

# **SWAT 228: Feasibility and usability of the TMRN-TMRP communication wheel for trials: A non-randomised SWAT process evaluation using RE-AIM**

## **Objective of this SWAT**

To evaluate the feasibility and usability of the TMRN-TMRP communication wheel for developing a trial communication plan in the real-world setting.

## **Additional SWAT Details**

Primary Study Area: Trial Design

Secondary Study Area: Qualitative, Communication strategy

Who does the SWAT intervention target: Trial Team, Researchers, PPI Personnel

Estimated resources needed to conduct the SWAT: Medium

Estimated cost of the SWAT (£): 10,000

## **Findings from Implementation of this SWAT**

Reference(s) to publications of these findings: N/A

Primary Outcome Findings: N/A

Cost: N/A

## **Background**

Communication is a crucial aspect of a clinical trial's lifecycle. It transcends all clinical trial stages, from decisions over research priorities, and all aspects of trial design, analysis and reporting, right through to dissemination. It was identified as a key priority by the Trial Conduct Working Group of the Trials Methodology Research Partnership (TMRP) in the UK. A sub-working group (SWG) was established in April 2020 to refine and progress the communication research agenda and they identified two priorities: 1) determining key communication stakeholders, and 2) identifying when to interact with each stakeholder during the clinical trial cycle. Members drafted and refined the TMRN-TMRP communication wheel, to answer these priority questions [1]. After multiple iterations, the SWG decided to test its usefulness in a trial setting. This SWAT will assess the effectiveness of the TMRN-TMRP communication wheel in assisting the design and implementation of the communication strategy for the BONANZA-GT trial.

Host Trial Population: Adults

Host Trial Condition Area: Critical Care

## **Interventions and Comparators**

Intervention 1: We will use the RE-AIM framework to plan the intervention and process evaluation. The planning tool on the RE-AIM website [2] will guide us with questions at each stage, e.g., who, and how, we plan to reach in the intervention?

The TMRN-TMRP communication wheel will be used at the initial trial team meeting for BONANZA. The trial principal investigator will distribute the wheel to all members of the trial team, public patient representatives, and lead the discussion to develop the communication strategy for the BONANZA-GT trial. The meeting will be audio/video recorded for evaluation.

Method for Allocating to Intervention or Comparator: Not applicable

## **Outcome Measures**

Primary Outcomes: Usefulness of the TMRN-TMRP communication wheel for developing the trial communication strategy.

Secondary Outcomes: Number of times the TMRN-TMRP communication wheel was referred to during the BONANZA-GT trial team meeting.

## **Analysis Plans**

1. The analysis will be both qualitative (primary outcome) and quantitative (secondary outcome). The trial team meeting will be recorded and transcribed and we will analyse how the wheel was used and referenced during the writing of the trial communication strategy.
2. The discussion with the SWAT principal investigator, after the trial team meeting, will be recorded and transcribed and analysed thematically.
3. All comments and analyses will be collated and used to update the communication wheel.
4. Process Evaluation Implementation and analysis: At meeting's end, the SWAT principal investigator will lead a discussion using a pre-prepared topic guide to evaluate the wheel's effectiveness, usability, appropriateness of stakeholders and stages of communication, and its impact on the communication plan. We will also seek feedback and recommendations for improvements. The principal investigator and co-applicants will discuss an update to the communication wheel based on feedback.

### **Possible Problems in Implementing This SWAT**

This is a low-risk SWAT which involves trial team members, including PPI members. We do not anticipate problems. However, it is critical this SWAT is implemented at the early stages of the design meetings for the host trial.

### **References Cited in This Outline**

1. [https://www.hrb-tmrn.ie/2024/02/01/tmrn\\_tmrp\\_comms-wheel/](https://www.hrb-tmrn.ie/2024/02/01/tmrn_tmrp_comms-wheel/) (accessed 17 June 2024).
2. <https://re-aim.org/applying-the-re-aim-framework/re-aim-guidance/use-when-planning-a-project/planning-tool/> (accessed 17 June 2024).

### **References to This SWAT**

None

### **Source of This SWAT**

People to show as the source of this idea: F Shiely, C Lonergan, A Sharry, A Nichol, A Willis, V Russell, S Faisal, A Parker, Ahern J, Conlon E, S Treweek, L Hays, on behalf of the Communication Sub-working Group of the MRC-NIHR-TMRP.

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