Minutes of the meeting held on Tuesday 12 December 2006, The Himsworth and Fletcher Rooms, UKCRC, 20 Park Crescent, London, W1B 1AL

Present

Members

Nick Partridge – INVOLVE (Chair)
Dr Alison Austin - Office of Science and Technology (OST) / Department of Trade and Industry (DTI)
Dr Richard Barker – The Association of the British Pharmaceutical Industry (ABPI)
Professor John Bell – The Academy of Medical Sciences (AMS)
Professor Colin Blakemore – Medical Research Council (MRC)
Professor Sir Alasdair Breckenridge – Medicines and Healthcare Products Regulatory Agency (MHRA)
Kalipso Chalkidou – National Institute for Health and Clinical Excellence (NICE)
Simon Denegri – Association of Medical Research Charities (AMRC)
Mr Glyn Edwards – BiolIndustry Association (BIA)
Yvonne Greenstreet – GlaxoSmithKline (GSK)
Dr Russell Hamilton – Department of Health (DH)
Professor Alex Markham – Cancer Research UK (CRUK)
Sir Jonathan Michael – NHS Confederation
Professor Bob Stout – NI Health & Personal Social Services
Dr Liam O’Toole – UK Clinical Research Collaboration (UKCRC)
Dr Alison Spaull – Scottish Executive Health Department
Dr Mark Walport – The Wellcome Trust
Professor John Williams – Welsh Assembly Government
John Wilkinson – The Association of the British Healthcare Industries (ABHI)

Observers/Invited

Dr Helen Campbell – Department of Health (DH)
Dr Janet Darbyshire – UK Clinical Research Network (UKCRN)
Sarah Fox – Department of Health R&D (DH)
Catherine Johns – Department of Health R&D (DH)
Chris Watkins – Medical Research Council (MRC)
Roger Wilson – UKCRC Public and Patient Involvement Project Group (Chair)
Louise Wood – Department of Health (DH)

UKCRC Secretariat

Dr Sue Bourne
Hannah Brown
Dr Matthew Hallsworth
Dr Ngozi Okwudili-Ince

Dr Janet Valentine
Philippa Yeeles
Dr Andrew Speakman
Gerardine Spiers
Announcements and Apologies

Apologies

Professor Sally Davies – Department of Health
Paul Hubbard – UK HEFCE
Candy Morris – Strategic Health Authorities
Professor Adrian Newland – Academy of Medical Royal Colleges (AOMRC)
Peter Selby – UKCRN Observer

Announcements

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

The Chair welcomed Dr Richard Barker – APBI as their new Board Representative

The Board was asked to note that Candy Morris will continue as the Board Member for the Strategic Health Authorities, Mark Britnell will replace Adrian Pollitt as the SHA Alternate.

1) Minutes of the last UKCRC Board Meeting 19 September 2006 UKCRC/06/31

The minutes were accepted as a correct record of the meeting held on 19 September 2006.

Matters Arising

WHO Trial Registration Platform

Following the last meeting on 19 September 2006 the Board wrote to WHO as agreed to express its support for global registration of trials. The letter also expressed concern that the WHO had not done enough to address the concerns of industry or of academics involved with trials not intended for pharmaceutical licensing. The WHO Scientific Advisory Group met in November 2006. The UKCRC’s letter provoked debate and appeared to prompt a rethink. The Board noted that:

- The new WHO project manager is now putting less emphasis on published criteria for primary registers, and more emphasis on close working-level collaboration between existing US, UK and Australian registers as starting point for international network of registers.
- More effort is under way to check that the 20 items are suitable for all trials within scope of WHO definition.
- The Advisory Group recommended that WHO should aim to maximise registration even if some data is delayed, rather than insist on complete 20-item data set and register fewer trials.
- WHO are not ready to retreat from the ideal of registering phase I trials with all 20 items including commercially sensitive ones. But they are ready to prioritise so that this principle does not hold up global registration of trials affecting evidence for treatments in use.
The Board noted that at some point there was a proposal to register the outcomes of clinical trials. Was this now the case? The Secretariat agreed to clarify this issue.

**Post meeting note:**
The WHO intends to define a standard summary of the outcome of a clinical trial. It is considering experience with ICH and Consort. It has yet to decide whether such summaries should appear routinely on trial registers. It is likely to reach a view by November 2007.

**Cooksey Review**
The Board congratulated Professor John Bell on his new role as acting Chair of the Office for Strategic Coordination of Health Research (OSCHR). The Board agreed that it would leave the in-depth discussion of the Cooksey Review and its implications for the UKCRC until the next Board meeting but recognised the need to leave flexibility in the Workplan.

John Bell updated the Board on OSCHR. Between now and Christmas he will be working on what OSCHR will look like and early in the New Year will be meeting with broad stakeholders. The job will be made simpler by the existence of the UKCRC. It was noted that John Bell will no longer sit on the Board as the AMS representative. Board members shared his optimism and enthusiasm but also recognised that there was potential overlap between activities of the UKCRC Board and OSCHR. A close working relationship would need to be maintained in order to avoid duplication.

**Research Assessment Exercise (RAE)**
The Board expressed its concern about the potential impact of the introduction of a metrics based system on translational and clinical research. The Board asked the UKCRC Secretariat to discuss this issue with Paul Hubbard (HEFCE) and explore whether a letter should be written from the UKCRC expressing this concern.

**UKCRC General**

2) **Chief Executive’s Report**  

**Progress Report**
The Board noted that the UKCRC Progress Report 2004-2006 has been distributed to UKCRC Partners, key stakeholder groups and other interested parties as well as being cascaded through Partner organisations’ networks. If further hard copies are needed or additional contacts are identified please let the UKCRC Secretariat know.

3) **UKCRC 2007/2008 Draft Workplan**  

The Board considered the draft UKCRC Workplan for 2007/2008 and welcomed the proposed increased emphasis on communication and plan for continued implementation of ongoing activities. The following points were raised in discussion:
• The Board welcomed the draft Workplan and noted that the proposed work was mostly continued implementation of ongoing work. They considered the renewed emphasis on communication and consolidation appropriate for this stage in the UKCRC lifecycle.

• The Board noted that, as had been previously agreed, the work of UKCRC should be in two phases and that the ‘change leadership’ phase would begin to tail off, probably after the next year. It was agreed that in the future the changing role of the UKCRC would need further discussion by the Board.

• The Cooksey report recommended that the UKCRC facilitated greater collaborative working between universities and the NHS. The Board agreed on the importance of close working between these two stakeholder groups. Given the timing the draft Workplan did not include this activity. Further thought would need to be given to this issue and any UKCRC involvement discussed at the next Board meeting. It was recognised that the membership of the Board may need to be re-examined in light of this activity.

• The Board stressed the importance of the work in section 2.2.5 Regulatory and Governance Environment Specific Objectives around non-commercial agreements.

• Industry representatives raised the importance of ensuring a UK-wide approach in key areas in particular in relation to opportunities offered by harmonised NHS IT platforms. It was recognised that NHS IT programmes were largely policy driven which presented challenges, however where opportunities did exist it was important to ensure the research elements were closely joined up. It was agreed that the Secretariat would facilitate discussions about IT platforms between the four UK administrations and the Board noted Industry’s offer to assist in these discussions.

• The Board recognised that despite progress being made in a number of areas that Incentives for Research in the NHS needed further work. It was noted that ongoing activities including the move to more contract based relationships in R&D in England would impact on this area. However, it was agreed that further discussions on how to take this Workstream forward where needed and a redraft of this section of the Workplan should be discussed at the next Board meeting.

In summary the Board endorsed the proposed Workplan subject to amendments taking into account the Cooksey recommendations and inclusion of a new plan for the Incentives Workstream. These two areas will be discussed at the next Board meeting in March 2007.

4) UKCRC Budget Committee Report to the UKCRC Board

The Board welcomed the report from the Budget Committee summarising expenditure to date and the draft proposed budget for 2007/2008. The Board recognised the rigorous management of the budget by the Secretariat and thanked Jenny Kiff from the Wellcome Trust for her assistance to the Budget Committee. The proposed ‘steady state’ for the 2007/2008 and recommended roll over of surplus funds from the 2006/2007 to the 2007/2008 budget was approved by the Board. A final proposed budget for 2007/2008 would be presented to the March 2007 Board by which time details of the expenditure of the current financial year would be known.
UKCRC Activities

5) **Workforce and Careers - Update Paper**  UKCRC/06/35

5a) Delivery of the integrated academic training programme

Members of the Board noted that good progress is being made. The Board considered Annex 2, which detailed the outcome of the second round of the national competition to run the training programmes supporting Academic Clinical Fellowships and Clinical Lectureships. It was noted that the programmes in this round have all been awarded to endangered (rather than mainstream) specialties and that this might result in a number of anomalies and gaps in provision of training. The Board were informed that a third round of the competition will take place in 2007 to address these issues. A meeting of the Clinical Academic Careers Panel and other key stakeholders is being organised for May/June 2007.

The Board noted that the Association of Medical Research Charities (AMRC) and the UKCRC are jointly organising an event in March 2007. This will give AMRC members an opportunity to learn more about the changing clinical research environment and to consider how they can best work in partnership with the new academic clinical pathways that are being developed.

The Board accepted the offer of a paper at the next Board meeting, on the approach that is being taken in Scotland to developing the clinical research workforce.

5b) Nurses in clinical research

The Board was informed that the report has been redrafted and is currently being shared with key stakeholders prior to final circulation to the UKCRC Sub Committee for Nurses in Clinical Research. It is expected that the public consultation period will commence in January 2007. The report will be circulated to all members of the Board once it has been signed off by the Sub Committee.

6) **Regulatory and Governance – Update Paper**  UKCRC/06/36

The UKCRC Board noted the update on work to streamline the regulatory and governance environment and agreed that good progress was being made in this Activity and in particular noted that:

- The revised version of the model agreement for contract pharmaceutical research (mCTA) has now been published

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

7a) **UKCRN – Update Paper**  UKCRC/06/37

The UKCRN update paper was presented to the Board and four areas were highlighted for attention:
• Communication – Progress on establishment of the Networks has been impressive and rapid, but this will need to be backed up by a coordinated communications strategy. Communicating about the Networks will be led by the UKCRN Coordinating Centre, but it is important that any communication is integrated with the UKCRC’s overall communications strategy. The Board highlighted that many decisions on the placement of industry trials are made outside the UK. The communications strategy should include a high profile marketing campaign to industry outside the UK.

• A UK-wide infrastructure – The Board noted the increasing effort going into ensuring the close working of the different elements of the UKCRN across the UK. For example, the UKCRN Coordinating Centre is currently mapping out a matrix of the areas where it will lead and those areas which are specific to each of the four nations across the UK. The four UK Health Departments also stressed the importance of presenting the UKCRN as a UK-wide infrastructure rather than four separates sets of infrastructure.

• Comprehensive infrastructure England – The Board noted that the move to a comprehensive infrastructure in England will be carefully managed to minimise any potentially destabilising effects of the transition of funding. Communication will be particularly important during this process.

• Industry’s needs – The Board were reminded that industry has some very clear issues that the networks will be addressing, including information requirements, R&D approvals and transparent costings. The Board were updated that 56 industry studies are currently under discussion with the Networks, 17 contract studies have already been adopted and two studies would not have come to the UK without the presence of the Networks. The Board were assured that the existing Networks have a strong history of working with industry and there is no difference in the willingness of the new Networks to engage with industry, they will just need to move at different speeds reflecting their different levels of maturity. A new group has been established to ensure consistency of processes across the TCRNs and the Industry Roadmap Group will continue to monitor progress.

In discussion the Board requested that some specific information be reported at future meetings on numbers and types of new and existing trials being delivered by the Networks. They Board also welcomed that a detailed presentation on implementation on the Comprehensive Research Network will be given at a future meeting.

The Board were also updated on the valuable discussions at the Research Funders Liaison Group meeting. In particular the issue of developing a sustainable approach to enabling academic leadership and portfolio development was discussed. The pros and cons of the Clinical Studies Group model were currently being examined.

7b) Experimental Medicine - Update Paper

The Board were updated on progress with the initiative, as follows:

• Work is now under way at the UKCRN CC to develop a database of experimental medicine activities. The project is to be supervised by William Rosenberg (UKCRN Director of Experimental Medicine) and will be overseen by a core group of funders.

• Several funders have made an “in principle” commitment to support the networking of Experimental Medicine facilities, if the right model can be developed. A redrafted proposal for this work would be circulated to funders soon.
7c) Connecting for Health - Update Paper

The Board was updated on the progress of the three parallel research engagement activities with Connecting for Health in England:

- Care Records Development Board’s Secondary Uses working group
- UKCRC/Connecting for Health simulations
- Exploration of a Public Private Partnership

The Board heard of action taken to increase cross representation between the UKCRC R&D Advisory Group and the Care Records Development Board’s Secondary Uses Working Group and received an update on the November 2006 joint meeting.

The Board received a letter from Harry Cayton in which he briefly outlined plans to take forward the development of the National Information Governance Board (NIGB). The Secretariat undertook to invite Harry Cayton to attend the next Board and update on the developments of the NIGB and wider DH information governance activity.

The Secretariat was asked to consider the potential of the simulation activity informing wider policy questions including NICE guidance.

Although the Board noted the positive engagement from CfH with the research simulations they were unclear that CfH engagement on the wider Care Records Service issues had been successful. They expressed concerns about the implications this could have for secondary uses of healthcare data.

It was hoped that any Comprehensive Spending Review/ Public Private Partnership bid could explore opportunities for developing links across National IT systems to support research and suggested that OSCHR might play a useful facilitatory role in such discussions.

8) Research Coordination - Update Paper

8a) UK Health Research Analysis

The Board heard a report of progress in this area:

- Good progress had been made in partnership with the AMRC on the project to analyse the research portfolios of other charities. Several training workshops on the classification system had taken place and charities were returning data for analysis.
- A meeting at the ABPI had taken place to consider an analysis of Industry research data. There had been positive reactions from GSK, Pfizer and Astra Zeneca. Further discussions on the analysis proposal are to take place.

8b) Public Health

It was reported that the Public Health Research Strategic Planning Group had finalised plans for proposed ‘centres of excellence’. An “in principle” commitment of £20m joint funding over 5 years had been made by eight partner organisations. An open meeting had been arranged for January 2007 to explain the process to the research community.
The Board noted the importance of academic capacity building in this field and heard that ‘centres of excellence’ had been chosen as a model for action partly because a significant element of capacity building will be supported. In this context it was also noted that public health specialists had done well in the recent UKCRC Academic Clinical Fellowships calls.

8c) **Microbiology and Infectious Diseases**

It was reported that work was continuing at the Microbiology and Infectious Diseases Research Strategic Planning Group.

9) **NHS Incentives - Update Paper** UKCRC/06/41

The Board noted the letter from Mike Burrows recommending that the Incentives Subgroup be put on ice and that provision would be made for continuing work in two areas:

- The Healthcare Commission Standards
- UK-wide work to promote the benefits of research to the NHS

The Secretariat agreed to report back to the Board on the outcome of further discussions with the Healthcare Commission and to revise the UKCRC Workplan to recognise work required to take forward a UK-wide incentives agenda.

10) **Public Awareness and Patient and Public Involvement** UKCRC/06/42

The Board was briefly updated on the status of current projects.

Public Awareness:

- The booklet for members of the public, *Understanding Clinical Trials*, has been produced
- The leaflet, *Clinical trials: What they are and what they are not*, will shortly be completed and both publications will be launched together early in 2007
- The Board noted that both the booklet and the leaflet have been developed with input from the Industry contacts and other Partner organisations and that this project spans across the areas of public awareness and public involvement
- A project is underway to develop a web based resource that will signpost teachers and students to educational resources on clinical research. This project may also lead to the development of new educational resources if the scoping study of what is currently available identifies significant gaps in provision.

There are currently 4 patient and public involvement projects underway of which 2 were described in more detail:

- INVOLVE is leading on the development of *People in Research*, a UKCRC web based project that aims to help members of the public make contact with
organisations that want to actively involve people in clinical research. The pilot site is due to go live in January 2007 with a public launch planned for April 2007.

- The AMRC is leading on a project which focuses on the question – how can research funders effectively judge the quality of patient and public involvement in research proposals? An application for an award has been made to the Wellcome Trust, the outcome of which will shortly be known.

The Board’s attention was also drawn to the fact that the Public Awareness Task and Delivery Group will shortly be considering how it can significantly raise the profile and range of work that it undertakes in 2007/08.

11) **Update on Performance Measures / Metrics**  

The Board was reminded that following the RAND study the agreed approach was to avoid duplication of effort by identifying performance measures and metrics that were collected by the UKCRC Partners and to bring these together annually. It was recognised that in some areas metrics already existed and these could serve to provide a ‘baseline’ whereas in other areas measures were under development and ‘baseline’ data was not available. In particular new metrics were being developed to assess the performance of the new clinical and experimental medicine infrastructure. It was agreed that work would continue to collate these metrics as developments continued and that available existing baseline measures would be presented at the next Board meeting.

**Other**

12) **NCRI Report -Draft Report from the NCRI Strategic Planning**  

The Board noted the aims of the report and advised the following be highlighted in comments to NCRI:

- There had been insufficient engagement with NHS opinion in preparing the report, bearing in mind the reliance on NHS facilities. The NCRI should explore ways of getting more input.
- Some consideration will need to be given to the potential use of PET for diseases other than cancer.
- The report will need to map the current facilities (in HEI’s, NHS and the Private sector).
- There is extensive experience of PET in the United States, the report will benefit from building on this available information.
- The recommendations from the report need to be extracted into the Executive Summary.
- There was a need to emphasise the workforce challenge.

13) **Any Other Business**

No issues were raised.
Next meeting: 14.00 –17.00 14 March 2007, UKCRC, Himsworth and Fletcher Rooms, 20 Park Crescent, London, W1B 1AL