Health Research Authority

Agenda item:	8
Attachment:	A

HRA Board paper
5 February 2020

Title of paper:	Research transparency: final Make it Public strategy
Submitted by:	Juliet Tizzard, Director of Policy Naho Yamazaki, Head of Policy and Engagement
Summary of paper:	To seek Board approval of the final Make it Public research transparency strategy and plan for launch and implementation
Reason for submission:	For approval
Further information:	The paper covers: • An update on funding for the implementation of the Make it Public strategy • A finalised strategy and implementation plan for publication
Budget / cost implication:	Cost of launch within 2019-20 engagement budget
Dissemination:	The strategy will be launched shortly after the Board meeting and a launch event will be held in early March
Time required:	15 minutes

Research transparency: final Make it Public strategy

1. Introduction

1.1. The Board considered a final version of the Make it Public research transparency strategy on 10 December 2019. The Board was assured a that robust process had been followed, with feedback from a wide range of stakeholders, and was particularly pleased to see the engagement from patients, participants and the public, who made up around a quarter of people taking part in the consultation.

1.2. The Board agreed with the contents of the draft strategy. However, due to the General Election, the Board did not approve the strategy for launch and implementation. It was agreed that the launch of the strategy should be postponed and that the Board should consider at the 5 February meeting a costed implementation plan.

2. Update on funding

2.1. Since December, the Department of Health and Social Care has committed to increasing our grant-in-aid in the financial year 2020-2021 to reflect increased activity. The increase includes an allocation for implementation of the Make it Public strategy.

3. Implementing the strategy

3.1. There are 10 commitments in the strategy, sitting under the three mission areas of Making transparency easy, Making transparency the norm and Making information public. We have made minor edits to the strategy (Annex A) and further developed the implementation plan.

3.2. We have identified seven streams of work to implement the strategy, linked to the 10 commitments:

- Reviewing our guidance and standard conditions to researchers and sponsors about their research transparency responsibilities
- Modernising the Research Summaries tool to provide individual study information
- Running an engagement programme, using the Make it Public brand
- Establishing ongoing monitoring on study reporting and developing a framework for measuring performance
- Carrying out an options appraisal on a model for UK clinical trials registration
- Aligning expectations across funders and regulators
- Introducing sanctions into the Approvals process

3.3. The plan shows the key areas of activity planned for 2020-2021 and how they link to the 10 commitments.

4. Next steps

4.1. Once the Board has approved the Make it Public strategy, the immediate next steps are to:

- Publish the strategy
- Write to the new Chair of the House of Commons Science and Technology Committee (membership not announced yet)
- Hold a launch event of the strategy in early March

4.2. We will then start the implementation programme from 1 April 2020.

Annex: Strategy and implementation plan

Make it public: transparency and openness in health and social care research

Health Research Authority

February 2020

Foreword

About this strategy

Why research transparency is important

The UK has a thriving health and social care research environment. More people take part in research studies each year, and donations to medical research charities are on the rise. Health and social care research findings translate into better care for patients and service users, and improvements to our health and wellbeing. They also lead to economic growth.

Scientific and medical publishing has become more open over recent years and new initiatives are driving towards research findings being ever more freely available. This is making research findings more accessible to researchers and others working in health and social care. However, the people who take part in research studies want to know about the findings of research too.

Transparency about what research is going on, and what its findings are, is important for patients, service users and the public. It builds trust and accountability, acknowledges their contribution and encourages participation in research. It's also essential for research and care professionals. It leads to improvements and avoids duplication of effort. It enables findings to be used to develop new and better treatments for patients and service users, and to identify the best ways for us to stay healthy and well. It also helps improve the quality of research.

When research is carried out openly and transparently, everyone benefits:

- patients and the public can see what research is taking place or has completed and access clear information about the results
- patients, service users and carers can find out about research that is relevant to them, giving them the opportunity to join studies
- health professionals, commissioners, researchers, policy makers and funders can use research findings to make informed decisions.

What do we mean by research transparency?

When we talk about research transparency, we mean:

- registration: making it public that a study has started
- reporting results: making it public what the study has found
- informing participants: letting those who took part know what the study has found, and
- sharing study data and tissue: enabling further research.

All of these types of transparency are important. However, the focus of this strategy is on the first three: registration, reporting results and feeding back to participants. These are the

immediate priority areas for the HRA. Others in the research system are best placed to promote appropriate sharing of study data and tissue, though we may focus on this aspect of research transparency in the future.

What types of research does the strategy cover?

This strategy covers health and social care research taking place in the UK which involves people, their tissue or their personal data, and which require review by an NHS research ethics committee. There are many different types of research studies, some of which are covered by legislation with specific requirements around research transparency.

Clinical trials are research studies that test the safety and effectiveness of interventions such as medicines, medical devices, surgical techniques, public health measures and behavioural therapies. Some areas of this strategy – such as taking action in cases of non-compliance – will apply only to clinical trials to start with. We will extend the strategy to cover these other types of research in a later phase of work.

Other areas of the strategy – such as informing participants about the findings of a research study – apply to all types of research. Besides clinical trials, these include observational studies, questionnaires and studies using patient data or human tissue only.

The role of the Health Research Authority (HRA)

Everyone involved in research – from researchers and funding bodies to registries, publishers and the public – has a part to play in making health and social care research open and transparent. However, the HRA has a legal duty to promote research transparency and is taking a leading role on behalf of the research system across the UK to champion openness and drive change in performance.

We are uniquely placed to do this because we review, in partnership with the devolved administrations, all health and social care research studies involving people, their tissue and their personal data - around 5000 studies each year– before they begin. We also set national policy for the conduct of research, laid out in the UK Policy Framework for Health and Social Care Research.

What is in this strategy?

The strategy sets out our vision for research transparency and our mission in helping to make it happen across the UK. We also outline planned activities in three key areas: registering research studies, reporting results and informing participants.

Our vision for research transparency

Our vision for research transparency is that trusted information from health and social care research studies is publicly available for the benefit of all

To help achieve the vision, the HRA will work with key players across the research system, patients and the public to:

- Make transparency easy
- Make transparency the norm
- Make information public.

We will **make transparency easy** by:

- Being clear about what we expect of sponsors and researchers and what they can expect of us
- Supporting good practice through guidance, learning and clear communication
- Having a high-quality, interconnected research approvals system
- Reminding researchers and sponsors when reporting is due.

We will **make transparency the norm** by:

- Working with research funding bodies and other regulators to make sure that expectations around research transparency are consistent and aligned
- Rewarding and celebrating good practice and highlighting poor performance
- Taking action where researchers and sponsors do not fulfil their research transparency responsibilities.

We will **make information public** by:

- Ensuring that all clinical trials taking place in the UK are registered, unless the sponsor has permission to delay this to a later stage
- Publishing or sharing accessible information about individual studies and their findings
- Working with partners to ensure that information for the public is easy to understand.

Registering research studies

Information about each research study should be made public before the research begins. In the case of clinical trials, this means before the first patient is recruited, unless the sponsor has permission to delay this to a later stage. This is called registration and the expectation is set out in the UK Policy Framework for Health and Social Care Research:

> In order to avoid waste, information about research projects (other than those for educational purposes) is made publicly available before they start (unless a deferral is agreed by or on behalf of the research ethics committee).

Clinical trials

Clinical trials of medicines are automatically registered on the EU Clinical Trials Register. Currently, we expect sponsors to register other types of clinical trials such as those for medical devices, surgery, public health and behavioural interventions. However, despite it being a condition of research approval by the HRA, these clinical trials are not always entered onto a public registry. We want to fix this, so that there is full visibility of all clinical trials from the beginning of the study.

In future, the HRA will register clinical trials (other than clinical trials of medicines) on behalf of the sponsor using data that applicants submit for their study to be approved, unless a sponsor has been granted permission to defer registration. We will work with stakeholders to determine the most appropriate way to achieve this. The benefits of this will be:

- all clinical trials taking place in the UK are visible to the public
- data can be shared with recruitment services, such as Be Part of Research, so that more people are able to join research studies
- sponsors and researchers will be able to spend more time on keeping study information up to date because they will no longer need to register the study themselves
- the HRA will be able to focus on ensuring reporting at the end of the study because we will no longer need to chase sponsors to register.

Other types of research

There are around 2500 research studies approved each year that are not clinical trials. These include observational studies and questionnaires.

Unlike for clinical trials, registration is not currently a condition of research approval for these studies. For the time being, this will remain the same. We will continue to publish information about all approved studies on our website through an improved and expanded version of the existing Research Summaries tool.

Reporting results

It is important that the results of individual research studies are shared publicly. This is an expectation in the UK Policy Framework for Health and Social Care Research:

> Other than research for educational purposes and early phase trials, the findings, whether positive or negative, [should be] made accessible, with adequate consent and privacy safeguards, in a timely manner after they have finished.

Publishing results in a peer-reviewed journal is important but it isn't always achievable or findings then accessible to the public. For clinical trials, as a minimum, the record in the registry should be kept updated as the study progresses, including adding a summary of the results. However, we know that this isn't happening in a significant number of cases, even where there is a requirement to do so, such as for clinical trials of medicines.

At present, applicants seeking HRA's approval for their research study are asked how they will disseminate the results of the study, including to the people who took part in it. On approval, they are told that they must submit an end of study report within 12 months of the end of the study. However, there is no defined dataset for this and current resources don't allow us to chase overdue reports.

In future, we will make it clearer to applicants at the time of study approval that they have to submit an end of study report 12 months after the study has ended. We will take a more proactive approach to prompt sponsors and researchers of clinical trials to keep their study information up to date in registries and all studies to submit end of study reports, through systems improvements and monitoring. We will publish the information we receive.

Measuring performance and taking action

We will use information submitted in the end of study report as a basis for measuring research transparency performance and for taking action in cases of non-compliance.

We will publish an annual report, describing our own work to improve research transparency and, once we have the appropriate data collection and monitoring system in place, transparency performance in the research community. We will celebrate good practice and highlight poor performance, by publishing transparency performance about individual sponsors.

We will take into consideration the extent to which the applicant has fulfilled their transparency responsibilities in relation to their previous studies, when reviewing new studies for approval.

As part of the implementation programme, we will work with stakeholders to define a dataset for end of study reporting and determine what information we will publish, share with others and use as the basis for reviewing the applicant's past transparency performance. We will also work with stakeholders to develop a policy for how we take account of past performance when reviewing new studies for approval.

Informing participants

Patient and public involvement, participation and engagement is the cornerstone of good research. When researchers work with patients and the public to plan individual studies, recruitment is easier, research participants are better looked after, and findings are more relevant to patient needs. Researchers should work with patients to develop information about the study, whether that's information about the goal of the research or about what it found.

Giving participants information about the findings of a research study is an important part of good public engagement and a key aspect of research transparency. It respects participants and acknowledges their contribution. It is also an expectation in the UK Policy Framework for Health and Social Care Research:

> Information about the findings of the research [should be] available, in a suitable format and timely manner, to those who took part in it, unless otherwise justified

When applying for research approval, applicants are asked to describe their dissemination plans, including whether they plan to inform participants about the study findings. Many say they do not intend to do so. Many of those that do intend to inform participants fail to do so.

To ensure better feedback to participants, we will:

- change the question we ask applicants from whether they will share study results with participants to how and when they will share them.
- ask researchers and sponsors to submit a lay summary of the study results to the HRA, as part of the end of study report, which we will then publish on the Research Summaries tool.
- produce new guidance on how to inform participants about study findings, taking into account the types of research which may make this more of a challenge, such as research involving adults without capacity, emergency research and research in which participants are likely to die from their existing illness.

As part of the implementation programme, we will work with stakeholders to determine how this will work in practice and to draft new guidance.

Taking action

Non-compliance in submitting a lay summary of study results will be highlighted in the annual report containing the sponsor's performance against transparency requirements, outlined in *Reporting results.*

How we developed this strategy

This strategy has been developed with the help of the Research Transparency Strategy Group which was established by the Health Research Authority in February 2019. The Group's members were:

- Professor Andrew George, non-executive Board member, Health Research Authority (chair)
- Marise Bucukoglu, Head of Research Governance, University of Edinburgh
- Professor David Edwards, Professor of Paediatrics and Neonatal Medicine, Kings College London
- Dr Cham Herath, Executive Medical Affairs Director UK & Ireland, Merck Sharp & Dohme Limited
- Dr Simon Kolstoe, University of Portsmouth and research ethics committee chair
- Dr Síle Lane, Head of International Campaigns and Policy, Sense and Science/AllTrials
- Dr Julie McCarroll, Programme Manager, Northern Ireland Public Health Agency
- Alex Newberry, Head of NHS Research Governance and Informatics, Welsh Government
- Professor Sir Stephen O'Rahilly, Professor of Clinical Biochemistry, University of Cambridge and Director, MRC Metabolic Diseases Unit, University of Cambridge
- Dr Marina Parry, Senior Research Associate at UCL Cancer Institute
- Derek Stewart, public contributor/patient engagement
- Nisha Tailor, Director of Policy and Public Affairs, Association of Medical Research Charities
- Professor Matt Westmore, Director of the Wessex Institute, Faculty of Medicine, University of Southampton

The Research Transparency Strategy Group developed a draft strategy which was put out to public consultation between June and September 2019. The Group finalised the strategy using feedback gathered through the consultation and the strategy was adopted by the devolved administrations and by the HRA Board in February 2020.

Our commitments in detail

Project	Link to strategy	Activities
Reviewing our guidance and standard conditions for approval	1. Being clear about what we expect of sponsors and researchers and what they can expect of us 2. Supporting good practice through guidance, learning and clear communication	• Review existing guidance on our website and in the Integrated Research Application System (IRAS) and update to clarify research transparency requirements and best practice. **(Timeline: April 2020)** • Review outcome letters and associated standard conditions and update to clarify research transparency requirements and best practice. **(Timeline: Sept 2020)** • Prepare revised guidance for a new UK-wide portal for health and social care research and undertake user research to gather information on the best format to present this information. **(Timeline: TBC)** • Change the question in IRAS so that applicants are asked how and when they will inform participants about the study findings. **(Timeline: TBC)** • Develop learning modules on research transparency for researchers, sponsors and HRA staff. **(Timeline: During 2020-2021)**
Modernising the Research Summaries tool to provide enhanced individual study information	9. Publishing or sharing accessible information about individual studies and their findings	• Improve and expand the Research Summaries tool to publish information about approved studies including lay summaries produced at the beginning and end of studies. **(Timeline: TBC)** • Add performance information about individual studies to the Research Summaries tool. **(Timeline: 2021-2022)**

		• Include information about studies with support from the Confidentiality Advisory Group in the Research Summaries tool. **(Timeline: 2021-2022)**
Running an engagement programme, using the Make it Public brand	6. Rewarding and celebrating good practice 2. Supporting good practice through guidance, learning and clear communication	• Develop a communications and engagement plan to support behaviour change as part of an ongoing Make it Public campaign. **(Timeline: April 2020)** • Develop communications tool for use by HRA staff at external engagement activities. **(Timeline: April 2020)** • Hold the first transparency annual meeting one-year on from the strategy launch. **(Timeline: March 2021)** • Publish the first annual research transparency report. (Until we are able to use performance data, this will report on HRA's work and highlight good practice.) **(Timeline: March 2021)**
Establishing ongoing monitoring on study reporting and developing a framework for measuring performance	4. Reminding researchers and sponsors when their reporting is due 7. Taking action where researchers and sponsors do not fulfil their research transparency responsibilities	• Design a model for a study information monitoring function and recruit staff. **(Timeline: June 2020)** • Set up an implementation group and agree on a) a standard dataset for the end of study report; and b) how this data will be used to measure performance. **(Timeline: From June 2020)** • Develop processes and commence manual follow-up for end of study information, analysis and reporting. **(Timeline: TBC)** • Develop a policy for how we will assess transparency performance and how that should be reflected in the annual report and when reviewing new studies for approval. **(Timeline: TBC)** • Design and implement automated reminders and electronic submission of end of study information (phased introduction by study type). **(Timeline: TBC)**

Carrying out an options appraisal on a model for UK clinical trials registration	8. Ensuring that all clinical trials taking place in the UK are registered before the first patient is recruited, unless the sponsor has permission to delay this to a later stage	• Carry out an options appraisal for a model for registration of UK clinical trials. **(Timeline: September 2020)**
Aligning expectations across funders, regulators, and publishers	5. Working with research funding bodies, other regulators and publishers to make sure that expectations around research transparency are consistent and aligned	• Establish a stakeholder forum and develop work plan for 2021-2022. **(Timeline: From June 2020)**
Introducing sanctions into the Approvals process	7. Taking action where researchers and sponsors do not fulfil their research transparency responsibilities	• Introduce performance assessment into review of new studies. **(Timeline: 2021-2022)**