



**The power of redefining responsibility:
a diverse & inclusive clinical trial journey**

A case study for the **BHBIA DE&I committee 2024**
by Biogen, Langland & boxee



EXECUTIVE SUMMARY.

PROBLEM.

Inclusive clinical trial data is crucial in ensuring health outcomes are equitable for all patients.

SOLUTION.

Two 2.5 hour expert panels with clinical trial investigators and academic leaders from under-served ethnic populations (UPs), in parallel to two patient and caregiver advisory boards
Sharing experiences of barriers and their solutions to engage UPs

LEARNINGS AND IMPACT.

Collaboration is key to building long-term trust - which is essential to engaging UPs in clinical trials e.g. supporting 'Patient Champions'

Biogen have prioritised and defined actions to improve equitable access to clinical trials e.g. identifying community groups for long-term collaboration



THE PROBLEM.

The need for inclusive clinical trial data is crucial for introducing safe and effective treatments relevant to underserved ethnic populations, ensuring that health outcomes are equitable for all patients in the UK.

As it stands, patients from underserved ethnic populations are hugely underrepresented.

In particular, clinical trial inclusion of those from under-served ethnic populations (UPs) is very limited. Take COVID clinical studies for example: despite being disproportionately affected, representation of under-served ethnic groups in COVID clinical studies is 9.26%, below the UK population average of 13.8%. In vaccine trials, representation is just 5.72%.

The real-world impact of this is huge: put yourself in the shoes of a doctor recommending a vaccine and not knowing how it will affect your patient or whether it will work at all. Imagine yourself as the patient receiving a medication that hasn't been tested in anyone like you.

While life expectancy is generally higher for people from under-served ethnic groups in the UK, they experience poorer health outcomes in certain conditions, like metabolic and mental health conditions. These outcomes could be improved by generating more representative data.

Biogen wished to know how they could be a part of the solution to this problem.



WHAT WE MEAN BY 'UNDER-SERVED.'

The NIHR-INCLUDE1 project identified the term 'under-served' by diverse stakeholders including patients and the public as the most appropriate term through a consensus workshop.

The term reflects the perspective that the research community needs to provide a better service for people in these groups – the lack of inclusion is not due to any fault of the members of these groups.

The term 'under-served' reminds us of this perspective in a way that alternative terms such as 'under-represented' do not.

The 'under-served ethnic' populations we focused on:

- Asian, Asian British: Indian
- Asian, Asian British: Pakistani
- Black, Black British: Caribbean
- Black, Black British: African

<https://www.nihr.ac.uk/news/nihr-research-ethnicity-data-provides-insight-on-participation-in-covid-19-studies/26460>

THE SOLUTION.

A collaboration between **Biogen** (biotechnology company), **Langland** (a Publicis Health Company specialising in clinical trial recruitment and retention) and **boxee group** (market research) was established.

Techniques we used throughout to ensure we kept the problem in sight and uncovered the best solutions:

- ❑ Desk research
- ❑ Internal learnings e.g. ongoing patient and caregiver work
- ❑ Multiple rounds of internal discussion
- ❑ Constantly challenging our assumptions
- ❑ Critically thinking about whether the objectives / questions were fit for purpose

The collaboration didn't stop there. Most importantly, we spoke directly to people that 'live and breathe' clinical trial recruitment in under-served ethnic populations. This included clinical trial investigators who were not only from the same communities as these UPs, but had experience of engaging with our key ethnic populations, as well as academics that had published in the field of inclusive CT recruitment.

Our goal was to give these experts a platform to share, discuss and debate what inclusive clinical trial engagement in the UK truly looks like.

Throughout, we all listened and learned, with open ears and open minds, about the challenges that prevent under-served ethnic populations from being fairly represented in clinical trials; what impactful solutions are in place already, and how pharmaceutical companies, clinical trial sites and HCPs could, and should, be driving these efforts.

These advisory boards formed part of a larger-scale project. In parallel to speaking to HCPs and experts, two advisory board were run with patients and caregivers from South Asian and Black communities in the UK to get their insights on barriers and solutions to clinical trial participation. Hearing their needs first-hand allowed for a non-biased view of the current landscape in the UK.



THE APPROACH.

Truly listening and learning takes **commitment and time** to understand problems, and we felt we had a responsibility to give that to our experts.

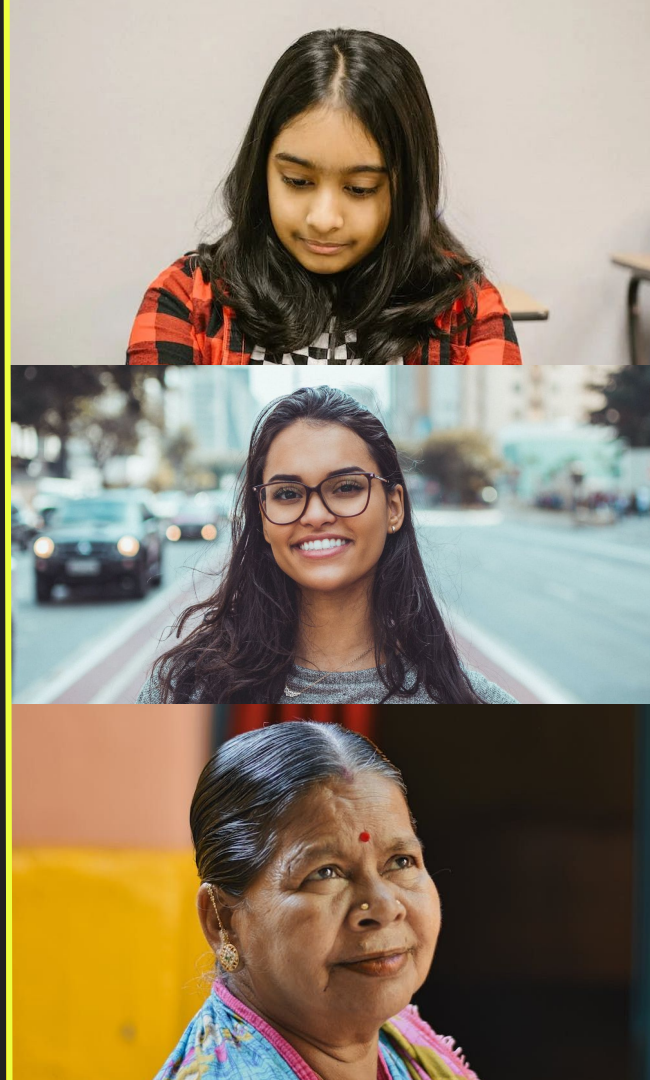
Therefore, we arranged two working sessions with our experts

1 BARRIERS TO UP PARTICIPATION IN CLINICAL TRIALS

2 BEST PRACTICE FOR INCREASING UP INVOLVEMENT IN CLINICAL TRIALS

We also had a **day in between for space to reflect** - not just for Biogen, Langland and boxee to think more deeply about the content from Session 1, but for our experts to gather their own thoughts too.

Different techniques helped to ensure there was **constant collaboration between experts** despite it being in a virtual environment. It kept participants energised and engaged, and also made the sessions enjoyable. At the end of the day, we're all human and humans are at their most creative when they're having fun.





THE RIGHT PEOPLE IN THE ROOM

When we asked our experts why they were passionate about improving clinical trial access for underserved ethnic populations, the majority answered: ***"because this affects me; I am the under-served population."***

These responses outline our recruitment approach: we ensured a mix of ethnicities - in fact, **5/6 of our experts were from the specific under-served ethnicities we were focused on** - as well as an even gender split and a range of ages. It was important to us that we discussed and understood nuances between ethnic groups and having diversity within our sample helped us achieve this.

BIG LEARNING: REDEFINING RESPONSIBILITIES

Pharmaceutical companies must not expect under-served ethnic populations to take on this challenge: they have a responsibility to build equitable access to clinical trials for all patients, inclusive of under-served ethnic populations.





THE UNMET NEED

However, all the ideas in the world mean nothing if **we're not continually measuring success** along the way and identifying what UP engagement methods and tools work best.

We learned that this is lacking in the UK, largely due to funding, and those working on the frontlines of UP engagement are **desperate for such insights** in order to **speed up the progress to equitable representation** in clinical trials.

Commitment doesn't last the length of one clinical trial.

It starts long before the trial begins and lasts as long as the community you're engaging with need your support.





THE BUSINESS IMPACT

Biogen have **critically assessed these insights** and learnings and have since **prioritised and defined actions** they will be taking moving forwards. Examples include:

- ❑ **Define DE&I criteria** for the site selection process to ensure Biogen are **working with sites who are inclusive and committed to equitable access to CTs**
- ❑ **Support sites locally** to ensure they **have the means and resources to engage effectively** with their communities to educate and empower communities. Ultimately, **building long term relationships** with community organizations and physicians
- ❑ **Seek innovative opportunities** to be more inclusive through technology and vendors and to **give back more to these communities** - examples from the research include engagements with radio stations, collaborative feedback sessions, educational website 'portals', fitness classes etc.
- ❑ Continue to **influence this work 'from the top'** through **trade organizations and policy change**

"These insights have been incredibly **valuable** in helping us **identify priorities and how to approach them.**"

- Health Equity Lead

GIVE BACK MORE.

A LEARNING FOR MARKET RESEARCH

Often, we as market researchers are so focused on the experiences, thoughts and feelings of respondents that **we focus less on what we are giving respondents in return.**

At the end of our second panel, we asked all of our experts for one final thought. They unanimously agreed they'd not only enjoyed the sessions and were positively surprised to see such interest from a clinical trial sponsor, but they appreciated the chance to speak with others fighting the same cause and take note of the solutions that had worked well for them.

"I just want to say **thank you.** It has been very enjoyable, and I have to say that I didn't expect to...learn from each other and I think this is a very important thing to highlight. And there are some take home messages for me personally in the future when doing research or clinical trials. So **I've learned a lot, thank you.**"

- Clinical Trial Investigator

Giving back and collaborating demonstrates commitment and fosters trust; another critical learning from this project.



FINAL THOUGHTS.

We hope this challenges the industry to rethink their own responsibilities to under-served ethnic populations and inspires a commitment to long term engagement, not just taking insights but giving back. Ensuring everyone experiences equitable health outcomes.

