TRIAL FORGE
SWAT Network

UNIVERSITY of York

SWAT DELIVERY

To ensure the smooth delivery of your Study Within A Trial (SWAT) you should consider:

Patient and Public Input: Patient and Public Involvement (PPI) is very important when planning a SWAT, just as it is in trials. This can help to develop or modify the SWAT intervention, so it is suitable for the patient population.

This may be people with the relevant condition, their carers or in trials including children, PPI could be family members (e.g., parents, siblings, guardians, and carers). PPI members can be involved in various phases of SWAT planning. For example, in a SWAT of information materials, they can contribute to the development of these, using their insights to ensure that the content in these documents is relevant to participants.

Additionally, PPI can also help researchers decide if participant information sharing or consent for the SWAT is required.

Navigating Ethical/Approval Pathways: Most SWATs need research ethics approval however some SWATs may not require approval:

Is ethical approval required?	Possibly not	Yes
SWAT Type	Operational or study management SWATs, which usually involve trial staff. Although these SWAT interventions may affect participants, they focus on activities typically handled by the central trial team and so do not need to be described in detail in a host trial protocol and may not require prior approval.	SWAT interventions that likely change the design of the host trial. These SWAT interventions will possibly change the design of the host trial, change procedures undertaken by participants, or the information received by participants.
Example	A SWAT that will assess the effectiveness of different methods of training recruiters about the study e.g., training face-to-face vs training via video conferencing.	A SWAT that will assess the effectiveness of a participant information sheet developed by the trial team, versus one developed with PPI, on trial recruitment.

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SWATs can be included in the main host trial approval, or separately as part of an amendment:

	Pros	Cons
Included in the main host trial approval	You can include all the information and context of the SWAT study in one document and get approval for both studies at once.	• If you want to make an amendment to the SWAT, the entire host trial protocol may have to go back through ethics. • Reviewers who are unfamiliar with SWATs may raise queries about participant consent/ information if the amendment solely focuses on the SWAT.
Included seperately as part of an amendment	• The SWAT can be included at any point in the trial. • Amendments to the SWAT protocol will not affect the host trial's document.	• Additional staffing time is required to submit an amendment • Reviewers who are unfamiliar with SWATs may raise unnecessary queries about participant consent /information if the amendment solely focuses on the SWAT.

Top "approval" tips:

- Be sure to differentiate between what is part of the SWAT and what is part of the host trial.
- Note if the SWAT has previously been approved and conducted by someone else.
- Before submitting to an ethics committee, teams are advised to discuss the need, or not, for consent with the study PPI group, other relevant stakeholders, and/ or the appropriate ethical bodies (e.g., HRA, REC) whilst reviewing other elements of the SWAT and reflecting on this discussion.
- Alternatively, allowance can be made in the host trial protocol to provide appropriate consent for SWAT inclusion. For example, if the host trial has obtained consent to contact a participant by a range of methods (e.g., postal, email, telephone, SMS) then this would cover SWAT interventions such as newsletters, different cover letters, or SMS reminders.
- It is important to understand that there are different types of sponsor behaviours when it comes to embedding SWATs. There are sponsors who are knowledgeable about SWATs and have no difficulty in including them, and there are sponsors who are not familiar with SWATs and may be hesitant to incorporate them, especially considering that SWATs are often methodological rather than clinical. Knowing the type of sponsor being dealt with can help the research team approach them in the right way to obtain governance approval.

Sponsor Approvals: SWATs will usually require research governance approvals prior to implementation. Research governance can differ based on whether the SWAT is embedded within a single trial or across multiple trials.

- For an individual SWAT in a single host trial, it is recommended that the sponsorship of the host trial should also cover the SWAT.
- Where a coordinated SWAT evaluation is to be undertaken across multiple host trials sponsorship arrangements can be more complicated given the number of host trials involved and that many, if not all, may have different Sponsors. It may be preferable for the coordinating institution to cover the sponsorship for the SWAT.
- Where evaluation is to be conducted across multiple trials, Sponsors may also need to consider the provision of funding, data sharing or collaboration agreements accordingly.

Registering SWATs

Why register SWATs?

- To make it known to the broader research community which SWATs have been proposed or are ongoing.
- To facilitate SWAT replication.
- To enable coordinated conduct of future SWATs to fully answer questions.
- To facilitate transparency in research.

Where to register? The **SWAT repository** is the best resource for this.

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Analysis

As with any analysis undertaken within trials, the analysis of a SWAT should be pre-planned, and detailed within a Statistical Analysis Plan (SAP). This SAP can be contained either within that of the host trial or separately, but written prior to doing the analysis.

Analysis is often simple and so while this can be completed by a Statistician, it is also possible for other researchers or students to complete this.

Statistical considerations for SWATs: Due to the sample size of SWATs often being constrained by the size of the host trial, SWATs should be designed with meta-analysis in mind. This will ultimately ensure there is enough data to answer the SWAT question and that the results are reliable and generalisable. Therefore, if a SWAT is a replication of an existing SWAT, a meta-analysis combining all available data should be completed as part of the analysis.

Monitoring

Adherence to an intervention should be monitored throughout a trial; the same applies to SWAT interventions.

It is recommended to plan the SWAT intervention delivery monitoring from the outset, particularly for technology-based interventions especially if it is automated or delivered by a third party. This ensures that the intervention is carried out as intended.

To illustrate this, consider a SWAT intervention where an automated text message prompt is to be sent out to participants ahead of the research team sending out questionnaires. To ensure appropriate SWAT delivery, effective planning should involve contingency strategies for scenarios like participants providing incorrect phone numbers or expressing a desire to stop receiving text messages.

Overall, it is important that researchers complete and integrate effective assessments and monitoring from the beginning of the study, rather than act in response to technological issues that may arise later.

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