Why are clinical trials struggling with diversity?

Unpacking the status quo

- Traditional Randomised Control Trials (RCTs) **are** the backbone of clinical efficacy and safety data. **A risk-benefit approach underpins safety and efficacy in the licensing of medicines**.
- Safety and efficacy data are highly influenced by intrinsic: ethnicity, sex, age, genetic background and extrinsic: climate, education, access to healthcare factors.
- Hence, safety and efficacy data from an **RCT may not always translate to the real world 'effectiveness' of a medicine** (how efficacious the drug is in patients once marketed) which is governed by these complex intrinsic and extrinsic factors. **The diversity of clinical trial patients in the context of disease prevalence is key to capturing 'patient-orientated' outcomes in populations.**

Equitable access to trial participation: The Pandemic

Did the demographics of vaccine trial participants represent the vulnerable groups to whom infection with the disease presented the greatest risk of mortality? In the UK , research has shown that, during the first wave of the COVID-19 pandemic, **minority groups** (except for women in "Chinese" or "White Other" categories) **had higher rates of death post-exposure compared with the "White British" population.** This was **associated with social and economic deprivation and associated co-morbidities.** Similarly in the US, members of the Black, Latino, Pacific Islander and Indigenous peoples communities had twice the COVID mortality rate of Caucasian people.

Why are certain ethnic groups underrepresented?

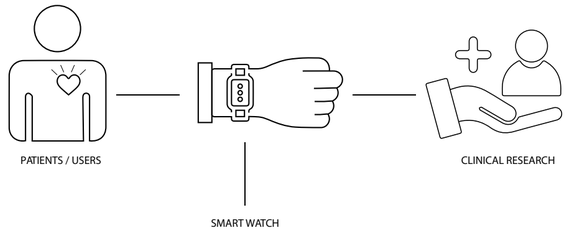
Throughout the pandemic, the issue of **vaccine hesitancy was compounded by ethnic disparities.** This is underpinned by **historical mistrust in healthcare** organisations, governments, and clinical research, which is still disproportionally **prevalent in some communities.** Factors influencing trust vary between ethnic groups. Documented experiences of discrimination, perceived structural inequalities impacting the access to and quality of healthcare, and concerns of trial under-representation are likely to influence trust issues. Without addressing fair and equitable access to clinical research there is a lack of breadth in safety and efficacy data. This deepens the mistrust in the regulation of medicines, **raising scepticism in the evidence that supports the prescribing label of medicines.**

Can technology help diversify clinical trials?

Decentralised clinical trials – where trials are conducted outside of traditional sites (i.e., within homes or within community hubs) – help to tackle the homogeneity of trial participation by addressing the factors that limit participation from individuals who are not able or willing to regularly visit a traditional study site such as a general hospital. Whilst this may create access barriers, i.e. the need for reliable broadband; **the theoretical benefits are clear to see in terms of socio-economic factors that limit trial participation** (i.e. childcare provision, transport, unpaid leave and social stigma). By bringing the trial to the patient, life-science companies can build upon established and trusted health practitioner-patient relationships. Patient-centric clinical trials allow for increasing awareness, enabling change to recruitment practices, working alongside patient advocacy groups, to achieve **equitable access to research and effective medicines.**

How to facilitate decentralised trials

Leveraging Digital Technology (examples below)



What comes next?

The time is now for life-science companies to develop strategies that address the disparity between the clinical trial population v the intended patient population. Regulators have already issued guidance to demand fairer demographic representation in clinical research - with stakeholders demanding more compelling evidence that medicines will be safe and 'effective' in the real world, pharma companies can expect a competitive advantage in this evolving area for those efforts.

Diversity, Equity and Inclusion in Clinical Research

Life Science Regulatory Solutions Practice Team Website

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