MakeItPublic

Transparency and openness in health and social care research

Make it Public: give us your views

This survey gives you an opportunity to influence the Health Research Authority's future strategy to improve public access to information about health and social research in the UK. Please read the strategy before you answer the questions.

The survey, which has nine questions, will take about 15 minutes to complete. There are four questions at the end about you and whether you want to stay in touch with us.

We are keen to understand why you have selected particular options, so please take a little time to complete the free-text boxes. It will really help us when analysing the responses and finalising the Make it Public strategy.

If you would like to know how we will use your data, please read our Privacy Notice.

What the strategy covers

Types of research

This strategy covers health and social care research taking place in the UK which involves people, their tissue or their personal data. Information about research studies of this kind should be made public.

The initial focus of this strategy is on clinical trials. These are research studies that test the safety and effectiveness of patient interventions such as medicines, medical devices, surgical techniques, public health measures and behavioural therapies. We will consider other types of research, such as observational studies and questionnaires, at a later stage.

Types of transparency

Research transparency refers to:

- registration (making it public that a study has started)
- reporting results (making public what the study has found)
- feeding back to participants (informing those who took part what the study has found), and
- sharing study data and tissue (enabling further research).

All these types of transparency are important. However, the initial focus of this strategy is on registration, reporting results and feeding back to participants. We believe that these are the priority areas for the HRA. Others in the research system are best placed to continue to enable appropriate sharing of study data and tissue.

1. Please indicate the extent to which you agree with the following statements.

The strategy should focus initially on clinical trials

Strongly agree
Agree
Neither agree nor disagree
Disagree
Strongly disagree

Please explain your answer
[optional free text box]

The strategy should focus initially on registration, reporting results and feeding back to participants

Strongly agree
Agree
Neither agree nor disagree
Disagree
Strongly disagree

Please explain your answer
[optional free text box]

Supporting good practice, making compliance easy

We have already decided to make the following changes to support good practice and make compliance easier.

2. Please tell us how important you think these changes are in improving research transparency. This will help us to prioritise.

	Very important	Moderately important	Of little importance	Not important	I don't know
Being clearer what we expect of sponsors and researchers					
Developing new learning packages to support research transparency					
Sharing best practice and celebrating improvement					
Making it clear what information from applicants we will make public and what we will share with others					
Introducing automated reminders for researchers and research sponsors to submit transparency data and to view the status of their studies					
Giving sponsors and researchers feedback on their transparency performance					
Flagging up individual studies where transparency information is overdue					
Sharing transparency performance data with funders, other regulators and registries					

Sharing the results of research studies with the people who took part

We want to make sure that the people who take part in a study are able to access the research findings in a format they can understand. This respects participants and acknowledges their contribution.

To ensure better feedback to participants, we have already decided to:

- change the question we ask applicants from whether they will share study results with participants to how and when they will share them (where appropriate)
- ask sponsors to submit a lay summary of the study results to the HRA (no longer than 12 months after the end of the study), which we will then publish.

3. What else, if anything, do you think we should do to improve feedback to participants?
[optional free text box]

Making sure all clinical trials are registered

Information about each clinical trial should be made public before the first patient is recruited, unless the sponsor has permission to delay this to a later stage. This is called registration. Clinical trials of medicines are automatically registered on the EU Clinical Trials Register. However, despite it being a condition of approval, around 30% of clinical trials of medical devices, surgery, public health and behavioural interventions are not registered. We want to fix this.

We expect sponsors to register their study before recruitment begins (unless they request a deferral), which can happen a few months after they seek approval. We do not ask them to give us the registration details when they do register. For the majority (around 90%) of sponsors we know that reminding them to register is effective.

We would like your views about the following options for ensuring registration of all clinical trials:

- Researchers must register their study before seeking approval. The advantage of this would be that 100% of studies are registered (except those with a deferral). However, the disadvantage would be that those studies which are not approved would have been registered.
- The HRA supplies data about clinical trials directly to a registry. The advantage of this would be that 100% of studies are registered (except those with a deferral) and the sponsor has less to do. The disadvantage is the cost of building the systems to send the data to a registry.
- The HRA becomes a registry itself. The advantage of this would be that there is no need to build the systems to send the data to a registry. The disadvantage would be that it may duplicate the work of existing registries.

4. Which of the options do you think is the most appropriate to ensure registration of clinical trials (please select only one)?
[radio buttons]

Researchers must register their study before seeking approval
The HRA supplies data directly to a registry
The HRA becomes a registry itself
Something else (please describe below)
Don’t know

Please explain your answer. If you have picked ‘something else’, tell us what you have in mind.
[optional free text box]

Monitoring transparency performance on clinical trials

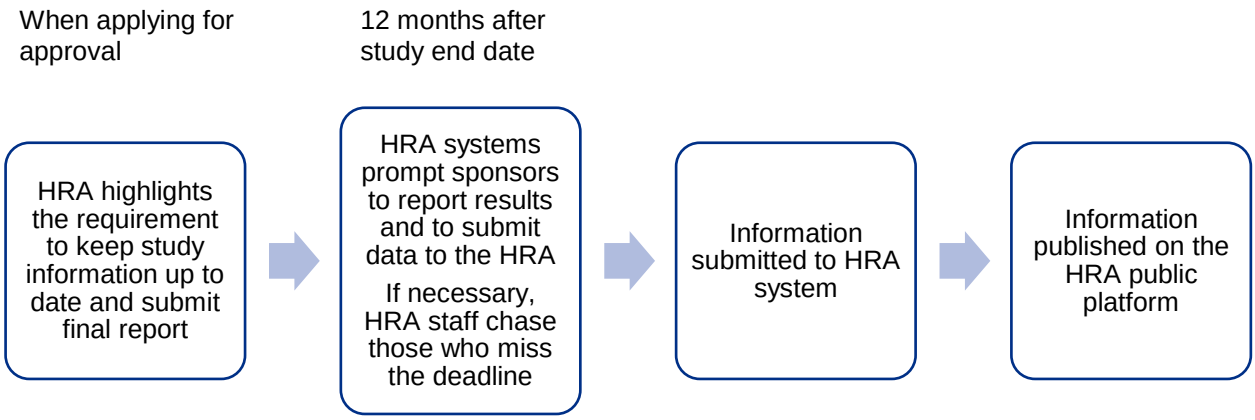
It is important that the results of individual clinical trials are shared publicly. Publishing results in a peer-reviewed journal isn't always achievable or accessible to the public. As a minimum, the study record in the registry should be kept updated as the study progresses, including adding a summary of the results.

Whilst it is a legal requirement for clinical trials of medicines, around 25% of sponsors do not report results on time. For other types of clinical trials, where there is no legal requirement, the reporting rate is likely to be lower. We plan to change our processes for all clinical trials to address this challenge.

Currently, applicants seeking approval from the HRA for their research 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 and current resources don't allow us to chase overdue reports.

We plan to make it clearer to applicants at the time of study approval that they should send us a final report 12 months after the study has ended. We will also take a more proactive approach to prompt sponsors for these reports. We will publish information we receive on the public platform or provide a link to information held in a registry or publication.

The process would look like this:



5. To what extent do you think that these steps will improve the reporting of results from clinical trials?
[radio buttons]

I believe very strongly that they will improve the reporting of research results
I believe that they will improve the reporting of research results
I believe that they will not improve the reporting of research results
I believe very strongly that they will not improve the reporting of research results
I don't know

6. What else, if anything, do you think we should do to improve the reporting of results?
[optional free text box]

Changes we could make

We believe that the plans and proposals in this strategy will bring about significant improvements in research transparency. However, we have developed some possible further steps we could take for dealing with individual sponsors who do not fulfil their research transparency responsibilities.

We are not proposing specific measures at this stage, but we are keen to hear your views about the approaches we could take. If we decide to pursue specific measures based on the feedback we receive, we will formally consult on them.

In deciding whether to take these actions, we need to consider not only what could be effective, but also what is reasonable. We would also only take actions once sponsors have had a reasonable opportunity to comply or to make a case for why they are unable to comply.

7. To what extent do you think the following actions would be appropriate?

	Not at all appropriate	Not appropriate	Appropriate	Highly appropriate	I don't now
Publish an annual 'transparency league table' highlighting individual studies which have information that is overdue					
Take into consideration the extent to which sponsors have fulfilled their transparency responsibilities in relation to their previous studies, when reviewing new studies for approval					
Fining sponsors with very poor transparency compliance rates (this would require a change in legislation)					

Please explain your answers
[optional free text box]

Things that might make it hard to be transparent

Researchers and sponsors have told us about things that make it difficult to comply with transparency requirements. Some of them are wider cultural or institutional factors and others are practical hurdles. Here are some examples:

- Limitations in the EU register make it hard to report results about certain types of clinical trials of new medicines
- Delays in the system for updating records on the EU register mean that results still appear to be outstanding when they are not
- Difficulties in reporting the results of trials because trial staff have left the sponsor organisation
- Lack of resources and clarity about responsibilities in sponsor organisations to adequately monitor and fulfil transparency requirements
- Lack of clarity about the transparency requirements for different types of studies
- Institutional pressures to publish in a peer-reviewed journal and apply for further research funding, rather than fulfilling transparency responsibilities on existing studies

We are not saying that these reported difficulties are acceptable reasons for failing to fulfil transparency responsibilities. However, we want to understand the difficulties so that we can help to address them where possible – and we are already working on that in some areas. We also want to make sure the changes we make are feasible for sponsors and researchers.

8. Please tell us about anything else that might make it hard to be transparent, as well as anything that would make it easier.
[optional free text box]

General comments

9. Please give us any other feedback about the strategy or our work to improve research transparency.
[optional free text box]

About you

10. Are you responding to this survey on behalf of an organisation?
[radio buttons]

No
Yes

If yes, please say which one and go to question 12
[Mandatory free text box]

11. If you are responding as an individual, how would you describe your role in research? Please select the one most relevant to this survey.
[radio buttons]

Research participant
Patient, service user or carer
Patient advocate or representative/public contributor/patient, service user or carer involved in designing research
NGO/other advocacy group
Research ethics committee member
Researcher - industry
Researcher - university
Researcher - NHS
Research manager - industry
Research manager - university
Research manager – NHS
Clinical research organisation
Sponsor - industry
Sponsor - university
Sponsor - NHS
Funder - public
Funder - charity
Healthcare professional
Other (please give details)
[free text box]

12. Where are you based?
[radio buttons]

In the UK
Outside the UK

13. Are you happy for us to contact you in future with information or news about our transparency work?
[radio buttons]

No
Yes

If yes, please give your email address
[mandatory free text box]