

# **SWAT 38: Cost implications of conducting a risk assessment prior to developing a monitoring plan for a multicentre clinical trial**

## **Objective of this SWAT**

Assess the cost implications of conducting a risk assessment prior to developing a monitoring plan for a multi-centre clinical trial, and examine if sites that conducted a risk assessment prior to developing their monitoring plan have less protocol violations compared to the sites that did not conduct a prior risk assessment.

Study area: Monitoring, Data Quality

Sample type: Participants, Researchers, Trial Team

Estimated funding level needed: Unfunded

## **Background**

Risk assessment is the cornerstone to risk-based monitoring (RBM) in clinical trials. When developing a RBM plan, the trial's protocol must first be assessed to identify risks within the trial that can be mitigated through monitoring. These risks primarily relate to the rights, safety and well-being of trials subjects, the Investigational Medical Product (IMP) where relevant and the likely credibility of the trial's eventual findings. A number of risk assessment tools have been developed to help clinical researchers conduct RBM. These tools support the assessment of risk in a clinical trial and provide guidance for subsequent monitoring activity that can mitigate the identified risks. Research is needed to examine if RBM strategies directed by risk assessment tools are non-inferior to traditional on-site monitoring using source data verification. This SWAT will compare the cost benefit of RBM and traditional monitoring simultaneously in a single trial: the TRUST Thyroid Trial. This is a randomised trial to compare thyroxine replacement versus placebo in 540 community dwelling adults aged  $\geq 65$  years with subclinical hypothyroidism (SCH). It has four study sites in Ireland, Switzerland, Scotland and the Netherlands. A risk assessment was performed by two of the participating countries (UK and the Netherlands) using risk assessment tools before developing and implementing their monitoring plan, while the other two countries (Ireland and Switzerland) did not perform a risk assessment prior to performing monitoring activity.

## **Interventions and comparators**

Intervention 1: Intervention group: Performance of a risk assessment prior to developing the monitoring plan (as done in the UK and the Netherlands).

Intervention 2: Control groups: No risk assessment prior to developing the monitoring plan (as done in Ireland and Switzerland).

Index Type: Method of Monitoring

## **Method for allocating to intervention or comparator**

Non-Random

## **Outcome measures**

Primary: 1. Costs (including staff time (i.e. manager or monitor) to complete the risk assessment; cost of risk assessment tool cost and any associated consumables; costs of on-site visits; time taken by trial staff and external monitors to correct protocol violations);

2. Protocol deviations in the trial (including inadequate or fraudulent informed consent; failure to meet inclusion/exclusion criteria; unreported serious adverse events; improper breaking of the blinding process; use of prohibited medication; incorrect or missing tests; mishandled samples; multiple visits missed or conducted outside permissible windows; materially inadequate record keeping; intentional deviation from protocol, Good Clinical Practice, or regulations by study personnel; and repeated non-compliance with study requirements in the same participant).

Secondary:

## **Analysis plans**

Cost-benefit analysis will be performed using standard methods.

## **Possible problems in implementing this SWAT**

We envisage no problems. A fuller protocol for the SWAT has been approved by the members of the TRUST Thyroid Trial publication committee.

## **References**

### **Publications or presentations of this SWAT design**

The completed SWAT will be submitted to Contemporary Clinical Trials for publication in 2017.

### **Examples of the implementation of this SWAT**

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