Health Research Authority

Health Research Authority Directorate Update 5 February 2020 HRA Board meeting

Approvals Service update

HRA Approval

Recruitment rates remain high, though this relates primarily to internal promotion within operational teams. Of note, Recruitment Panel agreed appointment of a third Band 8A Operations Manager. This adds to leadership capacity to supervise and support teams, further reducing the ration of direct reports to line manager, allowing greater 1-1 support. Further line management responsibilities are being rolled-out through the team in line with job descriptions and will be in tandem with training and support sessions, and a development plan for each member of operational staff.

Research Systems procurement has started to allow us to implement two important opportunities for automation to improve user experience, reduce burden on staff, and divert capacity to supporting applications:

- Electronic self-booking of REC meeting slots for applicants
- Electronic submission of amendments

A pilot project on remote minute-taking of REC meetings has commenced, which will explore the potential to reduce staff travel with consequent benefit to staff work-life balance.

In the Approvals Support Division, the electronic review project is making good progress. Twenty RECs have received visits to support the continued move towards review via the HARP Member Portal, and Chairs have been supportive in encouraging their members. New netbooks are being purchased for members to facilitate the move and 40% of members are now using the portal instead of requiring paper copies. The new instruction video has been completed and is live on the website.

The Support Team is working with the Comms team to develop recruitment material to increase both the number and diversity of REC members. Chairs are keen to support recruitment with organisations they are linked to, to further improve recruitment.

Guidance and Advice

Guidance activities supporting HRA and UK colleagues on range of activities, include:

- Mental Capacity Act (Northern Ireland) – as this was implemented with little advance notice on 1 October 2019, we have been working with colleagues in Northern Ireland to determine what is needed to support the implementation.
- Guidance content related to 4 Nations and UK Local Information Pack – in response to feedback we are working with colleagues across the UK to improve guidance related to applications using the IRAS Form as well as continuing to monitor feedback on the UK Local Information Pack guidance and making improvements as needed.

HRA Approval Programme Activities

We have achieved agreement between the contracting leads across the UK on the revised model Clinical Trials Agreement (mCTA). This version has been put to the Association of the British Pharmaceutical Industry (ABPI) and they have obtained member feedback, which appears positive. The UK leads will meet with ABPI shortly, with a very realistic prospect of gaining agreement such that the revised (General Data Protection Regulation (GDPR) compliant) mCTA, Clinical Research Organisation (CRO) -mCTA and Primary care mCTA can be published in the Spring.

The programme team have worked with the guidance and advice team in engaging with Medicines & Healthcare products Regulatory Agency (MHRA) on implementation of the EU Device Regulations and have created a proposal for a phased way of working more closely with MHRA as the new regulation takes effect.

The programme team have worked closely with DHSC and National Institute for Health Research (NIHR) Clinical Research Network (CRN) Coordinating Centre (CC) to ensure success of the business case from NIHR CRN for the creation of an on-line Schedule of Events Cost Attribution Template (SoECAT) to replace the current HRA-designed and maintained Excel spreadsheet. The criticality of the tool to UK regulatory approval and site set-up processes and, specifically in England, to the payment of Excess Treatment Cost processes make shortcomings with the current technology of the tool a significant risk. Ensuring that NIHR CRN CC prioritised the development of the on-line tool over other work of importance to them is a key achievement

The amendments tool continues to be piloted until the end of February 2020, and a work-group has been established to plan and deliver roll-out to alleviate staff burden and improve applicant/ sponsor engagement.

Policy and Partnerships update

Making our communications accessible

The communications team has made significant progress to bring the organisation's digital communications in line with The Public Sector Bodies (Website and Mobile Applications) No 2 Accessibility Regulations 2018. This involves changing the way that information is published to enable people with cognitive, visual, motor or hearing difficulties to access online information and making information accessible to all users.

The HRA website contains many downloadable documents, which are neither accessible nor searchable from the website. We have made some changes across

the website to make it accessible and reviewed how information is published on the top 50 most-visited pages accessible, with most information now available only in HTML. Some information will still be published in accessible documents.

Social media

The HRA_Latest twitter feed has passed 5000 followers for the first time, an increase of over 1500 (30%) since the same time last year. This is a significant increase in our social media reach, driven by campaigns such as #HRATips and #MakeItPublic, as well as enhanced engagement with stakeholders and followers.

Internal communications

The team is supporting significant programmes of organisational change with strategic internal communications including the change of all HRA email addresses, the move of London-based staff from Skipton House to Stratford and the launch of the 2020 Staff Survey.

Research transparency

The Policy and Engagement team continues to undertake stakeholder engagement to help socialise the Make it Public strategy, in advance of publication. This includes an update to the Transparency Forum, which met on 28 January. Forum members discussed the future of the Forum and agreed that it should be replaced with strategy implementation groups and an annual transparency conference. In parallel, we have been liaising closely with the Communications team to prepare for the publication of the strategy and consultation report, as well as a planned event to thank all those who took part in shaping the strategy.

The report of the audit of registration for clinical trials that received a REC favourable opinion between January and June 2017 is nearing finalisation. The purpose of this audit activity is to determine the number of clinical trials that comply with the condition of REC favourable opinion to register and in the process identify any reasons for non-compliance, and therefore any areas for improvement. The audit of trials that received a REC favourable opinion between January and June 2018 is now underway.

Data-driven technology

We continue to work on the draft guidance on the use of patient data in medical software development and plan to incorporate materials from this guidance when we look to update our training material on the topic of ‘personal data in research’. We have also been liaising closely with MHRA, NICE, CQC and ICO to explore closer working between these agencies in the provision of regulatory advice for AI-driven medical technologies.

Engagement

Following approval by the Leadership Team, we have initiated a series of interviews to map and record current external engagement activities by HRA staff and non-executive directors, to support the development of an engagement plan.

Public involvement in research applications
The analysis of public involvement reported in a sample of applications for REC review for the year up to December 2019 was completed in early January and reports of the findings are being prepared for both internal and public circulation.

Patient Focused Medicines Development
We have been concluding the arrangements for the HRA's membership of the international partnership organisation, Patient Focused Medicines Development, including a place on their governance board for Jim Elliott. Membership will contribute significantly to the team's work to support and encourage more pharmaceutical companies and clinical research organisations to involve the public in their studies that come to the HRA for approvals.

Governance, Information, Finance & Technology update

External audit
The HRA prepares an Annual Report and Accounts in time to be laid before Parliament prior to summer recess. The National Audit Office (NAO) contracts KPMG to perform the detailed fieldwork on our Report and Accounts. KPMG start their audit fieldwork this week at Skipton House. The interim audit usually takes a week in preparation for the final audit which usually takes place over several weeks in May.

This year the new accounting standard (IFRS 16, Leases) comes into effect for government accounts. It introduces a single lessee accounting model and requires the lessee to recognise assets and liabilities for all leases with a term of more than 12 months. This will have a material impact on the HRA's Accounts along with most organisations. To help inform DHSC / HM Treasury's understanding of this impact we have collated and submitted a return of the potential changes to DHSC.

2020/21 budget setting
Zero based budgeting exercise for 2020/21 is progressing in line with our timetable. Outline funding for 2020/21 has been confirmed by DHSC which will ensure HRA has sufficient capacity to support our core service delivery and government priorities. Detailed financial planning work is now taking place to understand our 2020/21 financial model in time to inform the finalisation of our investment appraisal process in February.

Member expenses
Discovery work in progress to understand benefits of rolling out electronic expenses to committee members. This follows the roll out of electronic expenses to staff members in April 2019.

Facilities
Facilities management (FM) contract now in place for both Nottingham and Manchester offices. Bristol office contract remains unsigned. This is being actively chased.

Improved WIFI has been rolled out throughout the HRA estate.

Estates

London office move. DHSC have signed the lease with the British Council. Programme governance has been set up and a communications plan will be developed this month to support the programme and ensure consistent messaging across the five organisations.

Corporate secretariat

Staff cascade is being tested for each directorate using data included in ESR (employee staff record).

Refreshed information governance incident reporting has been discussed at Information Governance Steering Group. Further adaption has been identified with a view of rolling out the new process in April.

The annual information asset review is currently taking place and is due to be completed by the end of February.

NHS BSA has performed a gap analysis on the HRA's approach to cyber security in line with Data Security and Protection toolkit standards. No significant control failings have been identified. Several recommendations have been made and are currently being considered.

Information governance internal audit review is currently being performed.

Quality Assurance

The following REC accreditation audits have taken place this quarter:

REC	Accreditation status
London – Surrey	Full accreditation under 2018 scheme (after completion of action plan)
East Midlands – Nottingham 1	Full accreditation under 2018 scheme (after completion of action plan)
London – Camberwell St Giles	Full accreditation under 2018 scheme (after completion of action plan)
London – West London & GTAC	Full accreditation under 2018 scheme (after completion of action plan)
London – Hampstead	Full accreditation under 2018 scheme (after completion of action plan)
North West – Haydock	Full accreditation under 2018 scheme (after completion of action plan)
London – Fulham	Full accreditation under 2018 scheme (after completion of action plan)

London – London Bridge	Provisional (action plan pending completion)
Newcastle & North Tyneside 1	Provisional (action plan pending completion)
Scotland A	Provisional (action plan pending completion)
Yorkshire & the Humber – Sheffield	Provisional (action plan pending completion)
East of Scotland 2	Full accreditation under 2018 scheme
London – South East	Provisional (action plan pending completion)
Yorkshire & the Humber – Leeds East	Provisional (action plan pending completion)
London – Riverside	Provisional (action plan pending completion)
East Midlands – Leicester South	Provisional (action plan pending completion)
South Central – Hampshire A	Provisional (action plan pending completion)
South Central – Oxford C	Provisional (action plan pending completion)
North West – GM Central	Provisional (action plan pending completion)

ICT infrastructure

Exchange On-Line is now in user acceptance testing with planned roll out throughout February. This work will provide improved service performance and better tools to meet HRA requirements. Collaboration software (MS Teams) is also being piloted to help support our estates and smarter working ambitions.

The HRA continues to be an active participant in the Future Services Programme which aims to replace our current out-sourced ICT infrastructure contract with a SIAM model (service integration and management) where the supplier management is bought back ‘in house’ to improve performance, value and control. Service desk functionality will move to this model in 2020. The HRA is also moving to a new mobile phone contract to support operational requirements and widen access to ethics committees. The HRA is represented on the FSP Board and on the various governance groups – including finance, commercial and technology.

Corporate Services update

Research Systems Programme

Summary:

The HRA Research Systems Programme is now back on track to plan and budget to deliver initial module to support the Combined Ways of Working pilot in collaboration with the Medicines and Healthcare products Regulatory Authority. Technical testing has gone well and testing with users is underway. We have procured resources for a further development, but uncertainty remains on budget for future work.

Combined Ways of Working Minimum Viable Product release (CWOW MVP Module)

The CWOW MVP module is the first release for HRA on the Pega platform. It is designed to facilitate applications and amendments for studies which are part of the Combined Ways of Working Pilot.

The benefits of the CWOW MVP module are below. Please note these are additional to the benefits of the CWOW Programme.

For applicants taking part in CWOW pilot:

- Ability to e-submit CWOW amendments – this is completely new functionality as all CTIMP amendments are currently submitted by email.
- Ability to e-submit CWOW applications, manage responses to “requests for information” on-line, and track where studies are in the process.
- Sponsor has complete oversight of projects being submitted.
- New modern interface and ability to influence further development features

For HRA and MHRA:

- Demonstration that integration of systems across organisations is possible.
- Platform from which to further refine functionality for Clinical Trials of Investigational Medicinal Products (CTIMPs).
- Automation of admin related to the CWOW pilot process so that staff in MHRA and HRA can undertake more value-added tasks relating to the CWOW pilot.

As collaboratively agreed with MHRA we remain on track to release to users currently in the CWOW Pilot in early March 2020. Systems Integration Testing went very well. User Acceptance Testing is underway; some small defects were found in cycle 1 and fixes deployed 24 Jan. Applicant users from CWOW pilot group will participate in User Acceptance Testing 3 – 5 February.

CWOW Module release

Work plan for Jan – April 2020

Development work

Refinement of the roles-based access to new IRAS functionality.

- Benefit to applicants: further refinement of roles to facilitate secure flexibility.

Simple portal for e-submission of amendments for non-CWOW studies.

- Benefit to applicants: no longer need to email amendments.
- Benefit to HARP users in HRA and the devolved administrations (HARP is the workflow system that is used to process study reviews): reduction of admin related to manual upload of large numbers of amendment document leading to opportunity for undertaking more value-added tasks for the benefit of applicants.

Online REC and/or study wide review booking

- Benefit to applicants: booking is available 24/7 by removing need to telephone during working hours/
- Benefit to HARP users in HRA: opportunity for more value-added tasks.
- Benefit to HRA: reusable work that can be slotted into workflow for studies in the future.

Admin improvements to existing HARP

- Benefit to HARP users: opportunity for more value-added tasks
- Release and communication plan to HARP users and applicants developed alongside devolved administrations.

Preparation work

- CWOW CTD: Working with MHRA on scope of work to further develop the CWOW module to include the current data set required for Clinical Trials Directive (CTD) and how required information can be made public.
- Planning how further development work on CWOW module will be delivered ahead of final outcome of business case submitted for whole procurement.

Progress on business case for whole procurement

- DHSC have asked for business case to be represented as a 5-case model.
- Resources procured to assist submission by 31 Jan 2020
- No date for outcome

Planning for target operating model for the future

Understanding what we need our staff structure to be and our strategy regarding employed development staff versus contracted staff is important as we move through the programme so that we can put in place the appropriate structures are we need to.

We are in the process of procuring consultancy support to understand our options and support decision making. We are holding dates in early March to kick off this work.

Programme Management Office (PMO)

The PMO has focussed on embedding the updated benefits management process. Benefits realisation plans have been reviewed and the benefits register has started to be populated and is being reviewed at the Transformation Board. This work has been informed by a previous Government Internal Audit Agency (GIAA) Audit.

The PMO has produced the portfolio dashboard that provides a monthly update on the progress of programmes and projects and is used by the Transformation Board and Leadership Team meeting to review progress. Support has been provided to project managers in the use of the project management process, feedback given on project documentation as well as ongoing support with KPI analysis, HRA Hub, Excel etc. Work is also underway to develop some SRO training materials and explore options for carrying out a project management maturity assessment.

HRA main telephone line

General nature of calls regarding the Approvals/Operations service have slightly improved as the changes to process bed in, although the proportion of calls around this still remain fairly high in comparison to other types of calls.

HR

Leadership Team reviewed actions taken to date on the 2019 staff survey action plan and a rolling plan will be developed to cover those actions not complete or started. The updated plan and review of current status has been shared with Staff Forum and Joint Negotiation Committee (JNC). Preparation has started to develop the 2020 survey questionnaire – a working group comprising management, staff representatives and HR is meeting to review the content on 30 January. Planned launch date for the 2020 survey is 24 February.

Policy review and development

A number of HR policies identified for action through the Audit & Risk Committee are being reviewed. The review is being undertaken to include input from management and staff representatives. The revised policies are expected to be rolled out end of March.

Equality, Diversity & Inclusion

The steering group has agreed a set of priorities for the work to focus on respect, awareness, training and development, social inclusion and recruitment. We are planning a workshop in March to develop more detailed work plans for these priority areas. In the meantime, the staff-led groups are becoming more established and are sharing blogs on the intranet about the themes and nature of discussions in their groups to help create broader understanding and awareness.

Smarter Working (linked to the estates strategy)

Sub-groups of the project team are attending workshops in February to develop some best practice / top tips guides for line management (with a particular focus on good practices when you're not co-located with your staff) and working well from homes and offices (e.g. taking breaks, staying connected with colleagues, etc). These aim to address some of the themes that came out from work we did with staff in our office locations.

Unison

Unison is active at the HRA. There are currently workplace reps in Manchester, London, and Nottingham. Bristol and Newcastle have workplace contact's but they are not accredited stewards.

Aside from issues raised at the quarterly JNC, Unison will also contribute to current discussion on reviewing some of the key HR policies at the HRA. The Unison E&D rep at the HRA is also a member of the E&D&I Steering Group and on some of the key self-organised groups which have arisen from the strategy work.