



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

Consultation Report

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DRAFT

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# 1. Introduction

**Our vision is that trusted information about health and social care research studies is publicly available for the benefit of all.**

Transparency about what research is going on, and what its findings are, is important for patients and the public. It builds trust and accountability. It's also essential for professionals. It avoids duplication of effort and enables findings to be used to develop new and better treatments for patients and service users. 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 and access clear information about the results
- patients, service users and carers know 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.

Whilst we all have a part to play in making sure that research takes place in an open and accountable way, we believe that HRA should champion and lead others on research transparency. That's 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](#).

Rather than publish a draft strategy and then seek comments on that draft, we wanted the public and research professionals to have more influence over the development of the final strategy. We worked with our Research Transparency Strategy Group to develop the overall vision and what we see as our mission in delivering that vision, as well as a series of commitments.

To gather views, we ran an online survey and held a series of open workshops across the UK. We also sought views from patient groups and Research Ethics Committees and the approvals staff who support them.

These views have helped us develop our final strategy. This strategy sets out our vision for research transparency and our mission in helping to make it happen across the UK. It also outlines our planned activities in three key areas: registering research studies, reporting results and informing participants.

## 2. Executive summary

The online survey had 489 responses (including emailed responses) and 236 people attended the UK-wide consultation workshops, a public involvement focus group, a Research Ethics Committee (REC) member's webinar or HRA staff workshops.

### **What the strategy covers**

In general, the majority of all the responses were supportive of the proposed scope of our strategy i.e. that the initial focus should be on clinical trials (research studies that test the safety and effectiveness of patient interventions such as medicines, medical devices, surgical techniques, public health measures and behavioural therapies) and that, whilst the appropriate sharing of study data and tissue is important, the initial focus of our strategy should be on registration, reporting results and feeding back to participants, with many citing the importance and relevance of these trials to patients and the NHS and their substantive contribution to the evidence base as reasons for their support. However, a significant number of people felt that, whilst it is appropriate and right that we focus on clinical trials, all health and social care research within the HRA's remit should be included in due course.

### **Making sure all clinical trials are registered**

We set out three options in the consultation to ensure registration of clinical trials. Of these, the option for the HRA to become a registry itself attracted the highest level of

agreement (34% of survey respondents). However, 50% of survey respondents preferred either “Researchers must register their study before seeking approval” or “HRA supplies data directly to a registry”. There was general support for a single place for registration for all studies and for the HRA to be that place. However, it was emphasised that whatever option is chosen, the process should be simple and easy with registration expectations made clear and guidance and training provided.

### **Reporting results (making public what the study has found)**

We have already decided to make important changes to support good practice and make compliance easier. 81% said that they believed or believed very strongly that these changes will improve the reporting of research results. Those who provided suggestions for further improvements emphasised the need for the HRA to work closely with other stakeholders across the system, particularly funders with whom compliance data might be shared, to help drive improvements in transparency. Many felt that, if we did so, significant improvement might be had without the HRA having to resort to sanctions.

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

We have already decided to reinforce the importance of feeding back by changing the question we ask applicants from whether they will share study results with participants to how and when they will share them (where appropriate). We will also require sponsors to submit a lay summary of the study results to us within 12 months of the end of the study, which we will publish. We asked for suggestions for what else we could do to improve feedback to participants. Several practical suggestions for how researchers could provide better feedback were put forward, not least being the closer involvement of patients and the public in developing feedback procedures and materials for research participants. As one person put it “Do this with participants, not for them.”

### **Sharing study data and tissue (enabling further research)**

Whilst many believed that the HRA could have an important role to play in the facilitation of data/tissue sharing this was not generally felt to be a priority for the HRA given existing high-profile initiatives to promote open access in research.

## **Next steps:**

### **Changes we will make**

We asked for views about how we should prioritise the changes we have already decided to make. Whilst the changes were all considered to be important the areas receiving the most support from both the online survey and workshops were:

- Being clearer what we expect of sponsors and researchers
- Making it clear what information from applicants we will make public and what we will share with others
- Introducing automated reminders for researchers/sponsors to submit transparency data and to view the status of their studies
- Flagging up individual studies where transparency information is overdue

### **Changes we could make**

We set out further steps we might take for dealing with individual sponsors who do not fulfil their research transparency responsibilities i.e.:

- Publish an annual 'transparency league table'
- Take into consideration sponsors transparency record when reviewing new studies for approval
- Fining sponsors with very poor transparency compliance rates

Both the use of league tables and taking into account the extent to which sponsors have fulfilled their transparency responsibilities when reviewing new studies received a high level of support, both online and in the workshops.

The suggestion that the HRA fine sponsors with very poor transparency compliance rates was much more divisive. 47% of online respondents did not support this sanction whilst 39% did. There was greater support from patients and the public completing the online survey for the use of fines (57%) than those directly involved in research such as research managers, researchers and Contract Research Organisations (CROs) (30%). Interestingly, those attending the patient and public

workshop, after a full discussion of the associated issues, changed their initial view that fines were acceptable to unanimously agreeing that they were not.

Whilst there was a strong feeling that the use of fines would “focus minds” many cited a lack of evidence that fines would promote compliance. It was felt that they would not address the current barriers to compliance and, instead, would damage good will, alienate the research community, and potentially make the UK a less attractive place to do research.

Several important overarching themes repeatedly emerged across all the responses we received on the steps we should take.

**Clarity** – The HRA will need to make its transparency expectations and requirements clear. This will require timely guidance regarding responsibilities and definitions backed up by training.

**Proportionality** – Many emphasised the need for any transparency strategy to be applied proportionately with sensitivity to the different types of research whether large commercially sponsored interventional clinical trials or qualitative student research. The strategy should consider its impact on those with limited resources as well as the need for appropriate commercial sensitivity.

**Patient and public involvement** – Many strongly argued for the involvement of patients and the public in research from the very beginning of the study as this is likely to promote transparency at all stages of the research. Researchers should budget for public involvement in their funding applications. It is not enough for lay summaries to be made public, it needs to be done well and public involvement will help this.

**EU Clinical Trials Regulation (EU CTR)** – Uncertainty over future access to the EU CTR portal for uploading transparency information (research summaries etc.) compounded by a lack of detail about the UK’s departure from the EU, was seen by many as a major barrier to transparency.

**Cultural change** – It is apparent that the realisation of our transparency vision will require significant cultural change across the entire research environment. Many supported a role for the HRA in facilitating this culture change.

**Collaboration** – The transparency vision set out by the HRA and the associated cultural change required can only be delivered if all relevant stakeholders cooperate. Everyone involved in research whether funders, researchers, sponsors, coordinators or publishers has a part to play in promoting transparency and openness in health and social care research. Many pointed out that the HRA needs to work closely with these and other stakeholders to promote transparency, deliver culture change and share information regarding compliance. Funders were singled out as having a particularly important role through the application of transparency requirements to their funding conditions and taking into account the applicant's transparency record when making funding decisions.

## 3. What we did

### 3.1. Online Survey

The online survey, hosted by Snap Survey, ran from 17 June to 6 September 2019.

The full list of quantitative survey questions and the responses received are detailed in Annex 1.

Whilst many of the online survey questions required responses to be given using a Likert scale we also asked respondents to explain their answers to some of the questions. This report summarises the main themes or points raised by respondents.

We received a total of **489** responses to the survey:

- **465 responses** via the online survey
- **24 responses** via email.

66 responses were received from organisations

The total number of unique responses received was **481**.

Almost half (48%) of responses were from individuals working in research either as researchers, research managers or for sponsors and Contract Research Organisations (CROs). We also received a significant number of responses (36%) from members of the public identifying themselves as 'patient, service user or carer', 'patient advocate or representative/public contributor/patient, service user or carer involved in designing research' or 'research participant'. Whilst the number of industry and charity sector responses were relatively low, corporate responses were received from the Association of the British Pharmaceutical Industry (ABPI), GlaxoSmithKline and the Association of Medical Research Charities (AMRC).

The full list of organisations which responded is listed in Annex 2. Individual respondents are not named.

### **3.2. Workshops**

We held several events to complement the online survey and gain more in-depth feedback. These consisted of:

- Open workshops
- Webinar for research ethics committee members
- Patient and a Public involvement focus group
- HRA staff workshops

#### **Open workshops**

Five open workshops were held across the UK in London, Manchester, Cardiff, Belfast and Edinburgh.

You can [download the slide set](#) used in each location.

You can also see a video of the presentations from the Edinburgh workshop on our [YouTube channel](#).

Workshops outside England were organised jointly with colleagues in the devolved administrations. Workshops were free and open to anyone, attendance was managed via the public web-based ticketing platform Eventbrite with attendees registering in advance. A range of methods were used to advertise the workshops including the HRA website/newsletter/social media accounts, regional media and partner stakeholder organisations' communication channels.

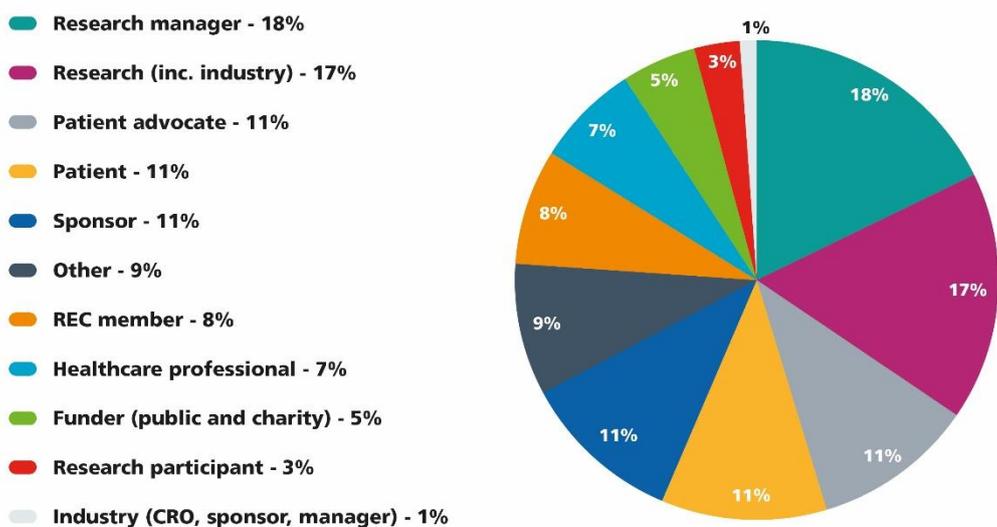
A total of 161 people attended the workshops:

- London - 42
- Manchester - 29
- Cardiff - 26
- Belfast - 35
- Edinburgh - 29.

When registering to attend the workshop, participants were asked to indicate their role in research (they were able to choose more than one category). Of the 161 participants, 25% were patients, patient advocates and research participants, 18% were research managers and 17% were researchers.

**Figure 1 – Pie chart showing how workshop participants described their role in research.**

How would you describe your role in research?



Pie chart summary. The pie chart shows how the workshop participants described their role in research. Research manager occupies 18%, researcher including industry occupies 17%, patient advocate occupies 11%, patient occupies 11%, sponsor occupies 11%, other occupies 9%, REC member occupies 8%, healthcare professional occupies 7%, funder (public and charity) occupies 5%, research participant occupies 3%, industry including CRO, sponsor and manager occupies 1%.

[Download a csv file for pie chart data from figure 1.](#)

The format of the workshops varied slightly to suit the local audience, but all involved a plenary and table-based discussion around the three key topic areas in the strategy (registration, reporting and feeding back) and an exercise to prioritise planned activities. Attendees were pre-assigned to tables, to ensure a mixture of perspectives were represented in the discussions. Views expressed during the plenary were captured by a member of HRA staff and table discussions were noted either by the facilitator assigned to each table, or by attendees themselves. For the prioritisation task each attendee was asked to indicate what they felt should be the first, second and third priorities for implementation.

### **Research ethics committee members webinar**

An online slide presentation of the strategy was given. Following this, attendees were able to instant message and email questions and comments. 24 members attended.

### **Patient and a public involvement focus group**

A focus group comprised of patients and members of the public was held at the HRA's Nottingham office. Participants were recruited through the Nottingham University Hospitals NHS Trust Patient and Public Involvement team. 10 people took part.

The group were given a short talk on the strategy by a member of HRA staff and then the public and patient representative for the Research Transparency Strategy Expert Group facilitated group discussions on the key areas of the strategy and the role of public and patient involvement in research transparency.

### **HRA staff workshops**

HRA staff workshops were held in each of the five regional HRA offices. Staff at each office arranged their own workshop to discuss the strategy which were supported by staff members directly involved in the development of the strategy. 41 members of staff took part in the workshops.

## 4. How we analysed the responses

### 4.1. Online Survey

A qualitative content analysis approach was used to identify, analyse and interpret patterns of meaning (or "themes") within the qualitative survey response and workshop data. The survey data was downloaded in Excel format and screened for duplicates which were removed prior to analysis (duplicates were identified by subsequent submissions by the same individual (the most recent submission was retained and analysed) or direct duplication of the data by the online software (the first occurrence of the data was retained and analysed). 4 emailed responses were also incorporated manually into the dataset including one response which contained 20 individual Contract Research Organisation (CRO) responses collated by the UK Clinical Research Collaboration (UKCRC).

HRA staff were sent the survey data in Microsoft Excel format and allocated a subset of questions to code. Once the data had been systematically coded they were subsequently reviewed by the whole team to identify common codes and to establish common terminology where possible. The codes and the coded data produced by one team member were cross checked by another to confirm that the codes were reasonable, complete and had been applied consistently.

### 4.2. Workshops

A similar qualitative content analysis approach was taken to analyse the comments from the open workshops. All the written comments from the group discussions were collated into the three discussion areas and analysed by a member of HRA staff to identify common themes. Cross cutting themes that occurred across topic areas were also identified along with any suggestions and explanatory quotes from the plenary sessions and group discussions.

To quality assure the analysis the member of staff reviewed the raw workshop data again in-light of the online survey analysis to ensure that any differences between the two were highlighted for deeper analysis. Another member of HRA staff also reviewed the workshop data to ensure all themes had been identified.

The prioritisation tasks for the five workshops were collated, scored and ranked to establish a preferred order for implementation of planned activity to improve research transparency.

## **5. Summary of responses**

### **5.1. What the strategy covers**

In our consultation we asked whether our proposed strategy covered the right types of research (clinical trials) and focussed on the right types of transparency (registration, reporting results and feeding back to participants). We suggested that others in the research system are best placed to continue to enable appropriate sharing of study data and tissue. The majority (67%) of respondents either agreed (40%) or strongly agreed (27%) that the initial focus of the transparency strategy should be on clinical trials. However, 19% either disagreed (15%) or strongly disagreed (4%) with this approach.

The majority (77%) also either agreed (44%) or strongly agreed (33%) that the HRA should focus on the elements of transparency described in the strategy consultation. Only 9% disagreed (7%) or strongly disagreed (2%) with this proposal.

This general support for our proposed scope of the strategy was also expressed by attendees at our workshops and REC members who joined the webinar.

## **Clinical trials vs all studies**

Those who agreed with limiting the scope of our strategy to clinical trials gave reasons related to the importance and relevance of these trials to patients and the NHS and their substantive contribution to the evidence base. Many cited the burden that can often be associated with participation in complex trials; promoting transparency in this area properly respects those who take part in these trials and their commitment. As one person remarked “Clinical research is the type of research that patients involved with make the most sacrifice for... it is important and respectful that we should try our hardest to inform patients involved with clinical trials of the results.... Clinical trials are also best placed to change clinical practice”

Many respondents felt that clinical trials were ‘a good place to start’ and were the easiest in which to drive positive improvements in transparency given existing legal and policy frameworks. For example, the Academy of Medical Sciences (AMS) thought that “...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.”

However, in both the survey and the workshops, a significant number of people, even where they agreed with the stated focus, highlighted that this should be the initial and not the sole focus with other types of research included as soon as possible.

Those who disagreed cited the importance of transparency for all research and the fact that clinical trials do not take place in isolation but build upon the findings of other research. Transparency was, therefore, needed across the whole research environment; not least because this would facilitate research collaboration.

Some respondents felt that transparency was important because it properly respects those who take part in research and so should be applied to any studies that involve people. Others, including workshop attendees, cautioned against a two-tier approach.

One research manager who disagreed with the suggested focus said “The same sponsors will sponsor both clinical trials and other types of studies. Applying a phased approach can potentially create confusion among sponsors and CIs [Chief Investigators] involved in all types of studies. To avoid ambiguity, focusing on all types of studies from the start may be more appropriate.”

### **Proportionality**

Several respondents stated that the strategy would need to be applied proportionately. They were particularly mindful of the limited resources available to some researchers to comply with transparency requirements, such as students, but also several emphasised the need to protect commercial sensitivity, especially for phase I studies and the need to maintain the current deferral arrangements for registration.

### **Types of transparency**

Reasons given for agreeing with limiting the scope to registration, reporting results and feeding back to participants were based upon the view that these are the most important aspects of transparency. It was felt by many that these aspects had the highest public interest and tackling these would lead to improved public trust and encourage engagement and participation in research. Many also considered that these were the aspects for which full transparency could be achieved most easily by the HRA in view of existing requirements for clinical trials. However, many respondents felt that the sharing of study data and tissue would still need to be tackled later, pointing out that the HRA could have an important role in facilitating this. Some preferred that the strategy include the sharing of tissue and data from the start.

A number of suggestions were made to increase transparency beyond the proposed focus including making research protocols public and a call for greater transparency regarding how topics for research are identified and funded and how this might benefit from increased public involvement.

## 5.2. Making sure all clinical trials are registered

Many researchers told us that there are a number of barriers which hinder their ability to register their studies. Several highlighted the lack of functionality and usability of current clinical trials registries. One said, “Registries need to be fit for purpose, easy to use and responsive in order for investigators to have the confidence that their time will be well spent engaging in transparency activities”. Others pointed out that, currently, there are no single registries that are suitable for all types of study.

We set out three options in the consultation to ensure registration of clinical trials:

- Researchers must register their study before seeking approval
- The HRA supplies data directly to a registry
- The HRA becomes a registry itself

Of these the option for the HRA to become a registry itself was the most preferred (34% of survey respondents). However, 50% of survey respondents chose either “Researchers must register their study before seeking approval” (27%) or “HRA supplies data directly to a registry” (23%).

There was general support across all workshops for a single place for registration for all studies and for the HRA to be that place. However, it was emphasised that whatever option is chosen, the process should be straightforward with registration expectations made clear and guidance and training provided. The majority of REC members, contributing through the webinar, agreed that registration should be a pre-requisite for approval but there was support for a single place for study information and limited support for the HRA becoming a registry or linking to existing registries.

However, one REC member cautioned that consideration needs to be given to the additional resources this would require.

The public involvement workshop group agreed that there is a need for a central registry for all types of research that is easily accessible by the public and that this

should be managed centrally by the HRA. They emphasised that this should not be burdensome for the researcher.

We asked for explanations to support stated preferences:

### **The HRA becomes a registry itself**

Those that preferred that the HRA becomes a registry cited the benefit of everything being in one place, particularly as HRA already holds the relevant data through applications submitted using the Integrated Research Approval System (IRAS). The possible duplication that might result from a requirement to register interventional clinical trials on medicinal products on both the HRA's register and the European Union Drug Regulating Authorities Clinical Trials Database (EudraCT) was felt to be outweighed by having a comprehensive and definitive register of all research in one place. Although it was pointed out at the workshops that there was already duplication in the current system which causes confusion for both professionals and the public. Many considered that creating a single HRA registry could result in cost saving, standardisation of requirements, assist tracking of longitudinal studies and provide information on all types of research (e.g. qualitative and quantitative and commercial and non-commercial) in one place. If the HRA were a registry itself then this could support the administration of any proposed sanctions. However, the importance of data quality was raised and the need for quality assurance.

One person suggested that the HRA "... is the key body to protecting and promoting patients and the public in research - therefore it should become the "go to" website/place for all things research for everyone in the research system (researchers, sponsors, public, patients etc). It has NHS branding and would therefore be a trusted place."

The issue of accessibility was raised by many in response to questions around registration and publication, both for researchers and the public. Many supported the principle that the registration of studies should be free and easy for researchers and sponsors and that this information should be freely available in appropriate and accessible language for all audiences including researchers, sponsors, patients and

the public. It was suggested that lay summaries of the research need to be included and that any registry would need to have an effective, user-friendly search engine.

### **HRA Supplies the data**

Those that favoured this option believed that this would reduce duplication of registration data whilst ensuring, automatically, that all trials would be registered before they start. However, this option would depend upon providing interoperability with other registries, which would require additional resources and technical solutions.

There was some support for this option in several workshops, but it was felt we shouldn't 'reinvent the wheel' and should instead make better use of existing resources.

### **Researchers register before approval**

Concerns were raised at workshops that this option would result in 'ghost studies' being registered i.e. applications which did not go on to receive approval but would still remain on the registry. This, it was thought, would be a waste of resources. In addition, it was felt that some researchers may not have the funds to register ahead of approval. However, some survey respondents disagreed with this suggesting that a requirement for researchers to register their study prior to approval would mean that they would be available for scrutiny (even if they did not receive HRA approval). As one respondent noted an explanation of why the study did not receive approval "...would increase transparency even further, as it would give funders and researchers insight into planned trials as well as those which are approved, hopefully reducing duplication and/or increasing collaboration"

### **Other options**

We also asked whether there were other options that should be considered. Some raised the possibility that the HRA should withhold their approval until research is registered. Although one person preferred that approval could be given but revoked "within xx days of HRA's approval...if they hadn't provided it".

At the workshops there was a reasonable amount of support for this option with some also suggesting that registration should be made a prerequisite for approval through the validation checks made prior to accepting a research submission for HRA review.

### **5.3. Reporting results (making public what the study has found)**

As with registration we were told by many researchers that there were significant barriers to ensuring that all results are published within the required timeframe. For example, the time spent on applying to journals, waiting to be accepted and then waiting for publication means that there are often delays in updating registries with study results. Furthermore, it was suggested that issues around copyright mean that researchers may be unable to report their results until after the publication of their research. One researcher explained “Challenges in getting papers accepted in high impact peer reviewed journals can delay dissemination of results (as sometimes have to submit to multiple journals in succession before acceptance). Most journals won't publish data published in full elsewhere so can't post results elsewhere to fulfil transparency requirements until paper is published.” It was suggested that if a limited amount of information could be placed on the register, which did not breach copyright, this might avoid these problems and further promote transparency compliance.

Whilst there was agreement that staff turnover presented a real barrier to transparency, there was a feeling that improved succession planning coupled with better education and training could improve compliance.

The need for cultural change was frequently emphasised in workshops. This would support:

- raising awareness of the social and moral responsibility to report findings
- ending the current bias for only reporting positive results
- reporting research findings in ways other than peer-reviewed journals

In the consultation we presented plans to make it clearer to applicants at the time of study approval that they need to submit a final report to the HRA within 12 months of the study end date. We also proposed to take a more proactive approach to prompt sponsors for these reports and publish information we receive on a public platform or provide a link to information held in a registry or publication.

We asked, “To what extent do you think that these steps will improve the reporting of results from clinical trials?”. 81% of survey respondents believed (61%) or believed very strongly (20%) that they will improve the reporting of research results.

We also asked for feedback regarding what else we should do to improve the reporting of results. There was a strong message that working closer with stakeholders across the system would help drive compliant behaviour without the HRA needing to impose sanctions. It was felt that most impact would be achieved if the HRA work closely with funders to share transparency performance data to inform funding decisions. As one person put it “if PIs [Principal Researchers] know this information is available to funders and could have a negative effect on future funding it is more likely to get a result.”

Many respondents mentioned the need for standardisation of processes, systems and datasets to facilitate the reporting of results coupled with the use of plain language. It was suggested that involving patients and the public in writing lay summaries would be helpful as reports can often be very technical; “It’s not true transparency if no one from the public can actually read it!”. Others emphasised the need for a single place to find trusted information on clinical trials which “...must include as a minimum a lay summary of the proposal and a lay version of the results – whether positive or negative, and whether the trial has completed or been prematurely terminated”.

## **Timing**

In workshops, opinions were split on whether a period of 12 months to submit end of study reports/results was appropriate. Some thought 12 months was appropriate whilst others thought 12 months was too long because, they suggested, there is a

moral duty to report results in a timely manner. Others felt that a period of 2 years might be more realistic to allow time for the navigation of peer review processes and copyright issues. Proportionality was a consideration for some attendees who suggested that larger, more complex studies should be allowed more time to report. Some highlighted the need for clearer definitions regarding the 'end of study' date, 'results' and what is meant by 'publication'. In several workshops the proposal for reminders and chasers to be sent was well received, but it was noted that such reminders would be needed well in advance of the 12-month deadline e.g. at 6 months.

## **Location**

Attendees at workshops supported the HRA's pledge to "publish information we receive on the public platform or provide a link to information held in a registry or publication". However, it was considered that there are too many places to put this information and each registry has its own requirements. In addition, public and patients currently do not know where to find this information, so a central place would be helpful. It was noted that there are also difficulties updating information held on the registry as the study progresses due to staff turnover and access rights. The need to publicise the HRA platform holding study information was emphasised with directions on how to access it included on all participant information sheets. Some thought that the publication of this information might duplicate similar information held on the National Institute for Health Research's (NIHR) 'Be Part of Research' website. Others were concerned about who would check the quality of the information as this would be very resource intensive.

Attendees at the REC webinar supported making all results public, including negative results. One member suggested that making transparency compliance a fundamental part of the Research Excellence Framework exercise would act as a further incentive.

## 5.4. Sharing the results of research studies with the people who took part

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). We will also ask sponsors to submit a lay summary of the study results to us (no longer than 12 months after the end of the study) which we will then publish.

Many of the responses we received supported the importance of feeding back to participants with several pointing out that any information fed back needs to be accessible and easy to understand.

It was pointed out that feedback is an ongoing process and participants should be kept informed of the trial's progress throughout, with many emphasising that the onus should not be placed on the participants to seek out this information. One patient captured the real importance of feedback in acknowledging the contribution made by research participants pointing out that "it can be very frustrating to take part in something and not really know how you actually contributed or what results related to you". The wife of a participant who died whilst taking part in research explained how feeding back to next of kin can be helpful for the grieving family: "I believe it's important for next of kin to still get this information. From my personal experience I was really interested in the results of a phase 3 study which my husband had participated in...It made me feel that even though he had died, he had contributed to improving the lives of other men in the future."

We also wanted to hear what else the HRA could do to improve feedback to participants. Some of the suggestions we received were:

- Create a central facility/registry
- Create feedback templates for researchers to use
- Provide/improve guidance on how to feedback to participants effectively
- Make feedback to participants a mandatory requirement
- Impose sanctions/penalties for non-compliance with proposed feedback

- Promote and endorse patient and public involvement to improve and create effective feedback methods to participants
- Highlight good examples of feedback.

Several practical suggestions were also made for researchers to improve the way they feedback study information such as:

- Asking participants what feedback they want and how
- Public and patient input in drafting research summaries/provision of good examples and templates
- Where research participants have poor life expectancy consider who should receive feedback and when
- Incorporate communication plans into the trial protocol (and build these costs into the research proposal) and tell participants at the start when they can expect feedback
- Host forums/events to present findings
- Regular updates/newsletters
- Work closely with key charities who provide their own lay directories of trials to ensure that information is made widely available
- ‘Thank you’ letters, which can help participants feel valued and respected.

However, some felt that participants should be allowed to choose whether they receive feedback and, if so, in what form. One patient advocate cautioned that “not all participants require a lay summary, and implying they do, could be patronising” whilst a charity funder suggested that researchers should “ask participants if getting feedback is important to them. make it clear to participants how they can get feedback. Get feedback from participants that have received feedback and ask if it was useful to them. Resource all of the above.” One NHS sponsor pointed out that “researchers assume feedback will be time consuming and costly. Providing ideas and opportunities for feedback which are neither of these things would be helpful.”

It was emphasised that any increase in the use of online methods to disseminate information to participants should not lead to discrimination against those who do not wish to or cannot access the internet. In some of the workshops it was felt that

researchers should build in feedback to their grant applications and funders should consider the applicant's past record with regards feedback.

A strong theme emerged that the involvement of patients and the public was key to providing feedback appropriately. This was summed up by one person as "Do this with participants, not for them."

## **5.5. Sharing study data and tissue (enabling further research).**

Whilst the majority (77%) of survey respondents agreed that the HRA should focus on the elements of transparency described in the consultation, a small number stated a preference for the strategy to include the sharing of tissue and data from the start and told us that the HRA had an important role to play in this area. One respondent explained "... sharing study data and tissue is crucial: it avoids unnecessary duplication of studies...supports reproducibility and informal peer review and lays the foundations for future studies. ...the HRA could make enhancements to the IRAS form and guidance to encourage researchers in this aspect of transparency (e.g. greater emphasis on consent for use of data/tissue in future research)." Others emphasised the need to include transparency of methodology including outcome measures so that the reported results could be assessed in the light of the originally proposed methodology, aims and outcomes.

In support of the proposed strategy focus (i.e. not including the sharing of study data and tissue initially) several respondents commented that, whilst important, the sharing of data and tissue should not be a priority for the HRA given the number of existing initiatives to promote open access in research that are already well developed.

## 6. Next steps

### 6.1. Changes we will make: Supporting good practice, making compliance easy

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

- 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

However, so that we can prioritise them we asked for feedback about how important these changes were felt to be.

At workshops, each attendee was asked to indicate what they felt should be the first, second and third priorities for implementation.

The majority of online respondents considered all of the options to be important or moderately important with only a handful suggesting that any of the options were not important.

The four areas receiving the most support from both the online survey and workshops were:

- Being clearer what we expect of sponsors and researchers
- Making it clear what information from applicants we will make public and what we will share with others
- Introducing automated reminders for researchers/sponsors to submit transparency data and to view the status of their studies
- Flagging up individual studies where transparency information is overdue

## **6.2. Changes we could make: Monitoring transparency performance on clinical trials**

We also asked for views about possible further steps we could take for dealing with individual sponsors who do not fulfil their research transparency responsibilities i.e.:

- 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)

### **Publish an annual 'transparency league table' highlighting individual studies which have information that is overdue**

69% of online respondents considered that this approach was either appropriate (37%) or highly appropriate (32%) with only 24% disagreeing ('Not Appropriate' = 19% and 'Not at all appropriate' = 5%).

More patients and the public (81%) supported this approach than research managers (61%), researchers (56%) and Contract Research Organisations (CROs) (58%).

Those who supported the publication of league tables thought they were a good way to incentivise compliance, prompt allocation of more resources to support transparency and increase accountability. One said, “public shaming and potential impact on approval of future studies will have an effect in an area where much is to do with reputation”. However, some suggested that such tables should be used to highlight good performance and good practice rather than identify poor performers.

There was considerable support for league tables across all workshops but, as with survey responses, some cautioned that the publication of tables could deter patients from taking part in research at certain institutions and thus should only be visible to professionals.

Where it was felt that the introduction of league tables would be a negative move the reasons given included there being too many existing league tables already. Many were concerned that ‘naming and shaming would have negative implications for individuals and organisations, that there may be valid reasons for non-compliance and that the approach would have a disproportionate effect on smaller organisations where there was a single poorly performing researcher.

The issue of data quality was also a concern for some who felt that the transparency data published in a league table must be up to date and accurate and that this will be resource intensive. Others were concerned that interpretation of the information would be dependent on who is reading the league table, particularly in the absence of any information to place the data in context. In addition, the effectiveness of this measure would depend on where and how the table is published. One researcher said “What researchers need least in the world is more competitive ranking. Please no league tables”. A university sponsor thought that “The transparency league table could be too simplistic and therefore not fair or informative. There can be factors out with the control of the investigator/sponsor that thwart a genuine desire to publish”.

A concern was raised at some workshops that league tables could lead to game playing with the fear that ensuring a good showing in the table could become more important than making real improvements to the quality of information fed back to participants. As one workshop participant put it “Sanctions are important – but

shouldn't lead to game playing – where the league table becomes more important than the patient”.

At one staff workshop it was suggested that participant information sheets should routinely include a summary of the sponsor's and/or researcher's past transparency performance. This they felt would give potential participants relevant information to help them decide whether this was a study they would wish to contribute to.

**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**

75% of online respondents considered that this approach was either highly appropriate (41%) or appropriate (34%) with only 19% disagreeing ('Not Appropriate' = 13% and 'Not at all appropriate' = 6%). As with the use of league tables, more patients and the public (92%) supported this approach than research managers (67%), researchers (71%) and Contract Research Organisations (CROs) (37%).

At the workshops people generally felt it would be appropriate for past transparency performance to be considered as part of ethical review. Some felt that as part of validation there should be a check that previous study results have been made available before another application can be accepted. Opinion was split on who should be held responsible i.e. the sponsor or the individual researcher. Several of those in favour of this sanction suggested a 'red card' or 'traffic light' system, rather than an all or nothing approach, so that there was an opportunity for improvement before approval was withheld.

Those supporting the consideration of past transparency performance when reviewing new studies for approval considered this to be a strong motivator and an important catalyst for compliance. One university researcher suggested that “Preventing researchers with a poor track record from carrying out research in the future would be a much stronger motivator than fining a wealthy pharmaceutical company.” And a patient, in dismissing fines, said it “...would be better to say they could not submit any further applications for funding to whichever body until they

have published previously funded studies. this would be more of an incentive/stick and have greater likelihood of compliance”.

One respondent commented that “There is currently no incentive for sponsors to pay due regard to HRA guidance/expectations of sponsors. There should be some mechanism by which poor performing sponsors are identified and their burden on the HRA systems are minimised by remedial action or, in extreme cases, exclusion.”

Some commented on whether the transparency record of sponsors or individual researchers should be considered. There was a slight preference, amongst those commenting, for focussing sanctions on researchers rather than sponsors. However, one NHS sponsor urged us not to “...let the actions of some researchers affect others”. One REC member considered that withholding approval would punish the researcher more than the sponsor.

Feedback from sponsors representatives suggested that preventing studies from being approved at an organisational level would give them increased weight in managing investigators. They urged the HRA to set clear criteria for when any such sanction might be applied and under what circumstances it would be removed.

Those who were of the opinion that this approach would not be desirable felt that blocking future approvals would result in less valuable research being undertaken which, in turn, would adversely and unfairly affect potential participants and patients.

Several people emphasised the need for the HRA to be clear about our transparency expectations, particularly if sanctions were to be used, and suggested that we should collaborate with others to ensure that we acted upon accurate information and to share that information with other stakeholders such as funders.

### **Fining sponsors with very poor transparency compliance rates**

Of the three options presented in the consultation this option received the least support overall. 47% of online respondents indicated that this option was either not appropriate (32%) or not at all appropriate (15%). In contrast 39% considered that this approach was either highly appropriate (21%) or appropriate (18%).

However, there was a marked difference of opinion between patients and the public and those involved in conducting research. The majority (57%) of patients and the public responding online supported fining sponsors (only 26% did not) whilst the same percentage (57%) of research managers researchers and Contract Research Organisations did NOT support the use of fines (with 30% expressing support for this measure).

At workshops there was generally less support for fines than other sanctions. It was noted that fines may not be appropriate for non-commercial organisations and would have little impact on commercial organisations for whom withholding approval would carry more weight.

Those supporting the use of fines for sponsors with poor transparency records expressed the view that this would concentrate minds, emphasise where the responsibility for meeting transparency requirements lay and highly motivate sponsors by showing that there are consequences for non-compliance. This, some felt, would best protect research participants.

Many felt that fines should only be considered after other, less punitive, methods for facilitating compliance had been tried. As one NHS sponsor put it “Rather than using ‘punishments’ it would be more helpful to tackle the issues and overcome the barriers to compliance with the transparency requirements.” Another researcher said, “The EudraCT reporting system has to improve before you can even think of fining sponsors”.

The patient and public involvement group thought, initially, that the introduction of fines was reasonable. However, following a discussion which highlighted the disproportionate impact this sanction might have on non-commercial organisations, the practicalities and costs of imposing, collecting and enforcing fines, who the money would belong to and how it would be spent, it was unanimously agreed that, whilst the publication of league tables and considering past performance were appropriate, the imposition of fines was not.

Opinion was divided at the workshops on whether sanctions should be introduced at all with many feeling that, before resorting to financial sanctions, there was a real need to:

- Improve support
- Ensure systems are working and infrastructure is in place
- Ensure HRA are clear about what is expected
- Provide appropriate guidance
- Introduce improvements before sanctions.

A range of arguments were advanced for not imposing fines to promote compliance with transparency requirements including:

- Lack of evidence that fines would promote compliance
- It could alienate the research community, destroy good will in the system and make the HRA the “bad guys”
- Making the UK a less attractive place to do research.
- They would not address the main organisational, logistical and financial barriers to compliance and could compound them by imposing a “regressive charge on financially weaker applicants”.
- Fines would need to be considerable to affect the behaviour of commercial companies.

A university researcher explained that “academic sponsors generally don't do things because they are terribly underfunded. Fines would make this worse not better”

Another pointed out that “research is already very hard to do and lots of people are put off from doing it, because it's too complex. Research is expensive, and you are proposing to potentially make it more so”.

Several considerations were raised regarding the introduction of any financial penalties, notably that reasons for non-compliance would need to be taken into account before any fine imposed and that they should be proportionate to the size of the sponsor organisation and their status. Others suggested that charities should be exempt.

Some thought that additional fines should be introduced for those sponsors who repeatedly fail to comply. It was also pointed out that additional resources would be required for the HRA to properly administer any new system involving fines.



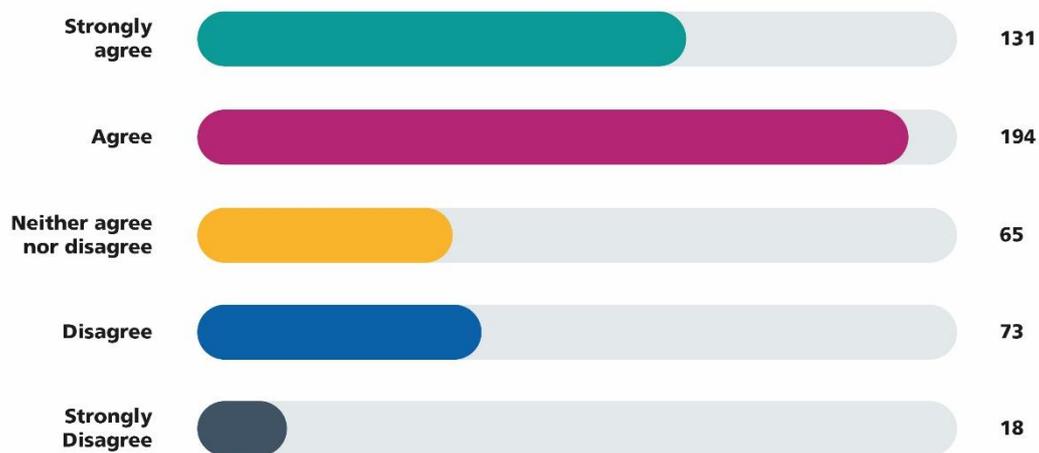
# Annex 1: Responses to online survey: Quantitative questions

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

**Question 1a. The strategy should focus initially on clinical trials**

**Figure 2 – Graph showing responses to question 1a.**

Q1a - The strategy should focus initially on clinical trials



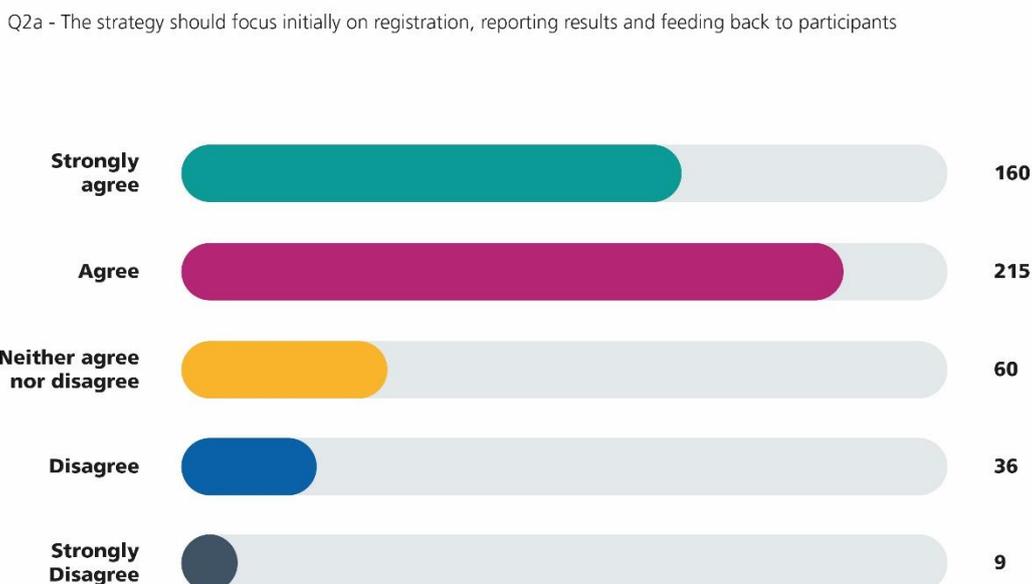
Graph summary: The bar chart shows the number of respondents who selected, strongly disagree, disagree, neither agree nor disagree, agree or strongly agree in response to the statement the strategy should initially focus on clinical trials. The most frequent response was agree which 194 respondents selected, followed by strongly agree which 131 respondents selected.

[Download a csv file for graph data from figure 2.](#)

## Question 2: Please indicate the extent to which you agree with the following statements.

Question 2a: the strategy should focus initially on registration, reporting results and feeding back to patients.

Figure 3 – Graph showing responses to question 2a.



Graph summary: The bar chart shows the number of respondents who selected strongly disagree, disagree, neither agree nor disagree, agree or strongly agree in response to the statement the strategy should focus initially on registration, reporting results and feeding back to participants. The most frequent response was agree which 215 respondents selected, followed by strongly agree which 160 respondents selected.

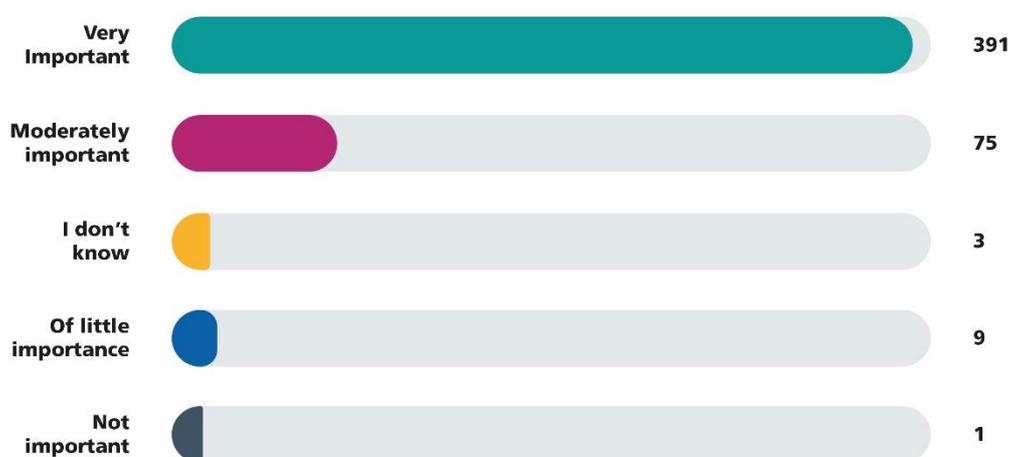
[Download a csv file for graph data from figure 3.](#)

**Question 3: Please tell us how important you think these changes are in improving research transparency. This will help us to prioritise.**

**Question 3a: Being clearer what we expect of sponsors and researchers.**

**Figure 4 – Graph showing responses to question 3a.**

Q3a - Being clearer what we expect of sponsors and researchers

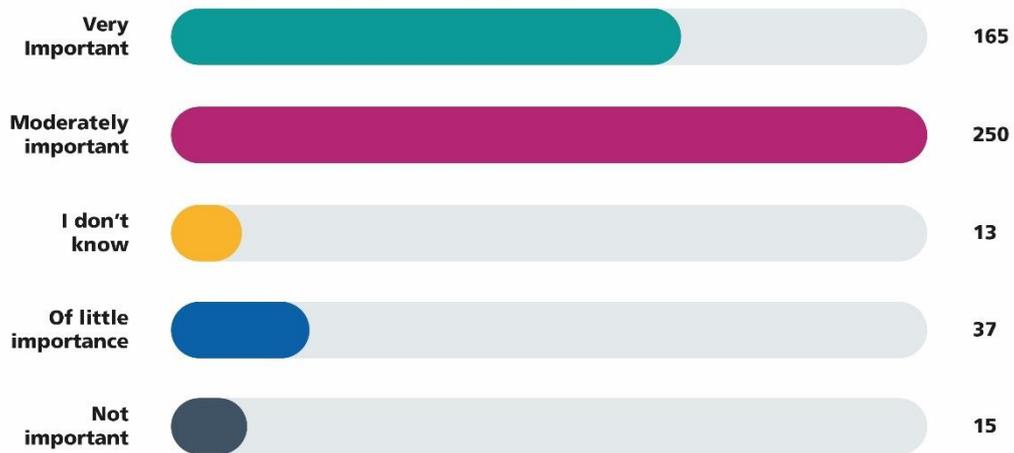


Graph summary: The bar chart shows the number of respondents who selected not important, of little importance, I don't know, moderately important or very important in response to the statement being clearer what we expect of sponsors and researchers. The most frequent response was very important which 391 respondents selected, followed by moderately important which 75 respondents selected.

[Download a csv file for graph data from figure 4.](#)

**Figure 5 – Graph showing responses to question 3b.**

Q3b - Developing new learning packages to support research transparency



Graph summary: The bar chart shows the number of respondents who selected not important, of little importance, I don't know, moderately important or very important in response to the statement developing new learning packages to support research transparency. The most frequent response was moderately important which 250 respondents selected, followed by very important which 165 respondents selected.

[Download a csv file for graph data from figure 5.](#)

**Figure 6 – Graph showing responses to question 3c.**

Q3c - Sharing best practice and celebrating improvement

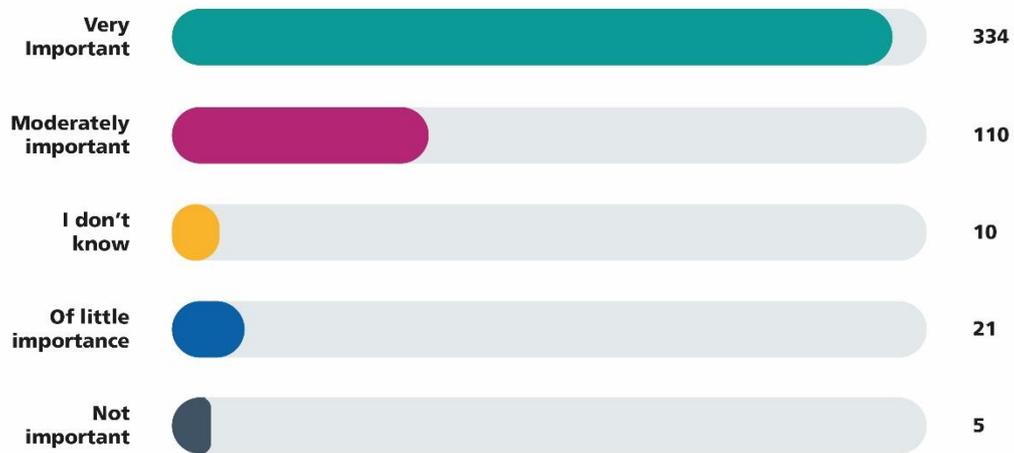


Graph summary: The bar chart shows the number of respondents who selected not important, of little importance, I don't know, moderately important or very important in response to the statement sharing best practice and celebrating improvement. The most frequent response was very important which 215 respondents selected, followed by very important which 214 respondents selected.

[Download a csv file for graph data from figure 6.](#)

**Figure 7 – Graph showing responses to question 3d.**

Q3d - Making it clear what information from applicants we will make public and what we will share with others

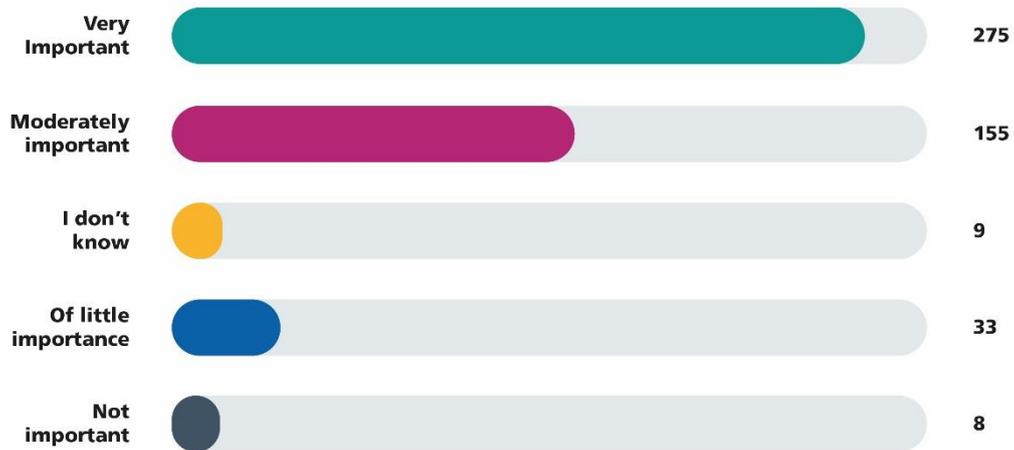


Graph summary: The bar chart shows the number of respondents who selected not important, of little importance, I don't know, moderately important or very important in response to the statement Making it clear what information from applicants we will make public and what we will share with others. The most frequent response was very important which 334 respondents selected, followed by moderately important which 110 respondents selected.

[Download a csv file for graph data from figure 7.](#)

## Figure 8 – Graph showing responses to question 3e.

Q3e - Introducing automated reminders for researchers and research sponsors to submit transparency data and to view the status of their studies

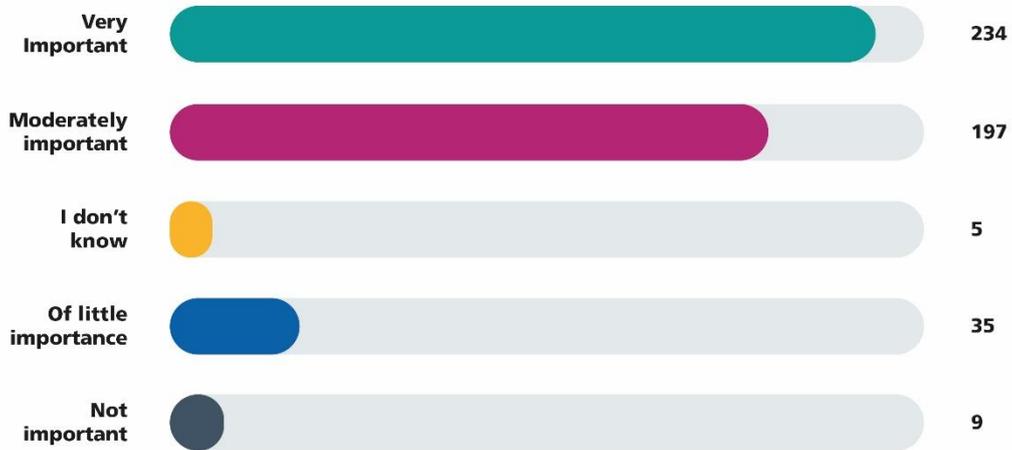


Graph summary: The bar chart shows the number of respondents who selected not important, of little importance, I don't know, moderately important or very important in response to the statement introducing automated reminders for researchers and research sponsors to submit transparency data and to view the status of their studies. The most frequent response was very important which 275 respondents selected, followed by moderately important which 155 respondents selected.

[Download a csv file for graph data from figure 8.](#)

**Figure 9 – Graph showing responses to question 3f.**

Q3f - Giving sponsors and researchers feedback on their transparency performance

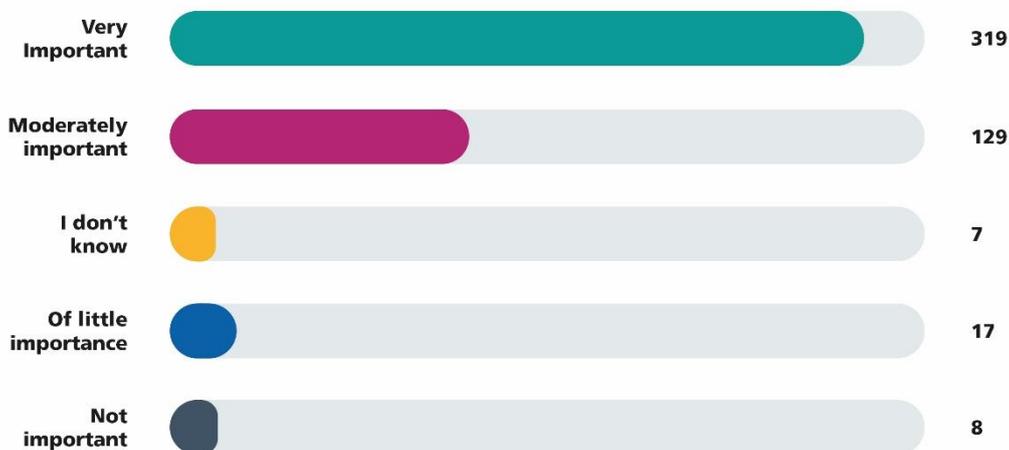


Graph summary: The bar chart shows the number of respondents who selected not important, of little importance, I don't know, moderately important or very important in response to the statement giving sponsors and researchers feedback on their transparency performance. The most frequent response was very important which 234 respondents selected, followed by moderately important which 197 respondents selected.

[Download a csv file for graph data from figure 9.](#)

**Figure 10 – Graph showing responses to question 3g.**

Q3g - Flagging up individual studies where transparency information is overdue

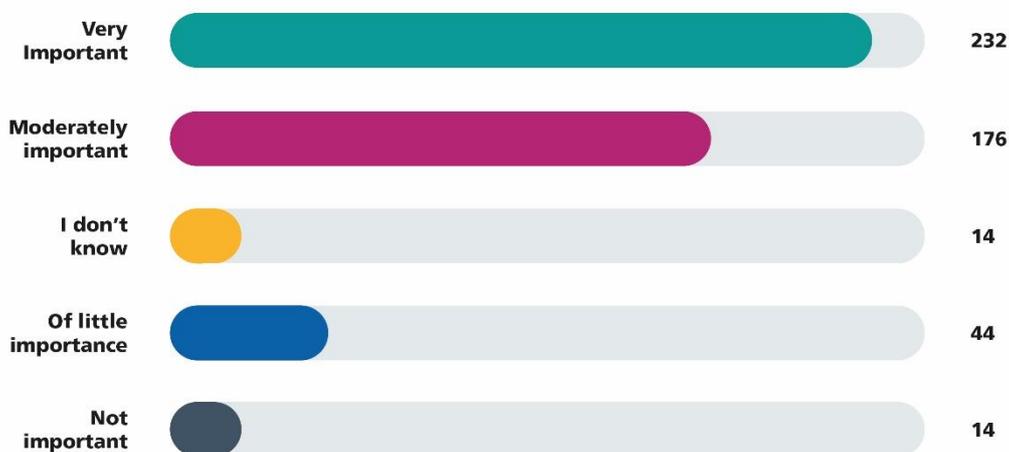


Graph summary: The bar chart shows the number of respondents who selected not important, of little importance, I don't know, moderately important or very important in response to the statement flagging up individual studies where transparency information is overdue. The most frequent response was very important which 319 respondents selected, followed by moderately important which 129 respondents selected.

[Download a csv file for graph data from figure 10.](#)

**Figure 11 – Graph showing responses to question 3h.**

Q3h - Sharing transparency performance data with funders, other regulators and registries



Graph summary: The bar chart shows the number of respondents who selected not important, of little importance, I don't know, moderately important or very important in response to the statement sharing transparency performance data with funders, other regulators and registries. The most frequent response was very important which 232 respondents selected, followed by moderately important which 176 respondents selected.

[Download a csv file for graph data from figure 11.](#)

## Q5. Which of the options do you think is the most appropriate to ensure registration of clinical trials (please select only one)?

Figure 12 – Graph showing responses to question 5.

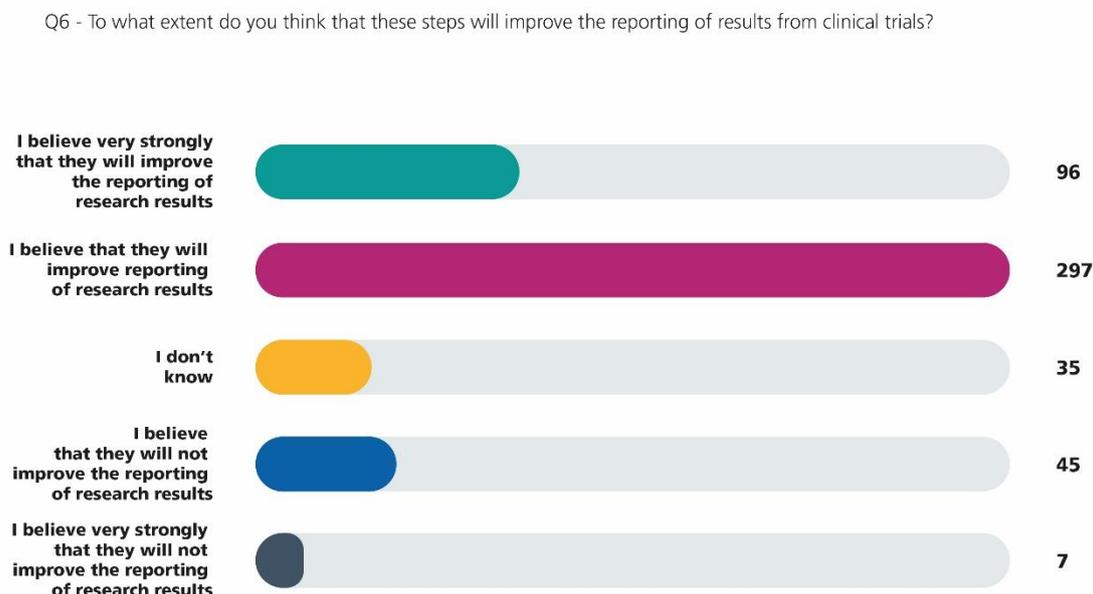


Graph summary: The bar chart shows the number of respondents who selected don't know, something else, HRA becomes a registry itself, HRA supplies data directly to a registry or researchers must register their study before seeking approval in response to the question which of the options do you think is the most appropriate to ensure registration of clinical trials (please select only one). The most frequent response was HRA becomes a registry itself which 164 respondents selected, followed by researchers must register their study before seeking approval which 132 respondents selected.

[Download a csv file for graph data from figure 12.](#)

## Q6. To what extent do you think that these steps will improve the reporting of results from clinical trials?

Figure 13 – Graph showing responses to question 6.



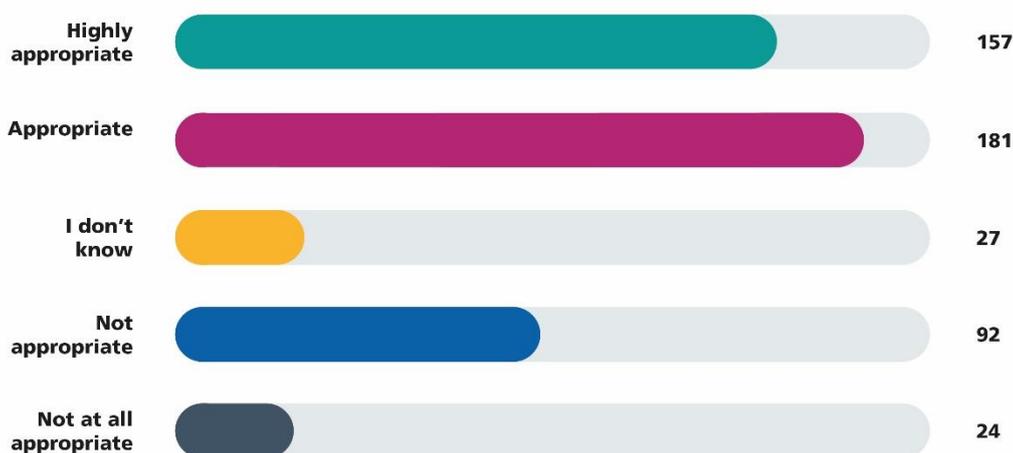
Graph summary: The bar chart shows the number of respondents who selected I believe very strongly that they will not improve the reporting of research results, I believe that they will not improve the reporting of research results, don't know, I believe that they will improve the reporting of research results, or I believe very strongly that they will improve the reporting of research results in response to the question to what extent do you think that these steps will improve the reporting of results from clinical trials. The most frequent response was I believe that they will improve the reporting of research results which 297 respondents selected, followed by I believe very strongly that they will improve the reporting of research results which 96 respondents selected.

[Download a csv file for graph data from figure 13.](#)

## Q8. To what extent do you think the following actions would be appropriate?

Figure 14 – Graph showing responses to question 8a.

Q8a - Publish an annual 'transparency league table' highlighting individual studies which have information that is overdue

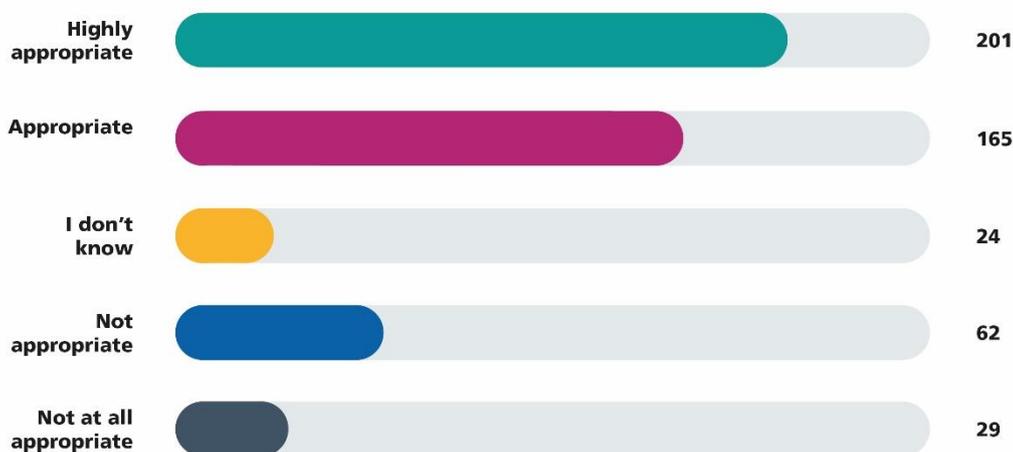


Graph summary: The bar chart shows the number of respondents who selected not at all appropriate, not appropriate, I don't know, appropriate or highly appropriate in response to the question to what extent do you think that following actions would be appropriate: publish an annual 'transparency league table' highlighting individual studies which have information that is overdue. The most frequent response was appropriate which 181 respondents selected, followed by highly appropriate which 157 respondents selected.

[Download a csv file for graph data from figure 14.](#)

**Figure 15 – Graph showing responses to question 8b.**

Q8b - 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

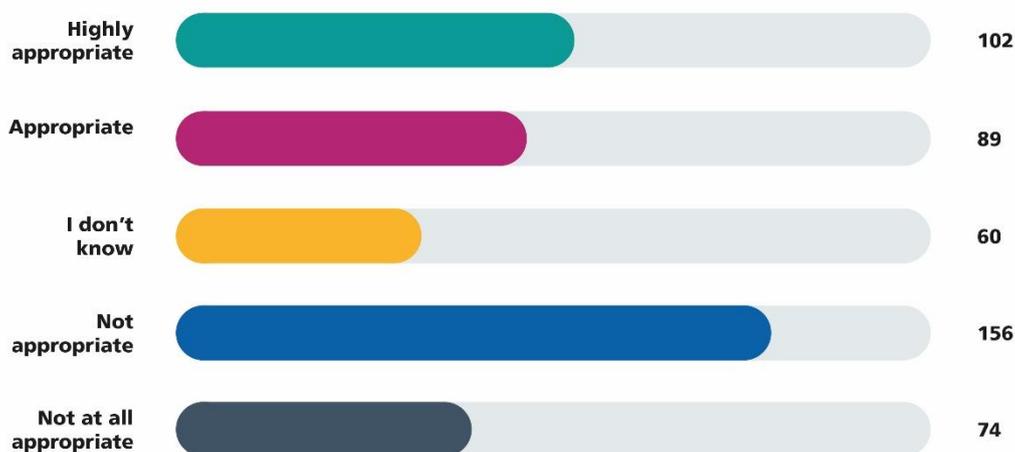


Graph summary: The bar chart shows the number of respondents who selected not at all appropriate, not appropriate, I don't know, appropriate or highly appropriate in response to the question to what extent do you think that following actions would be appropriate: take into consideration the extent to which sponsors have fulfilled their transparency responsibilities in relation to their previous studies, when reviewing new studies for approval. The most frequent response was highly appropriate which 201 respondents selected, followed by appropriate which 165 respondents selected.

[Download a csv file for graph data from figure 15.](#)

**Figure 16 – Graph showing responses to question 8c.**

Q8c - Fine sponsors with very poor transparency compliance rates (this would require a change in legislation)



Graph summary: The bar chart shows the number of respondents who selected not at all appropriate, not appropriate, I don't know, appropriate or highly appropriate in response to the question to what extent do you think that following actions would be appropriate: fine sponsors with very poor transparency compliance rates (this would require a change in legislation). The most frequent response was not appropriate which 156 respondents selected, followed by highly appropriate which 102 respondents selected.

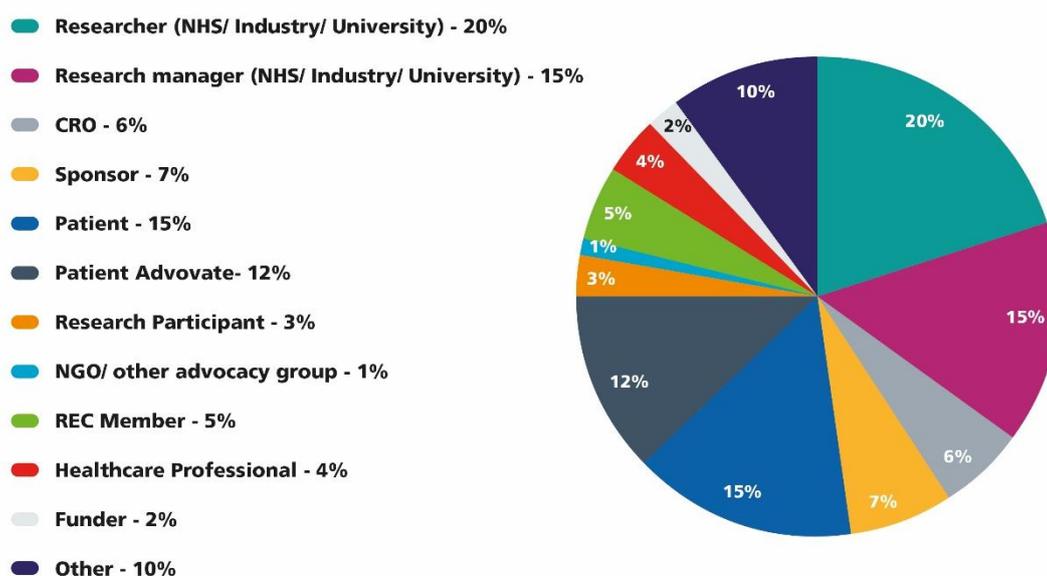
[Download a csv file for graph data from figure 16.](#)

**Q11. Are you responding to this survey on behalf of an organisation?**

Yes	14%
No	81%
Blank	6%

**Q12. If you are responding as an individual, how would you describe your role in research? Please select the one most relevant to this survey.**

**Figure 17 – Pie chart showing how survey respondents described their role in research.**



Pie chart summary. The pie chart shows how survey respondents described their role in research. Researcher (NHS/Industry/University) occupies 20%, research manager (NHS/Industry/University) occupies 15%, CRO (Contract Research Organisation) occupies 6%, sponsor occupies 7%, patient occupies 15%, patient advocate occupies 12%, research participant 3%, NGO/other advocacy group occupies 1%, REC member occupies 5%, healthcare professional occupies 4%, funder (public/charity) occupies 2%, other occupies 10%.

[Download a csv file for pie chart data from figure 17.](#)

**Q.13. Where are you based?**

In the UK 95%

Outside the UK 3%

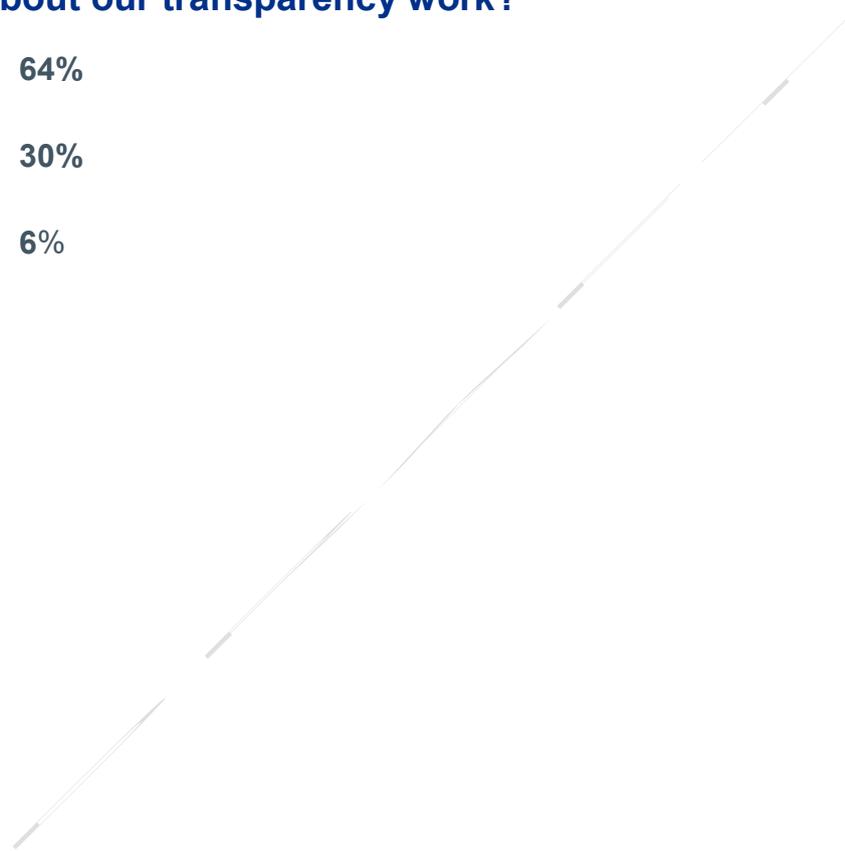
Blank 2%

**Q14. Are you happy for us to contact you in future with information or news about our transparency work?**

Yes 64%

No 30%

Blank 6%



## Annex 2: Organisations responding to the consultation

- The Association of the British Pharmaceutical Industry (ABPI)
- The Academy of Medical Sciences (AMS)
- The Association of Medical Research Charities (AMRC)
- Bournemouth University
- British & Irish Orthoptic Society
- British Dupuytren's Society
- British Pharmacological Society
- Cancer Research UK
- Cochrane UK
- Council of Deans of Health
- Cystic Fibrosis Trust
- DataLab, University of Oxford
- East and North Hertfordshire HS Trust
- East Riding of Yorkshire CCG
- Faculty of Health Social Care and Education, Kingston University and St George's University of London
- GlaxoSmithKline
- Guy's and St Thomas' NHS Foundation Trust
- Hammersmith Medicines Research (HMR) Ltd
- Hull University Teaching Hospitals NHS Trust
- ISRCTN Registry
- Joint submission on behalf of the Medical Research Council (MRC) and the Economic and Social Research Council (ESRC)
- Leeds and York Partnership NHS Foundation Trust
- Manchester University NHS Foundation Trust
- medConfidential
- Meningitis Research Foundation
- Newcastle Upon Tyne Hospitals NHS Foundation Trust/Newcastle University
- NHS Lothian
- NHS R&D Forum
- NIHR ACADEMY
- NIHR Clinical Research Network
- NIHR Evaluation Trials and Studies Centre
- Office of the NIHR National Director of Dementia Research
- Nottingham and West Bridgford Versus Arthritis
- Oxford Health

- Oxford University Hospitals NHS Foundation Trust
- Pancreatic Cancer Action
- Precision-Panc clinical trials programme and Glasgow Precision Oncology Laboratory, University of Glasgow
- Quotient Sciences
- Research COMMS
- Research Registry
- Richmond Pharmacology
- Sandwell and West Birmingham NHS Trust
- Sense about Science
- The Newcastle upon Tyne Hospitals Foundation NHS Trust
- The Queen Elizabeth Hospital, King's Lynn
- The Royal College of Midwives
- The Royal Marsden NHS Foundation Trust/The Royal Marsden Clinical Trials Unit
- The Royal Wolverhampton NHS Trust
- TranspariMED
- Turkish Clinical Research Association
- Union Chimique Belge (UCB)
- University College London
- University Hospital Southampton NHS Foundation Trust
- University Hospitals Birmingham NHS Foundation Trust
- University Hospitals of Leicester
- University of Birmingham
- University of Nottingham
- University of Warwick
- West Bridgford Versus Arthritis
- Wendy Fisher Consulting (WFC)