Minutes of the meeting held on Tuesday 6 June 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 Colin Blakemore – Medical Research Council (MRC)
Professor Sir Alasdair Breckenridge – Medicines and Healthcare Products Regulatory Agency (MHRA)
Aisling Burnand – Biologics Association (BIA)
Professor Alex Markham – Cancer Research UK (CRUK)
John Neilson – 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
Dame Bridget Ogilvie – Association of Medical Research Charities (AMRC)
Nick Partridge – INVOLVE
Peter Littlejohns – National Institute for Health and Clinical Excellence (NICE)
Dr Adrian Pollitt – 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
Sohaila Rastan – The Wellcome Trust
Professor John Williams – Welsh Assembly Government
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)
Marc Taylor – Department of Health (DH)
Louise Wood – Department of Health (DH)
Dr Helen Campbell – Department of Health (DH)
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)
Catherine Johns – Department of Health R&D (DH)
Sarah Fox – Department of Health R&D (DH)
Announcements and Apologies

Apologies
Professor Carol Black – Academy of Medical Royal Colleges (AOMRC)
Paul Hubbard – UK Higher Education Funding Councils
Allan Baxter – Senior R&D Representative from the Pharmaceutical Industry

Announcements
The Chair welcomed everybody to the eighth meeting of the UKCRC Board.

Attending the UKCRC Board for the first time was Dr Adrian Pollitt who will attend this and the next meeting in September as a temporary representative of the SHAs while a new Board Member is appointed to replace Neil Goodwin.

Also attending the Board for the first time as Observers were Catherine Johns as the DH lead for Networks and Sarah Fox, who has been newly appointed to Department of Health R&D England.

Ngozi Okwudili-Ince a new Programme Manager to work on Clinical Research Information Systems was also welcomed to the Board.

The Chair also took this opportunity to thank Neil Goodwin for his input into the UKCRC both as a Board Member and as the Chair of the NHS Incentives Group run by the UKCRC Secretariat.

1) Minutes

The minutes were accepted as a correct record of the meeting held on 9 March 2006.

Matters Arising

WHO Trial Registration Platform
As a member of the Scientific Advisory Group to the WHO’s International Clinical Trial Registration Platform, Marc Taylor updated the Board on the WHO initiative.

WHO’s recent announcement of a standard set of 20 items to be disclosed on registration had led to supportive editorials in The Lancet and the BMJ. The UKCRC Partners have previously expressed their support for trial registration in general. However, current approach being adopted by WHO raised some areas of concern.

The definition of a trial has been widened to capture any trial of a health intervention, whether or not it has a control group. However, the WHO team have so far engaged
mainly with stakeholders in trials of medicines for licensing. This much wider
definition will call for more work to test the standard with other constituencies.

The WHO have also decided to insist on disclosure of the full set of 20 items at
registration for all trials including early phase trials. The Pharma Industry are
concerned at the commercial impact of premature disclosure. Academics would also
like to be reassured WHO is not applying inappropriate standards.

The question for the UKCRC is how to show visible support for the principle of this
valuable initiative while at the same time warning WHO that further work is needed if
the UKCRC partners are to adopt the solutions WHO propose.

ABPI reminded the Board that the international pharmaceutical industry associations
had announced in 2005 that member companies would register all Clinical Trials
designed to look at therapeutic benefits, essentially Phase 2 Trials onwards. ABPI
does not see the advantage of registering trials earlier than this as many drug
candidates do not go beyond the proof of concept stage and premature disclosure
raises issues around commercial sensitivity, patients and intellectual property. The
industry had made a commitment to register any early phase trials that exposed
safety concerns.

The MHRA strongly supported confidential early registration of Clinical Trials which
already exists. Reference was made to an article in the New England Journal by
Janet Darbyshire. However the WHO's insistence on public registration of all 20
items before any trial begins could be more problematic. Concern arises if
commercially sensitive information is made public too soon.

It was also noted that ClinicalTrials.gov could not accept the criteria the WHO had
developed for recognising trial registers. In addition, WHO had issued an invitation to
tender for a searchable portal of recognised registers with technical standards which
exclude the approach used by the operators of the DH and MRC trial registers.

It was noted that the USA and Japan had already written to WHO on these issues. It
was agreed that more discussion outside the UKCRC Board was required and that
the UKCRC Secretariat would draft and circulate a letter to WHO stating its support
and concerns for the initiative.

Action:
• The UKCRC Secretariat would draft a letter to WHO stating its support and
  concerns for the initiative.

Scotland - Wyeth Initiative
Dr Spaull updated the Board on the recently announced partnership between NHS
Scotland, Scottish Enterprise, a consortium of Scottish universities and Wyeth
Pharmaceuticals. Overall this will provide a £50 million funding package for medical
research in Scotland. Wyeth Pharmaceuticals plans to invest an estimated £33
million over the next 5 years with Scottish Enterprise investing up to £17.5 million.

The Board agree that this initiative was a very good example of the public and private
sectors working in partnership and noted that the learning will be shared between the
Health Departments.
UKCRC General

2) Chief Executive’s Report

Communication
Members noted the range of communication activities carried out by the Secretariat. A copy of the third UKCRC Newsletter has been circulated to the wider research community and the Chief Executive is also in the process of meeting with all Board members to discuss progress. As the results of key pieces of work become clearer, the Secretariat will publish a series of summaries on the UKCRC website aimed at “bringing all the pieces together”.

UKCRC Two Year Progress Report
It was agreed that it was timely for the UKCRC Secretariat to produce a two year progress report, documenting progress made by UKCRC Partners over the two years since UKCRC became operational, October 2004 – 2006. The aim will be to publish the report in November 2006.

The Progress Report will provide an overview of the UKCRC and provide detailed information on each of its different activities including the main achievements and future plans. The UKCRC Secretariat will coordinate contributions and input from external activity leads where appropriate.

New Posts
The UKCRC Secretariat has now successfully recruited two new Programme Managers. Ngozi Okwudili-Ince joined the UKCRC on 5 June 2006 and will work in the area of Clinical Research Information Systems and Philippa Yeeles will be joining the UKCRC on 3 July 2006 focusing on Public and Patient Involvement.

Budget Committee
As previously agreed by the UKCRC Board, the Secretariat provided a report to the UKCRC Budget Committee in advance of the Board meeting. As the Chair of the Budget Committee, Nick Partridge, reported to the Board on the final expenditure for the financial year 2005/2006 and the consequent carry over that would be available for 2006/2007. Changes affecting the 2006/2007 projected budget that have come to light since the March 2006 UKCRC Board and the consequent use for the carry over were also reported on, and the approval of the Board was requested and granted.

Action:
• UKCRC Secretariat to produce a Two Year Progress Report.

Activities

3) National IT Programmes (Connecting for Health)

The UKCRC Board noted that the UKCRC R&D Advisory Group to Connecting for Health, chaired by Professor Ian Diamond, would have its first meeting at the end of July. The immediate task would be to test the potential for conducting research of the emerging architecture through a series of pilots. The Board agreed that the Group would benefit from the addition of someone who could put CfH in the context of NHS service needs.
The Board noted that the UKCRC Group will be working in parallel with the Care Record Development Board (CRDB) Secondary Uses Working Group, which is chaired by Professor Sir Robert Boyd and which is tasked with looking at governance issues and responding to the recent Better Regulation Executive Report.

The Board noted that this agenda was also moving forward in Wales where colleagues were working to ensure appropriate integration with Connecting for Health.

4) Regulatory and Governance

4a) Regulatory and Governance - Update Paper UKCRC/06/14

The UKCRC Board noted that a great deal of progress has been made in this area, they noted in particular that:

- The first meeting of the UKCRC Working Group, chaired by Professor Sir John Lilleyman, aimed at streamlining information requirements for permissions, approvals and reporting has taken place. The Working Group, which brings together the organisations involved in streamlining the environment, agreed on a phased approach to their work starting with the aligning of ethics and NHS R&D information needs. The UKCRC Board noted that the first meeting of the Working Group had been very constructive and that there is a high degree of buy-in from the major stakeholders to this programme of work.

- Agreement has been reached between the UKCRC and the Biosciences Futures Forum on a combined strategy for the early identification of and engagement with European regulatory developments. The "European Biosciences Intelligence Coalition" will provide a forum for bringing together and analysing a variety of different sources of information. A meeting to discuss the resourcing and implementation of the strategy is taking place within the next week. The UKCRC Board agreed that this was an important programme of work and that every effort should be made to take into account the full range of available intelligence resources, including those developed through the NHS Confederation.

- The UKCRC has played a key role in encouraging and facilitating coordination of activities in the area of the use of personal data in health research. Specifically the UKCRC Secretariat has developed a document that brings together and summarises all relevant activities of UKCRC Partners and stakeholders. This document is intended to be a "living document" that will be kept up to date and regularly disseminated. In addition a small group of officers have been brought together in a "coordination group" that is tasked with identifying additional activities, overlap of work and opportunities for additional actions. The UKCRC Board agreed that the present version of the update paper had already been very useful and that it highlights the communication gap between some communities. The Board emphasised the need for the UKCRC to actively work on this issue.

- The work on the model contracts and agreements has been steadily progressing. The revised version of the model agreement for contract pharmaceutical research (mCTA) has had sign off from the NHS Confederation, BIA, ABPI and Monitor. Northern Ireland, Scotland and Wales are working on their versions of the document. The accompanying guidance currently under preparation will provide the opportunity to resolve outstanding issues. The UKCRC Board agreed to work together to draft a statement endorsing the use of the mCTA and noted that once
it had been launched it would be followed by work on a tripartite agreement for pharmaceutical trials and a model agreement for medical device studies. The Board also noted that the model agreement for non-commercial research in the NHS, which has been developed by the UKCRC, the Association of UK University Hospitals and the Council of Heads of Medical Schools as well as going through two rounds of public consultation, is now with lawyers for review.

- The honorary contract research passport is on course to achieve national roll-out in April 2007. NHS Employers are currently looking at it with respect to checks made for different types of research and six month pilots of the passport are due to commence in July in four centres in England as well as in Wales and Scotland.

Action:
- The UKCRC Board agreed to draft a statement endorsing the use of the mCTA and noted it would be followed by work on a tripartite agreement for pharmaceutical trials and a model agreement for medical device studies.

5) Building up the Infrastructure in the NHS

5a) UKCRN – Update Paper UKCRC/06/15

The Board were updated on progress in implementing the UKCRN including the six Topic Specific Clinical Research Networks, the Primary Care Network for England and plans for a comprehensive research network for England. The Board were also updated on the development of clinical research networks in Northern Ireland, Scotland and Wales. The papers included a progress report and feedback from the UKCRC Board Subgroup for the UKCRN.

The Board discussed and approved the proposed criteria for inclusion of clinical research studies in the UKCRN portfolio. The Board were also asked to discuss the considerations around performance measures for the UKCRN and then feed back any comments to the UKCRC Chief Executive. The Board noted that positive feedback had been received from industry on the performance measures. The Chair highlighted that it would be useful to have an update at each Board Meeting on how many industry funded studies were running in the networks.

Action:
- An update to be provided at Board Meetings on how many industry funded studies are running in the networks.

5b) Research Funders Group Liaison Group Update Oral

At the December Board meeting the Board endorsed an approach to establish Research Funders Liaison Group meetings to develop an interface between funders and those leading the different elements of the UKCRN. The UKCRC Chief Executive updated the Board on the outcomes of the first meeting of the Research Funders Liaison Group and highlighted a number of issues:

- The funders had agreed to work together to map, manage and augment, where appropriate, the national Clinical Trials Unit (CTU) capacity. The UKCRN would take forward much of this work on behalf of the UKCRC with oversight from those organisations that fund the CTUs. The concept of CTU accreditation had been
dropped following discussion at the UKCRC Board, but part of this work would include developing a registration process for CTUs with the aim of raising standards in existing units.

- The UKCRN will carry out, on behalf of UKCRC, a modelling exercise to provide information on the number of trials likely to be developed, costs of different types of trials and the components of those costs (staff, running costs, source of funding).
- A flow chart will be developed for the UKCRN website targeted at a range of different stakeholders (PIs, funders etc) aimed at increasing understanding of the uses and benefits of the emerging network infrastructure.

The Board noted that the Research Funders Liaison Group had had some discussion about the role of Clinical Studies Groups (CSGs) and had agreed to work more closely with the TCRNs in order to ensure that the CSGs developed and were managed in a transparent, sustainable and strategic fashion.

5c) **Experimental Medicine**

The Board were updated on the progress of the three calls:

- The MRC call for projects and programmes is now completed
- The Cancer Research UK call for experimental cancer medicine centres is now completed and 5 new centres have been funded adding to the existing 14
- The Wellcome Trust led call for clinical research facilities will be completed shortly.

There was consensus amongst key stakeholders on the need to facilitate networking between the clinical research facilities and between the CRFs and UKCRN. These discussions had been informed by recent meetings on experimental medicine, organised by the Academy of Medical Sciences and the Association of British Pharmaceutical Industries.

Once completed the calls will be followed by a “sweep up” meeting where the funders would look at the new landscape and identify any necessary further actions.

The Board were reminded that the issue of VAT for clinical research facilities with the increased involvement with industry is still outstanding.

The Board welcomed the update and agreed that this initiative in experimental medicine was a very good example of the added value of partnership working under the UKCRC umbrella.

6 **Research Coordination**

6a) **UK Health Research Analysis**

Dr O’Toole reported that the publication of the UK Health Research Analysis had taken place on 24 May 2006 accompanied by a carefully managed publicity strategy. It was noted that over 18,000 PDF copies of the report had been downloaded from the UKCRC website in the 10 days since the launch.

Board members noted the report and the following issues were raised in discussion:
Dr Tiner reported that ABPI members had been informed of the report’s publication. ABPI, BIA and ABHI were actively exploring the feasibility of complementary analyses. Members noted that further detailed analyses of the data underlying the report were possible, for example within specific disease areas. Members noted that a future update to the analysis was not planned at this stage. However Dr O’Toole reported that several Partners were adopting the classification system within their existing administrative processes which would make future analysis exercises easier. The Board agreed that it would be desirable to promote similar analyses abroad for purposes of comparison - in order to inform the strategy and cost effectiveness debates and to advertise the UK/NHS as a unique health research resource. Board Members noted that the analysis indicated that funding in the area of Prevention research was lower than other areas. Members noted that at this stage no concerted actions were planned as a direct result of the analysis however the detailed analysis of the database was already informing the discussions and future plans of individual Partners and the work of the UKCRC Strategic Planning Groups.

Board Members expressed congratulations to Dr Valentine and the UKCRC Secretariat on the work that had gone into the analysis and its publication.

(a) Public Health

Professor Ian Diamond gave the Board an update on the work of the Public Health Research Strategic Planning Group.

Professor Diamond reported that, following the consultation exercises, consensus had been reached on two major actions:

- Exploitation of existing datasets; A call for proposals for secondary data analysis in this area would be launched shortly through the National Prevention Research Initiative
- Commissioning of major multi-disciplinary investments to improve infrastructure and capacity; Professor Diamond indicated that discussions were ongoing in this area involving major partners and action could be expected in the autumn.

Board members expressed support for the initiatives and agreed it was important that any action taken should facilitate multi-disciplinary working rather than isolating public health research practitioners from existing expertise based in universities and medical schools.

6c) Microbiology and Infectious Diseases

Dr O’Toole reported that the Microbiology and Infectious Diseases Research Strategic Planning Group had held its second meeting under the chairmanship of Sir John Lilleyman.

The Board noted that the results of a stakeholder consultation had been reviewed by the Group and several major issues were emerging. Potential solutions would be considered at the next meeting in October.
7) **Incentives**

The Board noted that work in this area was cross-cutting all UKCRC activities and that progress was being made against all the recommendations contained in the Research for Patient Benefit Working Party Report. The UKCRC response statement to the Healthcare Commission’s consultation was highlighted.

8) **Workforce**

8a) **Workforce and Careers - Update Paper**

The Board noted the progress in the drafting of the Nursing Report and agreed on the importance of an appropriate and comprehensive consultation of the report.

8b) **Academic Clinical Fellowships – recommendations for funding**

8c) **Clinical Lectureships – recommendations for funding**

The Board noted the recommendations of the Clinical Academic Careers Panel (CACP) from the national competitions for training programmes to support the Academic Clinical Fellowship and Clinical Lectureship phases for the Integrated Academic Training Programme. Members noted that there were some areas were few training programmes had been awarded such as clinical pharmacology and oncology. The importance of taking a strategic approach to funding new training programmes in the second phase was emphasised. The Board agreed that Professor Leszek Borysiewicz, Chair of the Clinical Academic Careers Panel should be invited to the next UKCRC Board meeting to discuss with members the approach to the next round of calls.

**Action:**
- Professor Leszek Borysiewicz, Chair of the Clinical Academic Careers Panel should be invited to the next UKCRC Board meeting

9) **Public Awareness and Patient and Public Involvement Activity**

**Public Awareness**

The Board were provided with feedback on public awareness activities and from the recent Task & Delivery group meeting. The Board noted that two main areas of work are currently underway:

- The development of a suite of generic information materials about clinical trials / research
- The development of an approach to highlighting currently available educational resources on clinical research and exploring the feasibility of creating educational packages on clinical trials / research.
**Patient and Public Involvement**

The Board noted progress in joint working on patient and public involvement and welcomed the fact that the recent project group meeting was so productive. Four main strands of work are being taken forward by the group:

- Building an evidence base for the value of patient and public involvement in research
- Development of a web based portal/exchange to bring together patients seeking to be involved in the clinical research process and those organisations with opportunities for patient and public involvement
- Development of criteria for funders to judge proposals for patient and public involvement in new funding applications
- Embedding of patient and public involvement in the job descriptions for the new NIHR Faculty

Colin Blakemore also updated the Board on the MRC’s plans to develop a ‘college’ of members of the public who want to be involved in research. Once this is established the MRC would be very willing to share this with other partners.

10) **NICE Update**  Presentation

Professor Peter Littlejohns gave a presentation to the Board describing the role of NICE and its research priorities.

During the presentation Professor Littlejohns emphasised the following points:

- NICE’s immediate work programme is driven by the Government, although its wider role is to establish broad NHS strategic research priorities
- NICE is a user of research and it also commissions’ research reviews. It also believes that its recommendations should be a wider driver of future research
- NICE now incorporates the Health Development Agency and hence has a major role in public health, the prevention of disease and promotion of good health
- NICE has extensive patient and public involvement at all levels, including a Citizens Council
- A NICE priority is to identify cost effective and ineffective treatments based on sometimes imperfect sources of research evidence
- NICE is keen to work with funding agencies and the UKCRC to facilitate the uptake of its research recommendations and to inform wider research priority agendas.

The following issues were raised in the ensuing discussion:

- Board Members noted that the newly established UKCRN offered an opportunity to conduct directed research quickly in order to answer questions of importance to the Health service.
- Board Members further proposed that clinical studies groups could play a role turning research questions into viable experimental designs. In addition members noted that there was a role for input from wider relevant health data sources such as Connecting for Health, patient registries and the General Practise Research Database.
• Nick Partridge highlighted the integrated patient and public involvement work within NICE’s operations as a benchmark of good practice.

The Board welcomed the presentation.

Any Other Business

There were no items for Any Other Business.

Dates of Next Meetings

Tuesday 19 September 2006  14.00 – 17.00  
Tuesday 12 December 2006  14.00 – 17.00  
Wednesday 14 March 2007  14.00 – 17.00  
Thursday 7 June 2007  14.00 – 17.00  
Thursday 20 September 2007  14.00 – 17.00  
Thursday 6 December 2007  14.00 – 17.00  

To be held at The Himsworth and Fletcher Rooms, UKCRC, 20 Park Crescent, London, W1B 1AL.