HRA Board paper
18 January 2023

Title of paper:	Supporting new ways to do research
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Summary of paper:	This paper seeks guidance on how the HRA can deliver its strategy commitment to support new ways to do research
Reason for submission:	For discussion
Further information:	This paper outlines a proposal for a new HRA innovation service, building on our learnings to date in data and AI and support of broader innovative activity. It provides three possible scenarios to establish this service. It poses the following questions: - Should we seek to establish an innovation service and what, if any, are the implications if we do not? - If so, what should be the scale of our initial investment – three costed scenarios are provided in section 6 - How should we seek to fund this? - To what extent are we comfortable that what we do to deliver our strategy is shaped by the funds available?
Budget / cost implication:	Initial investment in resource to seek external funding
Dissemination:	
Time required:	15 minutes

1. Introduction:

The HRA's strategy includes a commitment to 'support new ways to do research'. This paper proposes how the HRA might support innovative approaches to research into improving health and care and seeks Board's direction.

This paper draws on our work on Data and AI as an exemplar for an HRA innovation service. It has also been informed by the HRA's support for broader innovation activity, such as for decentralised trials, platform trials, and genomics services. It provides three possible scenarios to establish this service to enable the HRA to engage with innovators, horizon scan for innovative approaches to research, and respond proactively to make it easier to do research in new ways that people can trust. It poses the following questions:

- **Should we seek to establish an innovation service and what, if any, are the implications if we do not?**
- **If so, what should be the scale of our initial investment – three costed scenarios are provided in section 6**
- **How should we seek to fund this?**
- **To what extent are we comfortable that what we do to deliver our strategy is shaped by the funds available?**

2. Background:

Innovation is a key part of research – in developing innovative interventions or services, in innovative research methodologies, and in how regulators may need to be innovative in our approaches to make that research happen. Some innovations need HRA to change the way that we support research, but for others we can adapt the way that we do already do things. No innovations will get anywhere if people are not confident to take part in research to develop them.

Over time, we see changing trends in applications to the HRA to do health and social care research – both in the technologies and approaches that are being researched and the way that that research is done. See example of some recent trends at figure 1.
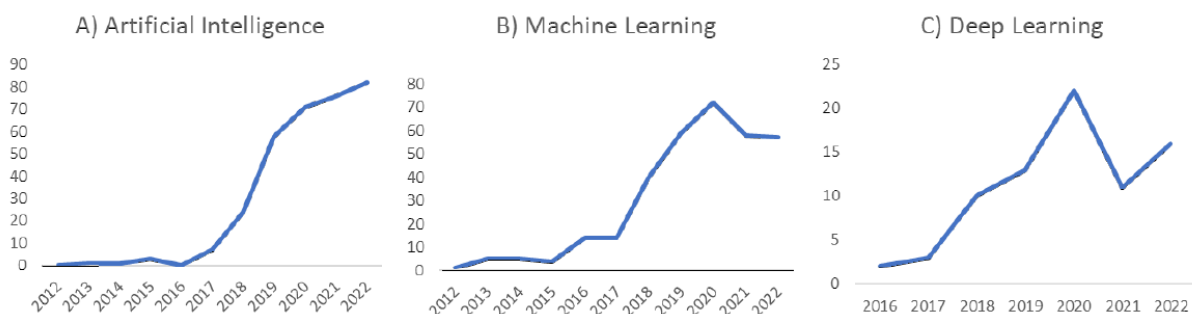

Figure 1. AI themed approval applications 2012 to 2021. Graphs showing assessment of IRAS applications using various data centric key words – A) artificial intelligence, B) machine learning and C) deep learning. The number of applications that contain either an AI or data-centric component are on the rise year-on-year. Note: searches were constrained by the current

functionality of HARP, and it is possible that several additional entries across the key words may have been missed. Key words obtained from peer-reviewed publications – listed in section 7.

From 2020 to 2023, the HRA secured external funding to support a Data and AI function. This function led or supported a number of activities to make it easier to do AI and data-driven research that people can trust:

- Co-ordinated review of medical device studies
- Streamlining the review of studies through the Confidentiality Advisory Group (CAG)
- Data Decision Tool (DDT)
- Identifying the regulatory issues for data holding structures (secure data environments / trustworthy research environments)
- Partners in the Multi Agency Advisory Service, an information platform that seeks to provide valuable and easy to navigate guidance on the regulatory and evaluation requirements at different stages of the development pathway for AI and data-driven technologies.

A number of these activities are ongoing, and some require further funding to realise their full benefits

- The data decision tool continues to be developed with a view to integrate into the new IRAS webservice.
- a joint business case by the Multi Agency Advisory Service partners is being prepared to secure further financial support to continue development to public beta and integrate this into the partner organisations' core business activity.
- Explore any changes to approvals services to resolve regulatory issues for data holding structures.

The HRA's 2022-23 business plan, as part of the focus to "work with research teams to explore new ways to do research and make them happen", committed to the "design and implementation of a case management service for innovative studies", which has yet to be developed in detail. This supports the HRA's role in the Research Recovery and Growth programme to realise the future of UK clinical research delivery.

3. An HRA innovation service:

Our work on data and AI has shown a number of activities that are valuable to support researchers and innovators to navigate existing approaches or support new ways to do research that people can trust.

- **Understanding**– the expertise to identify where researchers can navigate existing processes and ensure robust scrutiny that earns and maintains people's trust when they do, or identify where new approaches are needed
- **Coordination and standardisation** – the ability to work with research teams to explore new ways to do research and make these happen, working in partnership with other regulators and bodies within the research landscape.
- **Signalling** – to researchers and innovators that the HRA will work with them to do their research in a way that earns people's trust.

An HRA innovation service would seek to deliver the above to make the UK the easiest place in the world to do innovative research that people can trust.

The service might include:
- close engagement with communities of practice and horizon scanning with leading experts from academia, business, policy and third sectors to unearth intelligence on the drivers and challenges of innovative advances that impact on our remit.
- Analysis of this intelligence and interpretation by people with the appropriate domain expertise to communicate the scope and potential to impact on our statutory obligations and thereby facilitate cycles of continuous improvement.
- Identification of innovation priority areas relevant to HRA strategy and statutory function and action to enable us to be responsive to new opportunities within the research landscape so that people can trust our decisions.

It is sensible to build on the expertise in data and AI, regulatory expertise, and research expertise and insights that we currently have, to develop an innovation service. While we have taken a strategic decision not to invest in supporting data and AI research specifically, our strategy sets out a broader objective to support new ways to do research, many of which include data and AI approaches.

The operation of the HRA's data and AI function over the past years has demonstrated that our expertise is sought and valued and we continue to see a growing number of applications for research in this area. Building on this existing expertise would enable the HRA to continue to develop the existing work of the team in data and AI and learn from this to make an informed decision over the approach and value of a permanent and wider innovation service.

4. **This activity has a high resonance with government objectives, which may support access to external funding:**

   NHS Long Term Plan
   "We will **speed up the pipeline for developing innovations in the NHS**, so that proven and affordable innovations get to patients faster"

   DHSC Outcome Delivery Plan July 2021**:** includes reducing health disparities as one of five priority outcomes and identifies **'innovation**, technology and data' as a strategic enabler.

   Build Back Better: our plan for growth – March 2021 – sets out three core pillars of growth, one of which is innovation. includes a focus on 'supporting and incentivising the development of creative ideas and technologies' and **'Develop the regulatory system in a way that supports innovation**". Includes specific commitments to adapting our regulatory frameworks to maximise advantages of innovation in sectors including health and data, and a regulatory reform programme to boost growth and innovation.

   Life Sciences Vision sets out seven missions and makes a number of commitments for how to deliver them. Notably **emphasises the importance of earning public trust in the foreword**, referencing patients and the public as key partners whose "trust and buy-in will be critical to success in many areas'. Commitments include to

"**cut bureaucracy and red tape to create a more efficient and effective research environment** (namechecks HRA fast track)"

[The Benefits of Brexit](#) January 2022**:** sets out how the government plans to 'keep what works, change what doesn't' following Brexit. Includes:
- Five new regulatory principles:
  - Sovereign approach
  - Leading from the front "**focus on the future, shaping and supporting the development of new technologies and creating new markets**"
  - Proportionality "We will pursue non -regulatory options where we can"
  - Recognising what works
  - Setting high standards at home and globally, including "engage in robust regulatory diplomacy across the world, leading in multilateral settings"
- **Outcome-focussed, experimental regulator – "bold" "support innovation" "co-creation of future industries"**
- Our regulatory system will strengthen and support the UK's position as a global science and technology superpower "unleash innovation at an unprecedented pace, benefit UK citizens and catalyse our economic growth" "build back better and level up"
- Embrace new technologies "For example, cutting -edge medical technology promises significant benefits with improved health outcomes and it is therefore a high priority that it is regulated properly, allowing rapid and safe deployment—such as with Covid-19 vaccines. Our regulatory system will recognise that not every potential harm of an emerging technology turns into an actual harm of an established technology, while continuing to place the protection of consumers at the forefront of decision-making."

[Rishi Sunak CBI Speech 21 November 2022](#)
"we're absolutely committed to using our new Brexit freedoms…

…to **create the most pro-innovation regulatory environment in the world**…

…in sectors like life sciences, financial services, AI and data."

5. Potential funding sources to support an HRA innovation function:

There are some existing routes to financial support for part of an HRA innovation service:
- We included establishing a case management service in our initial bid to RRG and therefore have some funds earmarked to support this that are yet to be invested in this work.
- a joint business case by the [Multi Agency Advisory Service](#) partners is being prepared to secure further financial support to continue development to public beta and integrate this into the partner organisations' core business activity.

Further potential funders to support the HRA's innovation activities might include:
- NHS Transformation Directorate / NHS AI Lab – primary focus is to accelerate the safe adoption of AI into the front line of health and care, while building a robust ethical and regulatory framework to ensure patient and citizen safety. We have been asked to

submit a business case to the NHS Transformation Directorate for funding for activity to support the development of Secure Data Environments that people can trust.

- Accelerated Access Collaborative – brings together industry, government, regulators, patients and the NHS to remove barriers and accelerate the introduction of ground-breaking new treatments and diagnostics which can transform care
- NIHR – funds, supports and delivers high quality research that benefits the NHS, public health and social care
- Directly from the Department of Health and Social Care
- Innovate UK – Smart awards

It is important to note that any application for funding will need to be tailored to the priorities of potential funders, meaning that some funding may be specific to particular areas (e.g. data and AI) while other applications may be broader (e.g. innovation), which will have implications for how we are able to develop an innovation service.

6. Resource requirements to support an initial HRA innovation service:

The HRA already works to support new ways to do research as part of its business as usual activity. The following three scenarios explore different scales of approach to increase this activity to better support innovation in health and social care research.

All three scenarios focus on how such a service can be embedded in the HRA and inform our existing ways of working, rather than create an entirely new and distinct area of operation.

We have included the MAAS policy manager in all of these bids, reflecting our ongoing involvement in MAAS.

Scenario one: signalling, signposting and feedback loops
This is the lowest resource option, focusing on increasing signalling and signposting of existing HRA activities to support innovation in health and social care research and increasing feedback loops to boost collective intelligence and embed learning into future practice.

A dedicated engagement manager and policy manager and some additional communications resource would support the HRA to understand the innovation landscape and engage with this, ensuring that innovators knew about the HRA and saw us as welcoming and open to supporting new ways to do research. The team would feed-back insights to relevant part of the HRA business to inform planning and practice.

Pay:
Innovation Engagement manager: 7 1FTE – £62k
Innovation policy manager: 7 1FTE - £62k
Communications: 7 0.5FTE - £31k
Innovation policy manager (MAAS): 7 1FTE - £62k
Data and AI Privacy Specialist: 8a 1FTE - £69k
Total - £286k

Non-Pay:
Conference attendance

Travel

Likely return on investment – for HRA and UK research more broadly:
- Increase satisfaction among those seeking to do innovative research in the UK

- access to business insight to improve HRA practices

Risks:
- This scale of investment will only support a focus on specific areas of innovation, rather than provide a broad offer.

- It may be challenging to attract external investment without offering a 'new service'

Scenario two: Create an innovation champion and invest in proactive and marketed case management
A mid-resource option, creating a senior HRA innovation champion in addition to the policy, engagement and communications resource proposed in scenario one. This would provide greater visibility to the delivery of the innovation service's remit to increase signalling and signposting of existing activities to support innovation in health and social care research and increase feedback loops that boost collective intelligence and embed learning into future practice. The team would feedback insights to relevant part of the HRA business to inform planning and practice.

This would also add resource to our existing guidance and advice service to create capacity and capability to support a greater number of requests, and a higher level of support through 'case management'.

Pay:
Head of innovation function: 8b 1FTE (estimated) - £80k
Data and AI Privacy Specialist: 8a 1FTE - £69k
Innovation policy manager: 7 1FTE - 62k
Innovation policy manager (MAAS): 7 1FTE - £62k
Communications: 7 0.5FTE - £31k
Engagement manager: 7 1FTE - £62k
Public involvement coordinator: 6 0.2FTE - £10k
Guidance and advice manager: 7 2FTE – 124k
Total - £500k

Non-Pay:
Public involvement payments - £150 per person per day
Conference attendance
Travel

Likely return on investment – for HRA and UK research more broadly:
- Increase satisfaction among those seeking to do innovative research in the UK

- access to business insight to improve HRA practices

- Increase the profile of the HRA as a gold standard regulator that will work with research teams to explore new ways to do research and make these happen.

Risks:
- This scale of investment will only support a focus on specific areas of innovation, rather than provide a broad offer, although it could explore expansion into other areas as determined by intelligence and insight.

- In effectively raising the profile of the HRA's innovation offer we 'oversell' what we can deliver with the resources available. However, this could provide an opportunity to attract further partnerships and investment to enable us to deliver an expanded offer going forward.

Scenario three: Establish a broad innovation function

The highest resource option, proposing to establish an innovation function with sufficient resource to build insight and engagement across a broad range of areas of innovation and use this to inform practice, so ensuring that the HRA can make it easier to do new types of research.

This would also include work to develop our existing guidance and advice service to create a pathway tailored to supporting innovative studies (in effect, a 'case management' service).

The team would feed-back insights to relevant part of the HRA business to inform practice and work with those teams, where appropriate, to undertake continuous improvement and transformation projects.

Pay:
Head of innovation function: 8b 1FTE - £78k
Data and AI Privacy Specialist: 8a 1FTE - £69k
Approvals Improvement and Liaison Band 7 - 62k
Innovation policy manager: 7 1FTE - £62k
Innovation policy manager: 7 1FTE £62k
Innovation policy manager (MAAS): 7 1FTE - £62k
Regulatory specialist: 8a 0.2 FTE - £14k
Public involvement coordinator: 6 1FTE - £52k
Communications: 7 0.5FTE - £31k
Engagement manager: 7 1FTE - £62k
Project manager to support continuous improvement/change to BAU: 7 0.5 FTE - £31k
Senior Guidance and Advice manager: 8a 0.5FTE £35k
Guidance and advice manager: 7 2FTE – 124k
Total - £744k

Non-Pay:
Public involvement payments - £150 per person per day
Conference attendance
Travel

Considerations:

- This proposes a level of resource to support a function that can engage on a broad range of innovation, and support regulatory response and service improvement, but it will be important to identify a number of priorities areas in which to specialise to provide the most effective service.

Likely return on investment – for HRA and UK research more broadly:
- Increase satisfaction among those seeking to do innovative research in the UK

- access to business insight to improve HRA practices

- Increase the profile of the HRA as a gold standard regulator that will work with research teams to explore new ways to do research and make these happen.

- Support government objective for the UK to be a 'global science and technology superpower' with a regulatory approach that is "Leading from the front with a focus on the future, shaping and supporting the development of new technologies and creating new markets", "Proportionate" and "Setting high standards at home and globally"

- Earn public trust in innovative research through transparent and robust approach to supporting new ways to do research.

Risks:
- Ensuring that this function is embedded within the HRA and successfully informs our existing ways of working, rather than creating an entirely new and distinct area of operation.

- It will be important to ensure that any evolution of the HRA and its activities is supportive of its core mission and strategy. Success and profile may increase pressure to expand the role of the HRA.

- It may be challenging to attract external funding for a function of this scale. Robust proof of concept and long-term strategy will be needed.

7. Risks:

The following are risks associated with the overarching decision over whether to invest in an HRA innovation service. Specific risks associated with each scenario are provided alongside the scenarios above.

Activity shaped by funds available:
There is a risk of taking forward activities for which we can secure external funding, rather than those which have the strongest strategic fit for the organisation to deliver our objectives to make it easier to do research that people can trust.

For example, we may be able to secure external funding to take forward the multi agency advisory service, while finding ourselves reducing investment in other core work due to funding pressures. Or we may be able to secure funding for part of an innovation function, i.e. focused on data and AI, rather than a broader function.

- **To what extent are we comfortable that what we do to deliver our strategy is shaped by the funds available?**

Absent from a high priority government agenda

By not establishing an innovation service or better articulating its innovation offer, the HRA risks being absent from a high priority government agenda to develop a regulatory system that drives innovation to ensure that research findings can improve care faster.

Insufficient resource to respond to breadth of innovation opportunities once established, risk of 'overselling' what we can do

Considerable funding to support the development of subject matter expertise will be required to establish an innovation service that can effectively cover a breadth of innovation. There is a risk that we are constrained in our support of innovative research to data and AI activity, which may limit other activities that we may be expected to address once we promote our role in innovation, or emerging areas that we need to respond to.