Discover-NOW
Health Data Research Hub for Real World Evidence

Discover-NOW Citizens Advisory Group
Deliberation 1, Report

February, 2021

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Executive summary

Discover-NOW
Health Data Research Hub for Real World Evidence

Introduction

The Discover-NOW Board made a commitment to establish a Citizens Advisory Group in line with recommendations made by the OneLondon Citizens' Summit for how the public should be involved in ongoing oversight and development of policy relating to the use of health and care data moving forward.

Ipsos MORI, working in partnership with Imperial College Health Partners, was commissioned to design and deliver two deliberations over the course of 2021. This work is being supported by a Steering Group (see appendices) to provide challenge and scrutiny.

This report presents findings from the first of these deliberations, focused around public expectations concerning the conditions in place where non-NHS partners are accessing health and care data in a trusted research environment.

Methodology

The deliberation consisted of two virtual workshops in February 2021, comprising c40 Londoners recruited to reflect the North West London population.

Each workshop lasted three hours and included a combination of informative expert presentations and moderated group discussions in which smaller groups of around six participants reviewed stimulus materials and deliberated their views, experiences and expectations.

Deliberation question: ***What conditions need to be in place for non-NHS partners (universities, commercial organisations, charities) to have access to health and care data in a trusted research environment?***

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Executive summary

Discover-NOW
Health Data Research Hub for Real World Evidence

Initial attitudes, understanding and awareness around health and care data research

In line with previous engagement exercises, there was a **general lack of awareness** that data 'about me' is used in research and development.

On hearing more about health data research and the Discover-NOW Hub, **participants were positive about the potential for research** to progress diagnosis, treatment and cures. Unsurprisingly, given the current context, immediate links were made with COVID-19 and vaccines.

However the information raised **a number of concerns regarding the involvement of commercial organisations**, and **the potential for data to be used in other ways** (i.e. to inform an insurance-based model of healthcare delivery and by employers).

Initial views on the involvement of various non-NHS partners in research

Universities tended to be regarded as trusted to access data, on the assumption that they would be conducting research for the 'right reasons' (i.e. for the 'greater good' of improved public health and care) and without a commercial agenda.

Conversely, **commercial organisations accessing data for research raised discomfort with participants.** Commonly participants spoke of hidden agendas and such firms only being in it for commercial gain. Participants were also concerned about these organisations' security and protocols.

International companies accessing data for research was a cause for concern for some, with some misunderstanding around why such companies would want access to data about a different population, and worries over less stringent data protection standards.

Importantly, as the following slides illustrate, once the participants learnt more about the process and considered the issues in more depth, **they recognised the potential benefits of working with commercial partners** on the condition that strong access criteria and controls are maintained.

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Executive summary

Discover-NOW
Health Data Research Hub for Real World Evidence

Expectations concerning access

Participants received information from Discover-NOW on the Hub's current access model in addition to potential alternatives. The benefits and drawbacks of these different models formed the basis of their discussion.

All groups broadly **supported the diverse makeup of an Independent data access group** as ensuring data access requests are considered holistically. However, participants did highlight potential risks of **ensuring balance**, either being skewed by 'uninformed' members of the public, laypeople being 'railroaded' by specialists, or competing voices failing to agree.

Participants also broadly agreed that the lay members should be **representative** of the local area, however these was no agreement on how these should be recruited nor whether they should be remunerated.

Participants were concerned that the **data trust committee model** was too focussed on the uneducated public view. Similarly, **the independent scientific panel was seen as being skewed** too much towards a single view. Though there were some who valued this alongside an independent data access group.

Views concerning a local NHS sponsor were mixed. Some favouring local expertise, others leaning more towards an NHS sponsor from elsewhere in the NHS, and a group who felt this to be unnecessary so long as this voice was part of the independent data access group.

Data access contracts were favoured for their potential to deter data misuse, however cautioned for deterring organisations from requesting access. While **honorary contracts were felt to be highly dependent on other controls in place.**

Participants cautioned only allowing approved researchers access to data given it could restrict vital research by non-medical experts.

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Executive summary – access recommendations

Discover-NOW
Health Data Research Hub for Real World Evidence

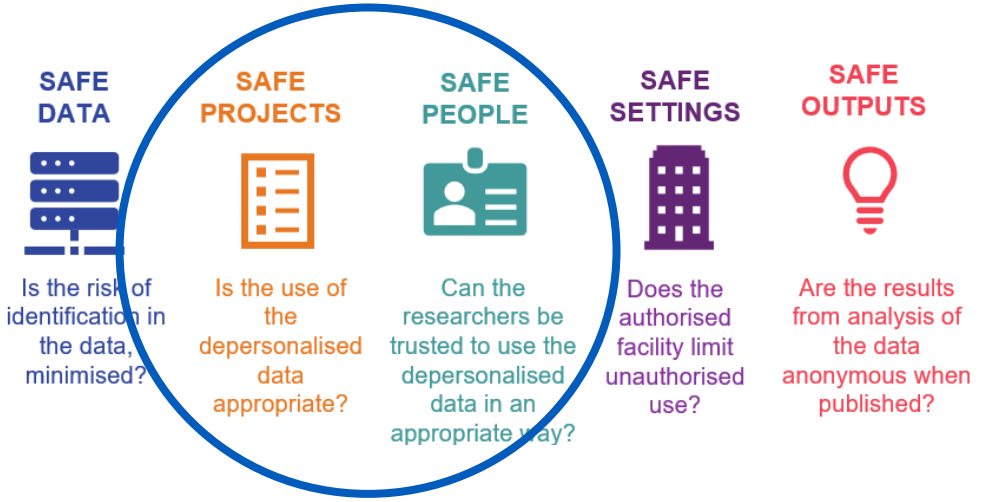
Governance

- All groups called for an **independent data access group** to provide genuine scrutiny and challenge, and ensure access requests align with NHS values, **with a range and balance of membership**:
  - Scientific expertise, researchers, patients (to represent the communities where data has come from), lay members (with some staying, others revolving), data protection experts, legal expertise, other experts (specialists), clinicians.

Access criteria

- Research requests should be **time limited** (but with review on timings in place every number of months to monitor progress)
- **Legal implications and penalties** including substantial fines which impact on employers and individuals for misuse
- **Only approved researchers**: Robust screening process and minimum requirements for those handling data (qualifications, experience)
- The access request **must show a real evidence gap**, and therefore justify the research that is being proposed / show how it is going to compliment other research in the area.

- Outside of the core recommendations, which represent consensus across groups above, some recommendations were made by specific groups:
  - Two groups suggested that there could also be an **independent scientific panel** that sits alongside this, because its important for independence.
  - One group was keen for a **NHS sponsoring clinician** for all requests (that could come from anywhere in the NHS), though other groups suggested this is not needed if there are clinicians on the independent data access group.
  - One group wanted non-burdensome contracts.



IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Executive summary

Discover-NOW
Health Data Research Hub for Real World Evidence

Expectations concerning controls

Participants also received information from Discover-NOW on the Hub's current controls regarding access to data and how these could be altered. They discussed:

- The trade-offs between only allowing anonymised aggregate data to leave versus linking de-personalised data with other Trusted Research Environments.
- The trade-offs between restricting access to specific datasets relevant to the study versus allowing access to the whole dataset (e.g. for AI/machine learning)
- Increased peer review of data analysis before leaving the TRE to ensure consistent interpretation of the real world data

Although participants often recognised the risks involved, most participants believed that **letting data leave the Trusted Research Environment (TRE) was necessary** for the greater good of important health research provided the other TREs have the same standards and controls. This was not universal however, as some felt strongly about keeping the data local and not transferring it to other TREs.

Participants broadly agreed with the concept of restricting data access to a specific subset in order to preserve the data's value. However participants thought that this concept needed flexibility in order to not restrict exploratory research such as AI or machine learning.

A common conclusion was that the level of access should be limited by default, and that more general access should be **justified by the research aims,** and that any change of scope would require a new data access request.

Increased peer review received unanimous support, with participants highlighting the risks of misinterpretation both for the public through the media and for the NHS in terms of reputational damage.

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Executive summary – controls recommendations

Discover-NOW
Health Data Research Hub for Real World Evidence

Linking with other Trusted Research Environments

All groups supported linking de-personalised data with other Trusted Research Environments with the following conditions:

- Extra approval process for applications where data needs to leave TRE
- De-personalised data will not leave the TRE unless there is a good reason – i.e. that it will advance the research / is necessary to get to the conclusion/findings
- The other TRE/s that the data is linking with have similar safeguards in place and can demonstrate this
- Criminal charges for any misuse of data (see data contracts above)

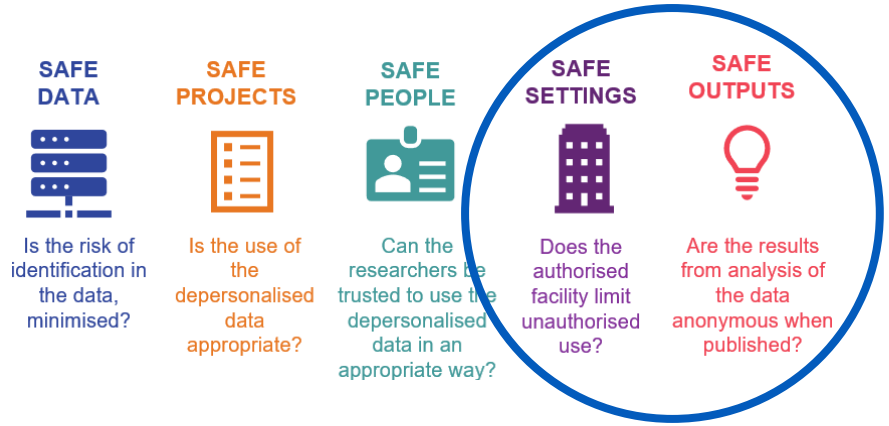
Ensuring safe outputs

- Widespread support for peer review of analysis before this leaves the TRE.
- Research outcomes should be published on the Hub website where possible.

What data can be accessed

There was more concern surrounding access to whole datasets, although more than half of the groups were supportive of this. If this was to happen, the following conditions should be in place:

- Needs to be really clearly justified why this is needed
- Time limited access, with clear auditing in place to ensure no misuse
- The scope of the research needs to be clear and not change without a new data access request being made.



IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Discover-NOW
Health Data Research Hub for Real World Evidence

1. Introduction and methodology

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Introduction and methodology

Discover-NOW
Health Data Research Hub for Real World Evidence

Discover-NOW, the Health Data Research Hub for Real World Evidence, is committed to engaging patients an the public in a meaningful way throughout its work.

The Discover-NOW Board made a commitment to establish a Citizens Advisory Group in line with recommendations made by the OneLondon Citizens' Summit for how the public should be involved in ongoing oversight and development of policy relating to the use of health and care data moving forward.

Ipsos MORI, working in partnership with Imperial College Health Partners, was commissioned to design and deliver two deliberations over the course of 2021. It is being supported by a Steering Group (see appendices) that provides challenge and scrutiny. This report presents findings from the first of these deliberations, focused around public expectations concerning the conditions in place where non-NHS partners are accessing health and care data in a trusted research environment (see Figure 1 for the full deliberation question).

Methodology

The deliberation consisted of two virtual workshops in February 2021, comprising c40 people recruited to be reflective of the North West London population. Further details of those who took part can be found in the appendices.

Each workshop lasted three hours and included a combination of informative expert presentations and moderated group discussions in which smaller groups of around six participants reviewed stimulus materials and deliberated their views, experiences and expectations. Further detail about each workshop can be found on the next slide.

What conditions need to be in place for non-NHS partners (universities, commercial organisations, charities) to have access to health and care data in a trusted research environment?

Figure 1: Deliberation question

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Introduction and methodology

Discover-NOW
Health Data Research Hub for Real World Evidence

Workshop 1:

- An introductory presentation to health data research, covering who is involved, why research is important and some examples.
- A presentation introducing Discover-NOW, de-personalised data, examples of research undertaken, how data is currently accessed, and the national data opt-out.
- A Q&A slot with experts to address emerging questions and concerns.
- A presentation about Trusted Research Environments, covering the five safes framework.
- Moderated discussion around a selection of case studies representing different research purposes and organisations involved.
- A presentation summarising findings from other public engagement exercises which have sought to explore attitudes to health data research.
- Moderated discussion around a selection of data access proposals demonstrating a range of examples of non-NHS partners accessing data for different uses.

Workshop 2:

- A recap of some of the questions asked in workshop 1 and answers to these.
- A playback of some of the emerging themes from discussions during workshop 1.
- A presentation introducing what currently happens at Discover-NOW concerning access to data and the controls that are in place, followed by an outline of a range of different options to explore.
- A Q&A with experts to address emerging questions.
- Moderated discussion around the different options concerning access models.
- Recommendation forming for access models.
- Moderated discussion around the different options concerning controls.
- Recommendation forming for controls.
- Moderated discussion around the benefits of research (to be further explored during the second deliberation).
- A presentation of the Citizens Advisory Groups' collective recommendations.

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Introduction and methodology

Discover-NOW
Health Data Research Hub for Real World Evidence

How to read this report

During this report, the conventions of qualitative social science reporting are used:

- We indicate via "a minority" to reflect views which were mentioned infrequently and “most” or “commonly” when views are more frequently expressed. We use “some” to reflects views which were mentioned some of the time, or occasionally.
- However, we also indicate strength of feeling even when views are expressed by a minority, as this may also give useful insight into the range of feelings which exist within different groups of people.

We are reporting perceptions rather than facts; in the case of this project there are various misconceptions our participants expressed about questions of fact, for example low awareness of research and why different organisations would require access to health and care data. We have indicated where we are reporting perceptions of participants, and where we are offering analysis of the implications of these perceptions.

Stylistic conventions

We have used the convention of describing the word data in the singular rather than plural, plus the terminology around patient data recommended by Understanding Patient Data (e.g. describing data as de-personalised).

Discover-NOW
Health Data Research Hub for Real World Evidence

2. Attitudes towards the use of health and care data for research

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Attitudes towards the use of health and care data for research

Discover-NOW
Health Data Research Hub for Real World Evidence

The first workshop started with a set of presentations to introduce health data research and the Discover-NOW health data research hub, covering the use of de-personalised data in research and the national data opt-out. Participants were encouraged to reflect on what they had heard, as well as to voice any concerns that they had at this stage and any questions (see Figure 2).

Participants immediately **associated research with active participation in research**: from joining clinical trails through to receiving health surveys in the post. Across the board, **there was a general lack of awareness that data 'about me' was being used in research and development**.

On hearing about the kinds of research that is underway there was **positive recognition that research is necessary for progressing diagnosis, treatment and cures.** Unsurprisingly, given the current context, immediate links were made with COVID-19 and vaccines.

However, there were a number of concerns raised:

- **Commercial interests** and a **lack of trust in organisations** accessing data.
- The **potential for an insurance-based model** of healthcare delivery, and data being used to feed into this.
- The idea of **employers accessing health data** with negative repercussions for individuals.
- The **potential for those with malicious intent** accessing and handling data.

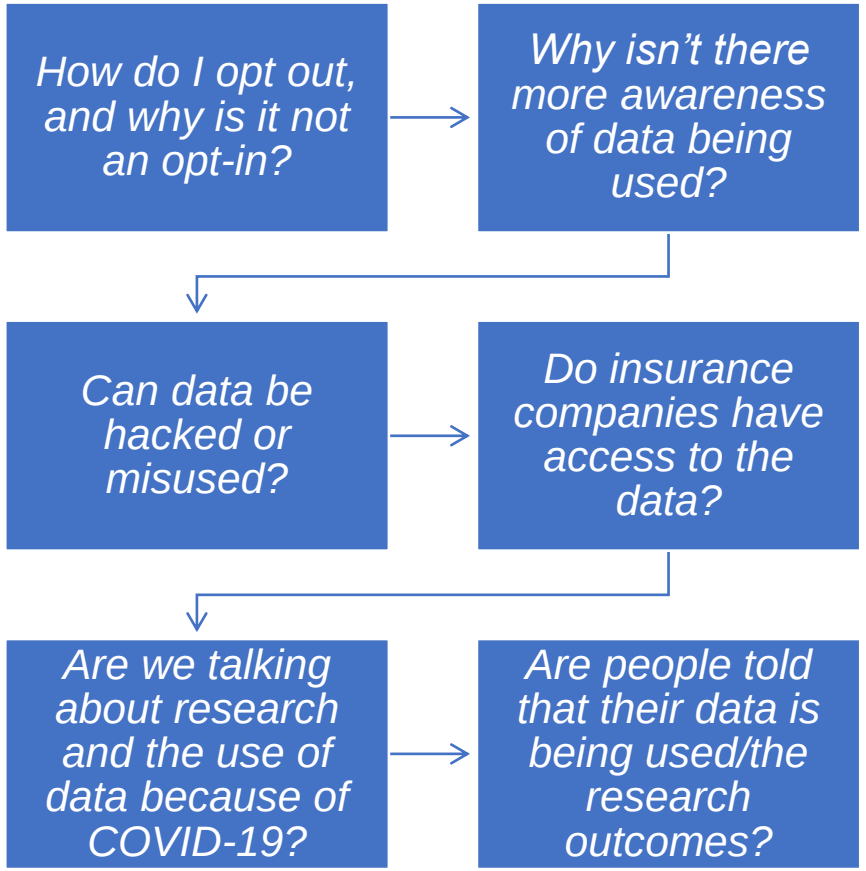


Figure 2: A selection of participant questions

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Attitudes towards the use of health and care data for research

Discover-NOW
Health Data Research Hub for Real World Evidence

Participants were introduced to the concept of a Trusted Research Environment (TRE), before discussing several case studies demonstrating the range of non-NHS partners involved in research, the varied purposes and benefits.

On the whole, the case studies generated interest and helped to socialise the different non-NHS partners requesting access to health and care data.

- **Universities tended to be regarded as trusted to access data**, on the assumption that they would be conducting research for the 'right reasons' and without a commercial agenda.

"I think that universities, generally, as long as the safe environments are adhered to, a university is one of the places you'd expect it. They do research, that's a standard thing. The fact it's a university isn't a cause for concern."

However, while some assumed that universities would have acceptable protocols and IT safeguards in place, others questioned the IT security within such institutions.

- **Commercial organisations accessing data for research, on the other hand, raised discomfort with some participants.** Commonly participants spoke of hidden agendas and such firms only being in it for commercial gain. There were also questions over their security and protocols, and fear that they would sell data on, or use it for other purposes.

"I am fully for it* [the idea of using de-personalised data for research purposes], *but I feel dubious when I hear names like GlaxoSmithKline. They are profit-making organisations. They are on the stock indexes. These companies' stocks have gone through the roof, they're in it for the money."

- **International companies too were questionable,** with some misunderstanding as to why they would want to access data about populations which are not relevant to their own. But also because of concerns over less stringent data protection standards.

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Initial reactions to data access proposals

Discover-NOW
Health Data Research Hub for Real World Evidence

Participants reviewed five data access proposals for research, from a range of non-NHS partners, and were asked which they found more/less appealing and why. Regardless of the organisations involved, proposals that attracted the most appeal were:

- Those which **showed promise for eradicating life limiting, serious illnesses**, such as cancer and stroke.
- Those which suggested that **the NHS was going to significantly gain** as a result of the research.

There was much interest in the dataset as a commodity, and participants often commented that the NHS should charge more than the sums suggested.

"There is an opportunity here for the NHS to make an absolute fortune, regardless of where they come from. People will pay anything for that data. It would be one very easy way for the NHS to have access to huge funds of money every year."

"For me it was the cost. The fees are ridiculously low in my opinion. Given where this will go and where companies what will be developing. We aren't charging enough in my opinion."

Opinions were very mixed on access to the entire data set vs. only the data needed to address a particular research hypothesis.

- There were those who wanted to limit access to just enough data that was needed. There was a general lack of appreciation for why whole datasets would be required.
- There were also participants who indicated they were comfortable with access to as much data as was needed, so long as they could be assured that safeguards were in place. This group often recognised the link between size of a dataset and accuracy/robustness of the research.

"I think it would okay to have as much information as they wanted. As long as we know it's being managed in the correct way. We want to know that it's being held securely and in the right hands."

Linked to this, some were strong on the idea of restricting exploratory or open ended queries, stating that researchers should submit a new data access request for each new data enquiry.

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Initial spontaneous views on access and controls

Discover-NOW
Health Data Research Hub for Real World Evidence

Throughout their discussion of the case studies, and subsequent data access proposals, participants began to consider how conditions and controls could be put into place to ensure trusted research access and use.

Participants' spontaneous ideas and questions, categorised using the relevant parts of the five saves framework, included the following

Safe people:

- DBS checks on individuals
- Organisations to prove their experience/expertise in analysing data before given access (especially important for small firms or start ups)
- Contracts in place with organisations accessing data
- Mandatory training for those accessing the data
- Only permitting full time members of staff at certain levels (i.e. Professors, possibly PhD students) to access data within Universities
- Audit trails in place
- Restrictions on screenshots when people are analysing the data
- Strict fines in place for misconduct.

Safe settings:

- Organisations to explain how they are going to guarantee data security when their employees are working from home
- Mandating access passwords (two-factor)
- Secure deletion of the data once analysis has taken place.

[Referring to audit trails] ***"The safe setting. If you had someone else who was accessing the data or where it was accessed from, not solely from the university. See who accessed it. When they accessed it. What time they accessed it. When they logged out."***

[Referring to penalties and fines] ***"Letting the company knows what happens if the data is compromised. We should be telling them - look there's a fine."***

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Discover-NOW
Health Data Research Hub for Real World Evidence

3. Expectations concerning access and controls and the Citizens Advisory Group's recommendations

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Discover-NOW's current access model, current controls, and potential alternatives / additions

Discover-NOW
Health Data Research Hub for Real World Evidence

The second workshop started with a presentation covering:

- Discover-NOW's current access model, including the local NHS sponsor
- Potential alternative models, such as data access contract or approaches from other data hubs (e.g. Data Trust Committee)
- Discover-NOW's current controls (e.g. restriction on downloading, exporting and saving data)
- Trade-offs around controls e.g. restricting access to just the data required for the specific research study versus the whole dataset for exploratory study (e.g. for AI/machine learning).

Again, participants were encouraged to reflect on what they had heard, as well as to voice any concerns that they had at this stage and any questions, such as:

Why do we need to give access to new data for AI?

How would you ensure a panel is objective and representative?

What are the penalties for data misuse by commercial operators?

What are the benefits for the NHS?

How quickly do you end access once they have finished analysis?

How often do you do audits? How long do they take?

How much are we charging for access?

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Access models – feedback on different options

Discover-NOW
Health Data Research Hub for Real World Evidence

The table below outlines the trade-offs presented and discussed with participants:

Control measure	✓	✗
Independent data access group *An independent group comprising clinicians, researchers, lay members and data protection / legal expertise that reviews data access requests*	• Range of different voices creating opportunity for genuine scrutiny and challenge • Independent	• Can create backlog of requests as group only able to meet at certain times • Resource intensive and members may require payment for their time
Local NHS sponsor *Data access proposals need to be sponsored / supported by a North West London NHS clinician before being approved*	• Ensures proposals are aligned with local NHS values and interests • Research findings have potential to fed into local NHS	• Can create delays as research proposals must have a NWL sponsor before progressing • Research could be limited to interests of local clinicians only
Data access contracts *Placing additional legal obligations on data accessors to act in a certain way (in addition to statutory ones) and that there are sufficient financial and other penalties in place*	• Legal ramifications and financial penalties if conditions are breached such as removing any future access requests • Restricts and controls how researchers access data	• Will require legal input and review (financial and time implication) • Smaller research bodies may be less likely to have access to legal support and therefore unable to undertake research
Only 'approved researchers' can access data *Those requesting access to the data should be able to demonstrate appropriate credentials and be trusted researchers. Examples includes having published work, research memberships/affiliations, data stewardship training and experience in using health data.*	• Likely to be funded research organisations prepared to take responsibility for their actions and vouch for the individual requestor. • Have a proven track record of trustworthy use of data	• Could potentially constrain access for researchers from non-standard backgrounds e.g. small charities, innovation start ups • May limit the research that can be undertaken

Access models – feedback on different options

Discover-NOW
Health Data Research Hub for Real World Evidence

The table below outlines the trade-offs presented and discussed with participants:

Control measure	✓	✗
Data Trust Committee *A patient and public panel (around 10 people) that has full oversight of research requests and voting rights. The Data Trust is supported by a team of non-voting professional advisors.*	• Data access decisions strongly influenced by the patient and public voice • Committee is assisted by experts in data research, information governance and data law	• Committee does not include clinical or scientific input to assess validity and viability of the research question
Honorary contracts *Honorary employment contracts are provided by the NHS to non-NHS personnel to enable them to access the data securely and safely*	• Can provide the NHS with some form of indemnity in respect of liabilities for any misuse • Quicker than formal hiring process	• Administrative burden to NHS Trusts and can take time to set up • Hard to convince some NHS organisations to take on the risk • Can be difficult for a single organisation to provide the contract when access is to linked data (from many orgs)
Independent scientific panel *Data access requests are reviewed by an independent scientific panel representing broader interests than NWL.*	• Group has the relevant expertise to assess the scientific and clinical validity and viability of the research question • Includes wider scientific views	• Group lacks other voices e.g. patients and the public, data protection expertise etc • May create a backlog of requests if group cannot meet regularly

Access models – feedback on different options

Discover-NOW
Health Data Research Hub for Real World Evidence

Independent data access group
An independent group comprising clinicians, researchers, lay members and data protection / legal expertise that reviews data access requests

- Initially, participants highlighted the difficulty of **ensuring balance** in this group, either being skewed by 'uninformed' members of the public, laypeople being 'railroaded' by specialists, or competing voices failing to agree.

"A potential problem I could foresee is a bit of gridlock. Competing voices. It may find reaching a consensus quite difficult because there's so many different groups."

- As part of this desire for balance, participants broadly agreed that the lay members should be **representative** of the local area.

"The lay members need to be a cross section of the area to understand what our needs are as opposed to the needs of other people."

- There was also disagreement on **how** lay people should be recruited. Some believed that random 'jury-style' recruitment would ensure representativeness, while others thought that lay members who 'opt in' would be more confident and committed. Similarly, on payment, they discussed whether this would improve diversity or encourage 'mercenary' behaviour.

"I would trust someone that volunteered, otherwise you'd get people doing it for the money."

- Despite some disagreement on these details, all groups broadly supported the diverse makeup of this group as ensuring requests are considered holistically, often in comparison with the public-focused Data Trust Committee or the expert-focused Independent scientific panel.

"The more information and knowledge you've got from areas of people and their expertise, it's got to be better in the long run."

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Access models – feedback on different options

Discover-NOW
Health Data Research Hub for Real World Evidence

Data Trust Committee

A patient and public panel (around 10 people) that has full oversight of research requests and voting rights. The Data Trust is supported by a team of non-voting professional advisors.

- Participants immediately compared this option unfavourably to an Independent Data Access Group due to concerns that this model was too focused on the public view and risked becoming 'political' or skewed by 'uninformed' or biased views if experts were not included in the decision-making.

"I think professional and scientific input is needed. The public don't know the full story. Our views would be biased an uneducated."

- However, a small minority highlighted that this group would still be informed by non-voting experts and that we ought to have faith in the public's ability to make decisions.

"As long as they have an inflow of information which is scientific, we mustn't underestimate [the public's] ability to deliver on such proposals."

Independent scientific panel

Data access requests are reviewed by an independent scientific panel representing broader interests than NWL.

- Like the Data Trust Committee, participants often rejected this option as being skewed too much towards a single view compared to an Independent Data Access Group or Data Trust Committee. They argued that it would lack the vital aspect of the public's lived experience.

"I don't like it. I think there's going to be tunnel vision focussed on getting the result, they haven't got too much skin in the game as opposed to the public or other people."

- In some groups, later in the discussions, participants reflected that this could be an effective 'extra layer' of scientific rigour on top of the diverse (but less 'objective') Independent Data Access Group, but other groups believed that this would add unnecessary administrative burden.

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Access models – feedback on different options

Discover-NOW
Health Data Research Hub for Real World Evidence

Local NHS sponsor
Data access proposals need to be sponsored / supported by a North West London NHS clinician before being approved

- Some participants valued the inclusion of a local NHS sponsor for their locally-specific expertise.

"Asthma, the South Circular, North Circular, there are specific places that have more of that illness."

- However, others believed that relying on a single individual could cause logistical issues (in terms of backlog) or problems with bias.

"I think just if it's down to the one person it's not great. They have their biases they might think they can only approve a certain amount…I think the more eyes the better."

- Participants often questioned the need for a local NHS sponsor, as opposed to an NHS sponsor from elsewhere in the UK who may have equivalent or greater expertise.

"Breast cancer is global. I think it's completely irrelevant whether they're from North West London."

- Some participants suggested, as a compromise, that a local NHS sponsor is included as part of a committee rather than acting alone.

IMPERIAL COLLEGE HEALTH PARTNERS
Ipsos

Access models – feedback on different options

Discover-NOW
Health Data Research Hub for Real World Evidence

Data access contracts
Placing additional legal obligations on data accessors to act in a certain way (in addition to statutory ones) and that there are sufficient financial and other penalties in place.

- Some participants stressed the importance of deterring data misuse, particularly when dealing with organisations from overseas.

"I do think they need to have a contract with them, because they're not in the UK. If anything went wrong, they wouldn't have a leg to stand on."

- However, others believed that this additional provision could dissuade organisations from applying and made suggestions such as: applying obligations proportionally by the size of organisation; and, allowing smaller organisations to co-apply with larger organisations who could take on the legal / administrative burden of a data access contract.

- Ultimately, however, most groups concluded that the existing legal limitations were sufficient and that this contract would add unnecessary administrative burden.

Honorary contracts
Honorary employment contracts are provided by the NHS to non-NHS personnel to enable them to access the data securely and safely.

- Participants did not have much to say about this option as they believed this would be highly dependent upon the **controls** that are in place.

- While some believed that the honorary contracts could help free up NHS resource, most groups concluded (as with the data access contracts) that it would add unnecessary administrative burden.

"That makes sense because you're freeing up a little bit of load from NHS in terms of the resources."

"It seems like a lot of faff for something that I don't think will make a difference."

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Access models – feedback on different options

Discover-NOW
Health Data Research Hub for Real World Evidence

Only 'approved researchers' can access data
Those requesting access to the data should be able to demonstrate appropriate credentials and be trusted researchers.

- While participants agreed with the **safe people** principle introduced earlier in the workshops, many argued that this option could restrict vital research by non-medical experts.

"I think you're limiting your opportunity for universities and other places to try and access it. If they're just approved researchers, you are limiting the amount of research done."

- Some participants thought that a good compromise would be to allow smaller organisations to partner with 'approved researchers'

"Maybe if there was an option for the smaller charities or start-ups to approach an approved researcher to approach on their behalf so that the approved researcher can do that."

- Refencing back to earlier discussions, and linked to the peer review option, **most groups decided that those accessing and analysing data should have to prove that they have the qualification/expertise and experience** to do so.

"Surely the researchers should have qualifications and experience of the analysis."

"It would be good to know if they have the correct training or qualifications to be able to access the data."

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Access models – recommendations

Discover-NOW
Health Data Research Hub for Real World Evidence

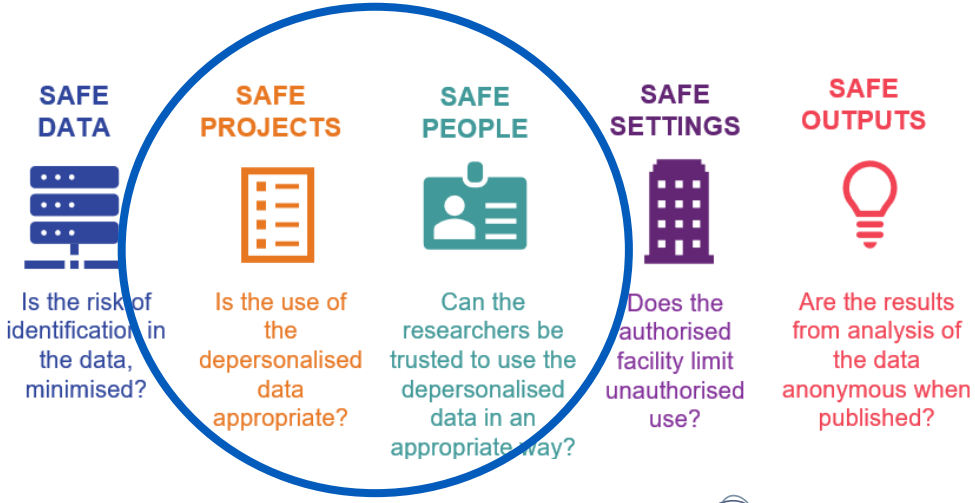
Governance

- All groups called for an **independent data access group** to provide genuine scrutiny and challenge, and ensure access requests align with NHS values, **with a range and balance of membership**:
  - Scientific expertise, researchers, patients (to represent the communities where data has come from), lay members (with some staying, others revolving), data protection experts, legal expertise, other experts (specialists), clinicians.

Access criteria

- Research requests should be **time limited** (but with review on timings in place every number of months to monitor progress)
- **Legal implications and penalties** including substantial fines which impact on employers and individuals for misuse
- **Only approved researchers**: Robust screening process and minimum requirements for those handling data (qualifications, experience)
- The access request **must show a real evidence gap**, and therefore justify the research that is being proposed / show how it is going to compliment other research in the area.

- Outside of the core recommendations, which represent consensus across groups above, some recommendations were made by specific groups:
  - Two groups suggested that there could also be an **independent scientific panel** that sits alongside this, because its important for independence.
  - One group was keen for a **NHS sponsoring clinician** for all requests (that could come from anywhere in the NHS), though other groups suggested this is not needed if there are clinicians on the independent data access group.
  - One group wanted non-burdensome contracts.



IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Controls– feedback on trade-offs

Discover-NOW
Health Data Research Hub for Real World Evidence

Participants also received information from Discover-NOW on the Hub's current controls regarding access to data and how these may be altered. The table below outlines the trade-offs presented and discussed with participants:

Control measure	✓	✗
Data doesn't leave the Trusted Research Environment *Analysis of the data can only happen inside the environment and **only** anonymised aggregate data can leave*	• Data use and access is controlled and audited in the environment • Reduces risk of reidentification • If data is moved, it is harder to insist controls are in place to ensure five safes are met	• Limits research value to one Trusted Research Environment's data set. • Limits the scale of research that is possible to the size of the data set in the single Trusted Research Environment • Limits novel research which uses machine learning and artificial intelligence techniques as this requires access to big scaled up and linked data sets
Access to restricted data set only *Restricting access to just the data required for the specific research question (hypothesis led research).*	• Easier to control access safely and securely - allowing access to all the data opens up the risk that data is misused • Ensures only relevant data is accessed	• Prevents more exploratory, predictive research from being undertaken that looks at whole data sets to identify patterns and predict trends.
Increased peer review of data analysis to ensure consistent interpretation of the real world data *Results of the data analysis and interpretation would be reviewed and checked before issue*	• Research findings are validated to ensure appropriate and consistent interpretation • Minimises the risk of mis-interpretation which could lead to mis-guided recommendations	• Requires NHS funded data management service to review and validate research findings – resource and cost implications • Additional checks may lead to delays in research being published

IMPERIAL COLLEGE HEALTH PARTNERS
Ipsos

Controls– feedback on trade-offs

Discover-NOW
Health Data Research Hub for Real World Evidence

Data doesn't leave the Trusted Research Environment
*Analysis of the data can only happen inside the environment and **only** anonymised aggregate data can leave.*

- This discussion often led to the broader question of why health and care data was held in separate hubs rather than in a central national repository. Some suggested centralisation as a means of reducing administrative burden and overcoming the restrictions of a solely urban/suburban population like North West London.

"It would make the researchers' lives a lot easier, just going to one cloud and place and everything is there."

- Others believed that it was wrong to have different hubs with different standards, as this would lead to a public good (health and care data) being treated as a market good.

"The government is creating hubs competing against each other and that will drive down standards. It's about competition with our data. It's making a commodity of our data."

- As a result of these potential different standards, a minority of participants felt strongly about keeping the data local and not transferring to other TREs in order to avoid misuse or loss.

"There's a lot of opportunity for leakage and abuse of data so I am wary about removing data from a trusted environment."

- Most participants, though recognising the risks involved in letting data leave the TRE, ultimately decided that this was necessary or even vital for the greater good of important health research provided the other TRE have the same standards and controls.

"I'm comfortable provided the security is tighter than ever before. There are certain circumstances where it's necessary. I'm surprised it's not happened in a pandemic. They should be doing this."

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Controls– feedback on different options

Discover-NOW
Health Data Research Hub for Real World Evidence

Access to restricted data set only
Restricting access to just the data required for the specific research question (hypothesis led research).

- Early on in discussions, participants broadly agreed with the concept of restricting data access to the data needed for the specific research question, in order to preserve the data's value.

"Restrict it* [otherwise] *you get a US company paying £100,000 and ending up with data worth £3m."

- However participants thought that this concept needed flexibility in order to not restrict exploratory research such as AI or machine learning. Several groups came to the same conclusion. That the level of access should be limited by default, that increased access should be **justified by the research aims,** and that any change of scope would require a new data access request.

"If they want to do more using AI, then their proposal should mention that. I think that should be clear in the proposal."

Increased peer review of data analysis to ensure consistent interpretation of the real world data
Results of the data analysis and interpretation would be reviewed and checked before issue.

- Increased peer review received unanimous support from the outset, with participants highlighting the risks of misinterpretation both for the public through the media and for the NHS in terms of reputational damage.

"I think it's quite dangerous for reports to be published that are misguided. If the newspapers pick up on that, there could be an uproar. Having this sort of control measure would be beneficial to know the results are true and correct."

- Although no participants highlighted any concerns with increased peer review, some did recognise the cost implications and believed that this should be reflected in the fees charged to requesting organisations.

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Controls - recommendations

Discover-NOW
Health Data Research Hub for Real World Evidence

Linking with other Trusted Research Environments

All groups supported linking de-personalised data with other Trusted Research Environments with the following conditions:

- Extra approval process for applications where data needs to leave TRE
- De-personalised data will not leave the TRE unless there is a good reason – i.e. that it will advance the research / is necessary to get to the conclusion/findings
- The other TRE/s that the data is linking with have similar safeguards in place and can demonstrate this
- Criminal charges for any misuse of data (see data contracts above)

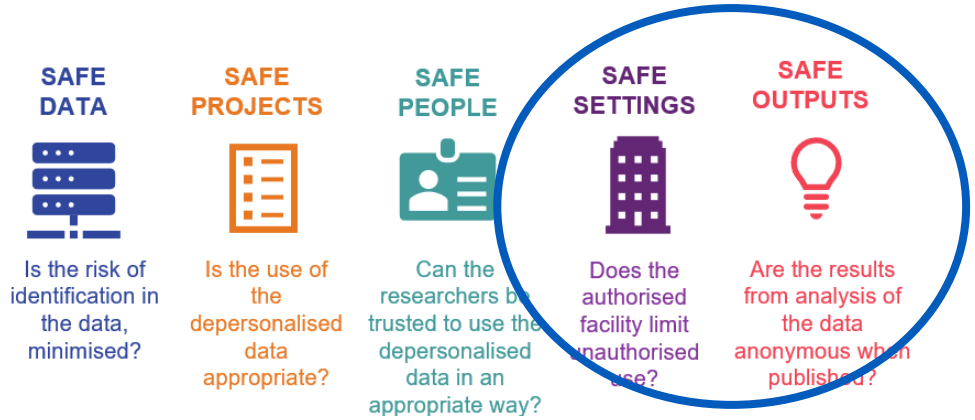
Ensuring safe outputs

- Widespread support for peer review of analysis before this leaves the TRE.
- Research outcomes should be published on the Hub website where possible.

What data can be accessed

There was more concern surrounding access to whole datasets, although more than half of the groups were supportive of this. If this was to happen, the following conditions should be in place:

- Needs to be really clearly justified why this is needed
- Time limited access, with clear auditing in place to ensure no misuse
- The scope of the research needs to be clear and not change without a new data access request being made.



IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Making the best use of benefits (an introduction)

Discover-NOW
Health Data Research Hub for Real World Evidence

In order to inform the next deliberation, participants engaged in a brief discussion at the end of the second workshop on the potential financial and non-financial benefits of health and care data research for Discover-NOW, the NHS and wider society, along with potential tensions and trade-offs. Below is a summary of the debates that arose across the different small discussion groups:

- Participants were divided on whether the benefits of the research should be shared locally, nationally, or both.

"If someone has taken the initiative to do it [conduct research] in North West London and something good has come out of it, why can't this be reinvested in North West London."

"I don't see the NHS as regions, I see it as the NHS."

"I think a percentage of the money coming in that that region has generated should go to that region and the rest should go to a central pot and then regions can bid for that funding as well."

- Fees piqued the participants' curiosity, in terms of how these are determined and whether there should be different charges for different types of organisations depending on their size and profitability.

"I'd be curious to know why we came to the figure, £20,000. Why not £30,000, £10,000 or £50,000?"

"If it is a large US tech pharma company looking to make big profits then they should be charged more. If it is a university looking to help further down the line the cost could be less."

- Participants also thought that monitoring and evaluation would be important to measure both financial and non-financial benefits of research using Discover-NOW's health and care data.

"[I] would want some information to suggest who's been targeted and what the end benefits were."

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Discover-NOW
Health Data Research Hub for Real World Evidence

Appendices

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Citizens Advisory Group Steering Group

Discover-NOW
Health Data Research Hub for Real World Evidence

To ensure that the deliberation process, content and direction is authentic and balanced Discover-NOW have set up a virtual CAG steering group to support and guide this work in an advisory critical friend capacity. This group consists of the following individuals:

Name	Organisation	Role
Alice Dowden	Health Data Research UK	Public Engagement and Involvement Officer
Avi Mehra	IBM	Associate Partner
Barrie Newton	Public	Citizen Partner
John Norton	Public	Citizen Partner
Kavitha Saravanakumar	North West London Collaboration of Clinical Commissioning Groups	Associate Director of Business Intelligence
Sanjay Gautama	Imperial College Healthcare NHS Trust	Caldicott Guardian, Chief Clinical Information Officer and Consultant Anaesthetist
Taj Sallamuddin	Information Governance Services/ Imperial College Health Partners	Data Protection and Information Lawyer. Data Protection Officer for ICHP
Tom Binstead	Telstra Health - Dr Foster	Director of Strategy and Analytics

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Citizens Advisory Groups' characteristics

Discover-NOW
Health Data Research Hub for Real World Evidence

The Citizens Advisory Group was recruited to reflect the diversity of North West London, including gender, age, housing tenure and socio-economic status - as demonstrated below.

40 participants took part in this first deliberation.

Gender

Female	23
Male	17

Age

17-24	3
25-29	5
30-44	13
45-64	13
65-74	4
75+	2

Socio-economic category

AB	10
C1	11
C2	12
DE	7

Housing Tenure

Owner-occupier	17
Social renter	5
Private renter	15
'Live with parents'	3

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Citizens Advisory Groups' characteristics

Discover-NOW
Health Data Research Hub for Real World Evidence

The Citizens Advisory Group was recruited to reflect the diversity of North West London, including gender, age, housing tenure and socio-economic status - as demonstrated below.

40 participants took part in this first deliberation.

Country of birth

UK	28
Outside UK	12

Ethnicity

White British	10
White Other	6
Asian/Asian British	8
Black/Black British	9
Mixed/Other	7

Health service user

Light	18
Medium	13
Heavy	9

London Borough

Brent	2
Ealing	5
Hammersmith & Fulham	4
Harrow	6
Hillingdon	6
Hounslow	7
Kensington & Chelsea	4
Westminster	6

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos

Experts who supported the deliberation

Discover-NOW
Health Data Research Hub for Real World Evidence

The Discover-NOW Citizen Advisory Group deliberative workshops were supported by a group of experts in health data research, public engagement and data law. The experts helped present and explain some of the key issues for discussion. After, they moved between groups, listening and helping moderators to answer questions.

Workshop 1, Wednesday 3rd February

- Ben Gordon, Executive Director, HDRUK
- Amanda Lucas, Information Director, ICHP/Discover-NOW
- Tim Hubbard, Associate Director, HDRUK
- Natalie Banner, Understanding Patient Data Lead, Wellcome
- Amy Darlington, Executive Director, ICHP/Discover-NOW

Workshop 2, Saturday 6th February

- Sanjay Gautama, Consultant in Anaesthesia and Intensive Care Medicine, Imperial College Hospital
- Amy Darlington, Executive Director, ICHP/Discover-NOW
- Amanda Lucas, Information Advisor, ICHP/Discover-NOW
- Taj Sallamuddin, Data Protection Officer, ICHP/Discover-NOW

IMPERIAL COLLEGE HEALTH PARTNERS

Ipsos