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.

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

The Academy strongly supports efforts to increase transparency around the existence, methods and results of clinical and health research. Making the findings of research that involves patients available is important for a number of reasons, including the following:

- Under-reporting of research can lead to avoidable harm to patients and can waste limited healthcare and research resources.
- Greater access to appropriately controlled data offers significant scientific benefits and helps ensure scientific validity, particularly for large studies where replication is more difficult.
- It helps to develop hypotheses and improves trust in clinical and health research.[1]

Overall, the majority of the Fellows we consulted **strongly agree** that this strategy should focus initially on clinical trials. Catalysing a change in the reporting and monitoring of clinical trials research is likely to be the quickest way of bringing meaningful benefits to patients. Therefore, clinical trials are an appropriate entry point to drive improvements in research transparency. Moreover, the comprehensive regulatory framework already in existence for clinical trials would provide a good conduit to achieving improvements in a more rapid and straightforward manner.

[1] Academy of Medical Sciences (2013b). *Clinical trial transparency*. http://www.acmedsci.ac.uk/policy/policy-projects/clinical-trials-and-data-disclosure/

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

A large proportion of the Fellows we consulted **agree or strongly agree** that each of the identified priorities are important steps towards improving standards. However, a small number of our Fellows did not agree that the strategy should initially focus on the priorities outlined above. Whilst there may be some debate over whether each of these factors are of equal concern – for example whether reporting of negative results is of greater issue than study registration – we acknowledge the need for compliance to improve across each of these areas.

As highlighted in the consultation, other organisations such as NHS Digital may be better placed to address the issues surrounding sharing of data and tissue. Given the complexity of the issue, any changes required by this strategy must align with other efforts across the sector to avoid duplication or conflicting requirements.

However, data sharing is crucial to fostering a culture of openness and transparency in research, and will be crucial in tackling issues of irreproducibility.[2] Ensuring patient confidentiality is a critical consideration and secure systems with appropriate safeguards will be essential to allow reliable and secure data access, whilst protecting individual privacy.[3] Further support for a culture change and encouragement of best practice in this area would be welcome.

[2] Academy of Medical Sciences (2015). Reproducibility and reliability of biomedical research: improving research practice. https://acmedsci.ac.uk/file-download/38189-56531416e2949.pdf
[3] Academy of Medical Sciences (2016). *Submission to the British Academy and Royal Society's call for evidence on data governance*. https://acmedsci.ac.uk/file-download/41614-583586af15320.pdf

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	X				
Developing new learning packages to support research transparency		X			
Sharing best practice and celebrating improvement		X			
Making it clear what information from applicants we will make public and what we will share with others	X				
Introducing automated reminders for researchers and research sponsors to submit transparency data and to view the status of their studies	X				
Giving sponsors and researchers feedback on their transparency performance		X			
Flagging up individual studies where transparency information is overdue	X				
Sharing transparency performance data with funders, other regulators and registries		X			

Being clear what we expect of sponsors and researchers

The Fellows we consulted viewed this measure as **very or moderately important**, with a majority expressing the former opinion.

Developing new learning packages to support research transparency

Opinions were divided on this action. Around two thirds of those we consulted thought this would be important, most commonly viewing it as **moderately important**. However, the remainder viewed this step as being of little importance or not important at all.

Sharing best practice and celebrating improvement

The Fellows we consulted were also divided on this measure. A large proportion stated it was important, with the majority viewing this action as **moderately important**. Conversely, a small number of those we consulted felt this measure was not important or of little importance.

Making it clear what information from applicants we will make public and what we will share with others

All of our consulted Fellows viewed this as a **very important** measure.

Introducing automated reminders for researchers and research sponsors to submit transparency data and to view the status of their studies

The vast proportion of our consulted Fellows viewed this as important. Half of the responses we

received noted this as a **very important** measure, whilst a good proportion felt this was of moderate importance. A very small proportion viewed this action as not important.

Giving sponsors and researchers feedback on their transparency performance
Views on this action ranged from very important to of little importance, with the majority of our fellows reporting that this was a **moderately important** or very important measure.

Flagging up individual studies where transparency information is overdue
The Fellows we consulted were divided on this measure. The majority expressed the view that this was a **very or moderately important** action, with the former being the most common response. However, a small proportion felt this was of little importance or not important at all.

Sharing transparency performance data with funders, other regulators and registries
Our consulted Fellows were also divided on this action. A significant proportion thought this was a **very or moderately important** measure, with the latter the most common response we received. A smaller proportion felt this was of little importance or not important.

3. What else, if anything, do you think we should do to improve feedback to participants?

The Academy believes that the existence, methods and results of clinical and health research involving patients – whether positive or negative – should be made swiftly available for patient, social and scientific benefit.[4] Patient friendly information should be available for all trials that are open for recruitment and it is important that such information is provided in a structured, tailored and unambiguous format. This should not merely be a more accessible version of the scientific abstract or study protocol, but rather highlight the purpose of the study, primary and secondary outcomes, safety information and the influence of findings on scientific understanding. The HRA could commission or support a service or system to assist researchers in constructing a comprehensible and accessible lay summary, especially for sponsors who may not have spare resource to enable this.

However, it is important to consider the added burden for researchers to meet an additional 12-month lay summary deadline. This could be mitigated through general encouragement of comprehensive, up-to-date entries on registries, and ensuring compatibility across systems to avoid duplication of information. Moreover, the HRA should work with journals and funders to ensure that there is easy to meet the requirements as well as those of the HRA for example, the 12-month lay summary deadline can present challenges as some journals may impose strict embargo policies which extend beyond the 12-month period and thus inhibit compliance (see also question 6).

To facilitate sharing of results with participants, information on result-sharing could be provided on the participant consent form. Further, a general obligation could be introduced requiring that the main study publication, where applicable, is made open access. The HRA may wish to consider whether commitment to pay for such open access becomes a condition of study approval.

Feedback on treatment allocation in blinded trials is a separate issue, which should not be confounded with the steps referenced above. However, timeframes in which this type of information should be conveyed to participants could also be considered, especially for trials where such information may have significant implications for the individual, such as trials involving pregnant participants.

[4] Academy of Medical Sciences (2013b). *Clinical trial transparency*. http://www.acmedsci.ac.uk/policy/policy-projects/clinical-trials-and-data-disclosure/

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

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.

The preference of those we consulted was split across the options outlined above. Whilst there was some support for each of the suggested measures, the most common response we received was for the HRA to action something else, as outlined below. There was a general view that the current requirements for registering studies (on platforms such as ClinicalTrials.gov or the EU Clinical Trials Register) should be sufficient, with additional requirements not desirable. However, we acknowledge that further work should be done to achieve full compliance.

Registering studies prior to seeking approval may prove effective; however, this may pose practical challenges. For example, in the event that ethical review leads to a change in design, the inflexibility of amending study details after registration may become problematic for researchers.

The HRA supplying data directly to a registry may help to automate the registration process. However, if this option is pursued, it will be important for the HRA to undertake an initial review to define a clear and robust set of questions to enable the HRA to perform this function without having to call on individual study teams multiple times with further queries.

We are keen to avoid unnecessary proliferation of registries.[5] Care should also be taken to avoid imposing unnecessary bureaucratic burden on researchers that inadvertently acts as a disincentive to engaging in clinical trials. Becoming a registry itself would be a costly option for the HRA, with the added burden of duplicating existing efforts. Although this is worth consideration, priority should be given to ensuring the UK is the most cost-effective environment for research. A new registry should require clear and up-to-date information on study progress, results and trial materials in order to be a valuable resource for researchers and funders, whilst mitigating the risk of duplicitous information.

An alternative approach to those proposed above could be the retaining of current requirements that studies are registered before the first participant is recruited, on the condition that confirmation of registration must be submitted before or with the first annual progress report. If a study has failed to do so, ethical approval could then be withdrawn.

[5] Academy of Medical Sciences (2013b). *Clinical trial transparency*. http://www.acmedsci.ac.uk/policy/policy-projects/clinical-trials-and-data-disclosure/

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

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

The Fellows we consulted held differing opinions on whether the steps outlined would improve the reporting of research results, with views ranging across the spectrum. A greater proportion of those we consulted believe that they **will improve the reporting of research results**, although a good proportion also felt that this was not the case.

6. What else, if anything, do you think we should do to improve the reporting of results?

It is crucial that flexibility is provided around targets such as a 12-month deadline for producing a summary of results once a trial has been registered. As discussed above, collaboration with journals and funders will be important if introducing further targeted deadlines, because:

- Researchers require time to rigorously analyse their findings.
- A single study may generate several papers that each may take time to prepare.
- Different journals have different times for peer-review.
- A paper may not be accepted by the first journal to which it is submitted.
- Researchers should have some initial degree of exclusivity to results otherwise there will be significantly less incentive to conduct important studies as the reward will be accrued by others.[6]

It is unclear what is required of researchers in terms of a 'final report'. It will be important for the HRA to distinguish whether this refers to a lay summary, publication of data, a scientific report or something different.

The HRA should also consider:

- Introducing incentives and support for study teams in achieving compliance targets, given the risk of further administrative requirements on researchers' already constrained time and resources, especially if sanctions are to be implemented (see question 7 for further details).
- Liaising closely with funders and the Medicines and Healthcare products Regulatory Authority (MHRA) - who also require final reports for Clinical Trials of an Investigational Medicinal Product - to avoid duplication and unnecessary burden on researchers. Streamlining the process for publishing results across the various platforms may be more desirable, rather than introducing a parallel system.
- Implementing a structured annual progress report, incorporating information on recruitment progress, protocol changes and safety issues. This would need to be accompanied by auto-reminders and a system to review compliance and robustness, but would ensure registries are updated throughout the span of a study and provide researchers with a clear structure for fulfilling requirements.
- Making information on previous reporting of results available to Research Ethics Committee's for consideration when reviewing new applications.
- Removing HRA approval for new studies which have not reported previous results within a considerable time frame. This should only be applied in cases where there was no legitimate reason for missing a reporting deadline.

[6] Academy of Medical Sciences (2013b). *Clinical trial transparency*. http://www.acmedsci.ac.uk/policy/policy-projects/clinical-trials-and-data-disclosure/

Changes we could make

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			X		
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			X		
Fining sponsors with very poor transparency compliance rates (this would require a change in legislation)		X			

Please explain your answers

Introduction of a transparency league table

The majority of the Fellows we consulted viewed the introduction of a transparency league table as an **appropriate** measure. However, a smaller number also viewed this action as not appropriate or not appropriate at all. Whilst this may be a reasonable first step in achieving compliance, it will be important to find the right balance and consider the disincentives to engaging in clinical trial research which this could create. The opportunity and morale costs of an unjust or improper 'naming and shaming' approach could be substantial.

Considering the extent to which sponsors have fulfilled their transparency responsibilities

Overall, a significant proportion of our consulted Fellows agreed this was an **appropriate** measure, although views were divided and ranged from not appropriate at all to highly appropriate. Withholding approval for new trials until previous trials have been reported could prove an effective sanction, encouraging sponsors to fulfill their transparency standards to avoid the potential reputational damage of not doing so. Research Ethics Committees may be best placed to consider previous compliance and, if needed, discuss with applicants any factors resulting in prior non-compliance. This approach would have the advantage of introducing serious consequences for non-reporting, without the uncertainty accompanying a fines-based approach (see below).

However, sponsors typically oversee a wide range of trials across different research groups; monitoring individual performance, especially past infringements, could be difficult. Care should be taken to avoid weakening academic sponsors, which could unintentionally result in negative repercussions for UK research. It would be crucial to ensure measures are suitably targeted, so compliant researchers, or cases where non-compliance was justifiable or unavoidable, are not unfairly penalised for the poor practice of others within their academic institution. It may be more attractive to consider how this measure could be implemented on a more individual basis.

Fining sponsors with very poor transparency compliance rates

Largely, the Fellows consulted agreed that fines were **not appropriate or not appropriate at all**. The level at which fines should be set in order to effectively discourage poor practice would be uncertain, and in some cases may not prevent future non-compliance. Fines should only be considered as a last resort and in the case of repeated poor practice. Overall, we believe that the

alternative options outlined in this consultation should be sufficient in achieving compliance.

Alongside these measures, accompanying incentives and support provision to researchers will be crucial; for example rewarding and showcasing best practice, which would help to disseminate and further encourage behaviours that promote greater transparency.

8. Please tell us about anything else that might make it hard to be transparent, as well as anything that would make it easier.

The following aspects would make it harder to be transparent, and means to address these challenges should be considered in the formulation of the HRA's transparency strategy:

- A lack of infrastructure provided by funders and sponsors to enable compliance with reporting, especially for smaller study groups.
- Difficulties in reporting the results of trials due to legal reasons, such as commercial sensitivity and intellectual property rights.
- Inability to produce laboratory results within a 12-month deadline if working with an international partner who does not share the same compliance obligations.
- Competition for space in journals[7] which may delay publication.

The following steps would make it easier to be transparent:

- The provision of support and incentives for researchers, from both sponsors and funders, to ensure that engaging in clinical trials is a rewarding activity which encourages best practice. For instance, including time and resourcing for compliance in funding packages or rewarding and showcasing good practice.
- Accepting publication in a peer-reviewed journal as a form of compliance, with the view that this information is more useful and transparent than submissions in the EU register.
- Structured and clear requirements for information provision on registries, aiming for an entry that can be completed by 'mid-level' researchers. This would reduce time burden on principal investigators and create a more seamless return process.
- Closer collaboration with journals, funders, the MHRA and other bodies to avoid duplicative or conflicting requirements which may hinder compliance. For example, many journals view any information in the public domain as jeopardising later publications, and publishing timescales may inhibit compliance.
- The introduction of a system that is interoperable with existing reporting systems, including ResearchFish, funder websites such as NIHR journal pages, Higher Education Institutions and Research Ethics Committees reporting systems, and existing trial registries.
- Requirements are often unmet due to different portals not capturing the same information. Developing a system that enables results from publications to be directly uploaded to public trial registries would assist researchers in meeting the regulatory requirements for trial reporting. The HRA may wish to consider undertaking a mapping process of the information that is required across these platforms to inform the development of such a system.
- Consideration of requirements that ensure registry entries are updated and provide clear, unambiguous information on study progress. In particular, maintenance of up-to-date trial materials, including protocol and patient information leaflets.

[7] Academy of Medical Sciences (2013b). *Clinical trial transparency*. http://www.acmedsci.ac.uk/policy/policy-projects/clinical-trials-and-data-disclosure/

9. Please give us any other feedback about the strategy or our work to improve research transparency.

The Academy supports efforts to increase the transparency of clinical trials, including compulsory registration of clinical trials, the publication of summary results in public registries and efforts to enhance the reporting of clinical trials. However, it is important to find the right balance. The community must embrace a 'no-blame' culture and care should be taken to ensure science does not become overly bureaucratic or cumbersome, which could hamper the scientific process.[8] The HRA must ensure that the complexity and cost associated with enhancing the transparency of non-commercial clinical research does not inadvertently act as a disincentive to engaging in clinical trials.

One important consideration is the resource required to achieve the different sorts of transparency proposed in this consultation. This will need to be balanced against the benefits that greater transparency could bring. For example, consideration should be given to who creates and maintains the requisite infrastructure and what costs will researchers incur in providing data. This is a particular challenge for non-commercial funders that often have less resources than industry.[9]

Incentives should be provided to support researchers in complying with transparency guidelines; we encourage research institutions and journals to provide incentives for complying with the guidelines use and to better enforce their adoption.[10] Higher education institutions and research institutes could support transparency efforts by providing appropriate training that address transparency, for example as part of research integrity training[11] – the HRA may wish to assist the development of such training.

Flexibility will also be crucial with the implementation of any new regulations, and duplicated efforts and conflicting requirements should be avoided. Coordination across the different trial registries in different countries is important to avoid duplication of effort and to increase simplicity.[12]

Transparency is an important issue for all those who conduct, fund, participate in and utilise the results of clinical trials in industry, academia, the NHS, charities and elsewhere. Solutions will therefore require the involvement of a wide range of stakeholders. The increasing number of cross-sectoral collaborations between these groups means that responsibility for transparency is increasingly shared.[13]

Given the implications of this strategy for clinical researchers, we believe that, it will be important that the research community is engaged in developing and evaluating effective

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[8] The Academy of Medical Sciences (2017). *Sources of evidence for assessing the safety, efficacy and effectiveness of medicines*. https://acmedsci.ac.uk/file-download/86466482

[9] Academy of Medical Sciences (2013b). *Clinical trial transparency*. http://www.acmedsci.ac.uk/policy/policy-projects/clinical-trials-and-data-disclosure/

[10] The Academy of Medical Sciences (2017). *Sources of evidence for assessing the safety, efficacy and effectiveness of medicines.* https://acmedsci.ac.uk/file-download/86466482

[11] The Academy of Medical Sciences (2015). *Reproducibility and reliability of biomedical research*: improving research practice. https://acmedsci.ac.uk/file-download/38189-56531416e2949.pdf

[12] Academy of Medical Sciences (2013b). *Clinical trial transparency*. http://www.acmedsci.ac.uk/policy/policy-projects/clinical-trials-and-data-disclosure/

[13] Academy of Medical Sciences (2013b). Clinical trial transparency. http://www.acmedsci.ac.uk/policy/policy-projects/clinical-trials-and-data-disclosure/

solutions – and that unintended consequences are avoided.[14] The Academy welcomes this opportunity to comment on the HRA's future strategy alongside the series of consultation workshops being hosted across the UK. In addition, the HRA should seek to consider how academic representatives with a deep understanding of the design, conduct and reporting of clinical trials, or experience working with patients to ensure appropriate interactions with the public, can be included further in the strategy delivery group.

[14] The Academy of Medical Sciences (2015). *Reproducibility and reliability of biomedical research*: improving research practice. https://acmedsci.ac.uk/file-download/38189-56531416e2949.pdf