End of programme PPIE Review

Background

Gut Reaction, our initial vision

"The purpose of our proposed Hub is to integrate genomic data with structured phenotypic data and previously inaccessible routinely collected longitudinal healthcare data from a large cohort of patients recruited to the NIHR BioResource with the common immune mediated diseases Crohn's disease and ulcerative colitis (IBD). The output will be a world-class, multi-dimensional integrated data resource for research and innovation; using a model based on open tools and data standards that could readily be scaled and replicated for other disease areas."

Gut Reaction aimed to combine information from NIHR IBD BioResource participants who consented to their medical records being used for research, and are undergoing genome-wide profiling, with:

- Digital pathology, diagnostic reports, and images from NHS Trusts (ten sites initially)
- Health Episode Statistics (HES) from NHS Digital
- IBD Registry data
- Whole exome and whole genome sequence data from the Wellcome Sanger Institute

The hub hoped to facilitate research that will benefit patients and the wider NHS by providing:

- Advanced data storage and analytical environments for managing multi-dimensional data at scale
- Methods that support the highest standards of data discoverability, security, anonymisation and governance
- A scalable and replicable model for other NHS data assets

The Gut Reaction team was made up of 6 workstreams, one of which focussed on Patient and Public Involvement and Engagement (PPIE) & Communications, which is at the core of this review.

PPIE in Gut Reaction

Gut Reaction's vision was to deliver meaningful and effective PPIE by working in partnership with representatives of the IBD community and the general public, developing proactive and lasting collaborations to support and maintain public trust in responsible use of health data. Our aims were to:

- Ensure PPIE was an integral part of Gut Reaction, adding value to outcomes
- Achieve a gold standard approach to PPIE and inclusivity, based on UK Standards
- Continually evaluate and improve our approach
- Work collaboratively with patients and the public, as equal partners in one team

To achieve our aims, we put in several initiatives, including developing, maintaining, and supporting a Patient Advisory Committee (PAC), as well as various subgroups and projects involving representatives designed to focus on different elements of the Gut Reaction programme. The PAC met quarterly and discussed topics such as data access, artificial intelligence, commercial models, and sustainability, with relevant workstreams coming to meetings to enable these conversations. We also created and implemented an Equality, Diversity, and Inclusion (EDI) policy, and facilitated several mechanisms for feedback and evaluation of our PPIE which were reviewed regularly.

Key achievements

Engagement

Throughout the course of the programme, we have engaged with patients and the public, including 1,627 patient/public attendances at meetings and other events. We are proud to have held 5 webinars, all involving members of our PAC, and have also co-developed several blogs and news articles with our PPIE representatives through Gut Reaction and our partners. Our animation, which we co-produced explains the Gut Reaction programme and the power of health data, has had more than 1,500 views. Working with Crohn's & Colitis UK, the team has also presented at two PPIE day events alongside PPIE representatives, which involved engaging a wider audience and gathering important insights on different aspects of the programme.

Alignment with the UK standards for involvement

Throughout the initial HDR UK funding period for Gut Reaction, we have prioritised reaching and including a wide range of individuals living with IBD. Listening to our PAC, building back up our PAC's membership, and learning from our earlier experiences, we recruited seven new PAC members to help ensure that we embedded diverse views and experiences in this programme. This increased diversity of views has been recognised (see Figure 1) and valued by the PAC, and the Gut Reaction team, alongside an awareness that there is still some room for improvement.

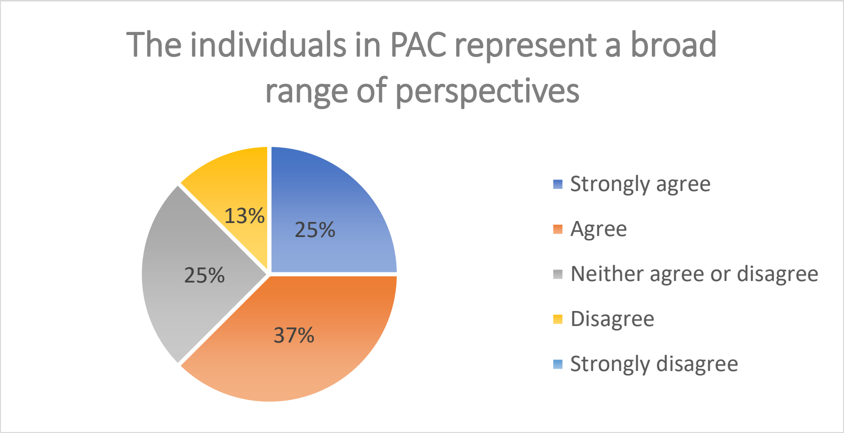

Fig.1.

To support our PPIE representatives, and the wider PPIE community, we have co-produced PPIE in health data research training. To date, 236 people have signed up to our training programme, which we believe to be the first of its kind, and we have had positive feedback from many. One PAC member said: *"First rate online training course about PPIE - I frequently refer back to my notes from this"*. We have also worked hard to ensure equality with the Gut Reaction team, and to ensure that opportunities to get involved are accessible to all, including implementation of a new payment policy to recognise PAC time and expertise. We also offer yearly 1:1 meetings to support PAC members learning and development, and to give an opportunity for feedback. We have offered further opportunities for learning and development through participation in topic-specific working groups and supporting collaboration with the Patient Led Research Hub to develop and undertake a research project based on individual priorities and interests.

Drafting and implementing a plan to measure the impact of our PPIE has allowed us to consider our PPIE activities and the difference that they make when reviewing our strategy and progress. This process has led to a greater understanding of the impact of PPIE on the programme, people, and organisations across Gut Reaction. It has also helped us to adjust and improve as the programme progressed and led to the data collected in this report.

Impact on Gut Reaction

The Gut Reaction PAC have been crucial to the development and refinement of our data access protocols. A key topic for discussion has been the process to access Gut Reaction data; the PAC subsequently developed a proposal for the NIHR BioResource suggesting mechanisms to improve PPIE in this process. The PAC proposal allowed for increased participant representation, transparency and an opportunity for meaningful participant and public influence on decision making. Involving patients in this process will help to ensure that we champion projects with maximum patient benefit, rather than for the scientific or academic interest, and will also help build trust in the wider use of health data. This proposal was accepted by the NIHR BioResource, and has been implemented, with the recruitment and induction of a new Patient and Public Review Group (PPRG) who will review all IBD applications for an initial 12 month period, now complete.

The PAC have also been involved in discussions about ensuring a balance between data safety and supporting important research; specifically, when it might be appropriate for data to be downloaded and what safeguards would be required if this was to occur. This has been an ongoing and complex discussion, which has culminated in Gut Reaction only sharing data as an exception, pushing for the use of a neutral Trusted Research Environment as the next best option, and if this is not possible, ensuring a list of safeguards are put in place before data is shared. The revised approach has been tested on an application from industry, supporting further discussion of how this can be implemented. Development of this guidance has required close collaboration within the Gut Reaction team, and PAC members have reflected on the change in views through this process: *"From a slow start to really embracing what we bring to the project"*. Alongside the PPIE training delivered to the Gut Reaction team, they have noted changed perspectives and use of learning in other projects and programmes.

Learning and impact

Throughout the project we have collated learnings and impact from our PPIE programme; we have held group discussions, conducted surveys, and gathered individual feedback through emails, review meetings and our feedback spreadsheet.

When we recruited our PPIE representatives, all individuals that took part in our impact evaluation survey reported that Gut Reaction either met or exceeded expectations in terms of providing a fair and transparent process to get involved. Figure 2 demonstrates further that our high standards in clarifying and sharing the role of the PAC with those involved.

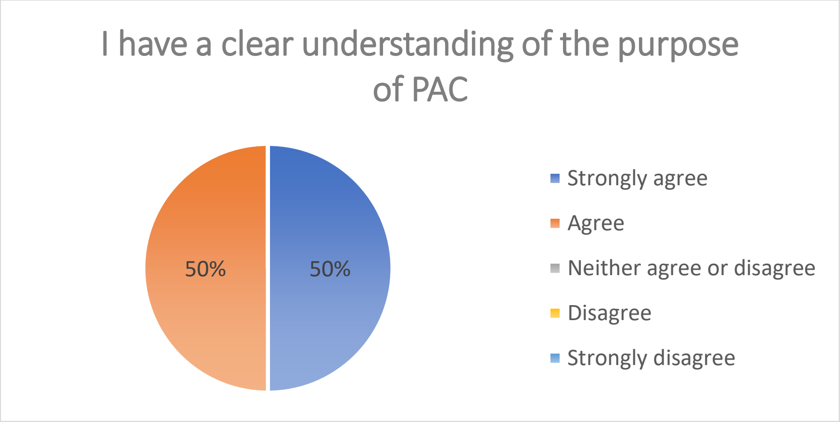

Fig.2.

As part of our PPIE workstream, we developed a strategy and implementation plan. Interestingly, 50% of PAC members responded ‘needs work’ when asked about whether a plan has been developed for involvement activities, with 25% feeling we met expectations and a further 25% reporting that we had exceeded them. This demonstrates the importance of communicating our strategy regularly.

When asked if there was visible and accountable responsibility for involvement throughout the organisation, 75% of PAC members felt that this met expectations and a further 25% felt it exceeded expectations. This is a very positive result for us, given our aim to embed PPIE in the programme. Furthermore, three quarters of the Gut Reaction team feel that there is a commitment to PPIE values and principles is demonstrated through the structure of the organisation. Potentially as a result of this, PAC report that their work makes a difference to Gut Reaction, see Figure 3.

> *“We have had senior programme leaders attend meetings and genuinely listen and value contributions.”*

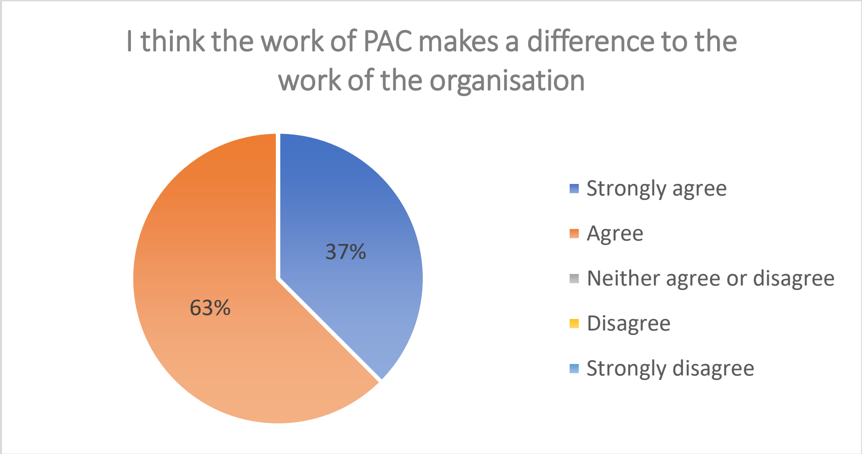

Fig.3.

Internally, 75% of the Gut Reaction team feel that PPIE influenced decisions in Gut Reaction some of the time, with a further 25% reporting that this was the case all of the time. However, there is still work to be done, and PAC members have raised that embedding PPIE earlier in pieces of work would be helpful, as would increased feedback and communication on these initiatives between meetings. One PAC member said: *"I don't have a view of what everyone is up to on the project so more transparency on this would be beneficial"*. Building in PPIE across a programme such as this should be a priority for all workstreams from the beginning, and planning this in advance could help more meaningful involvement. *"Some meetings felt like the PAC was "signing off" on developments, work streams and opportunities after the decision has been taken by professionals, leaving limited scope for deeper, more meaningful inclusion. At times, administration timelines and the organic progression of PPIE, seemed to be at odds which created a fine line between building new meaningful inclusive structures and meeting funding deadlines etc."*

Encouragingly, 63% of PAC members either agree or strongly agree that their views are heard, the remaining 37% neither agreed nor disagreed with this statement; we aim for everyone to agree with this statement in future. By reflecting on the feedback from 37% of PAC members that accessibility and appealing to different communities is an area for us that still needs work, we will be able to further our work in this area as the programme progresses.

Overall, 88% of PAC respondents feel better informed about health data, with one reflecting that *"We've been encouraged to get involved in many aspects of PPIE but also more generally in other health research activities too"*. Beyond the impact on the programme, PAC have raised that this opportunity has been a *"Great opportunity for professional and personal development"*. To this end, 63% of PAC members strongly agreed that this initiative has been a good use of their time and from Figure 4 and quotes below, our PAC have felt satisfied with their involvement in the programme.

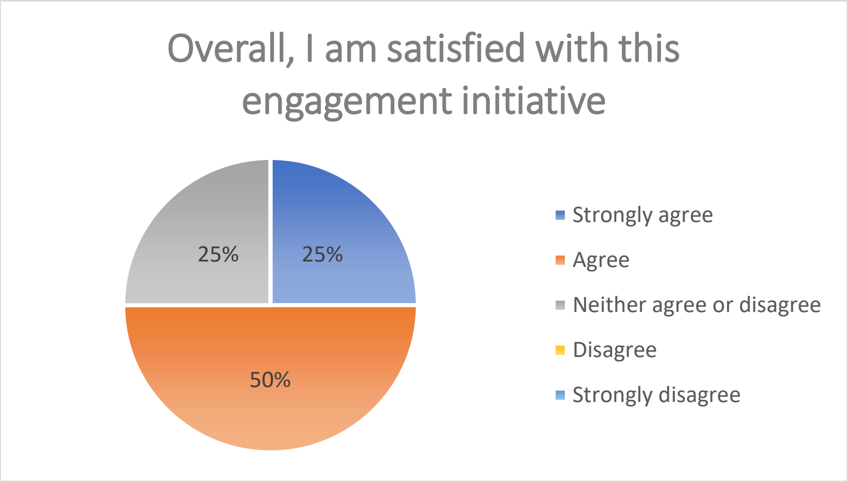

Fig.4.

"It feels really good to take a project all the way through to completion. It's been great to interact with professionals in a number of different fields, and to be treated with respect and parity."

"…the early stages PAC felt like it was there to meet a project requirement, but it has grown from there in the latter half of the project".

"As a group, we raise questions about the use of health data, which wouldn't happen without us."

Next steps

We have a high-level strategy to sustain Gut Reaction beyond the initial HDR UK funding term, which ends in August 2022, and central (NIHR) funding for the BioResource is confirmed until December 2024. With increased industry engagement, research charity funding (including the Helmsley Award), and opportunities to secure further academic funding, the NIHR BioResource confirmed they will sustain Hub activities beyond August 2022.

A commercial model for data access has been chosen for its simplicity and transparency. Securing upfront payment for data access has been selected as preferable to the complex (and long-term) arrangements required to support more ‘outcome based’ payment models. Costs of accessing data will depend on the size of dataset, granularity of data and the origin of the research application. Additional charges will apply for services such as curation and further linkage.

PPIE will continue to be a key part of Gut Reaction, and the NIHR BioResource is committed to ensuring this, see Figure 5. There will be a national participant advisory panel supporting the entire NIHR BioResource, by providing oversight and advice on key topics. The PPRG will be central to the data access process, on a 12 month pilot basis, with Crohn’s & Colitis UK will providing support to deliver and review this group. Gut Reaction PPIE representatives have been offered the opportunity to apply for both groups.

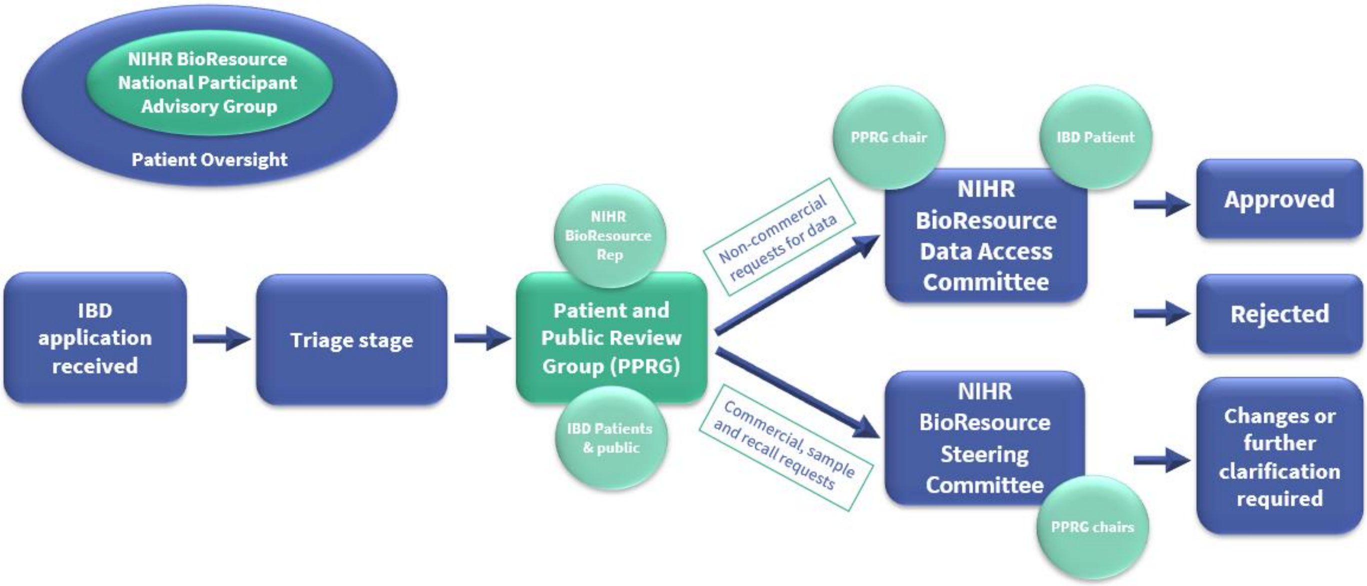

Fig.5.

To conclude this review and pull together the learning from the PPIE workstream of Gut Reaction, a complex, multi-organisation health data research programme, the PAC would like to provide recommendations for the future of the programme and for other health data projects looking to embed PPIE.

PAC recommendations for Gut Reaction

Based upon the learnings shared in this report, PAC would like to provide the following recommendations for ongoing PPIE specifically within the Gut Reaction programme:

1. Review ongoing PPIE and align with the wider NIHR BioResource strategy
2. Increase the depth of involvement in different areas of the programme, for example, PPIE representatives setting agendas, or creating outputs/reports as co-authors
3. Continue wider engagement through webinars – including providing feedback as to what has been learnt through the use of Gut Reaction data
4. Feeding back to the PPIE representatives involved, with an opportunity to see the longer-term impact of their contributions
5. Continue to support the learning of the Gut Reaction team around PPIE, as well as the learning and development of PPIE representatives
6. Promote Gut Reaction to researchers as much as possible, and with our support, put the patients' gift of data to work in a safe way.

PAC recommendations for other research programmes

Based on the learnings from this project, the PAC would like to make the follow recommendations for anyone hoping to embed successful PPIE in future research initiatives:

1. Embed PPIE from the very start – including creation of funding applications
2. Co-produce your PPIE plan in advance and ensure sufficient resource is allowed for, both in terms of time and finances to enable reimbursement for people's time. Make sure you regularly review and report back on this with your PPIE representatives
3. Set out clear expectations and role descriptions for PPIE representatives; in order that they are not deterred by a lack of technical knowledge, demonstrate that support is available; an interest in the subject and an ability to offer informed opinions, based on their lived experience is crucial, specific training should be facilitated by the PPE workstream
4. Build in variety and support all of your PPIE representatives. Create space for shared learning and team building, set meeting dates in advance and allow plenty of time for comments and ensure variety in timings and methods of engagement to enable all to get involved
5. Encourage involvement in all different parts of the programme from the start, particularly at organisational decision-making groups, and enable reporting back to the other PPIE representatives
6. Bring project partners and individuals on board from the outset with a shared respect and understanding of the credibility of PPIE – early and ongoing training and reflection is key
7. Have an open, honest dialogue with your PPIE representatives, encouraging two-way feedback and ensuring equality
8. Value PPIE representatives as a whole person and all the views and experiences they bring, giving scope for their learning and development
9. Ensure transparency at all times, including admitting mistakes, as this is more likely in the long term to gain the trust of patients. Don't be afraid to ask for advice.
10. Understand that patients and public will have differing opinions and that is ok, and in fact to be encouraged to ensure diversity of views
11. Stay focussed on the goal of improving management options for patients; the data and the research is a means to that end, not the end of itself.