

## Chapter 2

### **Trials Methodology Research**

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#### **Summary**

This chapter addresses trials methodology research (TMR) as an embedded feature of clinical trials training. Trials Methodology Research is about looking at the way health research is conducted, i.e., improving the tools and trade of research practice. Its purpose is to strengthen the methodology and reporting of clinical trials. There are specific challenges in clinical trials which affect the efficiency and internal and external validity of trials: recruitment, retention, patient and public involvement throughout the lifecycle of the trial, outcome selection, reporting and dissemination of trial results, to name but a few. This chapter will address these issues, and train the student on methods of addressing these challenges through evidence based research alongside, or within (SWATs - Studies Within A Trial) clinical trials. The students will learn about existing priorities in recruitment and retention, developed via a priority setting partnership, and how best to address incorporating these challenges in the design of their trial.

#### **Aim**

The purpose of this chapter is to introduce students to the concept of trial methodology, the science of research on research to make trials more efficient.

#### **Methods**

E-learning materials (study materials, links to publications), quiz questions, discussion boards.

#### **Learning Outcomes**

Students will

1. Describe and explain what the concept of trials methodology research
2. Explain the benefit of trials methodology research to the conduct of clinical trials
3. Identify key priorities in trials methodology research
4. Identify unresolved methodological challenges in clinical trials
5. Discuss the benefit of priority setting partnerships for TMR
6. Explain what is mean by a SWAT
7. Design a SWAT (Study Within a Trial) using the protocol provided
8. Discuss the advantages of SWATs
9. Identify when no more SWATs are needed

#### **Complementarity to CONSCIOUS I Materials**

This is an original chapter and was not taught in the CONSCIOUS project.

## Content

- 1 Introduction to the chapter
- 2 Introduction to Trials Methodology Research
  - 2.1 Trials Methodology Research Definition
- 3 The Trials Methodology Research Agenda
  - 3.1 The Delphi Method
  - 3.2 Key Characteristics of the Delphi Method
  - 3.3 What happens when the findings of our research are not published?
- 4 Priority Setting Partnerships (Priority I – unanswered recruitment priority research questions)
  - 4.1 About PRioRiTty I
  - 4.2 PRioRiTty I Methods - The Workshop
  - 4.3 PRioRiTty I Methods and Results
  - 4.4 Top 10 Research Priorities in Recruitment
- 5 Priority Setting Partnerships (Priority II – unanswered retention priority research questions)
  - 5.1 PRIORITY II Methods and Results
  - 5.2 The Priorities in Retention in Trials
- 6 Priorities for Methodological research on patient and public involvement in clinical trials
  - 6.1 The Patient's Perspective
  - 6.2 The METHODICAL Study
- 7 Studies within a Trial (SWATs)
  - 7.1 What is a SWAT
  - 7.2 Why Do We Need SWATs?
  - 7.3 What Are the Key Features of a SWAT?
  - 7.4 How Can We Encourage People to Do SWATs?
  - 7.5 What Would Make Doing SWATs Easier?
  - 7.6 Case Study of a successful SWAT, i.e. when another SWAT is not needed
  - 7.7 Trial Forge Guidance 2: how to decide if a further SWAT is needed
  - 7.8 Practical Things to Consider When Conducting A SWAT
  - 7.9 Writing a SWAT protocol
- 8 Conclusion