Minutes of the meeting held on 28 May 2014, Rooms 1&2, 13th Floor, MRC, One Kemble Street, London WC2B 4TS

Present

Members

Professor Dame Sally Davies – Department of Health, England (Chair)
Sir John Savill – Medical Research Council (Chair, items 6-7 only)
Dr Bina Rawal – The Association of the British Pharmaceutical Industry (ABPI)
Dr Helen Bodmer – Department for Business, Innovation and Skills (BIS)
Sharmila Nebhrajani - Association of Medical Research Charities (AMRC)
Simon Denegri – INVOLVE
Professor Peter Johnson – Cancer Research UK (CRUK)
Nicola Perrin – Wellcome Trust
Mike Stevens – Scottish Government Health Directorates
Dr Janice Bailie – Health & Social Care R&D, Northern Ireland
Steve Bates – BiIndustry Association (BIA)
Professor Jon Bisson – National Institute for Social Care and Health Research, Welsh Assembly Government (NISCHR)
John Hughes - Patient/Public Member
Sir Nick Partridge – Independent (Deputy Chair)
Dr Naho Yamazaki – Academy of Medical Sciences (AMS)
Professor David Haslam – National Clinical Institute for Health and Care Excellence (NICE)
Sir Gordon Duff - Medicines and Healthcare products Regulatory Agency (MHRA)
Dr Steven Hill – Higher Education Funding Councils (HEFC)
Professor Iain Cameron – Universities Representative
Joy Todd – Economic and Social Research Council (ESRC)
Dr Janet Wisely – Health Research Authority (HRA)
Dr Archie Prentice – Academy of Medical Royal Colleges (AoMRC)
Katie Petty-Saphon - The Association of University Hospitals UK (AUKUH)
Dr Russell Hamilton – Department of Health, England (DH)

In attendance

Tim Kelsey – NHS England
Dr Louise Wood - Department of Health, England (DH)
Peter Knight – Department of Health, England (DH)
Sarah Qureshi – Partnership Manager, UKCRC

Observers

Dr Helen Campbell – Department of Health, England (DH)
Jon Fistein – Medical Research Council (MRC)
Apologies and Announcements

Apologies
• Ron Kerr - NHS Confederation
• Dr Tim Cave – Senior Representative from the Pharmaceutical Industry
• Miles Ayling – NHS England

Announcements

The Board noted that:

• Andrew Russell, PPI member had departed from the Board. The Board thanked him for his valuable contribution. The Board agreed that his replacement should be advertised via open competition.

1. Minutes of the twenty-seventh UKCRC Board Meeting UKCRC/14/01

The Board approved the minutes of the last meeting.

2. Matters arising Oral

The Board was informed that the remaining budget of the Public Awareness sub-group (£3,457) has been donated to the AMRC in a workstream that supports patient data in line with the sub-groups objectives.

All other matters arising were covered in the agenda.

Discussion

3. care.data Oral

The Chair introduced Tim Kelsey as the National Director for Patients and Information at NHS England and Senior Responsible Owner of the care.data programme. Tim presented to the Board the current situation and future progress with the programme. He reminded the Board that care.data was a simple concept in which secondary users of data are able to access all NHS Activity across primary and secondary care. The objectives of the programme are:

1. To provide a safe resource.
2. The transformation of planning of NHS Services focussing on patient prioritisation.
3. The growth of the life sciences sector and research in general.

There was little dispute about the potential benefits of care.data, however its initial roll-out had proved controversial and for a combination of reasons ‘a pause’ had been announced. Aside from the poor communication about the programme, debate had focused on three main aspects:

1. The absence of adequate safe guards i.e. to prevent breaches of confidentiality.
2. The poor quality of the information being provided to the public
3. The opt-out clause; what it meant in practice and whether it was the right approach.

Tim underlined the fact that the care.data Programme Board was now listening to concerns in considerable detail via national and local events. A care.data advisory group formed of
critics and supporters had also been established to give an objective view on each element of the programme from now on. Immediate priorities included:

- Clarification around the opt-out clause, what patients would be opting out of and the consequences for them.
- The legislative measures being introduced via the Care Bill.
- Managing a phased roll-out focusing on 2/3 regional clusters each consisting of 100-500 GP practices followed by a period of evaluation including independent scrutiny by Dame Fiona Caldicott and the Chief Medical Officer, Dame Sally Davies.
- The relationship with the Clinical Practice Research Datalink (CPRD).

The Board was reminded that as a data resource NHS patient data is unparalleled.

In discussion the following was raised:

- A huge amount of money has already been invested in data sharing initiatives (approximately quarter of a billion pounds) by UKCRC Partners.
- The EU Data Protection Regulation is potentially of greater threat to the use of data for research purposes than anything else.
- It was both crucial and critical to ensure that care.data had the right relationships in place with other databases such as CPRD, which allows safe access for Research.
- The Professional Records Standards Body and the National Laboratory Medicine Catalogue were examples of organisations that had established good models for an underpinning framework that care.data might replicate.
- The governance of care.data needs further consideration. It would be worthwhile examining the approach taken by other nations: Wales had adopted a system of co-production; Scotland had taken a non-statutory route based on the concept of a library that does not include a patient opt-out mechanism and Northern Ireland has developed an honest brokers service backed by a memorandum of understanding.
- The overall percentage of opt-outs following the initial introduction was very low. However, higher rates existed at certain practices particular where campaigns had been led by GPs.
- Regular reports on the progress of the roll out of the pilot would demonstrate transparency and encourage confidence.
- The role of doctors was critical in the process. GPs should be viewed as ambassadors in the process.
- There are existing safe havens within Cancer via registers. These contain extractable high quality data. Should not this be the controlled process for delivering accredited safe havens?
- The Use of Personal Health Information in Medical Research (MRC, 2007) study demonstrated that patients and public have confidence in their personal health data retained by GPs and the NHS (87%) but not with medical researchers (11%).
- The Public Attitudes to Research Governance study (Wellcome Trust, 2007) indicated that patients would always wish consent to be sought if the information is identifiable.
- If the programme is continued to be pursued with too much zeal and haste, public and patient confidence will be undermined further. The setting of artificial deadlines would therefore not be beneficial.
- In terms of additional governance there is no scope to extend the remit of regional Research Ethics Committees to include this work or to increase the role of the HRA Confidentiality Advisory Group to cover this area.
- An ‘opt-out’ would increase health ‘inequalities’ particularly for those with mental illhealth.

In addition, it was explained that Genomic’s England’s data service can be viewed in a similar vein to the British Library where Genomic’s England is the library, the disease specific domains the various departments within the library and the data service the
precious books and artefacts and the information contained within these. Users such as the Genomic’s England research partners have to have their application to access various relevant books and artefacts approved and only then is controlled access authorised. No raw data will be allowed to be taken away from Genomic’s England’s data service.

The Board concluded that the benefits are so great that the need to get this right is paramount. There is a great deal of support from Partners to make this happen as well as relevant experience and expertise. In the past public opinion has consistently failed to be read accurately and now we must listen and act appropriately and move through evolution rather than revolution.

The Board requested that progress in this area be reported at future meetings.

**General**

4. **Spending Review Update**

Helen Bodmer reported that the allocations from the spending review for 2015-2016 had been published and the ring fence has been maintained; in support of the government’s commitment to science and innovation strategy. This includes an allocation to the Academy of Medical Sciences from the Science and Research budget for the first time. Russell Hamilton clarified that the overall increase for DH had been agreed, however the proportion for R&D had not been finalised.

Helen Bodmer also informed the Board that the Government has made a long-term commitment to invest in science and research infrastructure: increasing capital investment in real terms to £1.1 billion in 2015-16 and growing it in line with inflation each year to 2020-21. A Consultation on Proposals for Long-Term Capital Investment in Science & Research has been launched which seeks views on how the UK makes the most of this opportunity. This consultation is currently open and closes on the 4th July. This will form part of the Science and Innovation Strategy to be published alongside the Autumn Statement later this year.

The Board noted the position.

5. **Patient Involvement and Engagement**

Simon Denegri reported that the NIHR was conducting a strategic review of public involvement in research with the aim of developing a vision and key objectives for the next 5-10 years. Opinion is being canvassed currently and is being supported and funded by the NIHR. Evidence will be gathered until the end of June based on three main questions outlined in the paper. Partners were urged to respond directly. The review report and recommendations would be published in the autumn ahead of the INVOLVE conference on 26/27th November 2014.

He also reported that on International Clinical Trials Day (ICTD) on the 20th May the NIHR published their strategic plan for promoting engagement and participation in research through the NHS entitled ‘promoting a research active nation’.

The Board noted that the best way forward was in forming Partnerships in this and many other related areas.
6. **HRA Assessment and Approval for Research in the NHS**

Janet Wisely presented that the HRA Approval system for research in the NHS was now being introduced. There would be a phased roll out with no pilot sites. It was recognised from scoping work that the IRAS required change to create a single IRAS application form (rather than the current separate ethics and R&D forms generated on IRAS). The programme was a roll out of the new and support to manage and tackle change in the NHS. Specialist components such as pharmacy/radiation assessment would be rolled out of the process. Early support would be provided through interim processes for studies disproportionately affected by the current systems e.g. rare diseases. The main roll out would be by study type – health service research, then clinical in primary care and all studies by end 2015. There were considerable delays in current system with contracting, HRA validation would be against accepted standards and approved modifications sponsors and applicants would be warned that further deviation from standards would result in extra cost and delay. The HRA were now in the process of recruiting staff for the new process.

During discussion it was clarified that feasibility and decision to participate was a local decision for the individual NHS Trust, but it would not need local review or ‘permission’.

The Board noted that progress continued to made in this area.

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7. **Life Sciences Strategy**

Helen Bodmer reported that several collaboration announcements had been made such as the AstraZeneca MRC UK Centre for Lead Discovery. A delivery plan entitled ‘Work to Reduce Use of Animals in Research’ was published by BIS, the Home Office and DH in February with a one year on update expected early next year.

Louise Wood reported that there had been organisational changes. Nicole Mather had been appointed to the new role of Director of the Office for Life Sciences, which was now a joint office of BIS and DH. Will Cavendish has joined DH as Director General for Innovation, Growth and Technology; this is a new post.

During discussion it was noted that the trade organisations collectively wrote a 2 year on report and commentary on the government’s life sciences strategy. Overall it was found that good progress had been made and that initiatives such as the patent box made the UK attractive for life sciences. Good indicators were that the number of companies joining the ABPI has increased along with stock market shares in this area.

The Board noted progress in this area.

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**Reports from Subgroups and Fora**

8. **Experimental Medicine Funders Group**

John Savill reported to the Board that this group last met in March. Several collaborations regarding compound sharing are taking place. The call for a UKCRC UK Centre for Coordination of Tissue Resources was launched on the 22nd May. Eight UKCRC Partners provided the one million pounds of funding required and a decision on allocation is expected in August.

The Board noted progress in this area.
9. **R&G Forum**

The Board noted this paper for information.

10. **Health Research Analysis Forum**

Ian Viney reported that planning had begun for the third analysis for 2014/2015. A workshop would take place to determine the impact of the analysis so far and regarding updating of the Health Research Classification System. All resources required for this proposal would be found within the group. The main issue was of outsourcing the coding required, capacity for which may already exist within the group.

During the discussion the following was raised:
- The adding of sub-categories to the Health Research Classification System (HRCS) would be beneficial, but they should map back the original categories for longitudinal studies.
- The timing of the third analysis would be beneficial to the next Comprehensive Spending Review.
- The Forum is to compile the data and ensure that it is openly assessable for others to analyse.

The Board agreed the proposal.

**Collaboration**

11. **EU Data Protection Regulation**

Nicola Perrin reported that a block vote had taken place in the European Parliament and all the amendments had been accepted, including those of serious concern to the research community. The recent elections had not affected the regulation moving ahead and the Council was currently considering its position. The Commission was generally supportive of the research sector position. The Ministry of Justice continues to lead for the UK government in this area. Further developments are expected in the autumn.

The Board noted progress in this area.

12. **Office for Strategic Co-ordination of Health Research**

John Savill reported that OSCHR last met in February. Their discussions centred on molecular pathology and stratified medicine, with the development of MRC competition hubs in molecular pathology; and the Ministerial Industry Strategy Group. Anti-Microbial Resistance will be discussed further at their next meeting in June.

During discussion it was raised that a national service model for pathology and engagement with Genomics England was required.

The Board noted progress in this area.
13. **EU Clinical Trials Regulation**  

Gordon Duff reported that the regulation was adopted by the EU parliament in April. The process of introducing the IT infrastructure required for the single portal will now begin and should take two years. If this is not delayed the regulation would be implemented at this time. The regulation is seen to be an improvement as it introduces a risk-adapted approach as opposed to the previous directive that had a ‘one size fits all’ ethos. It also introduces a single portal, and one application for ethics and regulation, making the EU a more attractive place for clinical trials to take place. All trial summaries are required to be published within a year and the clinical study report within 30 days of the regulatory decision. Development of the single portal involves the UK and most of the UK’s requested amendments to the regulation have been included.

The Board thanked and congratulated the MHRA on a job well done. The new regulation has been introduced in super speed and has been found to be workable. All that remained was the development of the single portal operating system.

**UKCRC General**

14. **UKCRC Partnership Manager’s Report**  

Sarah Qureshi referred the Board to the position in the paper.

The Board noted the position.

15. **CTU Network Registration Process**

Sarah Qureshi informed the Board that the CTU Network had now undertaken three rounds of registration. The CTU Network now proposed that they move from a three-year cycle to a five-year cycle. It was clarified that units that lost their registration status could re-apply for provisional registration on an ad hoc basis.

The Board agreed the proposal. The Chair was thanked for the idea of the proposal.

**Activities**

16. **Promoting Research in the NHS**

Developments in Northern Ireland included:

- The second partnership call with NI HSC R&D Division and Atlantic Philanthropies for Dementia Care (2013) has received a good response with 2 million pledged over 5 years.
- The launch of a new mental health interest group within the Northern Ireland Clinical Research Network (NICRN) in January brings the total number of NICRN interest groups to 11.
- As part of joint working with the National Cancer Institute in the USA, Northern Ireland has recognised the need for further capacity building via the launch of a health economics fellowship in cancer.
- HSC R&D Division will invest an additional £750k to create two clinical research posts, as part of the recently awarded £5m Movember Centre of Excellence in Prostate Cancer Research based in Queen’s University Belfast and University of Manchester.
- The HSC R&D Division Knowledge Exchange scheme is gaining momentum, with 15 applications received for the latest call. This scheme aims to provide an interface
between research and adoption into service, policy or enterprise. Several projects from the earlier calls are now approaching successful completion.

- Dr Michael McBride, Northern Ireland CMO, launched a regional ‘Ok to ask’ public awareness campaign at Stormont on 20 May to coincide with International Clinical Trials Day. The launch was well received and events were also organised across the 5 HSC Trusts, NICRN and the NI Cancer Trials Centre & Network.

Developments in Scotland included:
- The imminent launch of the CSO research strategy.
- The revision of NHS Research Scotland (NRS) network structures now being implemented with the appointment of new Network Champions. Professor David Cameron has been appointed as the Cancer Champion.
- The development of another partnership with industry with the imminent announcement of a strategic alliance between NRS and Roche.

Developments in Wales included:
- Following the review of NISCHR’s funded infrastructure and programmes, proposals for change have now been approved and are being implemented starting with a competition for NISCHR Centres and Units that will cover the translational spectrum. The Centres and Units will replace the Biomedical Research Centre, Biomedical Research Units and Registered Research Groups resulting in a smaller number of focused entities that will be central pillars of the NISCHR infrastructure.

Developments in England included:
- Engaging patients locally via promoting the ‘Ok to ask’ campaign on international clinical trials day (20th May).
- International clinical trials day also saw the launch of ‘Promoting a research active nation’, a new programme encouraging public engagement and participation in health, social care and public health research.
- Work to promote the role of the clinical research nurse. There are 7000 in post and their role is being promoted via regional events. In addition, a Nursing Times Award has been introduced.
- New role of Medical Director of NIHR CRN CC reporting to Jonathan Sheffield, Chief Executive. This new role will act as a focal point clinical leadership across the Network.

17. **Open session of new research initiatives (Charity Partners)**  Oral

Charity Partners (AMRC, CRUK & the Wellcome Trust) were invited to given an update on research initiatives that they were involved in under this item. Among the items highlighted were:

- AMRC members increasingly collaborating to share the administrative burden of grant rounds even to extent of rare disease charities setting up restricted funds in the research funds of related charities.
- AMRC exploring venture philanthropy models with companies and financiers to try to find ways for emerging ideas to come to market quickly.
- Launch of the CRUK 5 year strategy, the aim of which is to increase the 10 year cancer survival rate to 75% from 50% in twenty years. CRUK anticipates a significant increase in research speed, with prioritisation of early diagnosis; prevention; precision medicine; therapeutic innovation, particularly in biotherapeutics, and cancers of unmet need including pancreatic, lung, oesophageal and brain tumours. New grant funding schemes will include a Programme Foundation Award for mid-career researchers; innovation awards for high risk projects; multidisciplinary awards to encourage interface research with the physical sciences, mathematics and other disciplines; immunology
awards targeted at non-cancer immunologists in order to increase critical mass in
cancer immunology; a grand challenge scheme to develop large consortia to address
leading problems, and strategic funding schemes to promote networking between
CRUK Centres.
• The Wellcome Trust has launched the second call of its Sustaining Health awards,
providing pilot funding for cross-disciplinary research connecting environment, nutrition
and health. There are two specific highlight areas: the health impacts of climate change
mitigation and adaptation measures; and how to feed 9 billion. Awards will be up to
£250k, and the deadline for concept notes is 25 July 2014.
• The Wellcome Trust’s Research for Health in Humanitarian Crises (R2HC)
programme (joint with DFID and EHLRA) has awarded grants to eight research
projects, including an examination of the effectiveness of simplified psychological
support delivered by supervised 'para-professionals' in conflict-affected areas, and a
study to validate a novel cost-effective method for pain control after earthquakes.
• The Wellcome Trust, in partnership with the MRC, published a policy and framework
on health-related findings in research in March 2014.
• The new Director of the Wellcome Trust, Jeremy Farrar, is reaching the end of a
programme of visits to many of the universities funded by the Trust in the UK, in a
process which has allowed him to listen and learn from the community about what
works, and what doesn’t work, with the Trust’s funding.

Other

18. Any Other Business

Antimicrobial Resistance (AMR)
The Chair informed the Board that one of the problems facing AMR is the lack of a rapid
diagnostic tool. The Longitude prize of 10 million pounds is subject to a public vote, and one
of the options is the development of an appropriate tool. Partners were urged to vote via the
BBC Horizon website by the deadline of 20th June. The relevant web link would be
circulated separately.

19. Goodbyes

The Board bid a fond farewell to Sharmila Nebhrajani and Sir Gordon Duff as they departed
the Board for new positions as the Chair of the Tissue Authority and Principal of St. Hilda
College, Oxford respectively. They were warmly thanked for their contribution to the Board.

Next meeting is on 9th October 2014 from 2pm-5pm. Rooms 1&2, 13th Floor, MRC, One
Kemble Street, London WC2B 4TS.