


Slide 1



The slide features the following elements:


- Logos:** HSC Public Health Agency (Research and Development), NHS SCOTLAND, Welsh Health Research Wales (Ymchwil Iechyd a Gofal Cymru Health and Care Research Wales), and NHS Health Research Authority.
- Main Title:** **MakeltPublic**
- Subtitle:** Transparency and openness in health and social care research
- Text:** Consultation workshop
- Graphic:** A bar chart with four bars of increasing height, colored pink, teal, blue, and orange from left to right.

- We all agree that research transparency is important – it makes for more open and accountable research, better recruitment to studies and enables the sharing of learning from research to inform future research and develop new treatments and services
- If you've read the strategy, you'll know that HRA has published a set of plans and proposals for improving transparency – we think they will work, but we know we don't have all the answers
- So, we are seeking views through this consultation – to make sure the strategy is feasible, focussed on the right things and acceptable to a wide group of people
- This workshop is part of that consultation, which involves four other public workshops, engagement with research ethics committee members and the staff that support them and an online survey. We want to hear your views today – and we'd like you to complete the survey too



Agenda

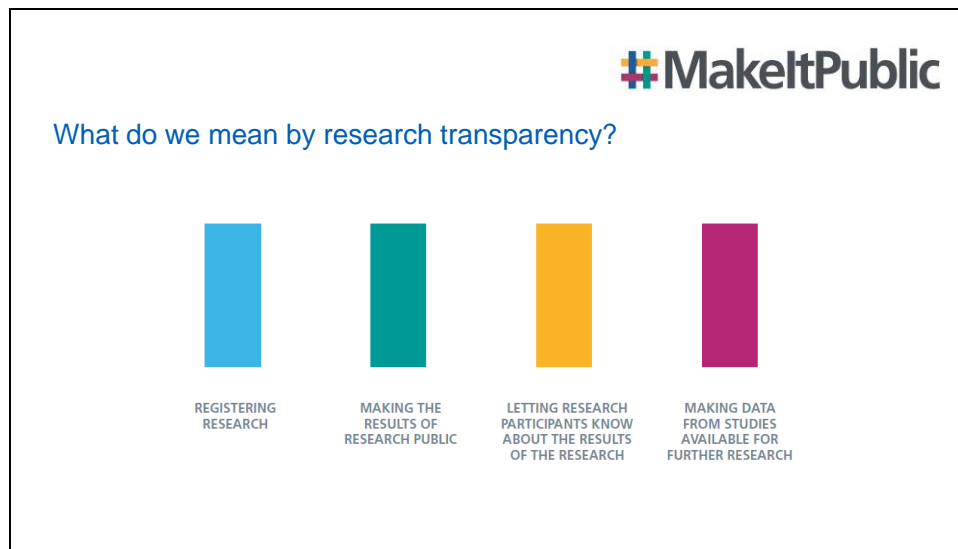
Session	Lead	Time
Lunch (30)		12.30
CMO's Welcome (10)		1.00
Introduction (10)		1.10
About the Make it Public strategy (20)		1.20
Plenary discussion: The strategy overall (30)		1.40
Key areas of the strategy (20)		2.10
Refreshment Break (15)		2.30
Table discussions: Key areas (70)		2.45
Comfort Break (5)		3.55
Table discussions: Priorities for implementation (20)		4.00
Summary and next steps (10)		4.20



- The day has been designed to maximise discussion – we want to learn from you: from your professional experience and your lived experience of taking part in research and as a member of the public
- We will introduce the strategy in a moment. After that, we will have a plenary discussion about the strategy as a whole. Then we will introduce some particular elements of the strategy that we'd like you to discuss in groups after lunch. We'll then break for tea and return to do a short prioritisation task – with stickers!
- We have a range of people here, with different experiences and interests in transparency. We want to hear from you all. So if I could encourage you to listen to others, focus on the question in front of you and give others an opportunity to take part. That will enable us to hear all voices – loud and quiet! – and get a sense of the range of views.




About the Make it Public strategy



Transparency in research can mean many things. It could mean openness about who is funding research, or about the researchers involved. So just to be clear about what this strategy covers, when we talk about research transparency, we mean:

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


We call these the four pillars of transparency and they make up the Make it Public logo



Why is transparency important?

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.



For the Research Transparency Strategy Group, transparency and openness is about sharing knowledge so that we develop better treatments and services, saving and improving our lives.

But just as important is public accountability. Half of research in the UK is funded publicly – through government funding and through charitable donations. To maintain that huge public contribution, we need to maintain trust in research..

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“The research community needs to be clearer and more distinct about what health research is taking place into things that matter to patients and the public.”

Derek Stewart
Patient

HSC Public Health Agency
Research and Development

NHS SCOTLAND

Health Research Authority

Derek Stewart, public contributor and patient on the expert group sums it up well when he says:

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Why have we produced the Make it Public strategy?

www.parliament.uk

Care Act

EU Trials Tracker

WHO'S NOT SHARING EU CLINICAL TRIAL RESULTS?

TRIAL SPONSORS HAVE REPORTED

60.2% OF DUE TRIALS

THAT'S 5952 TRIALS / OUT OF 9888 TRIALS REPORTED / DUE TO REPORT

BY LAW, ALL CLINICAL TRIALS ON THE EUROPEAN UNION CLINICAL TRIALS REGISTER (EUCTR) MUST REPORT THEIR RESULTS, IN THE REGISTRY, WITHIN A YEAR OF COMPLETION. THIS SITE TRACKS WHICH UNIVERSITIES AND PHARMACEUTICAL COMPANIES ARE


So, why are we doing this now?

Well, we've been working on transparency since the HRA has set up. The Care Act 2014 sets out our duties in this area.


But the publication of a report from the House of Commons Science and Technology Committee brought this issue to a head. The report made a number of recommendations to us to improve transparency.

And shortly afterwards came a new tool from the Evidence Based Medicine unit at the University of Oxford, showing research sponsors performance on reporting the results of clinical trials of medicines


These reports highlighted that we have a problem that we need to address and that's what the strategy is all about




How have we gone about it?




Andrew George (chair)




Marise Bucukoglu




David Edwards




Cham Herath




Simon Kolstoe




Sile Lane




Julie McCarroll




Alex Newberry




Stephen O'Rahilly




Marina Parry



Derek Stewart



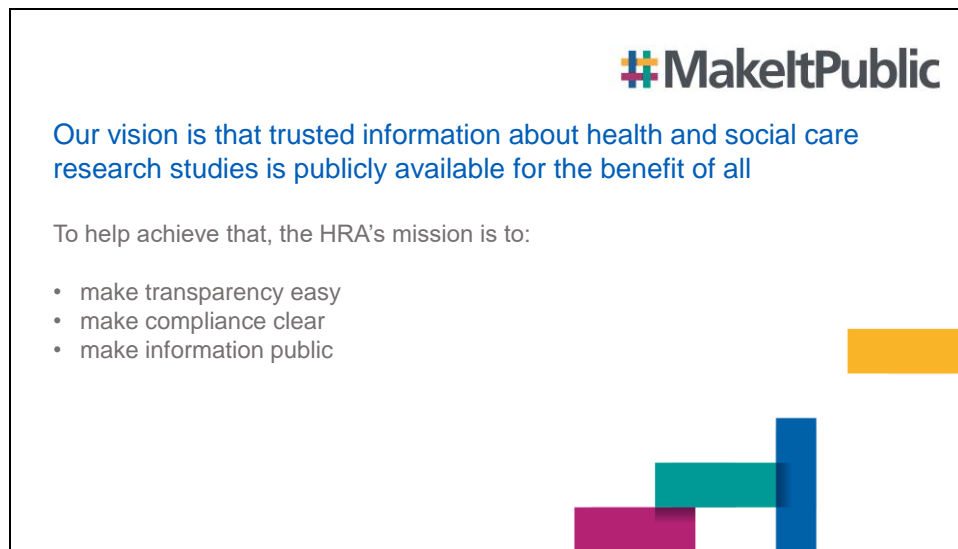
Nisha Tailor



Matt Westmore

How have we gone about producing this draft strategy?

We brought together a diverse group of people to help us. They are drawn from the university, charity and clinical communities, patients and research ethicists, funders, research managers and policy makers from across the UK's four nations. We worked together to draft the plans and proposals that we are presenting today



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

To help achieve that, the HRA's mission is to:

- make transparency easy
- make compliance clear
- make information public

So, what's in the strategy?

Our vision is quite simple

But to achieve it we need to plug some real gaps in information – which I'll talk about in a minute.

We can't achieve that alone, but we are taking a lead by doing a combination of things to change behaviour:

- make transparency easy
- make compliance clear
- make information public


So, with a combination of policy, information, systems, data sharing and creating public visibility, we think we can create real change



Changes we will make: supporting and making it easier

We will:

- be clearer about what we expect of sponsors and researchers at the different stages of the process
- develop new learning packages to support them
- share best practice and celebrate improvement
- make it clear what information we will make public
- introduce automated reminders for researchers and sponsors to submit transparency data
- give sponsors and researchers feedback on their transparency performance



In the strategy, our plans and proposals fall into three categories:

Changes we will make

These are changes that we have already decided to make. We have either started the work or will start soon. In the survey, we ask you to help us to prioritise these changes and make any suggestions for additional activities.

Changes we plan to make

These are areas where we plan to make changes but are seeking views about how to do that. We present a number of different approaches and ask for your views. This will help us to get the strategy right.

Changes we could make

These are further changes we could make if individual research sponsors do not fulfil their transparency responsibilities. We'd like to hear your views about them.

These are the changes we will make – firstly around supporting best practice and making compliance easier. If you know what's expected of you and you are reminded, and rewarded, you're more likely to do it




Changes we will make: making performance clear

We will:

- flag up on the public portal the individual studies where transparency information is overdue
- share transparency performance data with funders, other regulators and registries.




Then around making performance clear. If you don't know how well you're doing, you're not motivated to improve



Changes we will make: feeding back to participants

We will:

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



And finally around giving information to participants about what the study found. We really want to make a step change in this area to make feedback the norm.

Later today, we will ask you to prioritise the planned activities



What are we asking you today?

We would like to hear your views about:

- The strategy overall
- Achieving 100% registration of clinical trials
- Improving the reporting of results
- Increasing and improving feedback to participants
- Prioritising the things we've already decided to do

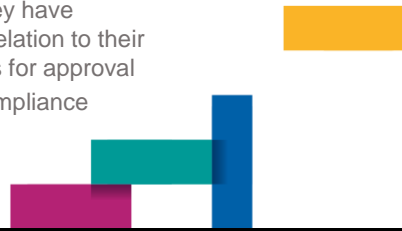




What are we asking you today?

We would also like to hear your views about taking further action if sponsors don't comply. We could:

- publish an annual 'transparency league table' highlighting individual studies which have information that is overdue
- take into consideration the extent to which they have fulfilled their transparency responsibilities in relation to their previous studies, when reviewing new studies for approval
- fine sponsors with very poor transparency compliance rates (change to the law required)





Why being transparent is sometimes difficult

- limitations in the EU register make it hard to report results about certain types of clinical trials of new medicines
- delays in the system for updating records on the EU register mean study information is out of date
- delayed reporting because staff have left the sponsor organisation
- lack of resources and clarity about responsibilities
- lack of clarity about the transparency requirements
- institutional pressures to publish and apply for further research funding



These are some of the practical and cultural pressures in sponsor organisations and those carrying out the research.


We are not saying that these reported difficulties are acceptable reasons for failing to fulfil transparency responsibilities.

However, we want to understand the difficulties so that we can help to address them where possible – and develop plans which avoid making them worse.




Plenary discussion: The strategy overall

Before we get into the detail of the strategy – we want to ask you some general questions



Questions: the strategy overall

- Does the strategy cover everything that you feel is important?
- Is it too ambitious/not ambitious enough?
- Have we missed anything important?



Our first question is about the strategy overall.

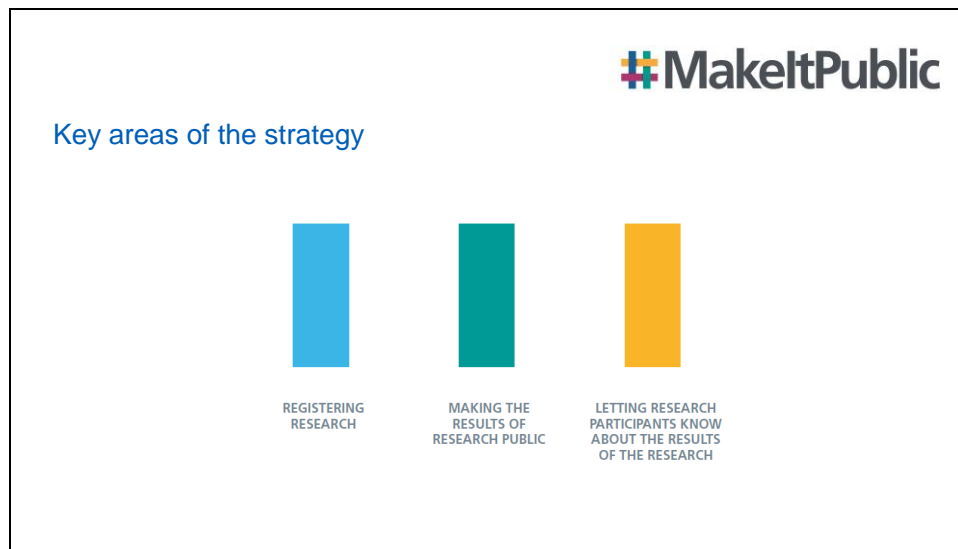
Do you feel that the strategy is pitched right overall? Does it cover the right things? We think it makes sense to focus initially on clinical trials and come to other types of research later – do you agree?

Is the strategy ambitious enough? Or pushing too hard?
Have we missed anything?



We'll get on to specific areas of the strategy in about 30 minutes, but for the next 30 minutes, we'd like to open the floor to general comments from you.



Key areas of the strategy




These are the three areas of transparency that the strategy is focussed on. I'm going to run through with you what the requirements are in each area, what the current level of performance is in each area and what the strategy proposes to address poor performance



Registering clinical trials: requirement


Principle 10: Information about the Research
Information about research projects is made publicly available before they start
(unless a deferral is agreed by or on behalf of the research ethics committee)



The UK policy framework for health and social care research sets out good practice in research through 19 principles.

Principle 10 is that...



So that's the requirement. How are researchers and sponsors doing in relation to that requirement?



Registering clinical trials: performance


Clinical trials of medicines:
100% registered

Clinical trials of devices, surgery, public health and behavioural interventions:
70% registered





Clinical trials of medicines (also known as CTIMPs) are automatically registered on the EU Clinical Trials Register, so registration here is 100%

But what about other types of clinical trials? Our audits show that only 70% are entered onto a recognised registry.



Registering clinical trials: options



1. Researchers must register their study before seeking approval.
2. The HRA supplies data about clinical trials directly to a registry.
3. The HRA becomes a registry itself.



We think we should aim to make registration 100% and these are the three options we've come up with for achieving that...


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

We're going to be asking you to discuss these options



Reporting a summary of results: requirement

Principle 11: Accessible findings
Other than research for educational purposes and early phase trials, **the findings, whether positive or negative, are made accessible... in a timely manner** after they have finished.



The image shows the cover of a document titled 'UK policy framework for health and social care research'. At the top, there are logos for 'NHS Health and Social Care', 'NHS Research Authority', and 'UK Research and Innovation'. The title is centered in blue text. At the bottom, there is a small reference number '18/000001'.


Let's move on to reporting results

Principle 11 of the Policy framework talks about the findings of research:

‘the findings of individual studies, whether positive or negative, should be made accessible... in a timely manner after they have finished’

Publishing in a peer-reviewed journal is important but, as a minimum, a summary of the results should be reported to the registry on which it appears 12 months after the study has finished


That's the requirement, but what is the performance?



Reporting a summary of results: performance

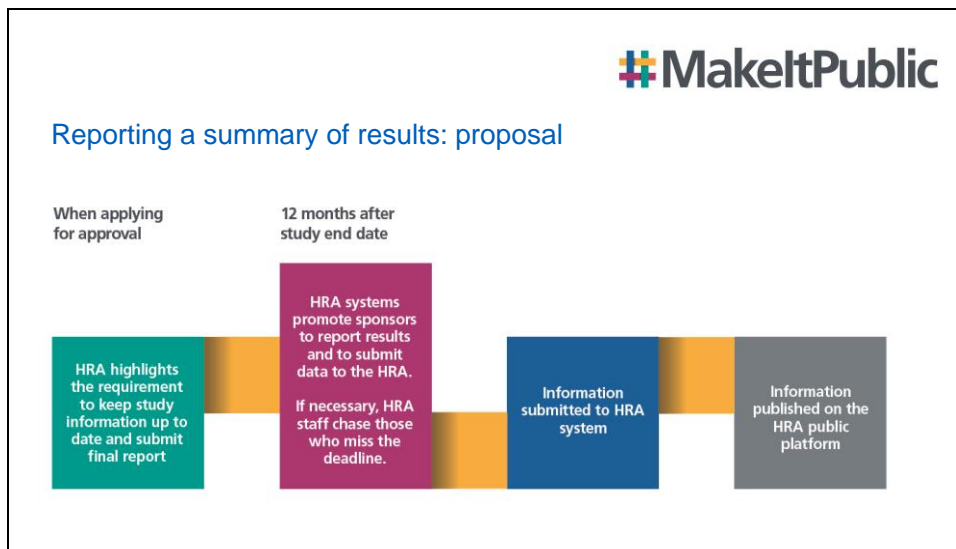
Clinical trials of medicines:
75% of UK studies reported on time

Clinical trials of devices, surgery, public health and behavioural interventions:
Unknown, but likely to be less than 75%



Talking about clinical trials of medicines, only 75% report their results on time – despite there being an additional legal requirement over and above the Policy framework that these studies report a summary to the EU Clinical Trials Register 12 months after the study has finished



What about other types of clinical trials? We don't know for sure, but we expect the number of these studies reporting their results to registries to be much lower than 75%.



We think that a combination of things will change this:


- We are clearer about the requirements
- We allow sponsors to see the status of their studies
- When a study is due to report, we prompt the sponsor. They report using a standardised approach
- We chase those who don't report
- We then publish the information, flagging up any unreasonable gaps in the information
- The record may include information from our own system (the lay summaries, key study findings) or point to information elsewhere (registry entry or publication)

We're going to ask your views about address this issues



Feeding back findings to participants: requirement

Principle 11: Accessible findings
Where appropriate, information about the findings of the research is available, **in a suitable format and timely manner**, to those who took part in it, unless otherwise justified.



The image shows the cover of a document titled "UK policy framework for health and social care research". At the top, there are logos for NHS Health and Social Care, NHS, and NHS Health Research Authority. The title is centered in blue text. At the bottom, there is a small reference number "14181001".

The third issue is around letting study participants know what the researchers found. Principle 11 also talks about making information available to the people who took part in the research.

But does that happen?



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Feeding back findings to participants: performance

Unknown, yet likely to be low


UK policy framework for health and social care research

We don't have data on this, but we do know anecdotally from participants that it doesn't. They are often keen to know what the research has found, but often don't hear about it. When they do, they are often sent a copy of the academic journal article, which is very hard to interpret.



Feeding back findings to participants: plan

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



We think that a combination of changes here will shift behaviour.

First, we need to change the expectation of researchers. At present, we ask them *whether* they will share the study findings with participants. We plan to change that to *how* they will share them

Then, we plan to ask researchers to provide a lay summary of the research findings to us as part of the end of study report. We will then publish that lay summary on our website, alongside other information about that study.



Break



Table discussions: Key areas of the strategy



Questions: registration

- How do we reach 100% registration of all clinical trials?
- How is registration helpful for patients/the public?
- Who should be responsible for registration?
- Should there be sanctions? On whom? What would be effective?





Questions: reporting results

- How do we ensure that all clinical trials are reported?
- What should 'publicly available' mean?
- Who should be responsible for reporting results?
- Should there be sanctions? On whom? What would be effective?





Questions: informing participants about the findings

- Is it enough that this information is published centrally?
- How do we make sure that participants are informed about the findings?
- How, when and by whom should information be given to participants?
- Should there be sanctions? On whom? What would be effective?






Comfort Break




Table discussions: Priorities for implementation



Question

- Please pick your top three priorities
- Why have you chosen them?

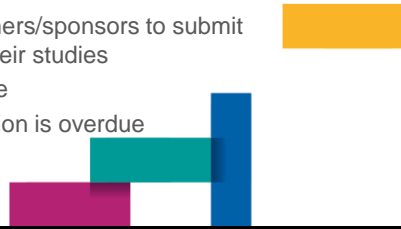


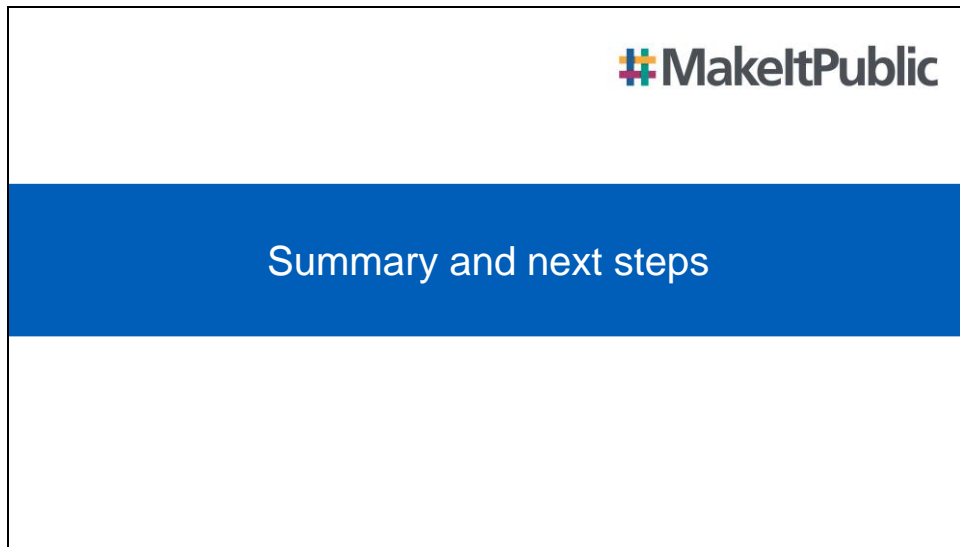
Facilitators will capture the reasons given – the options are [move to next slide]



Priority options

- 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/sponsors to submit transparency data and to view the status of their studies
- Giving feedback on transparency performance
- Flagging up individual studies where information is overdue
- Sharing transparency performance data with funders, other regulators and registries





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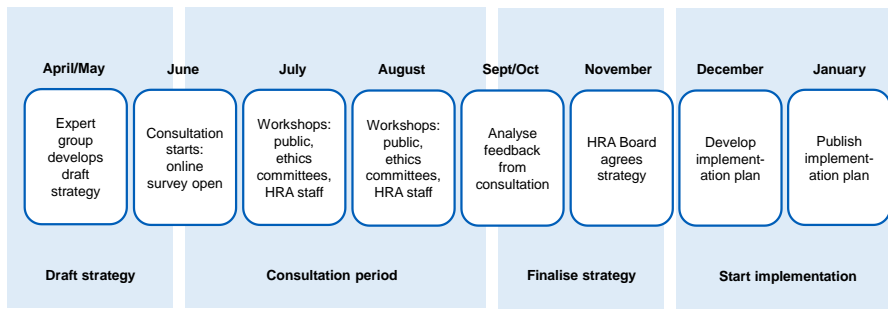
Summary and next steps

The slide content area is a rectangular box with a black border. It is divided into three horizontal sections. The top section is white and contains the logo "#MakeItPublic" in the top right corner. The middle section is a solid blue bar with the text "Summary and next steps" centered in white. The bottom section is white and is currently empty.

thoughts on the day, key things heard, reflections on our priority areas



Strategy timeline





After the consultation has closed

We will:

- Finalise the strategy in the light of feedback
- Publish a report summarising the findings of the consultation
- Present the strategy to the House of Commons Science and Technology Committee
- Meet with key players across the research system to agree a roadmap for achieving the strategy's aims

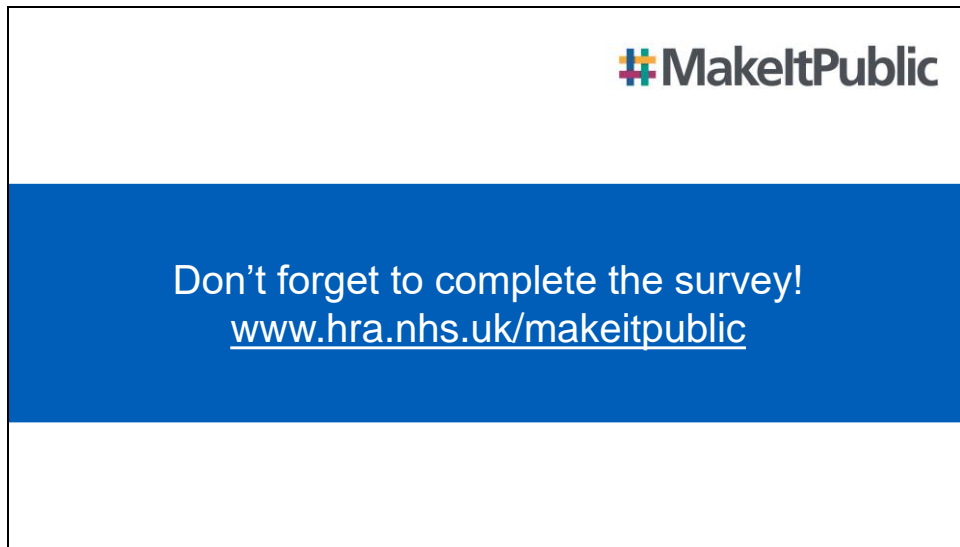


So, what will happen after the consultation has closed?

[read bullets]

The end of the consultation marks the beginning of a long process to achieve our vision of making research information public. We need to continue to work with those across the research system and to continue to listen to people like you.

For now, I'd like to thank you very much for taking part and giving us your views. They will shape the final strategy, ensuring that our plans are achievable, focused on the right things and rooted in the views of everyone involved in research.



In the meantime, please respond to the survey – we need your answers to those questions in addition to the views you've expressed today.

You can do that by visiting our website...



Join the HRA Public Involvement Network
Email hrapublicinvolvement@nhs.net
for further information