NHS
Health Research Authority

#MakeItPublic

Transparency and openness in health and social care research

July 2020

HSC Public Health Agency
Research and Development

NHS SCOTLAND
NHS RESEARCH SCOTLAND

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Foreword

Record numbers of people are taking part in health and social care research in the UK – around a million people each year. Research brings huge benefits to patients and service users, with the findings ultimately leading to the prevention of ill health, earlier diagnosis, faster recovery and better outcomes.

However, if those research findings are not made public in a meaningful and timely way, we do those research participants a disservice.

"To really maximise and value the commitment of patients, service users and healthy volunteers who take part in research, transparency and openness are essential. It also means they are more likely to take part in future studies."

By disseminating research findings widely, we also enable further research and provide a strong evidence base for commissioning services and making health and care policy.

The Make it Public strategy signals an ambition to transform research transparency in the UK. Its vision for trusted information from health and social care research studies being publicly available for the benefit of all is one that we can all share. The Department of Health and Social Care is committed to supporting the Health Research Authority (HRA) in its work on transparency.

Professor Chris Whitty
Chief Medical Officer for England and Chief Scientific Adviser for the Department of Health and Social Care

The Make it Public strategy is not just a strategy for the Health Research Authority.

"We believe that the strategy vision – to make information about health and social care research studies publicly available to the benefit of all – is one that everyone involved in health and social care research can sign up to. If we work together to make that vision a reality, we will help to retain the UK's reputation as one of the best places to do high quality research."

The Make it Public strategy has been shaped by the people and organisations it affects.The Research Transparency Strategy Group, which I had the privilege to chair, brought together a diverse set of views and experiences from across the UK and gave wise and thoughtful input throughout. The public consultation, which took place in summer 2019, allowed a wide range of people to shape the strategy further.

During the public consultation, we heard from hundreds of researchers and sponsors, patients and participants, funders and registries from across the UK who, like us, feel passionately about transparency and openness in research. What really rang out were the voices of the people who had taken part in research studies but never heard about what the study had found. They were frustrated and felt that things really need to change.

The Make it Public strategy is a response to those calls. It is time for change; better support and encouragement for researchers and research sponsors, greater visibility for patients and the public and fair consequences for those who don't take transparency seriously.

I'm grateful to everyone who has given their time, expertise and careful consideration to produce a strategy which is ambitious yet entirely achievable.

Professor Andrew George
Chair, Research Transparency Strategy Group

About this strategy

Why research transparency is important

The UK has a thriving health and social care research environment with more people taking part in research studies each year. 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 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 broaden our focus to include 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 requires 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 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

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 improvements 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 6000 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 and commitments

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:

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
3. **Having a high-quality, interconnected** research approvals system
4. **Reminding researchers and sponsors** when reporting is due.

We will make transparency the norm by:

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

We will make information public by:

8. **Ensuring that all clinical trials taking place in the UK are registered,** unless the sponsor has permission to delay this to a later stage
9. **Publishing or sharing accessible information** about individual studies and their findings
10. **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

Currently, clinical trials of medicines are automatically registered. We expect sponsors themselves 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.

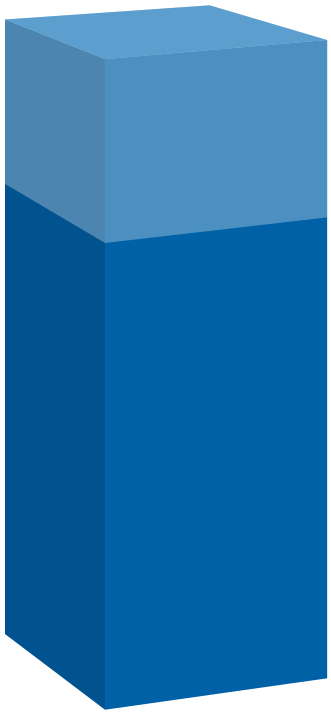
In future, the HRA will register clinical trials on behalf of the sponsor using data that applicants submit for their study to be approved, unless a sponsor has been granted permission to defer registration. We will work with stakeholders to determine the most appropriate way to achieve this. The benefits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



Registering research

30% **of clinical trials are not registered**

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 the 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 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 a final report within 12 months of the end of the study. However, there is no defined dataset for this final report 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 a final report 12 months after the study has ended. We will take a more proactive approach to prompting sponsors and researchers of clinical trials to keep their study information up to date in registries and all studies to submit a final report, through systems improvements and monitoring. We will publish the information we receive.

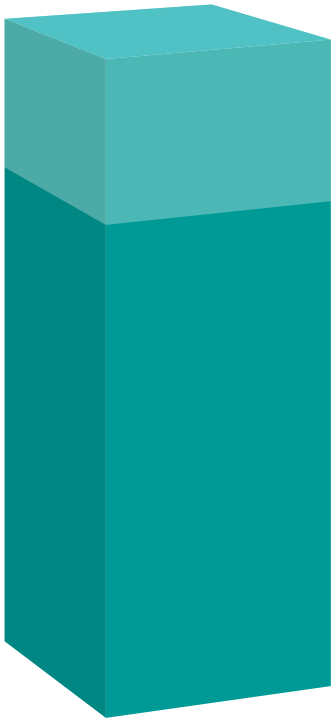
Measuring performance and taking action

We will use information submitted in the final 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 information 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 work to implement this strategy, we will work with stakeholders to define a dataset for the final report 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.



Reporting results

25% **of clinical trials of medicines are not reported**

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.

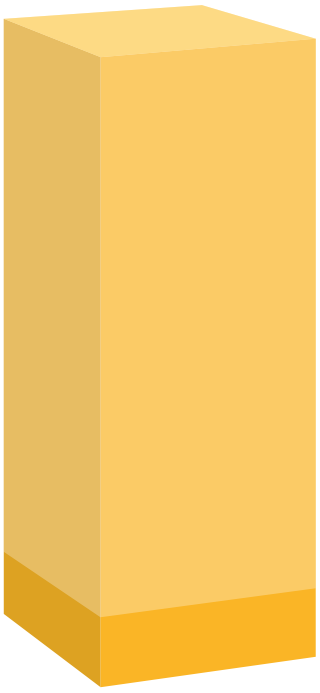
To ensure better feedback to participants we will:

- **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 final report, which we will then publish on our website
- **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 (page 6).



Informing participants

90% **of clinical trials have not told participants about findings**

How we developed this strategy

This strategy has been developed with the help of the Research Transparency Strategy Group which was established by the HRA 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, *formerly Head of International Campaigns and Policy, Sense about 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

We plan to implement the 10 commitments in the strategy through a number of different projects. Those projects are described below, with an expected timeline. Some projects are linked to our IT systems redevelopment where timelines are not yet defined.

Review our guidance and standard conditions for approval

Linked to strategy commitments:

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

PROJECTS	TIMELINE
Review and update existing guidance on our website and in the Integrated Research Application System (IRAS) to clarify research transparency requirements and best practice	October 2020
Review and update the information we give to successful applicants to clarify research transparency requirements	December 2020
Develop learning modules on research transparency for researchers, sponsors and HRA staff	December 2020
Further refine our guidance by undertaking user research to gather insights about the best format to present information	March 2021
Change the question in IRAS so that applicants are asked how and when they will inform participants about the study findings	TBC

Provide enhanced individual study information through our website

Linked to strategy commitment:

9. Publishing or sharing accessible information about individual studies and their findings

PROJECTS	TIMELINE
Improve and expand the research summaries site for providing information about approved studies	Spring 2021
Add lay summaries of research findings to individual approved studies on our website	2021-2022
Add information about support from the Confidentiality Advisory Group for individual approved studies on our website	2021-2022
Add research transparency performance information for individual approved studies on our website	2021-2022

Run an engagement programme, using the Make it Public brand

Linked to strategy commitments:

2. Supporting good practice through guidance, learning and clear communication
6. Rewarding and celebrating good practice

PROJECTS	TIMELINE
Continue to promote research transparency through the Make it Public campaign	Ongoing
Hold the first research transparency annual meeting, one-year on from the strategy launch	Summer 2021
Publish the first annual research transparency report, with performance data added over time	Summer 2021

Carry out an options appraisal on a model for UK clinical trials registration

Linked to strategy commitment:

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

PROJECTS	TIMELINE
Carry out an options appraisal for a model for registration of UK clinical trials	October 2020

Establish ongoing monitoring on study reporting and develop a framework for measuring performance

Linked to strategy commitments:

4. Reminding researchers and sponsors when their reporting is due
7. Taking action where researchers and sponsors do not fulfil their research transparency responsibilities

PROJECTS	TIMELINE
Pilot and develop a standard dataset for the final report with stakeholder input, starting with clinical trials of medicines	TBC
Develop processes and commence manual follow-up of final report for information, analysis and reporting	December 2020
Design and implement automated reminders and electronic submission of final reports	TBC

Align expectations across funders, regulators, and publishers

Linked to strategy commitment:

5. Working with research funding bodies, other regulators and publishers to make sure that expectations around research transparency are consistent and aligned

PROJECTS	TIMELINE
Establish a stakeholder forum to facilitate alignment of research transparency requirements	2021-22

Introduce sanctions into the approvals process

Linked to strategy commitment:

7. Taking action where researchers and sponsors do not fulfil their research transparency responsibilities

PROJECTS	TIMELINE
Develop a policy for how we will assess performance against research transparency requirements and how that will be used when reviewing new studies for approval	2021-22
Introduce research transparency performance assessment into review of new studies	2021-22