Minutes of the meeting held on Thursday 9 March 2006, The Himsworth and Fletcher Rooms, UKCRC, 20 Park Crescent, London, W1B 1AL

Present

Members

Professor Sally Davies – Department of Health (DH) (Chair)
Professor John Bell – The Academy of Medical Sciences (AMS)
Professor Carol Black – Academy of Medical Royal Colleges (AOMRC)
Professor Sir Alasdair Breckenridge – Medicines and Healthcare Products Regulatory Agency (MHRA)
Mr Glyn Edwards – Biologics Association (BIA)
Professor Alex Markham – Cancer Research UK (CRUK)
Richard Tiner – The Association of the British Pharmaceutical Industry (ABPI)
Sir Jonathan Michael – NHS Confederation
Simon Denegri – Association of Medical Research Charities (AMRC)
Nick Partridge – INVOLVE
Candy Morris – 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
Allan Baxter – Senior R&D Representative from the Pharmaceutical Industry
Peter Arnold – The Association of the British Healthcare Industries (ABHI)
Dr Russell Hamilton – Department of Health (DH)
Dr Liam O’Toole – UK Clinical Research Collaboration (UKCRC)

Observers/Invited

George Sarna – Medical Research Council (MRC)
David Lynn – The Wellcome Trust
John Williams – The Wellcome Trust
Peter Sneddon – Department of Health (DH)
Marc Taylor – Department of Health (DH)
Louise Wood – Department of Health (DH)
Dr Helen Campbell – Department of Health (DH)
Peter Selby – UK Clinical Research Network
Dr Janet Darbyshire – UK Clinical Research Network (UKCRN)
Professor Ian Diamond – UKCRC Public Health Strategic Planning Group (Chair)
Roger Wilson – UKCRC Public and Patient Involvement Project Group (Chair)
Aisling Burnand – BioIndustry Association Alternate Board Member (BIA)
Stephen Cook – The Association of British Healthcare Industries (ABHI)
UKCRC Secretariat

Dr Sarah Meredith     Dr Mags Sara
Dr Sue Bourne     Dr Andrew Speakman
Dr Janet Valentine     Dr Matthew Hallsworth
Susannah Keeling     Caroline Lane

Apologies

John Neilson – Office of Science and Technology (OST) / Department of Trade and Industry (DTI)
Sir Mike Rawlins – National Institute for Health and Clinical Excellence (NICE)
Paul Hubbard – UK Higher Education Funding Councils

Announcements and Apologies

Announcements

The Chair welcomed everybody to the seventh meeting of the UKCRC Board.

Attending the UKCRC Board for the first time were the newly appointed Alternate Board Members were, Candy Morris from the SHAs and Simon Denegri from AMRC.

Also attending the Board for the first time as Observers were Aisling Burnand, the newly appointed Alternate Board Member for BIA and Stephen Cook from ABHI.

Peter Sneddon – DH, John Williams and David Lynn – Wellcome Trust and George Sarna – MRC, attended the meeting for the item on the Strategic Analysis and remained as Observers for the remainder of the Board Meeting.

Also attending the Board Meeting as Observers were Ian Diamond, in his capacity as Chair of the UKCRC’s Public Health Strategic Planning Group and Roger Wilson, as Chair of the UKCRC’s Public and Patient Involvement Project Group.

1) Minutes

The minutes were accepted as a correct record of the meeting held on 8 December 2006.

UKCRC General

2) Chief Executive’s Report

Delivery and Communication

The UKCRC has been operational for approximately 16 months and is now moving from a ‘mapping’ to a ‘delivery’ phase. There are a large number of changes being implemented by Partner organisations across the shared UKCRC agenda. This unprecedented level of activity has put particular pressure on communications within the UKCRC and the links needed between the Partner organisations and the different Activities. The UKCRC is a prime focus for communication between Partners and will continue to explore new ways of keeping everyone informed.
The UKCRC Board were reminded of the importance of the UKCRC Guiding Principles in order to maintain momentum in the Partnership:

- Engage stakeholders through consultation and negotiation rather than representation
- Adopt a ‘solutions-based’ rather than ‘recommendations-based’ approach to problems
- Build on what is already working well
- Improve communication but not at the cost of momentum
- Add value by not taking on issues easily tackled by a single partner organisation

Board Members discussed the issue of communication with international and in particular European colleagues. In the near future it would be important to promote the changes in the UK environment but the Board agreed that the priority should be to get communication right within the UK first. It was suggested that Board Members should include the UKCRC in any talks which they might be giving both within the UK and overseas.

Evaluation of the UKCRC

As a follow up to the RAND Europe work on evaluation, the UKCRC Core Team is working with UKCRN CC and other stakeholders to identify a suite of performance indicators that are ‘hard wired’ into the system and routinely gathered by different stakeholders as part of their normal business. These will be brought together at regular intervals in order to monitor collective performance. It was noted that these metrics would be useful when a Strategic Review of the UKCRC takes place.

3) UKCRC Budget

Members were reminded that a budget of £1.252m for the financial year 2006/2007 was presented to the 8 December 2005 Board Meeting. At this time the UKCRC Board recognised the need for a budget that would allow the UKCRC Core Team to carry out the ambitious Workplan also presented to the Board at this time. However, before approving the budget the UKCRC Board requested that:

- the UKCRC Core Team should review the budget and try to make some budget reductions
- a Budget Committee should be established to look closely at the budget
- the UKCRC Core Team should secure Partner contributions for the financial year 2006/2007.

A Budget Committee was established and met for the first time on 6 February 2006. The Chairman of the Budget Committee, Nick Partridge summarised the key points from the Budget Committee discussions and their report to the UKCRC Board:

- The Budget Committee were satisfied with the systems in place for financial and risk management.
- The Committee agreed that the proposed budget had been tightly costed, and was in line with the original planned annual running costs after including inflation. Any increase in costs compared with 2005/6 had been adequately explained and reflected the move into a ‘delivery phase’.
The likely income to the UKCRC from Partner contributions is sufficient to meet the proposed budget.

The Committee recommended the budget be approved by the Board for 2006/07 of £1,240,664.06. This includes reductions made since the budget was presented to the December 2005 Board Meeting as well as the subsequent increase as a result of showing the increased costs of the SLA.

In the spirit of the UKCRC Board discussion and recognising the need to maintain momentum during the initial stages of UKCRC existence, the Committee agreed that in order for the UKCRC Core team to not delay recruitment of the two new posts further, the Chairman of the Budget Committee would e-mail Board Members recommending that recruitment commence without delay. This was done and recruitment is currently underway.

The Budget Committee finalised their own Terms of Reference and requested that the UKCRC Board approve the ToRs.

In response to the above points, the UKCRC Board:

- Agreed the Terms of Reference of the Budget Committee.
- Agreed that it would be useful for some Partner organisations to receive an estimated budget figure for the following financial year prior to the November meeting of the Budget Committee. This is necessary for Partner organisations whose finance system ran over a calendar year to plan for their contributions. It was therefore agreed that the Budget Committee would work with the UKCRC Core Team to provide an indicative budget figure in August/September 2006 for the following financial year 2007/2008.
- The budget of £1,240,664.06 as presented to the UKCRC Board was endorsed.
- It was agreed that in future those Partner organisations whose financial contributions are covered by DH would be shown as such.

The Chair of the Budget Committee thanked the contributions made by Genny Kiff of the Wellcome Trust and reminded Board Members of the importance of meeting their financial contributions and of making a commitment early in the financial year in order to allow budget planning.

4) Connecting for Health (National IT Programmes) UKCRC/06/04

This paper set out the Terms of Reference for the UKCRC Research and Development Advisory Group to the Connecting for Health Programme. The UKCRC Board welcomed the news that Ian Diamond had agreed to chair the group. The UKCRC Board noted that:

- The Terms of Reference had been approved by government ministers
- Membership was ad personam and will be designed to cover a range of interests and expertise.
• Industry is being involved
• The devolved administrations are keen to be involved
• The role of one of the programme manager posts currently being advertised for the UKCRC Core Team will be to provide the secretariat for this group

The Board highlighted the importance of clinical engagement with this programme of work.

Activities

5) Regulatory and Governance

5a) Regulatory and Governance - Update Paper UKCRC/06/05a

The UKCRC Board noted that:

• The programme of work in this Activity had been updated to take into account the DH strategy for England and other developments
• Having completed a phase of mapping the environment, activities were increasingly moving towards the negotiation and implementation of solutions intended to streamline the regulatory and governance environment
• Progress had been made, particularly in:
  ➢ Development of strategy that would allow for the early identification of and engagement with European regulatory developments
  ➢ Formation of a group, chaired by Sir John Lilleyman, which will through discussion and negotiation, streamline information requirements for permissions, approvals and reporting

The UKCRC Board agreed that Sir John Lilleyman’s group presents a valuable opportunity for harmonisation and standardisation and that NHS providers should be engaged early on in this process.

The AMS drew attention to the publication in January of their report on “Personal Data for Public Good: using health information in medical research” and highlighted the potential role for the UKCRC in impacting on the issues raised. The UKCRC Board welcomed the MRC’s plans to investigate patient and public attitudes to using personal data in medical research and the ABPI’s plans to publish guidance on the secondary uses of personal data.

5b) Update on the negotiations to revise the Model Clinical Trials Agreement for Contract Pharmaceutical Research in NHS hospitals UKCRC/06/05b

The UKCRC Board welcomed the completion of the revision of the model clinical trials agreement (mCTA) for commercial research and noted that this had resulted from a successful negotiation process between DH, ABPI and the NHS Confederation.

The UKCRC Board agreed that the success of the revised mCTA is dependent on:
• The document being seen as a routine way of doing business
• Promulgation through both industry and the NHS
• Coordination with the devolved administrations’ relaunch of their versions
• A robust communications strategy

The UKCRC Partners agreed to develop a coordinated communications strategy for the relaunch of the MCTA.

6) Building up the Infrastructure in the NHS

6a) UKCRN UKCRC/06/06a

There were two elements to this paper:

i) An update on progress in implementing the UKCRN
ii) A proposal to take forward work on capacity and accreditation of CTUs

The Board noted progress in establishing the UKCRN, in particular key activities such as the selection of the topic-specific research network directors and identification of the local research networks for the remaining topics had now been completed.

Board Members were reminded that at their last meeting they had asked for further work to be done on the development of an “accreditation process” for clinical trials units. The paper before the Board had been revised and been recently discussed and approved by the Board Subgroup for the UKCRN.

The Board noted that accreditation was part of a broader strategy to develop and maintain the capacity for specialist trial management in the UK. The process was aimed at ‘raising the bar’ and improving the quantity and quality of the available expertise. It was proposed that accreditation would comprise two levels; full accreditation for CTUs demonstrating all key competencies, or provisional accreditation for those demonstrating most key competencies and with evidence of working towards the rest. The process would involve an ongoing review process which would include periodic review of accredited units and any new applications.

Board Members supported the overall aims to build capacity and raise standards. They recognised the need for a facilitated approach or ‘accreditation process’ to ‘raising the bar’ and maintain standards. The principles were accepted but further thought was needed on the language to be used, particularly on the term “accreditation” before this process could be finalised. UKCRN CC would work with a subgroup of funders of CTUs to come up with the most appropriate wording.

In summary, the Board agreed the following:

i) A mapping exercise should be carried out to assess the capacity and competencies for trials management
ii) The list of key competencies should be developed
iii) A review or “accreditation” process should be carried out.

The Board stressed the importance of ensuring that the process is managed carefully under the oversight of the major key funders of Clinical Trials Units.
6b) **Experimental Medicine**

The Board was updated on progress in Experimental Medicine. It was highlighted that, at the end of the three calls for proposals, there would be a need for a ‘sweep up’ meeting between funders to analyse the new experimental medicine environment and discuss any potential future or current unmet needs. Members noted that the Experimental Medicine Activity had been a useful framework for all the funding organisations to work together to ensure that information is shared at key stages. Cross-representation on funding committees had been extensive.

7 **Research Coordination**

7a) **Public Health**

An oral update on progress with the Public Health Strategic Planning Group was delivered by Professor Ian Diamond.

This was an area were there are a number of existing reviews to draw on. In addition to drawing together the findings of these exercises, the SPG had undertaken its own consultation process and had had an impressive response (over 40 replies). In reviewing the responses the group had identified four research areas to focus on: physical activity, nutrition, addiction and tobacco. The SPG member organisations lead reviews into each of these areas. Cutting across these were a number of areas for proposed action by the SPG:

1. Capacity building
2. multidisciplinary working
3. Secondary analysis of existing datasets
4. Methodology

The SPG members were currently discussing solutions across this matrix of issues and would agree a set of actions at their next meeting. A draft report will be developed during the summer.

7b) **Microbiology and Infectious Diseases**

The Board Members noted that this group had now had its first meeting and was currently conducting a consultation exercise.

7c) **Strategic Analysis**

Dr Liam O’Toole presented a confidential summary of the results of the UKCRC strategic analysis of health research. The Board was reminded that this is the first time that an analysis on this scale has been attempted anywhere in the world. The establishment of the UKCRC Research database and Strategic Analysis had been overseen by the Database Working Group, a Board Subgroup.

The analysis was a major undertaking which involved collecting 9638 individual research awards from 11 different funding bodies. Participating organisations included the health departments of the four UK nations, the MRC and the health relevant portfolios of 3 other research councils (ESRC, EPSRC, BBSRC). It also
included the portfolios of the three largest charities in the field (Wellcome Trust, Cancer Research UK and the British Heart Foundation).

Members noted that the analysis covered biomedical and health research awards that were live at any time between 1st April 2004 and 31st March 2005. The analysis only included UK awards with a clearly defined set of research objectives (principally peer-reviewed research awards). It therefore excluded significant sums devoted to R&D support costs and any funding supporting research outside the UK. The Strategic Analysis was a tool to inform strategic discussions not a national audit of research funding.

The analysis used a bespoke health research classification system designed by the UKCRC partners. The classification system itself was modelled on the International Classification of Diseases (ICD) codes and Common Scientific Outline, but has been adapted to classify the full spectrum of the participating organisations research activities. The classification system is sub-divided into 21 Health Categories and 48 Research Activity codes. To ensure consistency and accuracy, each award was separately classified by two independent coders (from a team of 18) and then reviewed by a member of the UKCRC Core Team.

It was acknowledged that the participating funders were from a range of different charity and government agencies with different roles and different drivers. The Analysis would therefore be used in a number of different ways.

The Board considered the results of the strategic analysis which focussed on an examination of the combined portfolio of the participating funders. The possible inclusion of individual organisational portfolios was proposed. It was agreed that the Secretariat would discuss this with each of the participating organisations. It was acknowledged that there are a number of factors which influence the level of research activity revealed in any one area: including the quality and size of the research workforce, scientific opportunity, researchability, burden of disease and fundraising capabilities. The Board agreed that careful presentation was needed in the final Report of the analysis.

Members agreed that it would add value to this exercise to explore the feasibility of adding the research portfolios of smaller medical research charities and Industry to the Database.

The Board noted that publication of this national Analysis was an international ‘first’ and had been a significant undertaking with input from a large number of people. Members in particular thanked Dr Janet Valentine and Dr Andrew Speakman from the UKCRC Secretariat and members of the Database Working Group (Dr George Sarna, Dr John Williams and Dr Peter Sneddon).

The Board agreed that the analysis was an important new evidence base to inform strategic planning and endorsed the proposed timetable for publishing the Strategic Analysis report by mid-May.
8) **Incentives**  

The Board was asked to note progress in this area. A number of R&D performance indicators had been included in the Healthcare Commission’s forthcoming consultation on the Annual Health Check 2006/07. A UKCRC response statement would be co-ordinated by Secretariat once the consultation had been issued. Members would also be encouraged to respond individually to the consultation to ensure that research is kept high up on the Healthcare Commission’s agenda.

9) **Workforce**  

Board Members were reminded that the national competitions for training programmes to support the clinical fellowship and lectureship phases for the integrated academic training programme were launched 6 October 2005. The applications for training programmes to support clinical fellowships were recently considered by the Clinical Academic Careers Panel and the results of these had been tabled for Board Members. The national competition for senior clinical lectureships, co-funded by HEFCE and the NHS, had also been launched. The Clinical Academic Careers Panel would be meeting in April to consider applications from organisational partnerships to host programmes to support Clinical Lectureships.

The Board noted that the scheme had been successful in attracting a large number of applications from institutions, although for this round a small number of institutions that had been expected to apply had not submitted an application. To inform the next round, in order to identify any gaps, an analysis would be carried out on the basis of geography, shortage specialties and host institution. Although it was noted that a large number of applications had been received in the shortage specialties, it remains to be seen whether the volume of programmes would match. An analysis of consultant vacancies and retirements would also be carried out.

The Board thanked Lisa Cotterill for her work in implementing these programmes.

The UKCRC Sub-Committee for Nurses in Clinical Research had met twice and had made progress in a number of areas. The third meeting of the Sub-Committee would be held on 10 March. Members will be updated on further progress at the next UKCRC Board meeting.

10) **Public and Patient Involvement and Awareness**  

The Board were updated on progress with the Public and Patient Involvement Activity and the Public Awareness Task and Delivery Group.

The Board noted that the UKCRC Public Awareness Task & Delivery Group chaired by Professor Colin Blakemore had held their first meeting and that the second one was scheduled for May 2006. This group had agreed to work closely with expert staff in Partnership organisations to take a number of pieces of work forward, including the development of a generic lay guide to understanding clinical trials and the development of generic leaflet introducing clinical trials. Development of a module on clinical research for the national curriculum or other appropriate educational package is also planned.
The Board noted that Roger Wilson had been appointed to chair the UKCRC Patient & Public Involvement Group. A UKCRC Patient and Public Involvement Project Group had been set up, to inform UKCRC activities in this area. This group would hold its second meeting in May. The ABPI expressed an interest in joining this group and it was agreed they would be invited to the May meeting.

Roger Wilson was congratulated on his NCRI 5 Year Formal Report which had been received extremely positively.

**Other**

**Any Other Business**

Professor Davies updated members on progress with the Treasury with regard to VAT for CRFs.

**Dates of Next Meetings**

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