TRIAL FORGE
SWAT Network

UNIVERSITY of York

SWAT DESIGN

SWATs often need to be repeated in several host trials to ensure sufficient statistical power from meta-analysis to answer the question.

SWATs can test the same intervention in several host trials running at the same or similar times (coordinated) or at different times (individual). Putting the same SWAT into numerous host trials all running at the same time (coordinated-simultaneous) gives faster answers but requires coordination.

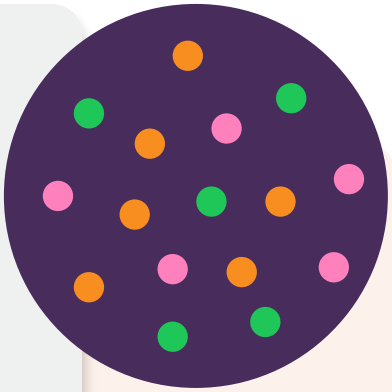
Here, we describe four key things to consider when designing a SWAT, whether it is a novel SWAT or a SWAT replication (i.e., that may be embedded across multiple host trials):

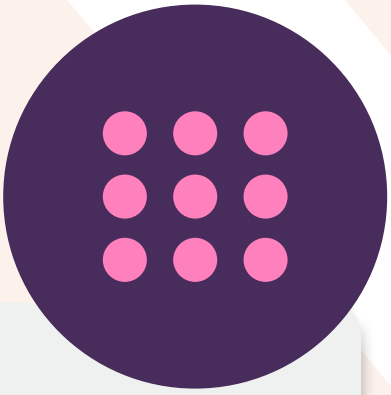
A. Randomisation: SWATs can be randomised or non-randomised depending on the research question.

Randomised SWATs

1. **Individual randomisation** is usually most suitable for interventions targeting trial participants, e.g., do text message pre-notifications boost participant questionnaire completion rates? With individual randomisation, participants are allocated to text pre-notifications (intervention) or no pre-notification (control).
2. **Randomisation by site** may be better for interventions focusing on on-site processes, e.g., assessing the impact of recruiter training on participant recruitment. Individual randomisation may introduce bias, and so randomising all recruiters in the same site to receive either the intervention or control would be best.

Randomisation can generally be independent and separate from the host trial's randomisation and can occur during the main trial recruitment or closer to the time point of interest.





Non-randomised SWATs

Not all SWATs use a randomised study design. SWATs can also be in the form of a qualitative study design, or a before and after study (observational) amongst others. For example, understanding motivators impacting trial participation is likely to be best completed using a qualitative non-randomised approach.

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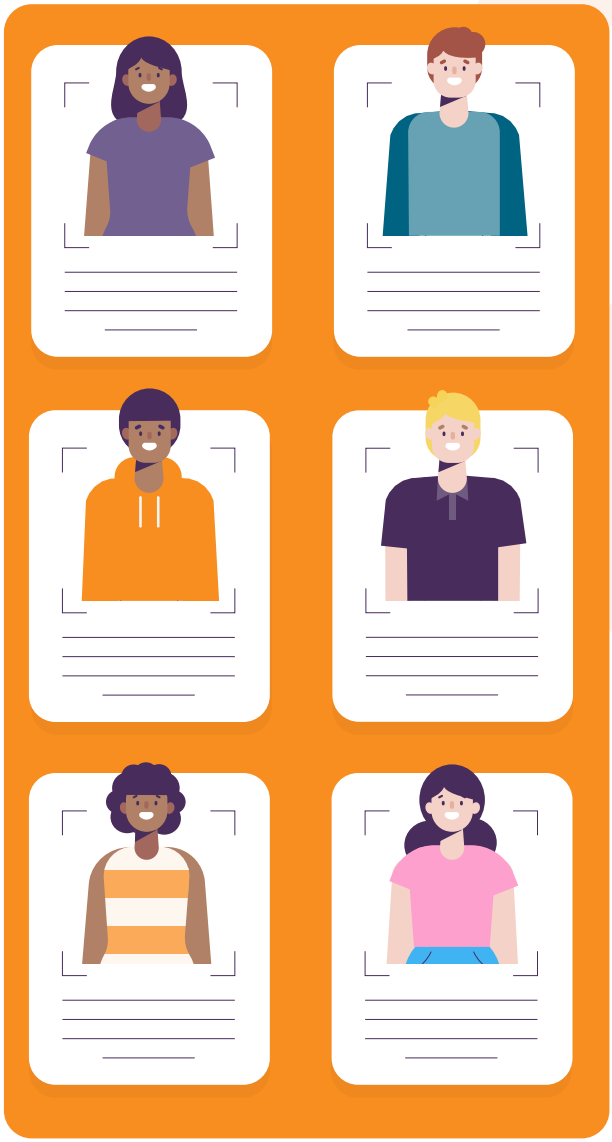
B. SWAT Replication: SWATs should be designed with meta-analysis in mind, to ensure there is enough data to answer the SWAT question.

This is important because:

- SWAT sample sizes are often limited by the host trial and may only contain a subset of the participants.
- Replications across diverse host trials and/or patient populations can improve generalisability and validity.



Deciding when to replicate a SWAT

Trial Forge Guidance 2 propose five criteria for deciding whether SWAT replications are needed:

- Is it very unlikely that further research would change confidence in the estimate of effect?
- Has cumulative evidence converged for this SWAT?
- Is the SWAT applicable in a range of host trials (use **PICOT** to answer this)?
- Is there a balance of benefits and disadvantages of the SWAT for participants?
- Is there a balance of benefits and disadvantages of the SWAT for the new host trial?

The cost-effectiveness of the SWAT should also be considered when evaluating the need for additional replication.

C. Outcomes and analysis: When replicating an earlier evaluation, the same outcomes and analysis techniques should be used to make it possible to combine results in a meta-analysis. Some outcomes and analyses that are commonly used include:

SWAT Type	Outcomes	Analysis
Recruitment	• Proportion of eligible participants consented. • Proportion of consented participants randomised.	Outcomes are typically binary, so using logistic regression that is adjusted as appropriate (i.e., clustering) would be suitable. Report as Odds Ratio and 95% Confidence Interval – or appropriate alternatives.
Retention	• Proportion of participants retained. • Completeness of returned data (e.g., questionnaire). • Number of reminders. • Time it takes to respond to questionnaires (after a reminder for instance).	Binary outcomes analysed using logistic regression, time-to-event data using Cox Proportional Hazards regression, and count data using Poisson models - or others as appropriate. All models should be adjusted appropriately - typically this would include any randomisation stratification variables and the host trial allocation. Results should be reports as the relevant statistic (i.e., Odds Ratio), and 95% Confidence Interval.
Qualitative	• Participant experiences (e.g., of the recruitment process).	Thematic analysis.

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C. Costs: An overview of associated costs or cost analysis is also useful. This may include a breakdown of costs or an additional cost per participant. SWATs may test changes to existing trial documentation or processes and do not need to be expensive.

Costs to consider include:

- Materials and resources required.
- Staff time to design the SWAT, randomise participants, prepare and/or deliver the intervention and complete the analysis.
- Publication costs.

Overall, if you apply these principles, you can design SWATs that are both impactful and cost-effective.

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