



Engagement Final Report

October 2023



TRE-FX PIE Final Report

1. Background

1.1. What is the project about?

Trusted Research Environments (TREs) are secure locations in which data are placed for researchers to analyse but the data can not be exported. Only data analysis can be exported, such as a graph or a results table. TREs can be set up to host many different data types such as administrative data, education data or hospital data. TREs work well when providing data from a single source, but it can be hard for a researcher to perform analysis across multiple TREs, this is especially true when data is to be analysed across geographical or governance boundaries, such as the devolved nature of healthcare in the United Kingdom.

The ability to perform analyses across multiple TREs is possible today, but there are multiple ways this can be achieved which makes it hard for any single solution to become a standard and to be accepted by multiple TREs. Many standards do also exist, but what is lacking is the adoption of a single set of standards to make the process much simpler.

TRE-FX assembled leading infrastructure researchers, technology providers (academic and commercial) and leading providers of TREs. The purpose was to demonstrate how existing tools and technology could be brought together to deliver a standardised mechanism for analyses to be performed between TREs. We collaborated with an on-premise TRE and two cloud based TREs, enhancing technologies already developed by ELIXIR and HDR UK to demonstrate that this can be achieved without compromising the five safe principles and can be delivered in line with all security and governance controls of the TREs. Our two technology partners were important in order to demonstrate that the new standardised processes were also able to be adopted by their existing approaches. By doing so, evidenced the acceptability of the approach for those running TREs and the suitability of the approach for existing suppliers of federated platforms.

Of paramount importance was to do this with the public involved, we had a member of the public chair our project meetings and held focus groups to ensure feedback was gained from the publics.

1.2. How does it fit into the DARE UK programme?

DARE UK aims to: Design and deliver a novel and innovative UK-wide data research infrastructure that is coordinated, demonstrates trustworthiness and supports research at scale for public good.

- Establish the next generation of trusted research environments (TREs) that will enable fast, safe and efficient sharing, linkage and advanced analysis of data, where it is legal and ethical to do so.
- Enable UK researchers and innovators to securely and efficiently harness the full power of linked datasets, modern digital platforms, tools, techniques and skills.
- Enable research and analysis on a broad range of potentially sensitive data from across the UK research and innovation spectrum.

TRE-FX delivered a framework and reference implementation for future enhanced federated services, against the core federation services area. This was feasible because an experienced consortium of TREs and service providers “smart assembled” existing services and frameworks. All deliverables were released open source. The framework was a component architecture, testing the feasibility of a ‘federation layer’ for the network of UK TREs.

The Five Safes RO-Crate provided the necessary hooks to support the integration with federated identity management, semi-automated disclosure control, and automated risk assessment for the output control components of the DARE UK programme required for implementation in a real-world setting. Close collaboration with other Phase 1b working groups has ensured our framework is robust and open for widespread adoption.

1.3. Why was PIE important in the delivery process?

TRE-FX identified the need for public trust in technical solutions that enable federated analytics. Solutions, regardless of how technical, must still be understood by the public and their input must be sought.

2. Aim

2.1. What did your PIE intervention seek to achieve, and how did it influence your project outcomes and the wider DARE UK programme?

Our PIE (Public Involvement and Engagement) intervention fostered meaningful engagement with the public to gather their insights and concerns, particularly on topics like federated analytics, data security, and personal data usage. By actively involving the public in workshops and focus group discussions facilitated by Alterline, we ensured that the TRE-FX project resonated with its intended audience and were aligned with their expectations and concerns. These interactions influenced the project outcomes by directly informing our technical designs, ensuring that they were both effective and sensitive to public sentiment. Furthermore, the feedback gathered underscored the potential advantages of advancing research, addressing concerns about data management, and highlighting the importance of clear communication. By integrating these insights, the wider DARE UK programme benefited from a more informed and holistic approach, ensuring data privacy, security, and effective communication are prioritised, which ultimately boosts trust and participation from the public.

3. Approach

3.1. Did you develop a PIE strategy and establish a PIE team as part of your project delivery strategy? Was the public involved in the development of your strategy and other decision-making processes?

Central to the TRE-FX projects strategy was comprehensive PIE, this included a member of the public chairing management meetings, and presenting at conferences. These activities played a pivotal role in ensuring the content presented by the project was suitable to empower the public with essential knowledge about the various aspects of the project, including information about federated analytics, the architecture of TRE-FX solution, how it gathers the required information in line with the Five Safes framework and how it can be integrated with existing TRE services.

By actively incorporating public feedback, assessing potential risks, and nurturing inclusive dialogues, the project balanced the technical capabilities with public and governance based questions. Through the integration of public perspective into both the project operation and design processes, the TRE-FX project paved the way for research that does not dilute key TRE governance criteria, but re-enforces those principles whilst providing a standardised mechanism for researchers to undertake analyses across multiple TREs.

Given the inherently technical nature of the project, a primary focus was placed on developing a strategy that effectively distilled complex technical concepts into accessible information for the public. The establishment of a dedicated PIE team was instrumental in facilitating continuous dialogue, garnering invaluable insights, and incorporating public feedback into the project's trajectory, thereby fostering a truly collaborative and inclusive environment.

An example of public involvement in the development of our strategy is evident in our approach to automation. While a significant portion of the technical solution for our project could have been automated from the outset, the team recognised the importance of public trust and input. In response to public feedback and concerns about unchecked automation, specific stages of the technical pipeline were integrated with manual checks to ensure accuracy and reliability. This approach balanced efficiency with the public's desire for transparency and oversight.

3.2. What method was adopted for your PIE activities? (e.g., surveys, focus group interviews, workshops, public events, etc.)

To strengthen its commitment to public involvement, the TRE-FX project commissioned focus groups and workshops run by Alterline. The TRE-FX team developed the content and the questions to be asked, but had no involvement in running the events to ensure there was no indirect influence on participants.

Through these focus groups, the TRE-FX project sought to ensure that the public's voice was heard in shaping the project's direction and goals. In addition to gathering valuable insights, the focus group discussions facilitated inclusivity, allowing diverse perspectives to inform the project's decision-making processes.

To further enhance understanding and accessibility, we worked on producing two explanatory videos, to elucidate the concept of federation and the technical dimensions of the project. The script for these videos were collaboratively written and reviewed with public members, ensuring that the content was both informative and resonated with the intended audience. This integrated approach ensured that our PIE activities were comprehensive and that they fostered genuine public involvement in the project's development and communication.

3.3. What specific steps or decisions did you take to make your PIE activities inclusive, accessible and collaborative?

To capture the thoughts, feelings and experiences of the members of the public, Alterline were asked to create 2 focus group reports and a range of follow-on meetings with PIE representatives. Participants were citizens of the UK and were a representative mix of ages, genders, backgrounds, education levels and country they live in.

Alterline recruited participants from a nationally representative research panel, ensuring that we recruited a strongly inclusive and diverse set of representatives from each country within the UK. Each participant was rewarded with a £35 incentive to say thank you for their time, after they had qualified for the criteria that was set out for the research and had completed the 1-hour focus group session.

These discussions allowed Alterline to explore how the TRE-FX concept would be greeted by the public, how it might be perceived and what questions or concerns people had about a project of this potential scale. The discussions allowed Alterline to capture the voice of the citizenry in their own words and allow conversations to develop amongst participants and understand the strength of feeling and to what extent there are any universal or divisive elements.

3.4. How did you promote your PIE activities?

In our concerted effort to promote our Public Involvement and Engagement (PIE) activities, we employed a multi-pronged outreach strategy. A significant step in this direction was securing the services of Alterline, a well-regarded entity with a vast network and diverse connections with the public across the UK. Their expertise and reach were instrumental in effectively disseminating information about our PIE activities to a broad and varied audience.

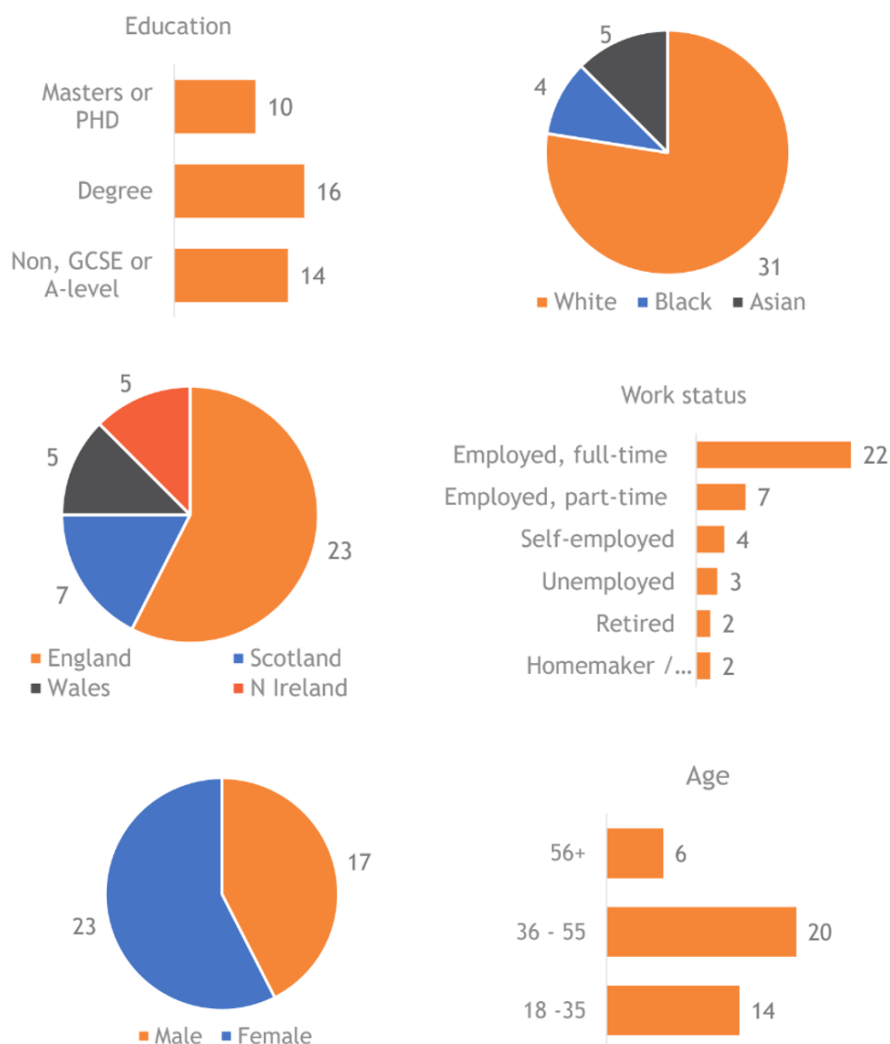
In addition, our collaboration with PIONEER further bolstered our promotional activities. PIONEER, with its established public groups and connections, served as an invaluable platform, allowing us to tap into existing networks and ensuring that our PIE activities reached stakeholders and interested parties effectively.

3.5. How did you arrive at your choice of audience, and why them?

In our endeavour to identify the most appropriate audience for our project, we strategically aimed for a representation that would accurately reflect the diverse landscape of the UK populace. As highlighted earlier in our report, we collaborated with Alterline, leveraging their expertise in audience engagement. Through their meticulous outreach, they successfully engaged a wide spectrum of the UK public, ensuring a well-distributed mix across age, gender, background, and educational levels. This targeted selection was crucial in capturing a comprehensive array of perspectives, allowing us to address the multifaceted needs and insights of the broader UK community in our project outcomes.

3.6. What is the demographic spread of your audience? (e.g., countries of origin, residence/locality, ethnicity, age, education, income bracket, etc.)

The charts below indicate the breakdown of demographic details of workshop 1 participants.



3.7. How did you translate complex information into public-friendly messages?

Addressing the challenge of distilling highly technical concepts into accessible, public-friendly messages demands a meticulous and inclusive strategy. Recognizing the intricacies inherent to our project, we prioritised public engagement from the earliest stages.

- **Early Engagement:** We understood that integrating public perspectives from the outset was pivotal. Engaging with the public at the inception allowed us to glean insights into how best to convey intricate details without overwhelming or alienating them. This early involvement not only informed our communication strategy but also built a sense of shared ownership and trust.
- **Diverse Representation:** Ensuring a diverse representation in our engagement sessions was paramount. By including voices from varied backgrounds and experiences, we were able to capture a holistic understanding of the communication needs and preferences of the community at large.
- **Public-Led Approach:** Rather than a unidirectional dissemination of information, we embraced a collaborative ethos. The public played an instrumental role in leading and shaping our approach. Their firsthand experiences and insights provided invaluable guidance in determining the most effective methods of communication.
- **Co-creation:** One of the standout features of our strategy was co-creating content. Members of the public actively participated in drafting text for scripts and brochures. This ensured that the content was not only accurate but also resonated with the wider audience.
- **Emphasis on Privacy:** Given the technical nature of federation and the potential concerns around data privacy, we were committed to transparency. Brochures co-created with the public explicitly addressed how federation operates and underscored the robust measures in place to maintain privacy.

In summary, our approach to translating complex information into public-friendly messages was rooted in collaboration, diversity, and transparency. By engaging with the public as co-partners rather than mere recipients of information, we were able to demystify technical concepts and foster a more informed and trusting community.

3.8. How did you communicate with your audience during and outside your core PIE activities? (i.e., channels and frequency)

In our structured approach to audience communication throughout the project, our overarching plan from the outset was centred on collaborative engagement. We dedicated ample time to develop materials in tandem with the public, ensuring their insights shaped our content. As part of our core PIE activities, we meticulously planned and conducted focus group discussions, which provided us with granular feedback. To further refine our understanding and foster deeper discussions, two workshops were organised: the first in July, followed by another in October. These platforms served as vital channels of consistent communication, ensuring our audience remained informed, engaged, and actively involved in the project's evolution.

3.9 Resources

In line with our project's strategic communication plan, we have dedicated specific resources to the creation of tailored informational materials. To this end, we commissioned the production of two co-developed brochures, structured to present the project's details in a manner easily comprehensible to the lay audience. Complementing this, two instructional videos are in the production pipeline. These videos have been designed to explain the concept of federation within the project's framework. Collectively, these resources, both printed and visual, stand as pivotal tools in our endeavour to effectively update the public about the project's objectives and the overarching theme of federation.

4. Activities and Timelines

4.1. What activities were conducted in your PIE process?

Activities encompassed two interactive workshops and targeted focus group discussions, serving as platforms for open dialogue and the exchange of ideas between the project team and the public representatives. Furthermore, the creation of accessible information materials, aimed to bridge communication gaps and foster inclusivity among diverse communities. Furthermore, sessions were held to discuss and review the script for the public-facing materials with members of the public.

4.2. How were these activities scheduled?

A project plan was developed amongst the partners and the PIE lead which involved setting specific dates for the creation and delivery of all aspects of the PIE work. This included:

- Creation of PIE materials
- Design and delivery of workshop one.
- Creation of the brochure and guide for members of the public explaining federation, trusted research environments (TREs) and the Five Safes.
- Design and delivery of workshop two.
- Creation of an additional brochure and guide for members of the public explaining RO Crates.
- Delivering the two explainer videos

5. Monitoring and Evaluation

5.1. What key performance indicators did you establish to track your PIE activities?

In our commitment to assessing the project's impact and ensuring its success, we identified several key performance indicators (KPIs) that played an instrumental role throughout the project's lifecycle. A significant KPI was our effort to ensure broad public engagement. We took deliberate steps to ensure that the diversity of our engagement groups resonated with the rich tapestry of the UK population, capturing holistic feedback and ensuring our project remained both inclusive and representative. This was a key criteria for the recruitment carried out by Alterline and these were reported across all our reports (See 3.6).

5.2. How did you monitor these activities, and over what periods?

Within the project, we closely monitored PIE activities using a clear and organised approach, guided by key performance indicators (KPIs). We checked attendance and participation during workshops, and feedback from focus group discussions to understand how effective our engagement was. Responses and the quality of feedback from the public were essential in determining how well our feedback processes were working.

We employed the Agile project methodology to track and manage progress, allowing for adaptive planning, continuous improvement, and prompt response to changes. This iterative approach ensured that our team remained flexible, efficient, and aligned with project objectives at every stage.

5.3. How did you measure the impact of these activities?

To quantify the impact of our activities, we implemented an evaluation framework, encompassing both quantitative and qualitative metrics.

A core component of our strategy was to ensure the effectiveness of our informational materials in terms of comprehension and resonance with our target demographic. We integrated feedback mechanisms enabling us to

understand the public's understanding on the topics and to pinpoint areas for refinement. By analysing feedback, we gauged the depth of interaction and identified sections that resonated most or caused most concern. This approach ensured that our materials were not just accessible, but also effectively understood, fostering a more informed and engaged audience.

5.4. How did you monitor your PIE promotion, and how would you rate participation?

The promotion and subsequent monitoring of our PIE activities was carefully planned, and we took steps to ensure meaningful and diverse participation. Central to this effort was our collaboration with Alterline, whom we commissioned to guarantee that our engagement reached a diverse and representative spectrum of participants. Their expertise was not merely in recruitment, but also in facilitating our workshops and focus sessions, ensuring a structured and comprehensive approach to feedback collection.

In its initial PIE workshop, the TRE-FX project set out to gather public feedback with the aim of refining the clarity and accessibility of our project content. Discussions focussed on pivotal aspects like the determining authority for a federated project's green light, stringent regulations surrounding data access, and the utmost importance of ensuring the safety of our project outputs. The insights from these dialogues proved invaluable. By seamlessly incorporating public suggestions into our technical design, TRE-FX highlighted its commitment to an iterative and inclusive approach.

Following the success of our initial PIE workshop, a second workshop was carried out in early October, with Alterline at the helm. This workshop dove deeper into intricate technical concepts, providing the public an enriched understanding of TRE-FX's strategies to bolster data privacy and maintain secure analysis mechanisms. After reviewing the detailed report produced by Alterline, we were thoroughly satisfied with the breadth and depth of feedback received, confirming the efficacy of our public engagement approach.

5.5. How did you collect feedback directly from your audience, and what does this feedback tell you?

Feedback from our audience was an integral component of our project's success, and we implemented a robust and methodical system to collect it via Alterline.

These focus groups examined participants' perspectives on various key themes that emerged from discussions related to Federated Analytics, including limited prior knowledge, understanding of provided documents, concerns, benefits, trust, communication, and data privacy. The findings shed light on important considerations and provide valuable insights for the implementation and improvement of Federated Analytics initiatives.

The insight reveals that participants initially had limited knowledge and awareness about Federated Analytics. However, the provided documents played a significant role in improving their understanding of the topic, explaining the concept in simple terms and utilising clear explanations with diagrams. Despite some initial confusion, participants expressed increased comprehension and appreciation for the potential benefits.

Participants highlighted concerns regarding data security, potential misuse, and the lack of control over personal data. Trust and accountability were deemed crucial, emphasising the need for external regulation and accreditation to ensure data security and prevent unauthorised access. Participants also stressed the importance of transparency and understanding in communication regarding data usage and consent. Clear and relatable messaging, provision of opt-in and opt-out choices, and sharing success stories were recommended to enhance public engagement and awareness.

The research highlights that participants understand the potential benefits of Federated Analytics to include, research collaboration, diverse data source integration, and improved research outcomes. Participants recognised the value of a centralised data pool and the potential for enhanced healthcare services. However, concerns were

raised about data management issues, differentiating between research and commercial use, and compliance with data privacy regulations.

6. Reflections and Lessons Learned

6.1. How were your PIE activities received?

Within the scope of the TRE-FX initiative, the feedback from the target audience was overwhelmingly positive. The interactive workshops and focus group discussions witnessed active participation and yielded valuable input from both public and patient representatives. This engagement facilitated an atmosphere of open communication and collaborative brainstorming, underscoring the project's commitment to inclusivity and transparency.

6.2. What key implementation successes and challenges arose from your PIE delivery process?

In the course of delivering our PIE process within the TRE-FX initiative, several key successes and challenges emerged.

Successes:

- **Enhanced Understanding:** Though participants began with a limited comprehension of Federated Analytics, the public-facing materials effectively bridged this knowledge gap. Post-engagement, there was a notable improvement in participants' understanding, attributing to the simplicity and clarity of the provided documents.
- **Recognition of Benefits:** The potential advantages of Federated Analytics, such as fostering research collaboration, integrating diverse data sources, and enhancing research outcomes, were well-understood and appreciated.
- **Acknowledgment of Communication Efforts:** The emphasis on transparent communication concerning data usage, the availability of opt-in and opt-out choices, and the sharing of success stories were received positively. Additionally, the introduction of the five safes framework was recognised as beneficial, though suggestions for further enhancements were made.

Challenges:

- **Data Management Concerns:** Participants raised issues related to data management, distinguishing between research and commercial utilisation, and ensuring compliance with data privacy norms.
- **Data Security Worries:** There was significant apprehension about potential data security breaches, misuse of personal data, and the perceived lack of control individuals held over their information.
- **Trust and Accountability:** Trust emerged as a pivotal factor. Participants expressed the necessity for external regulatory mechanisms and certifications to guarantee data security and deter unauthorised access.

In summary, while the TRE-FX initiative successfully elucidated the tenets and advantages of Federated Analytics to the participants, it also brought to the forefront certain reservations and concerns, underscoring the need for continuous dialogue, improvements in data security, and heightened transparency in operations.

6.3. What key learnings are important to consider in your project delivery strategy?

In light of the feedback obtained from our focus groups, the following key learnings are crucial to consider for refining the delivery strategy of the TRE-FX project:

1. **Enhance Content Presentation:** Prioritise enhanced readability by addressing feedback on document length and wordiness. Aim to incorporate bullet points, visuals like diagrams, and concise explanations, striking a balance between thoroughness and broad accessibility.
2. **Clarify Data Usage Protocols:** In response to concerns raised, elucidate details on data usage specifics: its intended use, the entities accessing it, retention periods, and associated security measures. Emphasise the project's commitment to use the data solely for genuine research endeavours.
3. **Amplify Transparent Communication:** Maintain transparent communication about data consent, purpose, and sharing parameters. Adopt plain language and user-friendly formats to ensure the public understands the project's objectives and processes.
4. **Bolster Data Security Protocols:** Incorporate stringent data security mechanisms to mitigate unauthorised accesses and potential breaches, ensuring adherence to prominent data protection guidelines like GDPR and mandating transparency and compliance from all data-handling entities.
5. **Promote Trustworthiness:** Foster trust by emphasising accountability. Contemplate external oversight measures and possibly the involvement of independent bodies to guarantee data protection and sanction any misconduct.
6. **Prioritise Individual Agency:** Empower participants by furnishing transparent consent processes and offering an opt-in default system, allowing them to decide the specific research project they wish to be part of. This will be challenging on a large scale so will need further exploration. The ideal solution would be to focus on reassuring the public so they trust the technology, rather than on a project by project basis.
7. **Expand Public Engagement:** Carry out outreach programs to teach the public about federated analytics. Use various communication methods to share success stories and highlight the real benefits of contributing data.
8. **Develop Robust Governance:** Create clear rules for fair and transparent data access. Make sure experts help with decisions to keep ethical concerns a top priority.
9. **Commit to Ongoing Monitoring and Improvement:** Adopt a proactive approach to routinely assess federated analytics implementations, drawing feedback from diverse stakeholders. Regularly fine-tune processes, security frameworks, and communication tactics to address any evolving challenges and consistently nurture public trust.

6.4. What key considerations will be crucial for future PIE activities in a similar context?

For future Public Involvement and Engagement (PIE) activities, ensuring readability and accessibility of content is paramount. It's essential to clearly convey data usage intentions and have stringent security measures in place. Trust can be bolstered by emphasising transparency, accountability, and robust governance frameworks. Offering individuals control over their data through clear consent options is crucial, as is continuously raising public awareness about federated analytics. Regular assessment, coupled with stakeholder feedback, will further adapt and refine PIE activities, aligning them more closely with public expectations and the overarching objectives of larger projects.

7. Discussion and Recommendations

7.1. What is your overall assessment of the PIE process?

Following our evaluation, we believe the PIE process implemented in the TRE-FX initiative has proven to be both effective and influential. The initiative successfully cultivated a collaborative atmosphere, eliciting active involvement and valuable input from public representatives. By employing structured feedback methods and

engaging sessions, we ensured broad inclusivity and enabled stakeholders to meaningfully influence the direction of the project.

7.2. What other developments are worthy of note?

Participants emphasised significant concerns about personal data control, underscoring the importance of trust in the system. The necessity for external oversight, adherence to data protection regulations, and transparent messaging were highlighted. Key findings also included the value placed on institution trustworthiness and data governance. Establishing expert-inclusive decision-making processes and addressing privacy concerns in the digital era were deemed essential for any new system's success.

7.3. What are the implications for the project and the DARE UK programme?

Clear and personalised communication was stressed by participants, who underscored the need for relatable messaging, including comparisons to the current situation, to effectively convey the benefits and advancements brought about by Federated Analytics.

In conclusion, participants' feedback underscores the importance of transparency and understanding in communicating data usage and consent. Clear and transparent communication, along with the provision of opt-in and opt-out choices, are vital for ensuring individual autonomy and control. Effective communication through success stories and case studies enhances public engagement and awareness. Special considerations for vulnerable groups, the role of GPs, and NHS endorsement further contribute to building trust and fostering a more receptive response to Federated Analytics initiatives.

7.4. What are your recommendations?

This project highlights the need for clear and transparent communication, trust, accountability, and robust data governance in Federated Analytics initiatives to win over public trust. It underscores the importance of addressing concerns related to data security, privacy, and control, while emphasising the potential benefits of collaboration, improved research outcomes, and enhanced healthcare services.

By implementing the recommendations provided by the participants, Federated Analytics initiatives can build trust, foster public engagement, and ensure responsible data sharing practices.

7.5. What are your next steps?

Future research could continue to explore and address the challenges and opportunities associated with Federated Analytics, promoting a comprehensive understanding of its potential in advancing research and improving healthcare outcomes.

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