PATIENT AND PUBLIC INVOLVEMENT ENGAGEMENT STRATEGY

For the

OXYGEN ACUTE THRESHOLD EVALUATION - GLOBAL TRIAL: (OXYGENATE-GLOBAL)

Version Number: v001

Date Approved: xx/xx/2025

Approved By: Leanne Hays

Effective Date: xx/xx/2025

1. SCOPE

This strategy applies to Patient and Public Involvement and Engagement (PPIE) within the OXYEGNATE-Global trial (a multicentre randomized phase III trial of conservative versus liberal oxygen therapy in hospitalized patients on non-invasive respiratory support).

2. PURPOSE

The purpose of this document is to outline the PPIE objectives of the OXYGENATE-Global trial, the strategy to achieve these objectives, and to guide the use of resources and activities.

3. STRATEGY

It is the strategy of the OXYGENATE-Global trial to embed meaningful PPIE to inform all stages of the trial. This strategy will guide activities to involve and engage patient and public contributors.

4. ROLES AND RESPONSIBILITES

The OXYGENATE-Global PPIE working and advisory groups with the overall steering and management groups are responsible for the application of this strategy. These group(s) include patient and public contributors, PPIE leads and coordinators in Ireland, Pakistan, national and international teams.

These groups will interact with other members and committees, where relevant, particularly the Equality, Diversity and Inclusion working group.

5. OVERARCHING STRATEGY

Introduction

Patient and Public Involvement is research being carried out 'with' or 'by' patients and members of the public rather than 'to', 'about' or 'for' them (https://www.nihr.ac.uk/get-involved/public-involvement). It is an equal partnership with two-way dialogue between researchers, patients and their family with lived experience of the condition and the public. This strategy details an international programme with the objective that OXYGENATE-Global is patient-centred, acceptable, accessible and important to patients and the public.

1. Involvement & Engagement

We will involve individuals with lived experience of respiratory support, hospital and / or ICU admission as patients, their family, friends and carers, members of the public and community leaders. We will leverage our international network of PPI groups in participating countries including Ireland, Pakistan and other low- and middle- income countries (LMICs) and our established Global Critical Care Patient and Public Advisory group with members from 5 countries including Ireland, the UK and Pakistan. We will also engage relevant patient charities and PPI organisations to widen our reach. We will support additional countries / regions to establish PPI groups to inform local processes, invite members to join the global group and continually involve new members during the trial. This will support our aim to improve inclusion and diversity within PPIE, aligned with our EDI Strategy.

Our PPI groups will inform the design, conduct and dissemination of the trial. They will be integral to our consent process and dissemination strategy, co-designing patient and public-facing materials.

Guided by our PPI groups, PPI contributors will be invited to join trial governance committees providing oversight and informing trial decisions.

Members will be reimbursed for their time in line with local / national guidance (PPI Ignite, Ireland), and any associated travel and expenses. PPI members will be recognised for their contributions, for example as co-authors / collaborators. Members will be invited to attend national and international meetings and conferences. We will maintain PPI logs of activity and impact and report using the GRIPP2 framework.

As involvement is typically limited to smaller groups, we will complement our PPI with patient and public engagement. Engagement is one-way exchange of information, including receiving information e.g. through public surveys and focus groups, or providing information e.g. public presentations, conferences. This will allow us to assess broad opinions of respiratory and ICU trials, further disseminate our trial, improve public patient understanding and thus, optimize participation from all perspectives.

2. Dissemination

Clinical trials are often not appropriately disseminated to patients, participants and the public. OXYGENATE-Global will co-develop a dissemination strategy with our PPI contributors. This will include the use of videos, infographics, with clear, visual and lay summaries. Dissemination through a variety of media will optimise reach such as media, social media, specific website landing pages for patients and their families, public presentations, conferences, newsletters and PPI groups, as examples, and dissemination through collaborations with key groups, charities and organisations. Materials will be adapted for diverse cultures, communication needs and translated into additional languages to improve accessibility of this global trial.

3. Support & Training

We will identify contributor support and needs at involvement start (adapted 'My Involvement Profile') with periodic assessment for any changes to ensure members are supported. PPI contributors will be offered training through existing programmes (e.g. PPI Ignite, https://www.learningforinvolvement.org.uk/). Education on a new topic is provided before discussion at meetings with tailored additional support and training provided based on contributor needs at and in between meetings. Participation in trial committees is supported by pre-meeting and debrief sessions with support during by the dedicated PPIE lead(s) and trial team. Conference, meeting and other opportunities will be shared.

4. Trial Processes

While not PPIE, research activities that aim to improve trial participation and experience for patients, families and PPI contributors are mentioned here. Depending on funding, we may conduct a study within a trial (SWAT), systematic reviews, public survey, focus groups and data analyses alongside the main trial. Research could assess participant, patient, family and public perspectives of respiratory trials. They could include assessment of different methods and tools to improve consent, dissemination, trial inclusion and diversity, improving future processes