Wessex SECURE DATA ENVIRONMENT
Part of the NHS Research Secure Data Environment Network
NHS

SDE Network approach to user and organisation validation: Wessex SDE insights and co-design input

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Contents

1. Background

This paper summarises insights from patient and public engagement (PPIE) and involvement activities undertaken by the Wessex SDE relevant to the NHS Research SDE Network's approach to user and organisation validation. It aims to support the national conversation on this topic and build on what people have already told us.

From the start, the Wessex Secure Data Environment (SDE) has run wide-ranging public engagement. We have heard views from people living in our coastal, city and rural communities. Although we have not held sessions focused solely or specifically on user and organisation validation, these issues have come up often in our discussions.

Feedback from our Seldom Heard Groups (SHGs) and the Wessex Public Panel on NHS Data (deliberative dialogue) was generally broader, looking at overall trust and governance. More recently, members of our Digital Critical Friends (DCF) Group (a standing group of 15 public participants) carried out a detailed review of our SDE's draft policy suite. Their reflections and recommendations are relevant and can play a role in shaping the national approach.

2. Key insights

Insight	Description & key questions	Raised by
A. "Rubbish in, rubbish out" – data quality and inequalities **(**Escalation Criteria, by inference)	Validation is not about checking datasets, but organisations should show they have credible governance and quality assurance (QA) practices in place. Weak or absent QA processes could undermine trust in any research they later propose. 1. Should organisations without clear data governance and QA frameworks be escalated for Committee scrutiny? 2. What kinds of quality assurance evidence should be required at validation stage?	Seldom-heard groups (carers, LTCs, visually impaired, LGBTQ+ contributors); Digital Critical Friends (policy review).
B. Safeguarding the vulnerable (Escalation Criteria + Decision Principles)	Public contributors stressed that vulnerable or marginalised groups risk exploitation or exclusion without explicit safeguards. DCFs also said that the Wessex SDE should think about intersectionality (the overlapping vulnerabilities) and look for evidence of real-life impact in its equality and inclusion work. The implication is that the SDE Network should also be thinking about equalities when it is approving organisations and individuals – particularly from the private sector. For example, by ensuring that they have suitable equalities policies in place. 3. Should organisations without robust safeguarding/equalities policies be escalated automatically?	Carers, Poverty Truth Commission, LTC groups, older people, seldom-heard groups; Digital Critical Friends – EqIA
C. Public 'red lines' on commercial access (Escalation Criteria + Decision Principles)	NHS and academic users are broadly trusted, but commercial organisations raise red flags. DCFs talked about a dual-track system: a simpler scorecard for academic users and a more rigorous framework for commercial applicants. For commercial partners our Public Panel sought to define the kind of organisations they wanted the NHS to work	Substance use/early recovery groups, LTCs, HIV+ contributors, deprivation groups, Wessex Public Panel; Digital Critical Friends – Pre-Check review.

	with as “positive partnerships”. These were organisations whose interests and objectives were aligned with the NHS, but also where the relationships were carefully regulated on an ongoing basis, with effective sanctions being part of that. 4. Should all commercial applicants be escalated for Committee scrutiny? 5. How should the NHS having “positive partnerships only” be defined and evidenced?	
D. Who decides & principles for decisions (Decision Principles)	Trust depends on clear governance and accountability. In the context of SDE decision-making participants want clarity on who vets applications as they come in (e.g. for completeness and technical compliance), who sits on committees, what criteria are they using, what happens with appeals, and what is the overall scheme of delegation. DCFs called for a published organogram and scheme of delegation, alongside a transparent appeals process. There is clear read across from this to the user and organisation validation process 6. How should responsibilities for validation be divided up, published and explained? 7. What guiding values (equity, independence, transparency) should underpin Committee decisions?	Young adults, carers, LTCs, LGBTQ+, Poverty Truth Commission, seldom-heard groups; Digital Critical Friends – Pre-Check and Equalities reviews.
E. Sanctions and continuous oversight (Decision Principles, with escalation implications)	Validation should not be seen is as a one-off approval. Participants want ongoing monitoring and meaningful sanctions for misuse (suspension, blacklisting, national sharing of breaches). Prior misuse or sanction history should trigger escalation. 8. Is SDE Network going to revalidate people regularly and monitor ongoing compliance? 9. What sanctions should be available – and when should they be applied?	Wessex Public Panel; Digital Critical Friends – recommendations on incident reporting and accountability.

	10. Should organisations involved in 'incidents' automatically be escalated back to the Committee for review?	
F. "Money shouldn't talk" – funding vs ethical decisions (Escalation Criteria, by inference)	DCF members stressed that financial contributions must not influence access decisions. The NHS needs to be clear that this separation exists, and validation feels like a good place to do this. 11. Should all financial interests and funders be disclosed publicly at validation stage – and what kinds of interests are important? 12. What kinds of interests would trigger escalation to the Committee?	Digital Critical Friends – Pre-Check review.
G. Blacklists vs Criteria (Escalation Criteria + Decision Principles)	Some sectors (weapons, tobacco, insurers, hostile states) were identified as red lines. At the same time DCFs cautioned against rigid blacklists, as this could stop some valuable research from happening, recommending instead criteria-based exclusion and carefully following money trails to subsidiaries or funders. 13. Should there be a national blacklist of prohibited organisations and/or flexible criteria applied case by case? 14. How much 'due diligence' is needed to reassure the public? 15. How should the Committee ensure handle indirect or hidden links to excluded sectors? 16. Should blacklisting decisions sit nationally or regionally?	Seldom-heard groups; Digital Critical Friends – Pre-Check review.
H. Precedent-setting Processes (Decision Principles)	Our Public Panel and DCFs had clear views on precedent setting and handling for the DAC process. We expect that the user and organisation validation Committee will have to deal with some cases where organisations look OK on paper but do not pass the 'tabloid newspaper' test – or are in a controversial grey area.	Digital Critical Friends – Pre-Check review.

	Decisions like that need to be clear and consistent, so having some kind of precedent-setting and handling process so there is consistency would be desirable. Our participants debated whether to rely on fixed red-line rules (which ensures clarity) or a case-history approach (which gives flexibility). They saw merit in both approaches and felt that perhaps a hybrid model may be needed. 17. Should validation outcomes establish binding precedents for future applicants? 18. How should precedents be reported, communicated, and made transparent? 19. How can precedent-setting balance fairness, adaptability, and avoidance of entrenching past mistakes?	
I. Transparency of Validation (Decision Principles, with escalation implications)	Public trust depends on making validation processes open and understandable. Our insights suggest that public trust will be supported by publishing criteria and decision-making process maps; using plain English and easy-read materials to communicate these; linking decisions to visible public benefits; and timely reporting of incidents and sanctions. 20. What validation criteria and outcomes should be published, and in what level of detail? 21. How can accessibility be ensured for people with low literacy or digital access? 22. Should disclosure include financial interests and conflicts of interest?	Digital Critical Friends – Pre-Check, Transparency Policy, Accountability and Disclosure Mechanisms.

3. Evidence base for insights

Section 2 set out the consolidated insights from all the patient and public involvement and engagement (PPIE) work undertaken to date by the Wessex SDE, that is relevant to the topic of user and organisation validation. This section provides the supporting evidence for those insights. It does not repeat the insights in full but instead explains where they have come from across three strands of activity:

- Engagement with seldom-heard groups
- The Wessex Public Panel on NHS Data
- The Digital Critical Friends' review of the SDE's draft policies

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Seldom-Heard Groups (2023–24)

The Wessex SDE started its engagement with seldom-heard groups (SHGs) to ensure that their input helped to shape the topics and format of subsequent PPIE activities. Between July 2023 and April 2024, over 600 people across Dorset, Hampshire, and the Isle of Wight contributed their views, in sessions convened with 37 community and voluntary groups.

The approach recognised that trust with seldom-heard communities takes time to build, and that engagement needed to happen in familiar settings with plain-language and culturally appropriate materials. Our team used "easy read" packs, visual prompts and trusted intermediaries to support inclusion.

Safeguarding the vulnerable

Participants consistently stressed that robust governance – including validation of users and organisations – was essential to protect vulnerable people. In particular carers groups, the Poverty Truth Commission members, and groups with long-term conditions raised concerns about who safeguards data for those unable to opt-out or fully understand the system. As one carer asked: *"For young people in care that can't verbalise, authorise, or understand, what's being put in place for them? Who advocates and helps them understand?"*

Unpacking the reasons for this, many contributors expressed concerns that the SDE might fail to meet their specific healthcare needs due to misunderstanding, discrimination or stigma. There were fears that sensitive health information, such as mental health conditions or rare illnesses, could be misused.

Groups with complex conditions, such as acquired brain injuries or autism, felt underrepresented in research. Whilst those affected by autism, HIV, and other stigmatised conditions worried that historical discrimination could be exacerbated by the SDE.

Additionally, there were concerns that, if not implemented correctly, the SDE could worsen health inequalities, particularly for those in high deprivation areas or with complex conditions. Experiences of stigma and trauma created significant barriers to trusting the NHS and engaging with the SDE.

"Rubbish in, rubbish out" – data quality and inequalities

Concerns about the accuracy and completeness of NHS data were widespread. This issue of data quality encoding is closely related to that of safeguarding the vulnerable; under or misrepresentation of vulnerable groups in datasets could deepen inequalities. One participant with a long-term condition explained: *"If my data is going into an SDE to drive research, the research will be flawed because the data is incomplete. No research can be accurate and meaningful if the data is incomplete, inaccurate, or incorrect."*

Reading this across into the context of user and organisation validation, there is an opportunity to address the issue by making checking that prospective users have an awareness of the risk and policies in place to address it. It may be that this is adequately dealt with the data access decision stage, but addressing this at validation would be an opportunity for the network to signal its awareness and action on this issue.

Public red lines on commercial access

Participants were generally concerned about private sector access to NHS data in any form, and in particular they were worried about data misuse by insurers and employers. Similarly, there were worries that research would focus on 'quick wins' or profits and so would neglect the needs of more marginalised or vulnerable groups and underrepresent rare or complex conditions. There is broad agreement on the importance of transparency and strong safeguards to prevent misuse and commercial exploitation.

As one member of a deprived community said: *"I'm convinced we'll be moving to an insurance-based model of health… at what point will treatment become very expensive based on the data that's in there?"*

Transparency of validation processes

Finally, our seldom-heard groups emphasised the need for actions and not just words. People want to see both successes stories and learnings from breaches or wrongdoing publicly reported to have trust. A visually impaired participant remarked: *"It is naive and patronising to use words like 'secure' and 'anonymous' – we hear that and take it like a pinch of salt."*

Wessex Public Panel on NHS Data (2024)

Between June and September 2024, the Wessex SDE convened a reflective sample of c.50 public participants from across the region to participate in a three-day deliberative dialogue.

Participants were supported with expert input and case studies and asked to define values and principles for how NHS data should be governed.

Public ‘red lines’ on commercial access

Like our seldom-heard groups, the Public Panel was cautious about industry involvement. Many members were wary of private companies accessing NHS patient data primarily for profit and emphasised that any industry involvement must be tightly controlled and clearly aligned with patient interests.

An underlying thread in discussions was a mistrust of industry motives, unless there are transparency and accountability in how companies are involved and how any benefits or profits are shared. They illustrate that the Wessex public is eager to see data used for the common good – improving health and healthcare for all – but only if robust safeguards, transparency, and fairness are in place.

Participants emphasised that the level of scrutiny applied should be proportionate and reflect the perceived risks, advocating streamlined and clear decision-making that accelerates worthwhile research while safeguarding public trust.

In practical terms, they were clear that this meant that partnerships with private companies must be collaborative, transparent, time-bound, and deliver measurable benefit, with clear and effective sanctions available in case of wrongdoing. They described these as the SDE having “positive partnerships only” and made this a ‘core value’ for the Wessex SDE.

Reading across to the user and organisation validation process we anticipate a similar expectation for proportionate scrutiny and definition of what positive partnerships look like. This might mean that NHS organisations effectively have a ‘fast track’ route whilst private sector organisations must pass a higher threshold of scrutiny.

Sanctions and continuous oversight

The Panel emphasised that organisations getting access to the SDE should not be a one-off gateway. They wanted continuous monitoring of organisations, clear sanctions for misuse, and national sharing of information about breaches.

The focus on sanctions was consistent throughout the Public Panel deliberations. Panel members public wanted to ensure that we don’t just report on breaches or misuse, but that the SDE was able to take action, and would actively use its available sanctions when necessary.

While specifics were not fully explored, some suggested sanctions included blacklisting, financial penalties, restricting future access for those who misuse data, stipulating remedial actions needed to bring organisations back into compliance, and sharing information publicly.

The principle of continuous oversight was not limited to the SDE does; public participants also effectively asked “who watches the watchmen”. They wanted the Wessex SDE to subject itself to external audit by trusted third parties to make sure that it was doing a good job. The same logic would apply to user and organisation validation, where our expectation is that the public would want to see some form of external audit being applied to the process

Who decides & principles for decisions

Participants stressed the importance of independent, diverse, and accountable governance. This included a proportion of public members on any decision-making committees and their ongoing involvement in overall governance of the SDE. We expect that the same principles would apply to the user and organisation validation process.

Precedent-setting processes

In their deliberations on the end-to-end decision-making process in the SDE, Panel members recognised that an efficient system could and should delegate routine, low-risk or repeatable decisions to the SDE operations team. They felt that clear precedents and rules should allow SDE staff to handle straightforward cases consistently, without overburdening the Committee.

At the same time, they were clear that ethically complex, sensitive or higher-risk applications – such as those involving commercial organisations, the use of sensitive data, or potential re-identification – should always be escalated to the Committee for direct scrutiny. This balance between delegation and escalation reflects a pragmatic principle: the Committee's time and expertise should be focused where public trust is most at stake, while ensuring efficiency and avoiding unnecessary bureaucracy.

Transparency of validation

Participants asked for criteria, outcomes, and processes to be published in accessible formats, to show how decisions are made and to reinforce public trust.

Digital Critical Friends Policy Review (2025)

The Digital Critical Friends (DCF) group is a standing body of 15 trained public participants who meet regularly to scrutinise the SDE. In 2025, they carried out a detailed review of selected draft policies, focusing on areas of high public interest such as the Pre-Check process, transparency, equalities, and accountability.

"Money shouldn't talk" – funding vs ethical decisions

In their review of the Pre-Check process, Digital Critical Friends highlighted concerns about the role of funding and sponsorship in decisions on data access. They felt strongly that financial contributions should not confer special treatment, with one member remarking: *"Just because someone puts money in, it shouldn't mean they automatically get approval or special treatment."*

The discussion was focused on the Pre-Check stage – where applicants disclose their funders and partners – and on keeping project prioritisation for operational or sustainability reasons separate from ethical decisions about access. The group's concern was essentially about managing conflicts of interest and ensuring transparency.

While the DCFs did not use the language of "validation," their reflections point to an important inference: validation is a logical stage at which conflicts of interest could be surfaced and addressed. Requiring organisations to disclose their funding relationships openly, and having clear criteria for when these trigger escalation, would help show that financial interests do not influence ethical access decisions.

Public red line on commercial access / Blacklists vs criteria

DCFs reinforced the need for stricter scrutiny of commercial users, recommending a dual-track evaluation. Their views here largely followed those of the seldom-heard groups. However, whilst seldom-heard groups more enthusiastic about having clear blacklists and red lines, the Public Panel approach, which likely reflects their greater engagement with the SDE project.

There were two main themes here. On the one hand, some participants felt that this could overly constrain the SDE and prevent valuable research from happening. On the other hand, some participants felt that this would open the SDE up to legal challenge. One participant warned: *"Having an explicit blacklist would result in legal challenges and rigidity… a robust ethical framework would be better."*

Who decides & principles for decisions

Digital Critical Friends stressed that trust depends on clarity and transparency in how decisions are made. They called for a clear scheme of delegation, ideally shown in a simple organogram, setting out who conducts the Pre-Check process within the Wessex SDE, who makes final decisions, and which cases are escalated to the Data Access Committee. They argued that applicants should have a right to reply during the process and that there should be a clear appeals route with published criteria.

They also emphasised that decision-making criteria must be explained in plain English using a tiered structure, so that both simple summaries and detailed information are available. Finally, they wanted personal accountability as well as structural accountability, with named contacts for queries or complaints. Together, these expectations show that the issue of "who decides" is as much about principles of transparency, fairness, accessibility, and accountability as it is about the Committee's membership.

Precedent-setting processes

In their review of the Pre-Check process, DCFs agreed that having a precedent setting process would be helpful and debated whether to use rigid precedent lists or a case-history approach. They saw merit in both approaches. On one hand, a prescribed list of precedent conditions could be highly transparent for the public, but it might lack flexibility or fail to account for changing contexts that make certain precedents irrelevant or inappropriate. On the other hand, a case-history approach would allow for more flexibility and nuance in decision-making but might be less transparent about why decisions have been made. They concluded that a hybrid approach may be needed, combining consistency with adaptability.

Transparency of validation

DCF recommendations included tiered transparency – with a start ‘simple, dig deeper’ approach to disclosure – public dashboards, and a degree of financial disclosure. They also stressed the importance of plain English: *“Simplicity is the one word we would prioritise.”*

Safeguarding the vulnerable

In their review of the Equalities Impact Assessment, DCFs highlighted the need to consider overlapping vulnerabilities, or intersectionality, and to show visible outcomes for under-served and vulnerable groups.

Synthesis

Taken together, these three strands of PPIE provide a strong and consistent foundation for the insights in Section 2.

- **Seldom-heard groups** highlighted mistrust, safeguarding, and the risks of exclusion.
- **The Public Panel** provided values-based principles for governance and oversight.
- **The DCF review** translated those principles into more specific / detailed policy recommendations.

We see a consistent picture emerging from the evidence across these strands, which gives assurance that the insights summarised in Section 2 are both grounded in diverse public perspectives and actionable in practice.