Valentine
Dr Mags Sara
Susannah Keeling
Hannah Brown

Apologies
Professor Alex Markham – Cancer Research UK (CRUK)
Dame Bridget Ogilvie – Association of Medical Research Charities (AMRC)
Peter Arnold – The Association of the British Healthcare Industries (ABHI)
Professor Carol Black – Academy of Medical Royal Colleges (AOMRC)
Allan Baxter – Senior R&D Representative from the Pharmaceutical Industry
Sir Mike Rawlins – National Institute for Health and Clinical Excellence (NICE)
Announcements and Apologies

Announcements

The Chair welcomed everyone to the sixth meeting of the UKCRC Board. The Collaboration had been going for 14 months and a great deal has already been achieved.

The Chair drew attention to the pre-budget Treasury announcement released on Friday 2 December. This was significant because it contained a positive endorsement from HMT and industry on the work of the UKCRC and also a commitment to open the Connecting for Health Programme in England for research.

It was noted that the NHS R&D Strategy for England was in the process of being signed off and was on schedule to be launched on 25 January 2006.

Apologies

Apologies were received from Professor Alex Markham (Cancer Research UK), Dame Bridget Ogilvie (Association of Medical Research Charities), Peter Arnold (The Association of British Healthcare Industries), Professor Carol Black (Academy of Medical Royal Colleges), Allan Baxter (Senior R&D Representative from the Pharmaceutical Industry) and Sir Mike Rawlins (National Institute for Health and Clinical Excellence).

1) Minutes

The minutes were accepted as a correct record of the meeting held on 15 September 2005.

Matters Arising

The MRC updated members on progress with the emerging Article 169s. It now appears unlikely that there will be biomarkers proposals within the first round of 169 proposals. However, a feasibility study beginning in October 2005 will run for 18 months.

2) Chief Executive’s Report

The aim of this oral update was to inform the Board about ongoing activities not covered elsewhere in the Board Papers.

The Chief Executive reminded Board Members of the launch of the new UKCRC website, which is designed to grow with the requirements of the Partnership. He requested that Partner organisations work with the UKCRC Core Team in order to create links between the UKCRC website and Partner organisations and vice versa.

The Chief Executive proposed that minutes of UKCRC Board Meetings and Board Subgroups should be made available on the UKCRC Website. Members agreed this should be done with the caveat that, on certain occasions, parts of the minutes might need to be kept confidential.
The Board noted that the UK Stem Cell Initiative Report had been published and that it called for the need for coordination between funders of stem cell research. The Government response to the recommendations proposed was that this coordination should be led by MRC through the UK Stem Cell Initiative (UKSCI). The MRC reported that a Stem Cell Funders Forum would be established in 2006 and agreed to keep the UKCRC Board updated on a regular basis.

Actions:

• The minutes from the Board Meeting will be posted on the UKCRC website.

3) Public and Patient Involvement and Awareness  UKCRC/05/37

The Board were updated on progress with public and patient involvement and the Public Awareness Task and Delivery Group.

The Board noted that Roger Wilson, current Chair of the NCRI Consumer Liaison Group, had agreed to chair the UKCRC Public and Patient Involvement Group. As a result a meeting of staff from UKCRC Partner organisations involved in patient and public involvement activities has been organised for 15 December. This meeting will bring together those people with expertise in this area and help shape the work of the UKCRC Group. It was also noted that Roger Wilson would attend future UKCRC Board meetings as an observer and provide input into the Public Awareness Task and Delivery Group.

The Board noted that the UKCRC Public Awareness Task & Delivery Group, chaired by Professor Colin Blakemore, had now met and a number of pieces of work initiated. The intention is to work closely with expert staff in Partner organisations to take these projects forward.

The Board highlighted the importance of both of these groups being involved in discussions on the issues of confidentiality and use of patient data, arising from the AMS report. There was also a need for more research in this area.

4) UKCRC Workplan  UKCRC/05/38

The Board noted that the first UKCRC Workplan covers the period until March 2006. The Paper before the Board proposed a new Workplan for the period April 2006 - March 2007.

The proposed Workplan contained a broad agenda of work including the following key targets:

• Completing the establishment of the UKCRN and initiating first studies
• Completing funding for the national framework for experimental medicine
• Completing the Academic Careers Subcommittee work on nursing careers
• Publishing the Strategic Analysis of UK Clinical Research Portfolio and facilitating strategic discussions
Identifying and implementing an agenda of actions in public health research in the UK
Establishing a National Regulatory and Governance Advice and Monitoring Service
Including research indicators in Healthcare Commission standards for 2006/7
Agreeing and initiating, with Connecting for Health, pilots to assess the use of NHS Care Record Service data to support interventional and observational clinical research

Over the past year the UKCRC Partnership has developed three methods of working that has allowed a broad range of activities to be pursued simultaneously:

- UKCRC activities led and administered by the UKCRC Core Team;
- UKCRC activities led by individual partners but administered by the UKCRC Core Team; and
- UKCRC activities led and administered by individual Partner organisations on behalf of the UKCRC Partners.

The Workplan stressed the importance of UK-wide working, and a set of “standard operating procedures” developed by the UKCRC Core Team were tabled and agreed. These are aimed at ensuring that there are no practical barriers to full engagement of all UK Administrations in any activity being developed under the UKCRC umbrella.

The Board welcomed the proposed Workplan and the following points were raised in discussion:

- It was recognised that the work of the UKCRC was likely to happen in two-phases. An initial change management phase, followed by a ‘maintenance’ phase. The role of the UKCRC would therefore need to evolve with time.
- The power and added value of a single UKCRC voice on key issues was acknowledged. In the coming year further opportunities for doing this should be explored.
- The Board stressed the importance of monitoring progress and agreed that a review of the UKCRC should take place after three years.
- Members welcomed the Core Team’s standard operating procedures to facilitate UK-wide working. However, the importance of complementing this with continued high level engagement across the four nations was stressed.
- The Board recognised the continued importance of the National Cancer Research Institute and the Funders Forum for Research into Ageing & Older People, but concern was expressed by some members on the added value provided by the other funders fora.

The Board agreed the proposed Workplan for the period April 2006 - March 2007. However, they recognised that, given the available resources, some prioritisation of activities might be needed. This would depend on the available budget, discussed under item 5.

5) UKCRC Budget

The paper before the Board was in two sections. The first section covered the agreed budget for the financial year April 2005 – March 2006. The second section proposed a budget for April 2006 - March 2007.
April 2005 – March 2006: Members noted that the agreed budget for this period was £887k. On the basis of current estimates, expenditure would be approximately £909k, including exceptional items such as developing the Evaluation Framework. UKCRC expenditure including the exceptional item would therefore over the £887k, but within the total contributions promised by Partner organisations.

The paper included a summary of the contributions promised by Partner organisations to meet these costs. The Board noted that some contributions were covered by the Department of Health, England and some organisations who had not contributed this year had indicated their willingness to contribute next year. The board noted that contributions for the financial year 2005/2006 covered the agreed budget and that a summary of the forecasted expenditure was available from the Core Team.

The paper also proposed a budget for the running costs of the UKCRC for the period April 2006 – March 2007, the period corresponding with the proposed UKCRC Workplan.

April 2006 until March 2007: The second section proposed a Budget of £1.252K for the next financial year. This was a slight increase over the original estimate of £1.1m for the establishment of the UKCRC. This increase included two new posts and an increase in the cost of the MRC Service Level Agreement for hosting the UKCRC Core Team. The Chief Executive also proposed the establishment of a Subgroup of the UKCRC Board to act as a Budget Committee to work on budgetary matters and ensure due diligence.

The Board recognised the need for adequate resources to tackle complex, multi-stakeholder issues. There was also support in principle for the recruitment of two new posts. However, Members agreed that it was important to establish whether contributions from Partner organisations could be increased sufficiently to meet the proposed budget. The Board agreed on the importance of momentum and avoiding micro-management to allow the UKCRC Core Team to move things forward, but welcomed the proposal to establish a Subgroup of the UKCRC Board to act as a Budget Committee.

The UKCRC Board agreed the following:

- The Core Team should negotiate financial commitments from Partner organisations for 2006/7
- A UKCRC Budget Committee should be established and meet early in the New Year to finalise the budget, in the light of the likely contributions from Partner organisations and report back to the Board.
- The membership of the Committee should be: Nick Partridge (INVOLVE), Diana Dunstan (MRC), David Lynn (The Wellcome Trust), Noreen Caine (NHS R&D England), John Williams (Welsh Assembly Government).

It was recognised that a decision on the budget should be taken as quickly as possible.

Actions:

- A Budget Committee will be established as a Subgroup of the UKCRC Board. The Core Team will provide the Budget Committee with a
revised budget, together with proposed commitments for the financial year 2005/2006.

6) **Evaluation Framework**

The Chairman reminded Board Members that RAND Europe had been commissioned to develop an evaluation framework for the UKCRC. Since the last Board meeting, RAND had produced a shortlist of performance measures for further consideration by the Board.

The Board thanked RAND for all the work that had been carried out in developing the evaluation framework. Members agreed that the measures identified provided a useful shortlist that could be further refined. The Board stressed the importance of choosing measures that could be easily collected and could be factored into the emerging infrastructure.

**Action:**
- It was agreed that the UKCRC Core Team would now work with Board members and the UKCRN to further develop a smaller set of indicators that can be easily measured and collected routinely. Work should start as soon as possible in order to generate the necessary baseline data.

7) **Connecting for Health (National IT Programme)**

The Board noted that agreement had been reached to set up a UKCRC R&D Advisory Group to Connecting for Health (CfH). This would be jointly sponsored from the Department of Health by Professor Davies as Chair of the UKCRC and Richard Jeavons, Deputy Director of the CfH Programme. The terms of reference for this Advisory Group are being finalised and will be circulated to Board members when they are signed off.

The Board welcomed the reference to Connecting for Health and research in the Chancellor’s pre-budget statement. They noted that the joint workshop between the UKCRC and CfH, organised by DH and MRC had been very productive and positive recommendations had emerged. Members also stressed the importance of ensuring that a joined up approach to research was developed across all the UK NHS IT Programmes.

8) **Regulatory and Governance**

a) **Regulatory and Governance Update Paper**

The Board noted that progress had been made with this Activity’s objectives and that Sir John Lilleyman has agreed to chair a group that will be tasked with looking at the information requirements for regulatory approvals and permissions. The terms of reference for this group will be circulated to the Board shortly.
b) **AMS Report – Personal data for public good: using health information in medical research**

The Board noted that the next item was to have been a discussion of the published Report "Personal data for public good: using health information in medical research" from the Academy of Medical Sciences (AMS). However, work on the report was still ongoing and the paper before them only contained the draft recommendations.

The Board welcomed the fact that the Academy was studying this important area. They also agreed that research using patient data was crucially important to improving the health of the public. Members recognised the need to strike an appropriate balance between, protecting the rights of vulnerable sectors of the population and, public interest in the potential of research to answer important public health questions. In this context, the Board welcomed the recommendation to engage with the public in tackling the major issues and encouraged the Academy to use the sort of language that was most likely to bring this about.

**Action:**
- Board Members agreed to send further comments to the report's author Professor Souhami, and would consider the role of the UKCRC in facilitating change in this area once it had seen the full report and also taking into account other impending reports on this subject and the UKCRC workload with budget.

9) **Building up the Infrastructure in the NHS**

a) **UKCRN**

There were three elements to this paper:

i) An update on the development of the UKCRN
ii) A paper proposing a Clinical Trials Unit Review
iii) A paper proposing the establishment of Research Funders Liaison Meetings

The Board noted progress in establishing the UKCRN. The Board noted that remodelling of the Primary Care Network is now underway and the launch of a Primary Care Research Network-England (PCRN-E) had been advertised. It was hoped that this would develop into a UKPCRN in time. A project to map the clinical research infrastructure in the UK is underway and the UKCRC Core Team had approached Partner organisations requesting information. This resource would inform the development of a comprehensive UKCRN and also provide a valuable information source to inform Partner organisations strategic discussions and funding decisions.

The Board noted that proposals to develop an "accreditation process" for Clinical Trials Units had been discussed by the Board Subgroup on the UKCRN. Members acknowledged the importance of carrying out a review of capacity in this area and linking groups of methodological expertise into the emerging infrastructure. However, it was agreed that further work was needed on terminology and definitions before this process could be finalised and the Board looked forward to considering further proposals in the future.
The Board noted that proposals to develop an effective interface between funders and those leading the different elements of the UKCRN had been discussed by the Board Subgroup on the UKCRN. In particular the establishment of regular Funders Liaison Meetings bringing together the different stakeholders was proposed. This would happen twice a year immediately following meetings of the UKCRC Board Subgroup on the UKCRN and Dr Dunstan has agreed to act as independent chair.

The Board endorsed the proposed approach to developing an effective interface between funders and the UKCRN and stressed the need for an independent chair.

b) Experimental Medicine Update UKCRC/05/42b

The Board was updated on progress on the Experimental Medicine Initiative and welcomed the collaboration between funders in this area.

The Board were asked to note the importance of developing an appropriate approach, and funding, for facilitation of networking between the clinical research facilities, the UKCRN and the CRUK / Health Departments’ experimental cancer medicine centres and industry.

10) Research Co-ordination UKCRC/05/43

The Board was asked to note that the UKCRC Strategic Planning Group on Microbiology and Infectious Diseases Research had been set up with Professor Sir John Lilleyman as Chair and the first meeting is planned for early next year. The Board also noted that the Strategic Analysis was progressing on target and the first results would be presented at the March Board Meeting.

11) Incentives UKCRC/05/44

The Board were reminded that the UKCRC NHS Incentives Subcommittee had been working with the Healthcare Commission to explore potential for inclusion of research activity and governance indicators in the assessment of an organisation’s performance. A joint workshop had been held in November with the Commission. The Workshop had identified a number of potential R&D performance indicators that could be included in the forthcoming Healthcare Commission consultation. It has also been agreed that a joint working group will be set up to develop a forward plan to inform the refinement of research indicators to be used in 2007/08. The Board welcomed these developments and highlighted the importance of ensuring that the burden of data collection was kept to a minimum.

Board Members noted that the Commission will be issuing the next consultation document around the developmental standards early in the New Year.

The Board noted the ongoing work with the Advisory Committee on Clinical Excellence Awards. Members highlighted potential difficulties in handling those academic clinicians coming from outside the UK into the process.
Action:
- The UKCRC Core Team will draft a joint UKCRC response to the next consultation and remind Partner organisations in addition to respond individually.

12) Workforce and Careers

The Board noted that work on implementing the recommendations of the Academic Careers Report was proceeding to time and to plan, but that much work still needed to be done with the Royal Colleges. There are also some residual issues for Public Health Medicine.

It was recognised that work on developing new career structures for clinical researchers is complicated and labour intensive so the exercise for nurses was likely to be similarly complex. In the context of future work on career structures, careful thought and discussion was needed before embarking on the third phase of this work to develop career structures for other relevant disciplines, including clinical scientists and allied health professionals.

13) Any other business

**Deputy Chair**

The Board agreed the need for a Deputy Chair who would be required to stand in for the Chair when there was a conflict of interest or if a UKCRC view needed to be expressed to Government. Therefore it was recognised that a Deputy Chair needed to come from a non-public body. The Chairman indicated that two nominations had been received to fulfil this role and both had agreed to serve. She proposed that the following two Board Members - Nick Partridge (INVOLVE) and Professor John Bell (AMS), should act as Deputy Chair. The Board approved the appointments.

**Dates of Next Meetings**

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<tr>
<th>Date</th>
<th>Time</th>
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<tr>
<td>Thursday 9 March 2006</td>
<td>14.00 – 17.00</td>
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<td>Tuesday 6 June 2006</td>
<td>14.00 – 17.00</td>
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<td>Tuesday 19 September 2006</td>
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<td>Tuesday 12 December 2006</td>
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Board Members are asked to note the change of date for the September 2006 Board from 12\textsuperscript{th} to 19\textsuperscript{th} and the December 2006 Board from 5\textsuperscript{th} to 12\textsuperscript{th}. 