

# Why should I consider embedding a SWAT in our trial?

## What is a SWAT?

SWAT stands for a 'Study Within A Trial' and it is a research study that is embedded within a larger host trial.

The aim of a SWAT is to evaluate or investigate different methods of organizing or delivering a specific trial process such as recruitment or retention.

## Why do we need to do SWATs?

Randomised trials are central to providing health care evidence that helps patients, clinicians and policy-makers to make evidence-informed choices about treatments and therapies. However, when it comes to making decisions about the design, conduct and reporting of randomised trials themselves, there is scant evidence to support them.

This means that trial process decision-making is largely based on instinct and experience, not evidence. Sometimes this is fine, sometimes it isn't. Without evidence it's hard to spot the difference before it's too late.

One way of building an evidence-base to support trial process decisions is to do a SWAT because they provide an opportunity to evaluate alternative options when conducting a trial process (e.g. patient recruitment, patient retention, reporting the findings) to provide much needed evidence about how the trial process can be improved.

## Key features of a SWAT

- Embedded within a host trial.
- Aims to resolve crucial uncertainties about trial processes.
- Does not impact the scientific integrity or outcome of the host trial
- Has a formal protocol.
- Can be evaluated in one trial but is also suitable to be conducted across numerous host trials either simultaneously or sequentially.
- As well as generate data for the future design and conduct of trials, SWATs can also provide data to improve decisions about the host trial it is embedded within.



[www.hrb-tmrn.ie](http://www.hrb-tmrn.ie)



[www.trialforge.org](http://www.trialforge.org)

Looking for SWAT inspiration? Have a look at the SWAT repository:

<https://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/SWATSWARInformation/Repositories/SWATStore/>

<https://doi.org/10.1186/s13063-018-2535-5>



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# Practical things to consider when planning a SWAT

## Cost

- Relatively inexpensive. SWATs tend to cost between £5,000/€5,500 and £10,000/€11,000. Ideally, SWATs should be included in the host trial from the beginning.

## Randomisation

- Depends largely on whether the SWAT question is focusing on measuring effect sizes. If it is looking at the effect of alternative methods of conducting a trial process, randomization should be considered. If the SWAT is not aiming to measure an effect size, it is highly likely there will be no need for randomisation.
- SWAT randomisation can be carried out separately to the host trial randomisation.

## Ethics

- Ethical approval guidelines for conducting research in humans can differ between countries so it is advised that researchers check national guidance.
- Likely that some SWATs will require ethical approval.
- In the Republic of Ireland, there is a system of national approval for trials of medicinal products but not for non-medicinal products and, therefore, for the latter ethical approval is usually sought from sites conducting the host trial and/or from the SWAT principal investigator's host institution.
- SWATs are generally low-risk and rarely add extra risk for participants so it is not normally necessary to get participant consent.
- SWATs focusing on staff but which directly impacts patients / participants (e.g. how information is delivered to participants), may require ethical approval.

## Analysis

- Generally simple so can be carried out by any member of trial team rather than a senior member or Principal Investigator.
- SWAT sample size calculations can be done in the normal manner using estimates of minimum important differences that the investigators believe are appropriate.
- For qualitative SWATs, a suitable qualitative methodological framework and methods should be applied.

## Implementing the SWAT

- SWATs generally do not need to run for the full duration of the host trial so any extra work should be modest and short-term.

## Publication

- SWAT findings should be put into the public domain and be accessible to others whether this is through being included in the host trial report, a separate publication or being included in a relevant systematic review.

### Adapted from

Treweek S, Bevan S, Bower P, Campbell M, Christie J, Clarke M, Collet C, Cotton S, Devane D, El Feky A, Flemyng, Galvin S, Gardner H, Gillies K, Jansen J, Littleford R, Parker A, Ramsay C, Restrup L, Sullivan F, Torgerson D, Tremain L, Westmore M, Williamson PR. Trial Forge Guidance 1: what is a Study Within A Trial (SWAT)? *Trials*. 2018;19:139.

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