Taking forward the UKCRC Regulatory and Governance Group

Background

The UKCRC Research and Governance Group was set up at a time when research governance was not centralised and had no oversight from a single collaborative group. Since its inception in 2014 HRA has successfully streamlined the set-up of clinical research in the NHS developing and implementing HRA Approval and integrated Devolved Administration working. With UK wide governance standards in place the landscape has changed significantly.

Jonathan Montgomery recently took over as chair of the UKCRC Regulatory and Governance Group (with HRA providing the support), a group set up before the HRA existed to create a single voice for research governance for clinical research under the remit of the UKCRC Board. At the first meeting under Jonathan’s lead, there was a very useful discussion about the future of the forum: what it should cover, who should attend and how it should work. One point from the minutes captures a key issue:

‘it was felt that there is a value in information sharing at a strategic level so long as this group does not duplicate other collaborative fora and that members of this forum are senior enough to drive change.’

Duplication

The HRA Collaboration and Development (C&D) Forum is a UK wide Forum for HRA partners to discuss timely and relevant topics, share intelligence in these areas with the aim to promote collaboration and foster joint working, influencing and aligning partner organisations agendas. The C&D Forum has a broader remit than the UKCRC RG Group, for example it has recently explored matters relating to generation and use of evidence by NICE in biotech areas, and supporting medtech in working with the NHS.

HRA established the C&D Forum in 2013, and between 2016-17 provided secretariat support to the UKCRC RG Group, in recognition that much of the RG related activity was being led by HRA.

With the significant delay to implementation of the EU Clinical Trials Regulation, the only remaining area of mutual interest for the UKCRC RG Group was the implementation of HRA Approval. During the implementation of HRA Approval, members of both groups have sought updates from the HRA on the development of the programme. With the successful transition to business as usual of HRA Approval, there has been limited interest in the UKCRC RG Group, and so there is now an opportunity to review the areas of mutual interest of the organisations involved in both groups.
Seniority of membership

The UKCRC RG Group primarily functioned as an information exchange and did not, of itself, drive change. Although a sub-group of the UKCRC Board, it did not receive specific tasks from the Board itself. In thinking about the future of the UKCRC RG Group there is an opportunity to consider whether it would be opportune to review the C&D Forum and to consider whether there is a role for separate groups, with a clearer distinction in remit, or one group. Both fora have a very similar membership, with some organisations sending the same individual to both groups for representation. The level of seniority is an important consideration as the UKCRC Board has chief exec level representation, so a new group should not stray into Board level remit, whereas the C&D Forum tends to have Director or Senior Manager level representation.

HRA strategy

At the same time, the HRA has been consolidating and developing its approach to strategic engagement. A new director of policy has been appointed and a review of policy and engagement approaches and staffing structure is underway. This work will result in more HRA capacity to drive the policy basis for collaboration on research regulation and related issues and to support engagement activity, including stakeholder fora.

Proposal

It is proposed that a new forum is established, replacing the current UKCRC RG Group and HRA C&D Forum, to act as the strategic driving force for governance and regulation across health and care research. It should act as an information exchange, a forum for discussion and a collaborative group which can work on issues that need addressing (gaps in the regulatory landscape, emerging technologies etc).

The membership of this forum should reflect the membership of UKCRC Partners and expand beyond that to cover relevant organisations in the developing areas of medical and social science. Members of the Forum should be senior (Directors for example) enough to drive change.

Due to the broad remit of the HRA this forum should be managed, governed and chaired by HRA enabling the maximum use of its statutory position and duties of co-operation in health and social care. The Forum would report to the HRA Board. It should provide reports and take commissions from the UKCRC Board in areas of Clinical Research.

The Forum should establish and oversee subgroups on strategically relevant topics to address important issues identified at the Forum meetings. Examples of these could be Research Transparency, social care and Artificial Intelligence. These would be managed by HRA and would report to the Forum.
Governance structure

Example Membership
ABHI, ABPI, Academy of Medical Science, AMRC, Academy of Medical Royal Colleges, BIA, BEIS (OLS), CRUK, DH, ESRC, HFEA, HRA, HTA, MHRA, MRC, NHS Confederation, NHS Digital, NHS England, NICE, NIHR (Funders, School for Social Care Research), Social Care Institute of Excellence, HSC Research and Development Division, HSCRW, PHE, CSO-Scotland, The Wellcome Trust, UKCRC.