

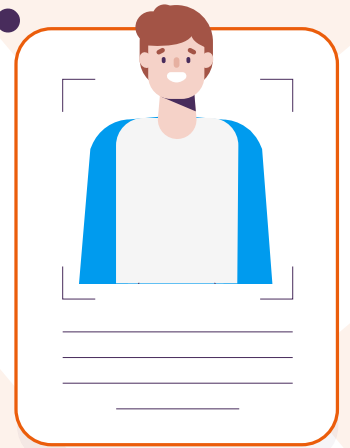
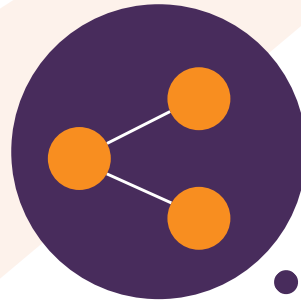
SWAT DELIVERY

Researchers need to think about some important things to make sure a Study Within a Trial (SWAT) works well. These important parts of a SWAT help make the study go smoothly and give the best results. Here are some things they may consider:

Patient and Public Input: Getting the input of patients and members of the public (PPI) is very important when planning a SWAT, just like in bigger (main) trials. PPI can help researchers to create or change a SWAT, so it is agreeable for the study participants. PPI can be people with the relevant condition (i.e., the one being studied in the main trial), family, members of the public, doctors, and so on.

Let's look at an example of what this means: In a study involving children, PPI may include family members like parents, siblings, and caregivers. The PPI members might work with researchers to create information materials that explain what participants and their families need to know before joining the study. Their advice can help to ensure the right information is included to support participants and their families in feeling more informed and confident to join the study.

Also, researchers are usually advised to seek PPI insight on if and when to provide participants with information materials or consent for the SWAT.



Navigating Ethical/Approval Pathways:

When we want to do something important, we often need to ask for permission. For instance, in many workplaces, you will need permission from a senior colleague, to take time off for a holiday. This logic applies to research as well. When you want to do a SWAT, you would need permission which is called Research Ethics Approval, which serves as a "go ahead" to do your SWAT.

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

Is research ethics approval required?	Possibly Not	Yes
SWAT Type	SWATs that mainly involve trial staff operations.	SWATs that change the design of the host trial.
Explanation	<p>Now, even though these types of SWATs may affect the trial participants, they do not affect them directly.</p> <p>They usually just focus on the research team (or trial staff) that are managing the day-to-day activities of the SWAT.</p>	These SWATs may make the main study work differently or may change the experience participants receive such as changing the participant information material from paper to video.
SWAT Example	A SWAT that is trying to find out what method of training recruiters about a study is the better. This can help researchers answer the question: Is it better to train recruiters face-to-face or train via video conferencing?	A SWAT that is trying to see if how they tell people about a study affects how many people join it. This can help researchers answer the question: Is it better to show videos or give out paper information to explain the study?

But where does the SWAT approval fit in a trial document e.g., protocol?

When we apply for approval, we may include the SWAT in the main study approval or add it separately as a study change.

There are pros and cons to each approach, for example, if included in the main study approval this means one approval covers all study elements, however, if changes are needed it may mean changing the main study plan too. Including it as a separate change can be more time-consuming but means study teams can include this at a time which is right for the main trial.

Sponsor Approvals

SWATs will require permission from a research governance team(s) before it can start. These team(s) (called Sponsors) are responsible for how the research is done, and to ensure that everything is completed correctly. Research governance can differ depending on the SWAT.

- If a SWAT is happening within one host trial, it's usually a good idea for the main trial's sponsor to also cover the SWAT.
- When a SWAT involves many different host trials, each might have their own Sponsor. In this case, it might make sense for the organiser of the SWAT to approach their Sponsor to oversee the whole thing.
- Also, Sponsors might also need to think about providing money, sharing data, or an agreed way to work together.

Top “approval” tips

- Explain what is part of the SWAT and what is part of the main study.
- It is always a good idea to check if other people have already gotten permission to do a SWAT like yours, so you can learn from them.
- Before going to a Research Ethics Committee for approval, it is good practice to talk about your SWAT with PPI or other people who know more about SWATs, or other people that know more about approvals, and seek their advice.
- If the main study already has research ethics approval for the planned SWAT intervention, this approval can also cover the SWAT. For example, if the main study has already taken permission to contact participants through various means such as via post, telephone, email etc then including a SWAT of participant newsletters, text messages would be covered by the existing approval.
- It is important to talk to study Sponsors (i.e., those in charge of the main study) in a way that helps them understand why a SWAT is important. This is because some study Sponsors already know a lot about SWATs and their benefits to research, so they easily say yes if the trial team want to include a SWAT in the main study. However, some Sponsors do not know enough about SWATs so they might not readily approve the inclusion of a SWAT.

Registering SWATs: It is important to register a SWAT as this means other people in the research community can know about your SWAT and can think about how it can affect their plans. They might be able to use the findings to inform their trial or may want to repeat the SWAT in their trial so we can be more confident of the findings. **The SWAT repository** is the best resource for this.



THE **SWAT** REPOSITORY

Monitoring: Making sure the SWAT is going as planned!

To run a smooth and successful main study it is essential that everything is planned and checked at every point in the study.

Researchers are advised to plan these checks (monitoring) before the study starts, especially if the SWAT is using technology (e.g., sending an automatic reply to an email).

This pre-planning process will ensure that the SWAT goes as planned.

Let’s look at an example: Imagine a SWAT testing the use of automatic text messages to make participants aware that they will soon be receiving questionnaires from the main study. Now, to make sure everything goes well, the research team needs to have backup plans in case for

example participants give the wrong phone number, or do not want to receive those messages again. This is so there is always a plan to handle the situation when a problem arises.

In summary, it is important that researchers plan and do regular checks from the start of the SWAT, and not just when there is a problem during the study.

Analysis: Before you can answer your SWAT question, it is good practice to have a plan in place on how you will analyse the SWAT data you plan to collect.

This plan is commonly known as the Statistical Analysis Plan (SAP) in the research community, and it is often written by a Statistician. This SAP can be a part of the main study plan or in a separate document, but what is most important is that it is ready before researchers start looking at the SWAT data they have collected.



Who does the SWAT analysis?

SWAT analysis is often simple, so while this can be done by a Statistician, it is also possible for researchers or students to do this.

What statistical analysis plans do you need to consider for SWATs?

SWATs have a limited number of participants, often because they can only have as many participants as their main study. For example, if the main study recruits only 100 participants, the SWAT can only have a maximum of 100 participants. But these numbers are usually not enough to answer the SWAT question.

So, it is a good idea to plan your SWAT such that it can be repeated (replicated) in other studies. This can help ensure that we can confidently say the strategy tested in the SWAT work, and that it works for a wide range of people.

Finally, if there have been multiple replications of a previous SWAT, researchers collect all the information from all SWATs and analyse it together. This way, they get a clearer picture of how well the SWAT works or does not work.

