HRA Achievements

Long term transformation of research governance

The HRA has made a sustained contribution to the transformation of research governance the achievements of which were captured as part of the 10th anniversary celebrations and which have been captured on the HRA's website. Particularly noteworthy achievements:

- Reducing duplication - Over half of applications to the HRA are for research that will take place in multiple places, from 2 to over 300 sites. Reducing duplication can have a big impact. The integrated research application system, HRA and Health and Care Research Wales approval, technical assurances and model agreements have all slashed inconsistency and duplication
- Reducing time - Combined review halves the time it takes for studies to get approval and cuts the time from application to recruiting a first patient by 40 days this process and others have seen a potentially step change reduction from **600 days from funding to first patient recruited to under 300 days**[1]
- A shared policy framework - A UK-wide shared policy framework setting out principles of good practice in the management and conduct of health and social care research in the UK replaced the four separate Research Governance Frameworks in each UK nation in 2017
- Research Transparency - making research transparency the norm, making it easy and making information public. thanks to our 2020 strategy
- Streamlining data driven research - Artificial intelligence (AI) and data-driven technologies offer huge potential for health and social care. We're improving the way that we review research involving AI and data driven technologies to ensure its always effectively regulated
- Public Involvement - Encouraging more meaningful involvement of the public in research. In 2010, just 19% of HRA research applications had public input. By 2019, 74% of applications did so

Culture change and innovation

Much of our focus is on our managed programmes and projects but the HRA delivers significant innovation and change outside of managed programmes. These changes can be significant on their own and build incrementally to make a big difference to external users, partners and stakeholders.

It is difficult to capture all of this work and so some example are given here in the interests for promoting further discussion.

[1] this is not a secure number, but an estimate based on CR timelines

Standardisation and coordination

One of our core functions is to standardise and coordinate the regulation, governance and conduct of research in the UK. We do this through a range of partnership working, soft influence and hard outputs and outcomes.

Examples of our tangible outputs and outcomes include:

- Developing a consistent UK wider approvals service.
- Human challenge studies during the pandemic
- Working with vulnerable groups traditionally underrepresented in research such as pregnant people.
- Establishing the public involvement matching service and current work on a sector wider shared commitment.
- Negotiating and publishing a suite of model agreements for commercial trials to reduce the time, cost and resources needed to set up health and social research.
- Working with MHRA to improve clinical trial legislation proportionately, and champion the inclusion of public involvement, diversity and transparency requirements.

Major programmes

Notwithstanding the point made above that the HRA makes a significant contribution outside of managed programmes, these are important and visible sources of benefits.

Headlines:

- The scale of improvement is significant with **14 major deliverables** achieved in 2021/22 and nearly **40% of projected benefits delivered** (the remainder due to be delivered in 22/23)
- This impact can be seen in overall **satisfaction scores from our users of 80%+**[2] being recorded on a regularly basis over the last year. This continues the path of innovation and improvement that the HRA has embarked since its establishment in 2011
- Work remains to be done on the portfolio of work and related benefits to make sure they are both feasible and consistent with developing strategic priorities for 22/23
- and, that the HRA is able to match capacity and capability with its future ambition for change and improvement

'Think Ethics' – the Ethics Review Programme

Think Ethics is putting participants and ethics at the heart of health and social care research. We are working together to make ethics review more innovative, efficient, and trusted:

[2] Those respondents scoring 7/10 or more in monthly satisfaction survey

- clear and concise study information designed with and for patients and study participants
- fast, proportionate review focused on key ethical issues in a consistent way
- a rewarding experience for diverse, skilled and committed members
- a streamlined and user-friendly service, attracting world-leading health research in the UK.

Description of desired change:

- More clarity for researchers leading to greater researcher confidence
- A streamlined set of questions aligned with how committees review studies
- Members spend less time reviewing studies and have greater focus on key ethical issues
- Research will follow new ethics review pathways, providing the right review for the right study

Already delivered:

- Fast track service which has halved the time it takes to review and approve research proposals from 28 to 14 days
- Fully digital online review service that will support inclusion
- Public dialogue work completed. HRA community and users contributed to what good consent materials and processes look like. Emerging findings look extremely helpful. Awaiting final report

Planned before end of 2022:

- A new approach to the development and review of participant information and consent arrangements in studies

To be delivered in 22/23:

- A new and more proportionate set of pathways for ethics review

UK Approval - part enabled by Research Systems Programme

Model for UK Approval that provides upfront transparency for stakeholders as to what is needed by whom, when and for what purpose (ideal paths) to ensure predictable and friction free passage of studies from pre-submission to delivery

Description of change:

- Significant efficiency savings delivered (committee members and HRA staff) enabling better use of capability
- Bring greater clarity in the system what information is needed when for whom and why it is needed
- Reduce effort/handling time, reduced eliminate duplication, increase consistency – all of which will result in research studies being set up more quickly
- Providing greater transparency about where an application is in the process and what needs to happen next at any time.

Already delivered:

- Aligned HRA and HCRW Approval, UK Local Information Pack and UK agreement on study wide review and amendment processes and associated tool – bringing greater consistency and reducing duplication
- Delivered initial models for the ideal paths and statuses for New IRAS ensuring effective and efficient navigation and completion

Deliver in 22/23:

- UK agreement on consistent site processes
- New IRAS website to provide UK regulatory front door

Study Set-up

Efficient study set up is the single most important area cited by commercial sponsors when looking to bring or keep their research in the UK. Cost and contracting negotiations increase time and encourage delays, reducing opportunities for patients to have access to important trials, including those in very early phase.

Description of desired change:

- attract research for their patients, by streamlining processes nationally, reducing negotiations, improving communications and setting out clear and straightforward mechanisms for commercial study set up, that includes costing and contracting commercial studies.
- enhance the ability of the UK to compete internationally for early phase commercially sponsored trials

Already delivered:

- 13 model template agreements already published which increases the speed and efficiency of study set up by having single agreed versions to use
- Technical Assurances aligned UK-wide which enable NHS/HCS to arrange the capacity and capability to participate, which reduces complexity and inconsistency

- Published ‘Set up of Interventional Research’ paper with MHRA
- Guidance that explains how principal investigator oversight can work and be compliant, when it is required across organisational boundaries. This also supports decentralised models of delivery, bringing research to where people are.
- Published guidance with MHRA on remote access to electronic health records for monitoring purposes
- Providing support to Sponsors and sites during the pandemic and beyond to ensure that monitoring of data quality and compliance can continue remotely and securely.

Planned before end of 2021/22:

- Supporting MHRA with implementation of new regulations for clinical trials to embed proportionality and efficiency, to remove unnecessary cost and barriers to undertaking clinical trials whilst ensuring robust safeguards for participants and the public
- Experimental Cancer Medicine Centre (ECMC) pilot initiated to explore new ways for sites and R&D offices to work when setting up early phase cancer studies

Deliver in 22/23:

- Start identifying learnings from ECMC pilot for roll-out to other settings
- Further model agreements published
- Amendments survey analysis and action plan**:** Analysis of amendments survey conducted to understand how we can improve amendments practice and make space for study set up. Amendments have been cited by sites and sponsors as a major burden and barrier to good study delivery.
- Phased roll out of the National Contract Value Review (NCVR) from April 2022 for commercial studies (RRG) which will streamline the costing and contracting process

Combined Review

Develop and deliver a single application route and a coordinated ethics and regulatory review leading to a single UK decision on a clinical trial

Description of change

- Enable a reduction in end-to-end timelines
- Support trials starting quicker

Already delivered:

- Combined fast-track service in place and all clinical trial submissions to be via combined process. Combined review halves the time it takes for studies to get approval and cuts the time from application to recruiting a first patient by 40 days.
- User perception:
    - 64% said making the submission was easier or the same (50% said the submission was easier or much easier)
    - 96% said the overall time difference had been shorter, much shorter or the same (50% much shorter or the same)
- Benefits cited (% of respondents):
    - 71% More streamlined
    - 36% Faster overall timeframes
    - 32% Less effort
    - 21% Less overall workload

Planned before end of 2021/22:

- Additional functionality added to IRAS for combined review to respond to user feedback.

Deliver in 22/23

- Additional functionality added to IRAS for combined review e.g. radiation, and user feedback addressed. IRAS website provides aligned guidance and resources
- Support MHRA in implementing new regulations for clinical trials to embed combined review processes and provide a platform for further improvements through guidance

Research Transparency

This programme is to implement HRA's research transparency strategy, Make it Public: transparency and openness in health and social care research. The Research Transparency programme is translating the Make it Public vision into practice by fulfilling the strategy's 10 key commitments covering registration of research, reporting findings, and communicating findings to participants.

Description of change

- Reduced burden and faster registration for researchers and sponsors; transparency of and access to clinical trial information for researchers and wider public; UK has a trial registry option outside of the EU.
- Improved visibility of and access to summary information for all health and social care research for wider public; better user experience through improved functionality
- Better information on sector's performance on transparency; increased pressure/incentive on researchers/sponsors to improve transparency including sharing results in a meaningful way; wider public perceive increased commitment to transparency by both HRA and researchers; HRA sees improved compliance with transparency requirements

Already delivered:

- Website and IRAS guidance updated to clarify transparency requirements and best practice
- Launched Plain Language Summary webpage and developed an e-learning module in response to feedback that researchers would welcome guidance in this area
- Automatic registration of CTIMPS on ISRCTN Registry
- New deferral policy (with accompanying SOP) operational

Planned before end of 2021/22

N/A

Deliver in 22/23:

- Enhanced research summaries tool on IRAS website (subject to timescale for delivery of IRAS website)

Health Research Authority

Streamlining data driven research

Streamlined application process, enhanced application governance and improved applicant communications supported by an enhanced decision tool that allows prospective applicants to decide what approvals are required for data and AI studies. A High-level design of a proportionate approval process for data holding structures

Description of change:

- Costs and time savings for HRA and researchers; reduction in unnecessary application

Already delivered:

N/A

Planned before end of 2021/22

- Completion of co-ordinated review of medical devices pilot with insights for roll-out to standard review service

Deliver in 22/23:

- Completion of pilot and supporting changes to streamline the review of studies through the Confidentiality Advisory Group
- Design of a decision tool to support the use of patient data in research
- High-level design of a proportionate approval process for data holding structures.