PANTHER PLATFORM TRIAL

EQUALITY, DIVERSITY AND INCLUSION STRATEGY

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1. SCOPE

This strategy applies to Equality, Diversity and Inclusion (EDI, Research Inclusion) within the PANTHER Platform Trial.

2. PURPOSE

The purpose of this document is to describe the strategy for Equality, Diversity and Inclusion within the PANTHER Platform, its objectives and utilising its resources.

3. STRATEGY

It is the strategy of the PANTHER Platform to enhance EDI within the platform and utilise this strategy to guide its activities.

4. ROLES AND RESPONSIBILITIES

This policy applies to the overall PANTHER Platform, to its members and its committees where relevant, particularly the PPIE and EDI working group, who are responsible for its application.

5. OVERARCHING STRATEGY ON EQUALITY, DIVERSITY AND INCLUSION

Introduction

Individuals of all backgrounds regardless of demographic, social or economic factors are diagnosed with respiratory failure and acute respiratory distress syndrome (ARDS) and should have the opportunity to participate in research. However, many groups are 'under-served' in research with lower inclusion, higher health burden and factors which are not considered but may affect their participation[1]. Such underserved groups may include those identified by the NIHR-INCLUDE project[1] or defined as having 'protected characteristics' (https://www.gov.uk/), however as this is an international platform these examples are not exhaustive and likely differ depending on the local context. Groups include age (younger and older), gender reassignment, married or in a civil partnership, women of child-bearing age, pregnant or on maternity leave, disability, race including colour, nationality, ethnic or national origin, religion or belief, sex, sexual orientation. Other groups include educational, employment or socioeconomic disadvantaged, people in alternative residential circumstances, remote areas and communities, those with language barriers, mental health conditions, disability and impaired capacity.

The PANTHER Platform aims to be as inclusive, diverse and equal as possible and strives for more representative involvement, engagement and trial participation. This can support the 'no decision about me, without me' approach with more generalizable results which translate to clinical practice for diverse groups and the potential to assess if different treatment responses exist across groups.

Equality, diversity and inclusion (EDI)

1. PANTHER Network

The PANTHER platform will follow established frameworks and guidance, in particular NIHR-INCLUDE Ethnicity, Impaired Capacity to Consent, Socioeconomic Disadvantage, Disability, European Lung

Foundation Inclusion and Diversity Guidance and international frameworks for different countries. Members will continue to engage with relevant external working groups e.g. TRIAL FORGE (trialforge.org), TMRP (methodologyhubs.mrc.ac.uk), ACTA (clinicaltrialsalliance.org.au/), EmPACT and EDI shared learning networks.

2. PANTHER Participating Sites

Training will be provided to participating site teams on enhancing EDI and cultural competence and sensitivity within their Site Initiation Visit and at investigator and research coordinator meetings with additional materials provided for further learning.

Diversity and inclusion data will be collected within the trial case report form (CRF) using the UK standardised CRF for protected characteristics where possible based on site and country norms. Protected characteristics will be monitored at regular intervals (6-monthly) and using the Screened, Eligible, Approached, Randomised' (SEAR) framework[2] with proactive site engagement, training and PANTHER meetings/events. Importantly, we will report on these characteristics in platform results publications and presentations.

3. Trial Participation

Platform and domain inclusion and exclusion criteria will promote inclusion with patients excluded only if they are unlikely to benefit from or are at risk of an adverse event related to the study intervention(s). Participants will be enrolled across a large network of sites and countries internationally, enhancing diversity and geographic reach.

Patient-facing documents including consent forms and videos, will be co-developed with our patient and public involvement (PPI) partners to ensure accessibility of information provided. These materials will be reviewed for accessibility with additional versions created as required with our PPI partners and country teams, for example low visibility or literacy, translations and cultural contexts.

Participant encounters such as consent and follow-up interviews will provide options for substitute decision maker (SDM) attendance and/or completion, translators and consider cultural sensitivity.

4. Involvement and Engagement

We will engage with patient and public groups that exist in participating countries, ELF European and non-European networks and establish an international group to improve EDI in our patient and public perspectives (PANTHER PPIE Strategy). We will work with our PPIE coordinators and patient organisations to facilitate additional languages at meetings and events, as required.

We will continue to garner wider opinions and understand participation barriers of patients, trial participants and the public through engagement activities, which may include public presentations/conferences, systematic reviews, focus groups, surveys and/or trial case report forms.

We will identify and engage with community organisations, liaisons and shared learning networks for under-served groups. We will host a community outreach event in select countries to discuss acute care medicine and ARDS clinical trials, platform trials, personalised medicine and trial participation in order to identify barriers and potential solutions to participation of under-served groups. We will invite interested community and faith leaders and event attendees to join our PPI group to empower

EDI within the platform.

5. Research

There are opportunities to conduct systematic reviews, studies within a trial (SWATs)[3] and long-term outcomes research, funding permitted, on inclusion and diversity within the PANTHER Platform, such as assessing barriers to participation, testing alternative approaches to recruitment and retention and /or communication. Sites with high levels of diversity or countries with indigenous communities among their patient population could be selected as the leading site(s) for such SWATs.

6. Dissemination

Clinical trials and their results are often not effectively communicated to patients and the public[4]. We wish to develop targeted multimedia dissemination to improve patient and public understanding of acute care medicine and ARDS clinical trials, in particular platform trials and personalised medicine including video, lay summaries and infographics with PPI members and dissemination through social media, a dedicated section of our website and PPI organisations/groups. We will aim to provide summaries for diverse participants to enhance inclusivity, guided by our PPI members and community organisations e.g. additional languages and cultural contexts, communication preferences, low literacy or vision. We will host patient and public conference(s) with our collaborating organisations (translated in multiple languages) and shared with diverse groups. We will engage with organisations working with underserved communities for advice on producing these documents and their appropriate dissemination means.

References

1. NIHR (2020) Improving inclusion of under-served groups in clinical research: Guidance from the NIHR-INCLUDE project. UK: NIHR. Available at: www.nihr.ac.uk/documents/improving-inclusion-of-under-served-groups-in-clinical-research-guidance-from-include-project/25435 (04/03/2025)
2. Wilson C, Rooshenas L, Paramasivan S, et al. Development of a framework to improve the process of recruitment to randomised controlled trials (RCTs): the SEAR (Screened, Eligible, Approached, Randomised) framework. Trials. 2018 Jan 19;19(1):50. doi: 10.1186/s13063-017-2413-6. PMID: 29351790.
3. Treweek, S., Bevan, S., Bower, P. et al. Trial Forge Guidance 1: what is a Study Within A Trial (SWAT)?. Trials 19, 139 (2018). https://doi.org/10.1186/s13063-018-2535-5
4. Bruhn H, Campbell M, Entwistle V, et al. What, how, when and who of trial results summaries for trial participants: stakeholder-informed guidance from the RECAP project. BMJ Open 2022;12:e057019. doi: 10.1136/bmjopen-2021-057019