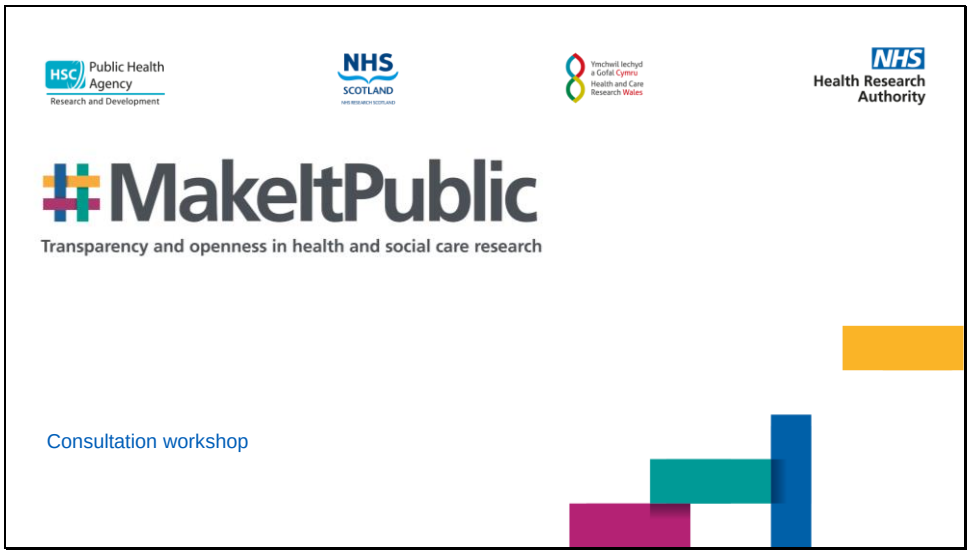
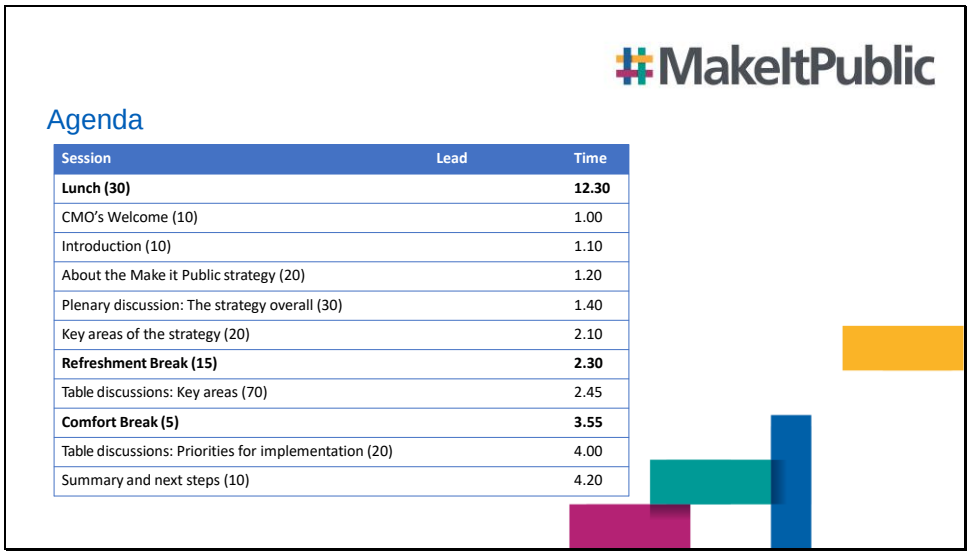
Slide 1



- 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

Slide 2



- 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.

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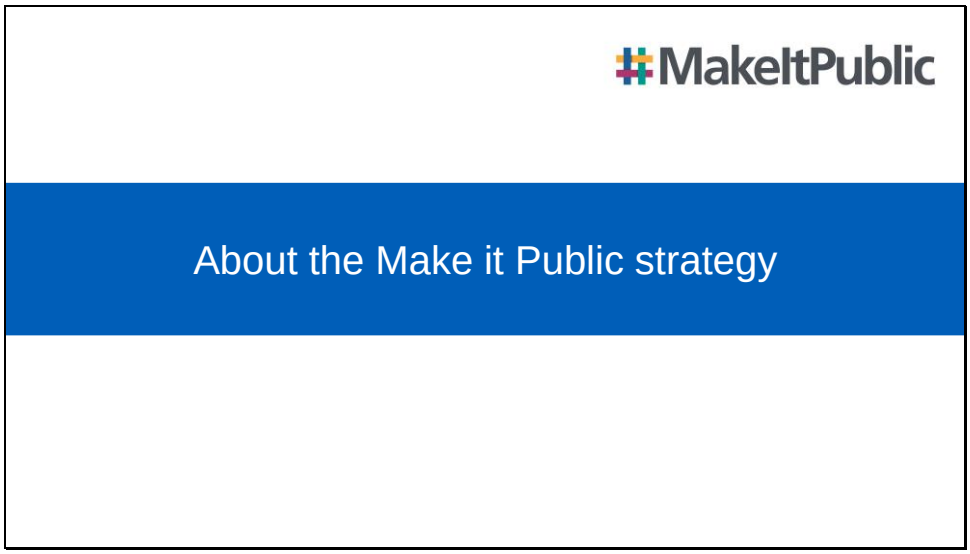

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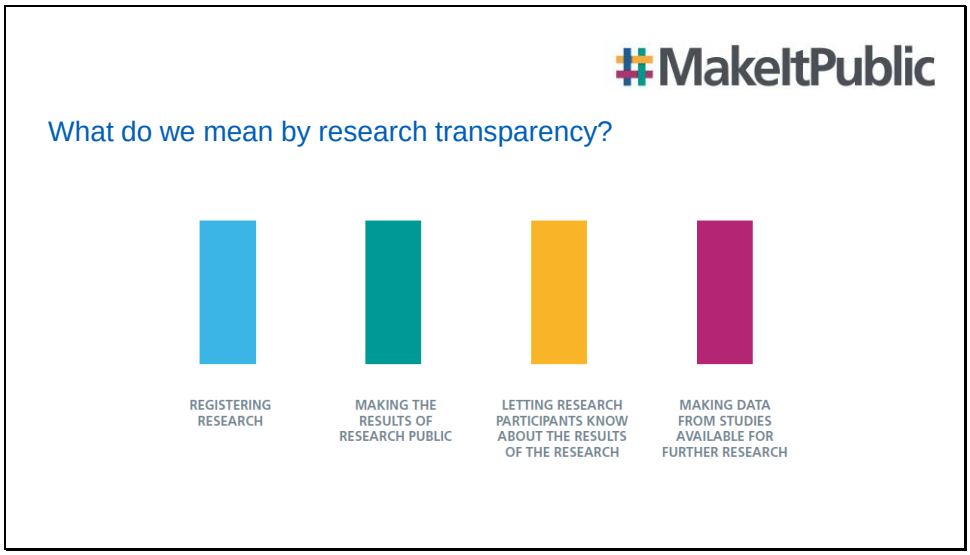


Transparency in research can mean many things. It could mean openness about who is funding research, or about the researchers involved. So just to be clear about what this strategy covers, when we talk about research transparency, we mean:

- 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

Slide 5

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 – though government funding and through charitable donations. To maintain that huge public contribution, we need to maintain trust in research..

Slide 6

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

Slide 7

So, why are we doing this now?

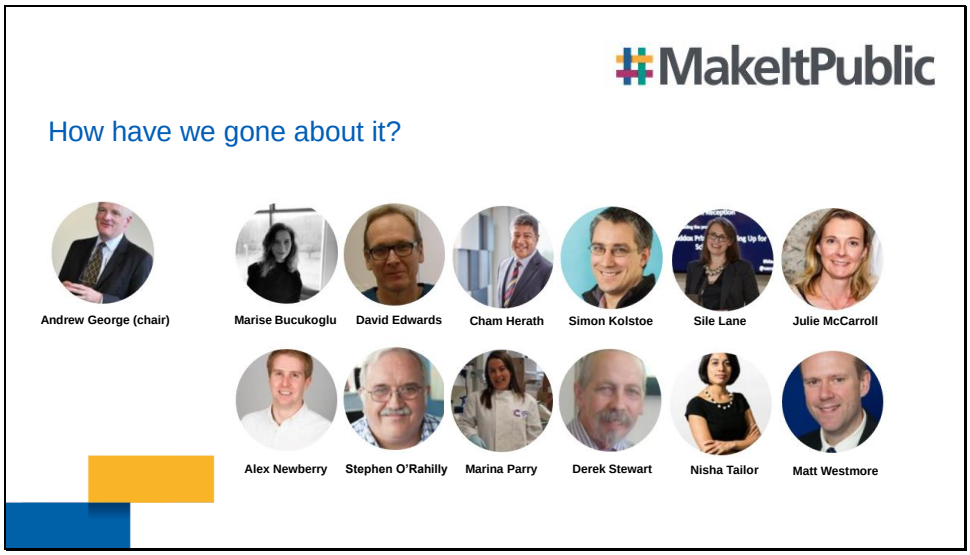
Well, we've been working on transparency since the HRA has set up. The Care Act 2014 sets out our duties in this area.

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

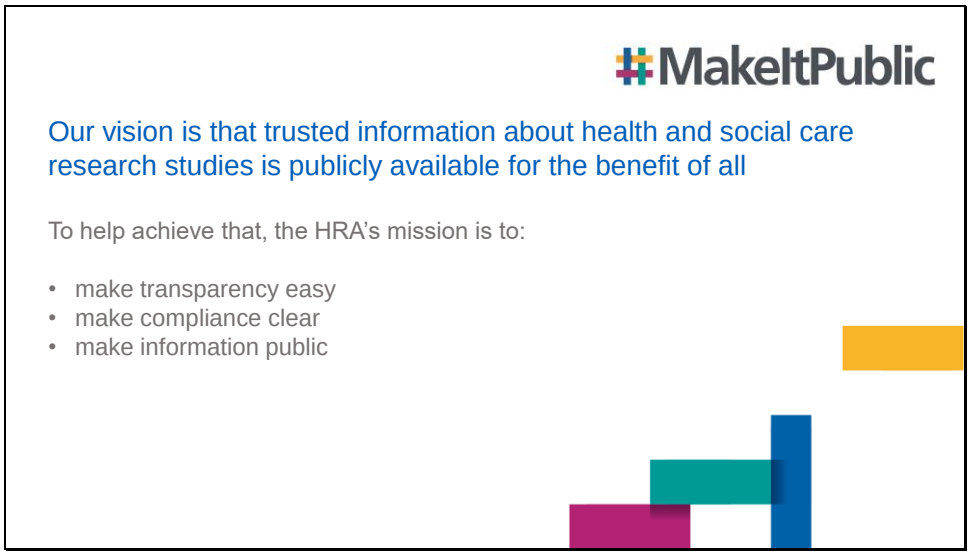
Slide 8



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

Slide 9



So, what's in the strategy?

Our vision is quite simple

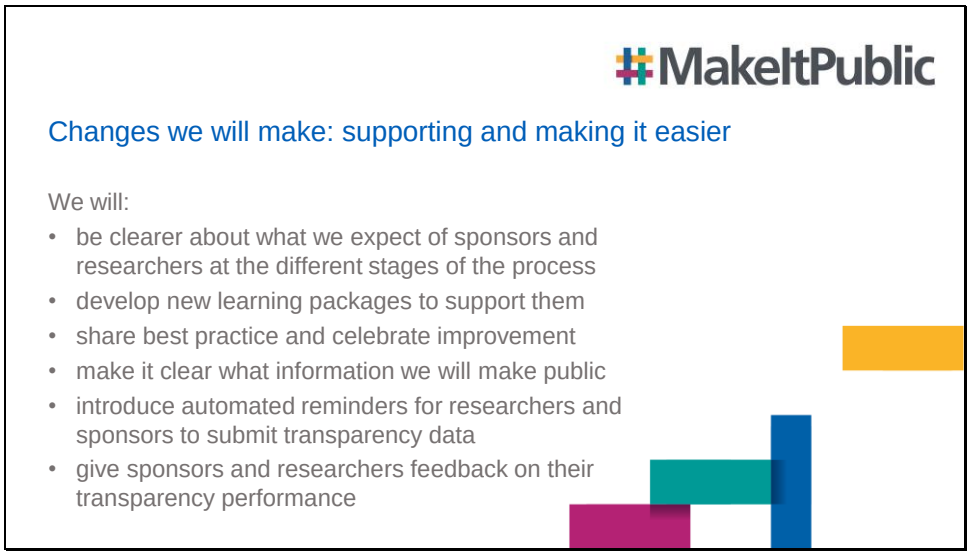
But to achieve it we need to plug some real gaps in information – which I'll talk about in a minute.

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

Slide 10

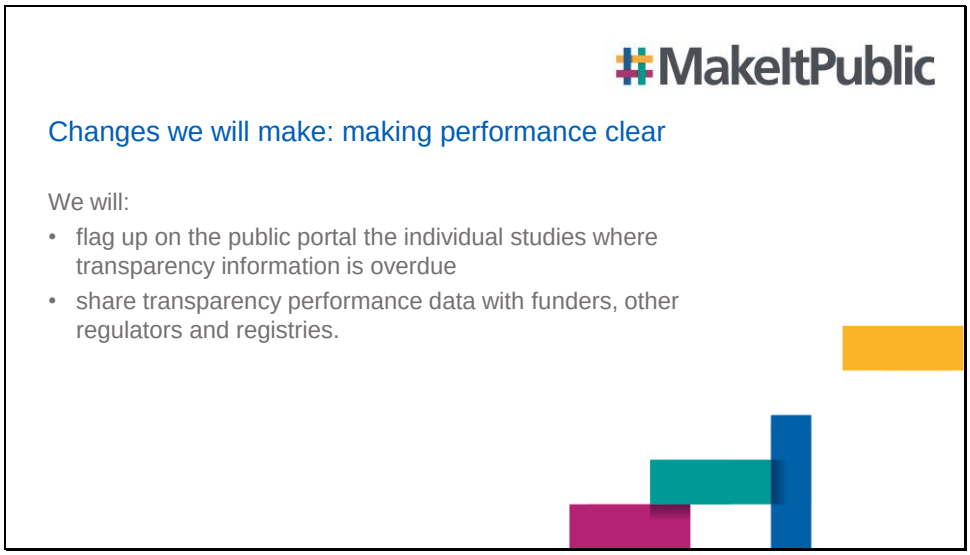


In the strategy, our plans and proposals fall into three categories:

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.

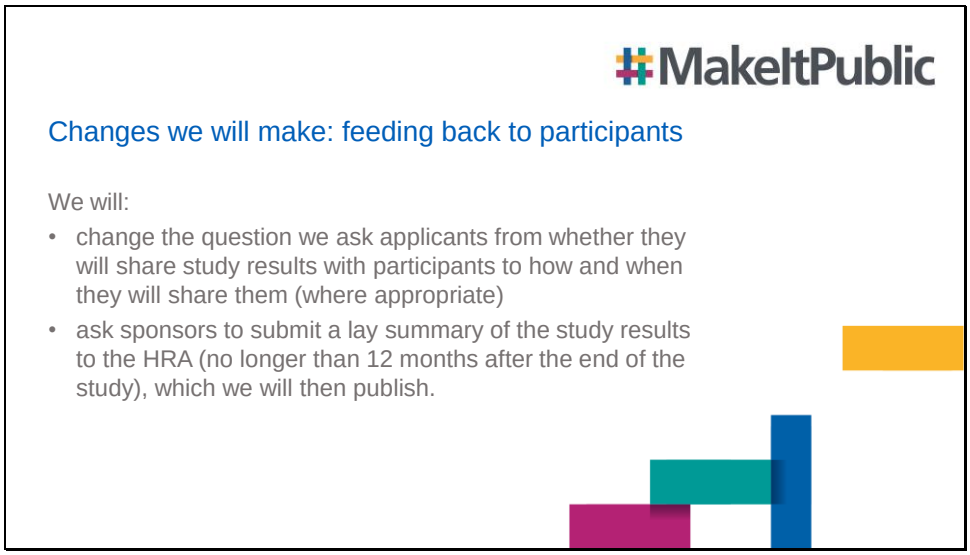
These are the changes we will make – firstly around supporting best practice and making compliance easier. If you know what's expected of you and you are reminded, and rewarded, you're more likely to do it

Slide 11



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

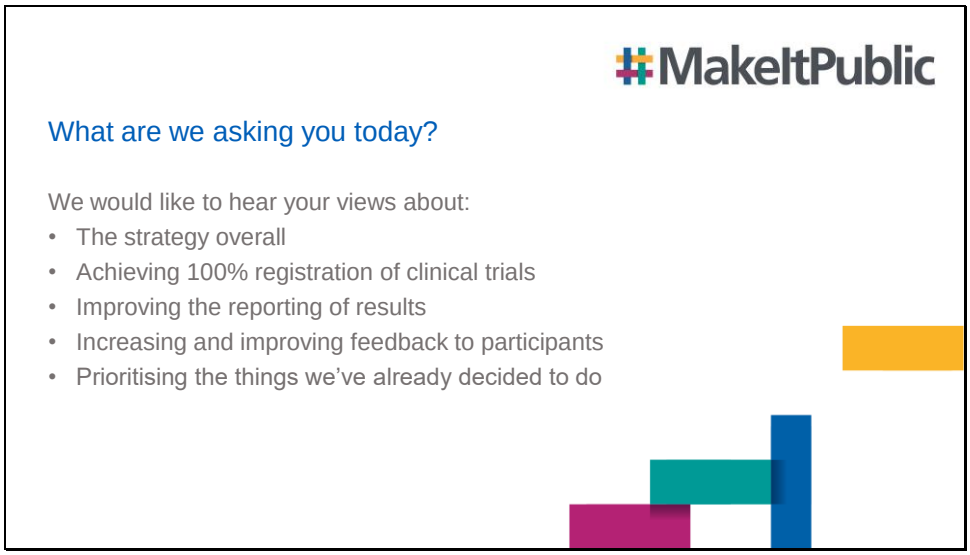
Slide 12



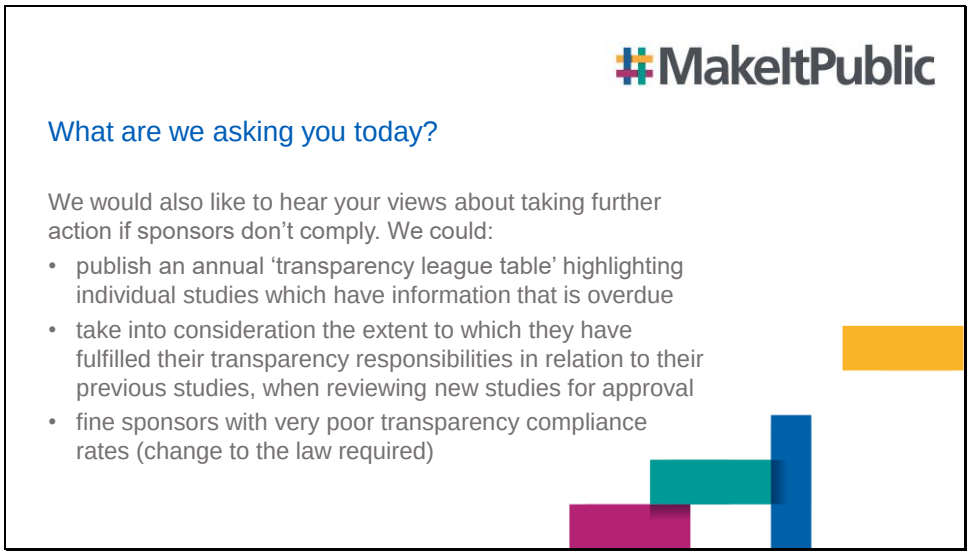
And finally around giving information to participants about what the study found. We really want to make a step change in this area to make feedback the norm.

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

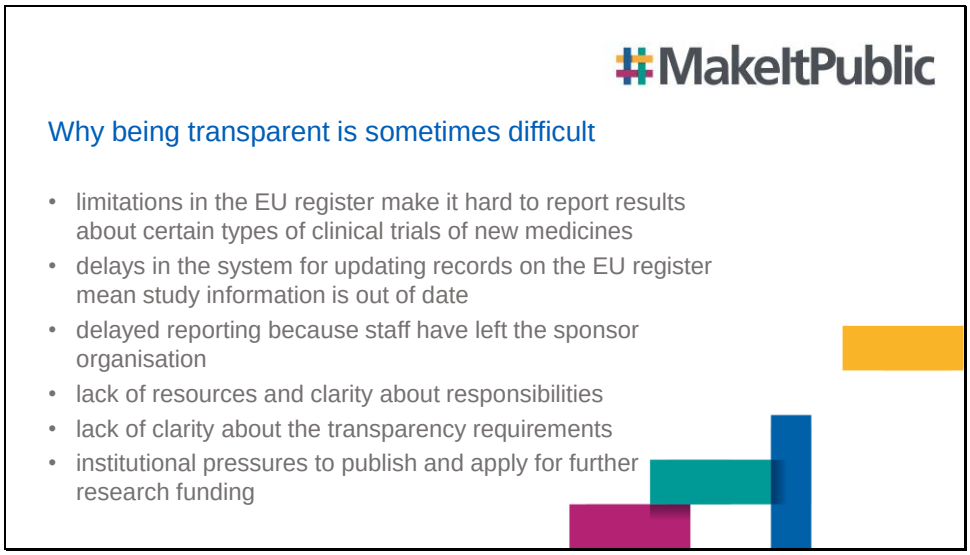
Slide 13


MakeItPublic
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

Slide 14


MakeItPublic
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)

Slide 15

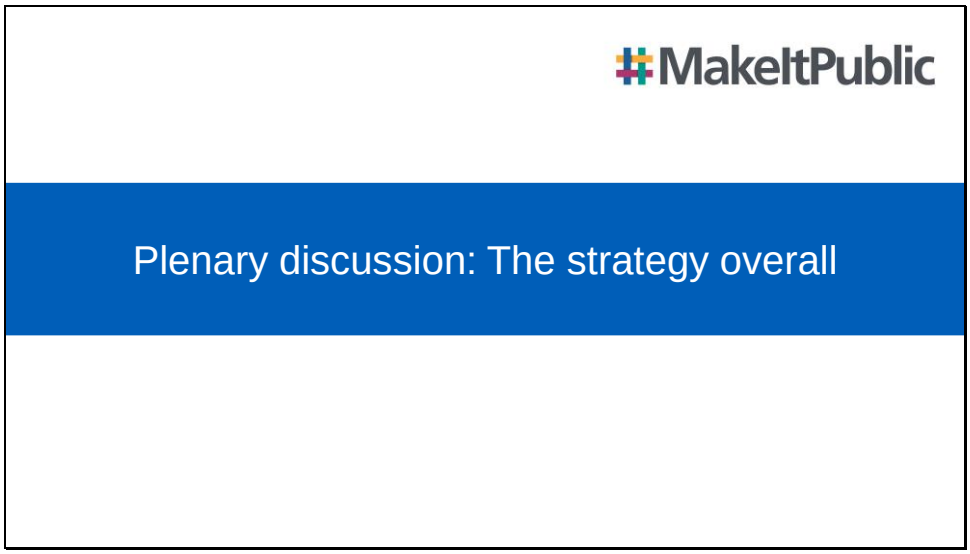


These are some of the practical and cultural pressures in sponsor organisations and those carrying out the research.

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

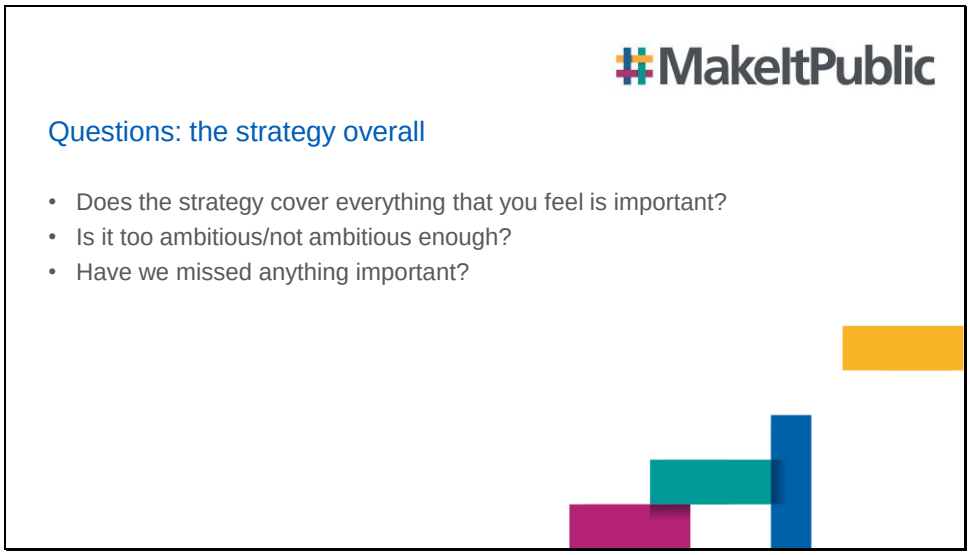
However, we want to understand the difficulties so that we can help to address them where possible – and develop plans which avoid making them worse.

Slide 16



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

Slide 17



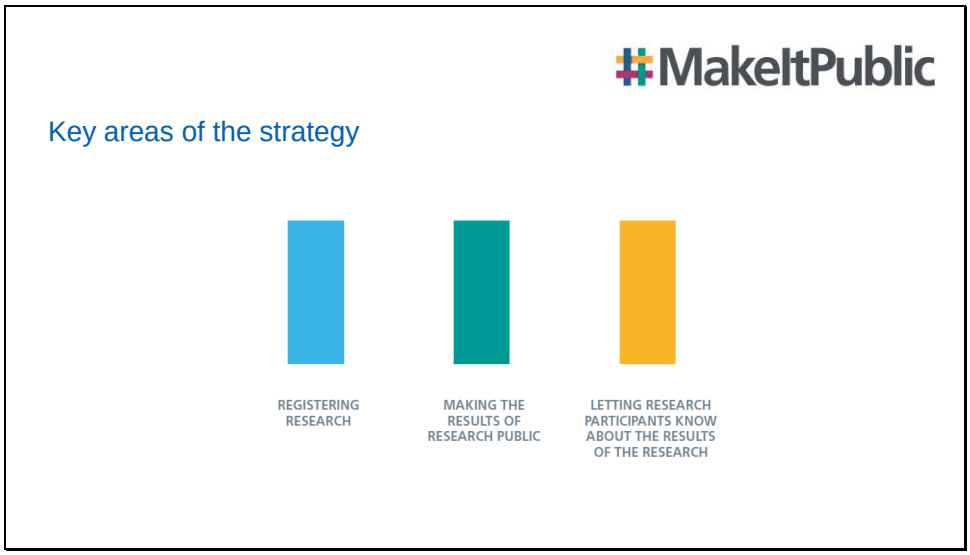
Our first question is about the strategy overall.

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.

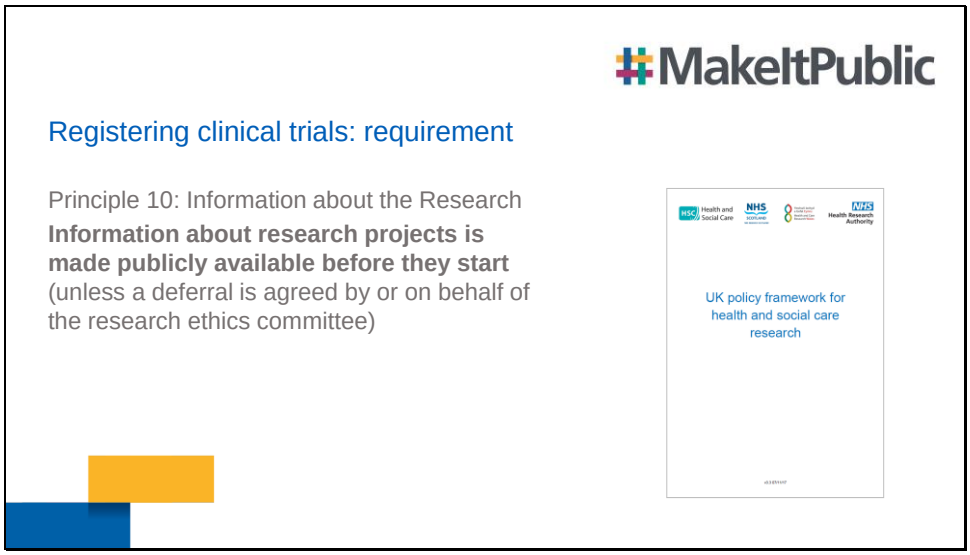
Slide 18

Slide 19



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

Slide 20

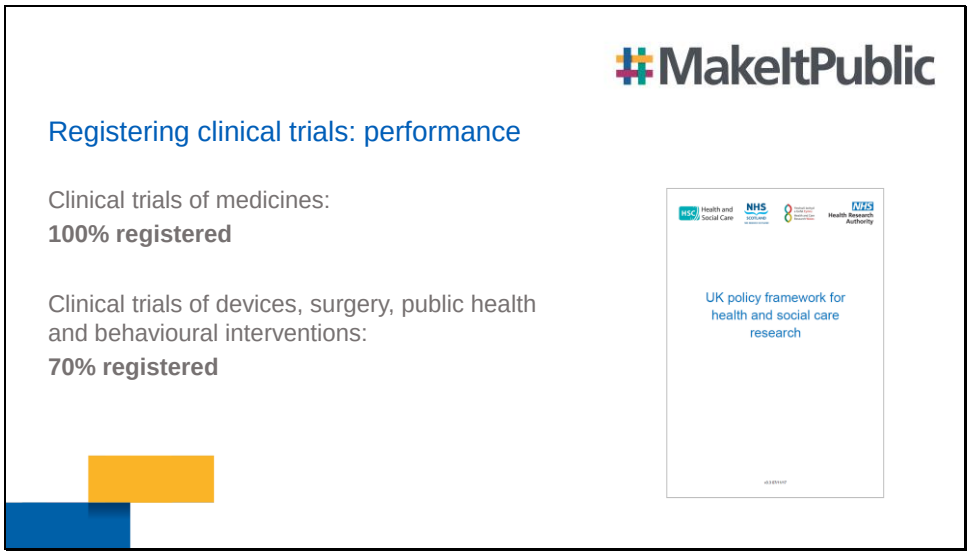


The UK policy framework for health and social care research sets out good practice in research through 19 principles.

Principle 10 is that…

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

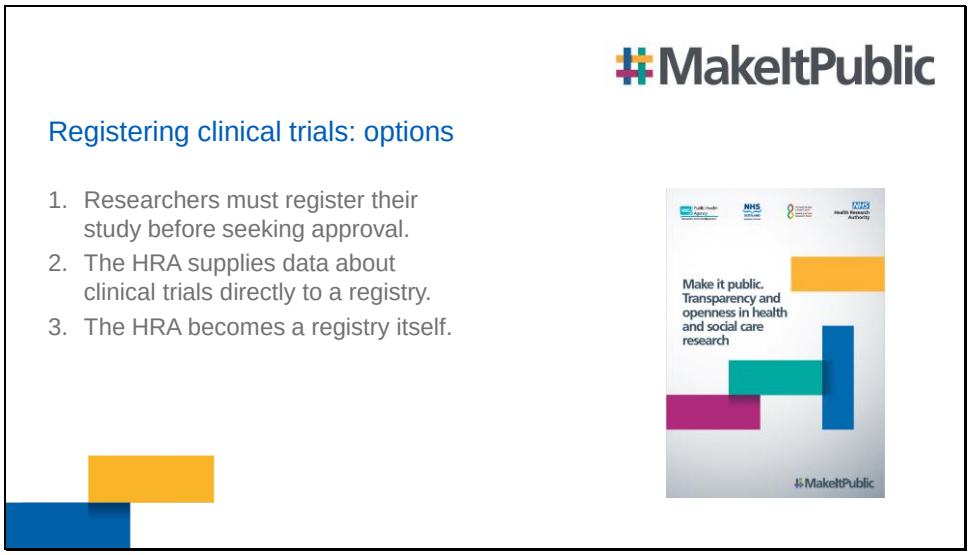
Slide 21



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.

Slide 22

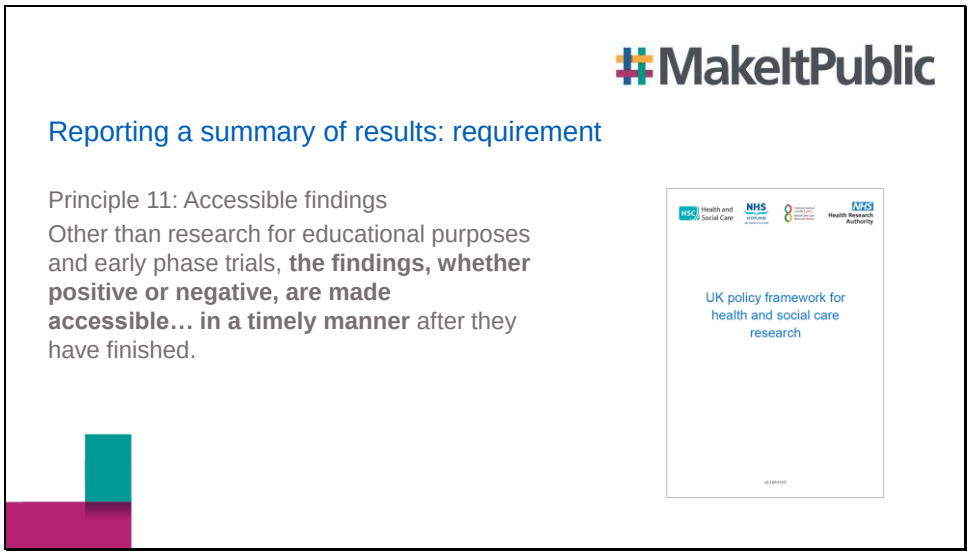


We think we should aim to make registration 100% and these are the three options we've come up with for achieving that…

- 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

Slide 23



Let's move on to reporting results

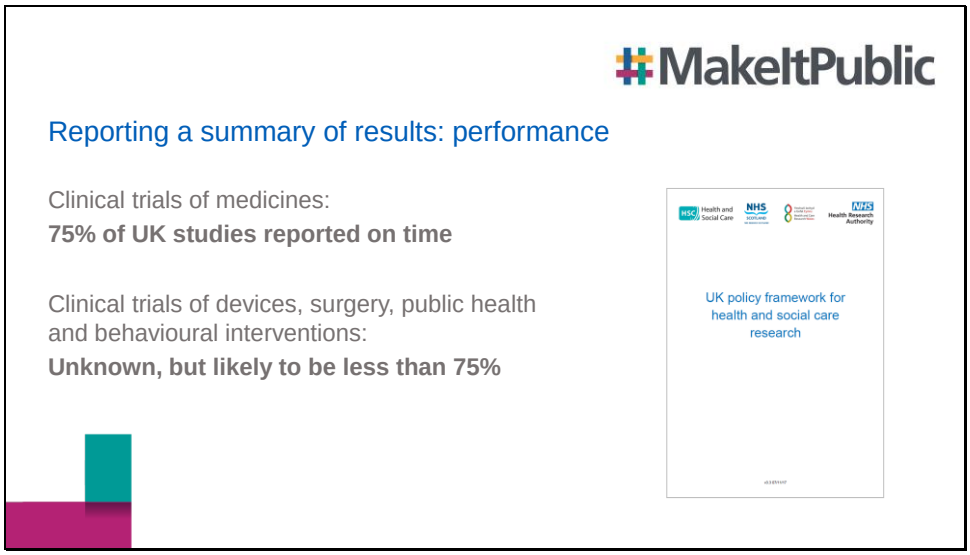
Principle 11 of the Policy framework talks about the findings of research:

'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?

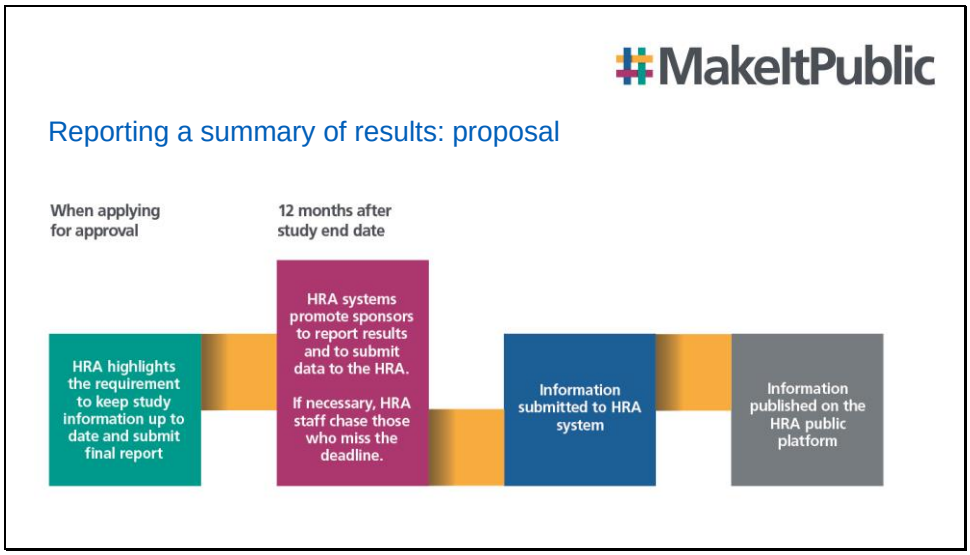
Slide 24



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%.

Slide 25

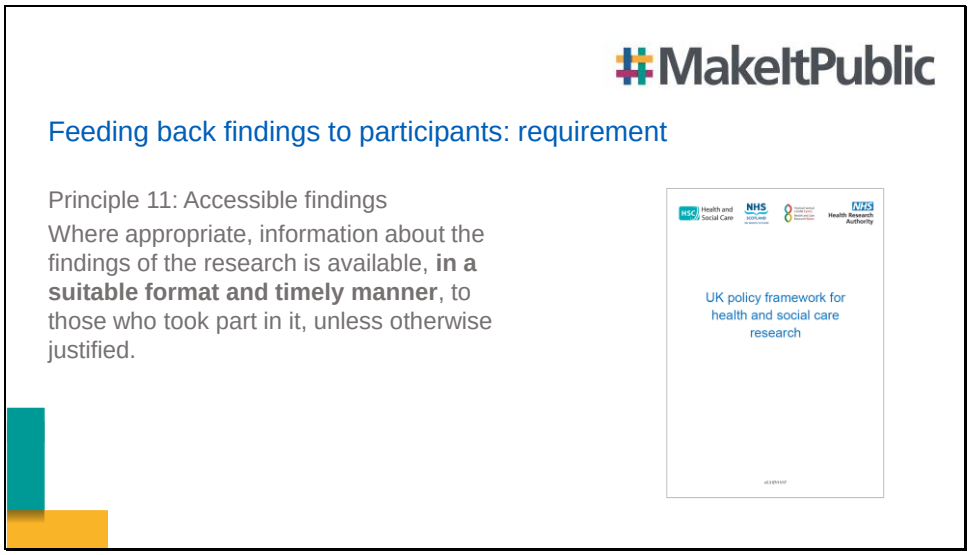


We think that a combination of things will change this:

- 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

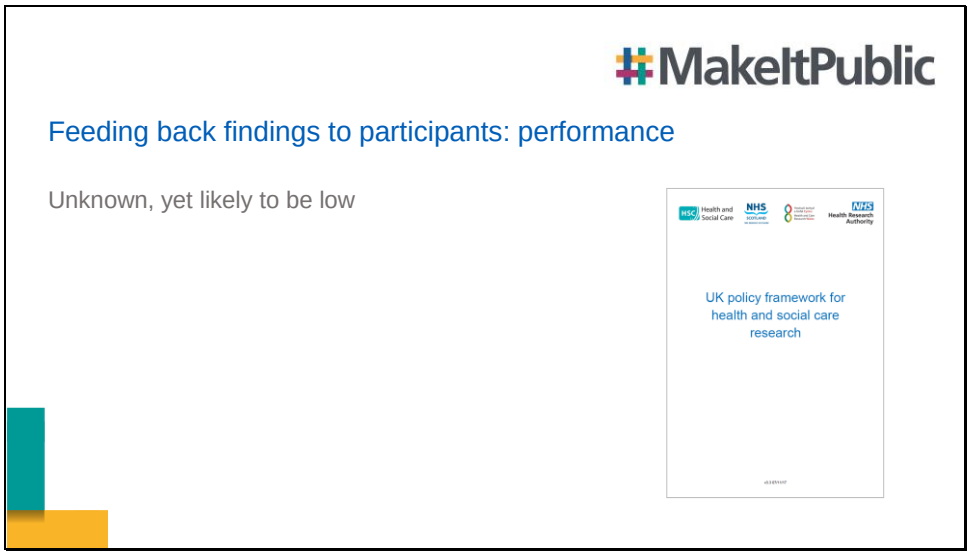
Slide 26



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.

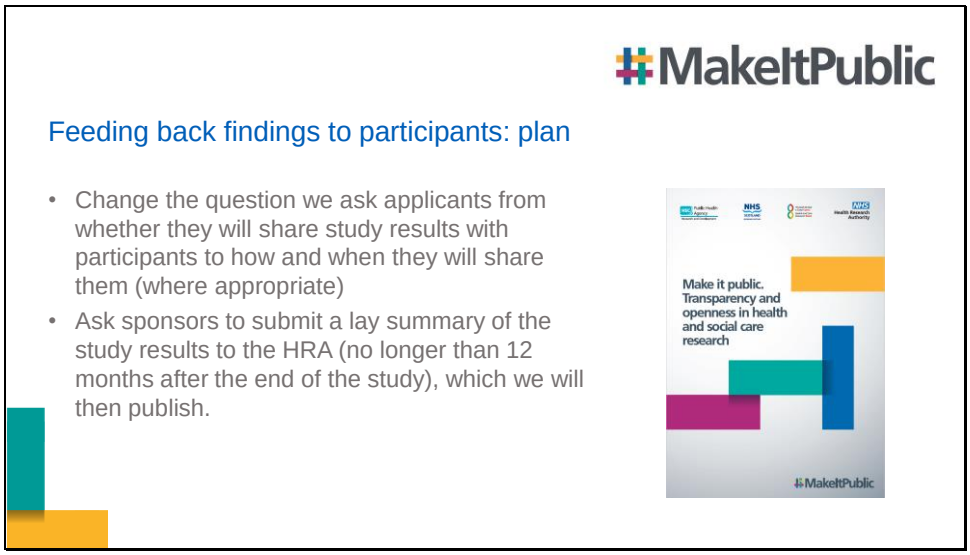
But does that happen?

Slide 27



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.

Slide 28



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.

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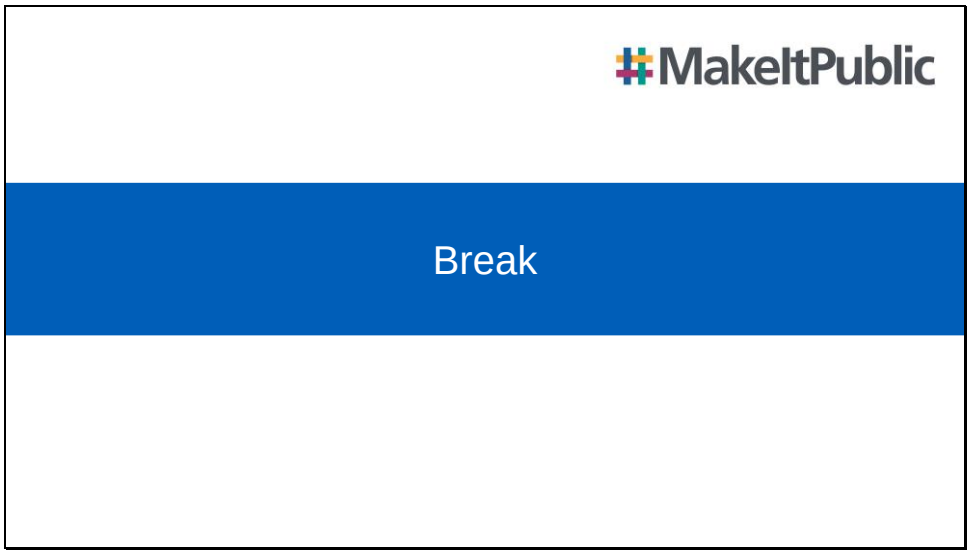
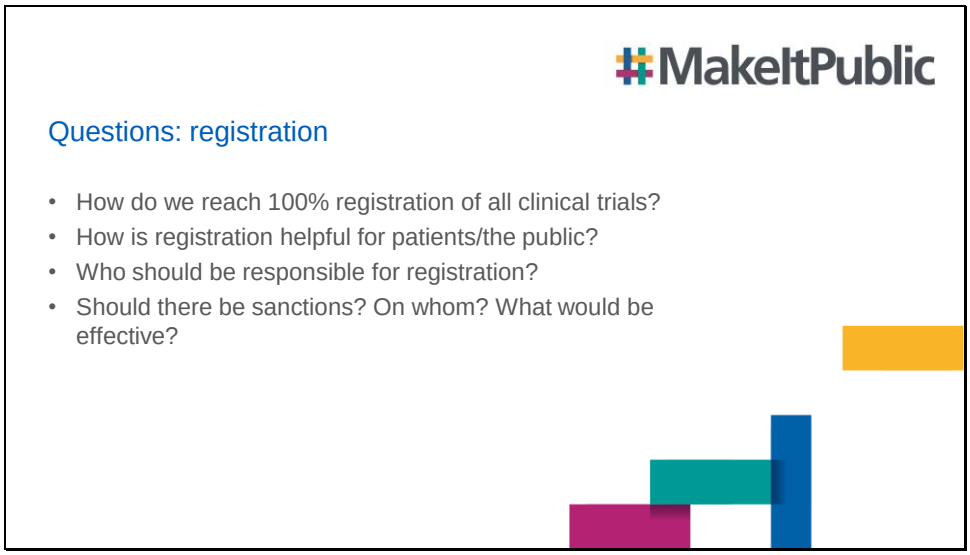


Slide 30

MakeItPublic

Table discussions: Key areas of the strategy

Slide 31


MakeItPublic
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?

Slide 32

MakeItPublic

Questions: reporting results

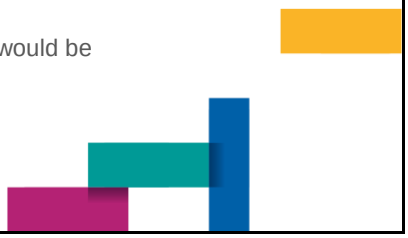
- How do we ensure that all clinical trials are reported?
- What should ‘publicly available’ mean?
- Who should be responsible for reporting results?
- Should there be sanctions? On whom? What would be effective?

Slide 33

MakeItPublic

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?



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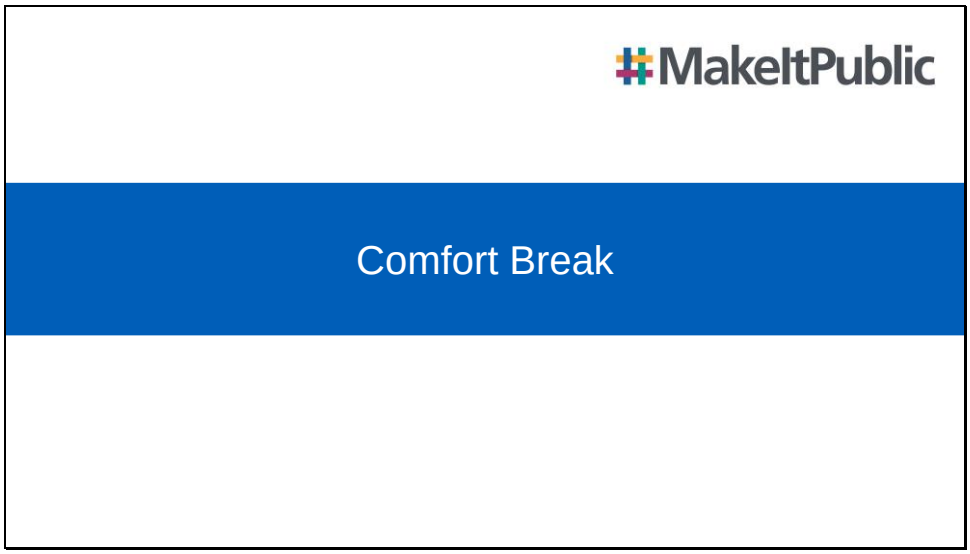


Slide 35

MakeItPublic

Table discussions: Priorities for implementation

Slide 36

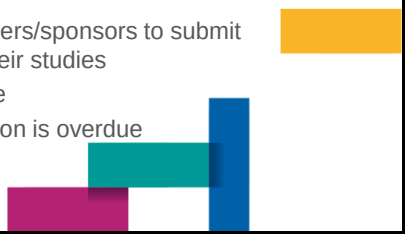
Facilitators will capture the reasons given – the options are [move to next slide]

Slide 37

MakeItPublic

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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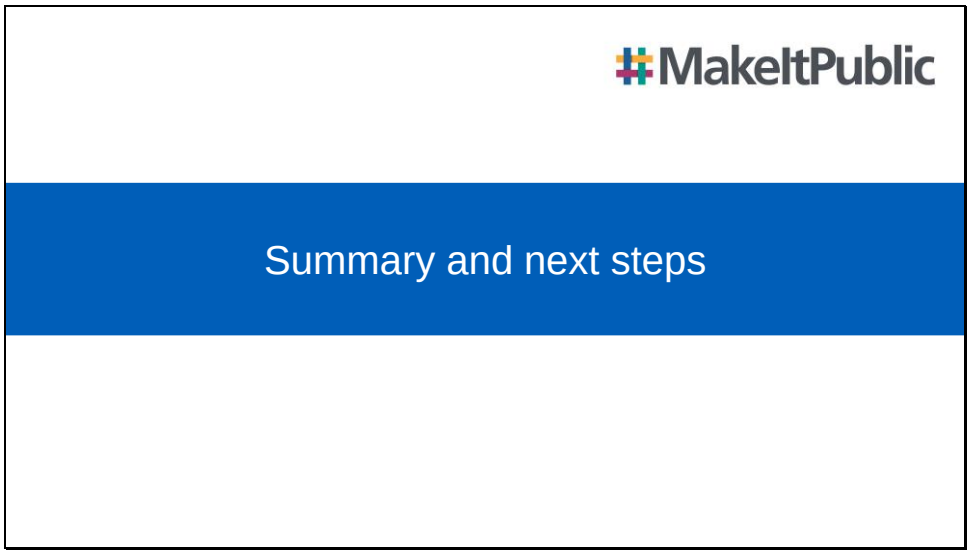
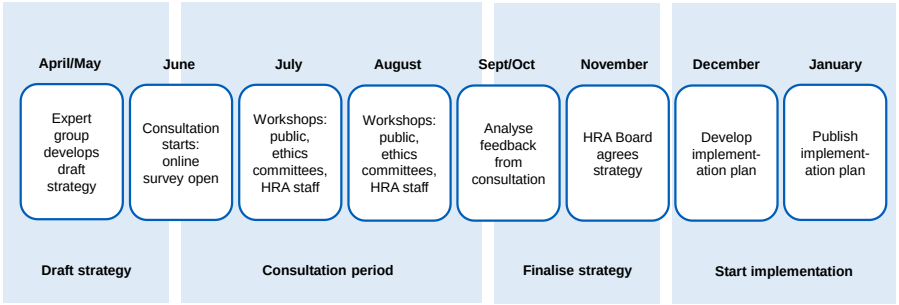


thoughts on the day, key things heard, reflections on our priority areas

Slide 39

MakeItPublic

Strategy timeline



Slide 40

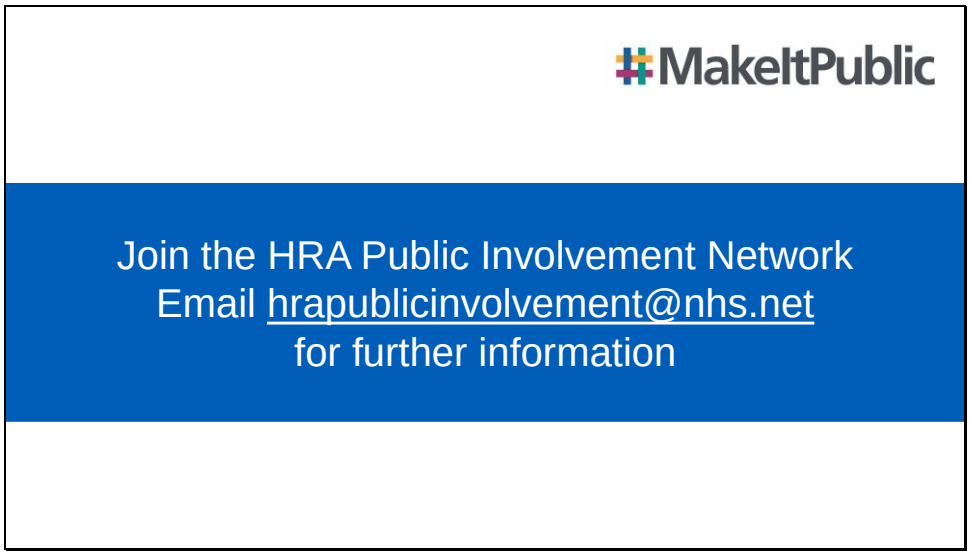
So, what will happen after the consultation has closed?
[read bullets]
The end of the consultation marks the beginning of a long process to achieve our vision of making research information public. We need to continue to work with those across the research system and to continue to listen to people like 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, focussed on the right things and rooted in the views of everyone involved in research.

Slide 41

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…

Slide 42


MakeItPublic
Join the HRA Public Involvement Network
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for further information