

AstraZeneca: Propose a tool to capture information during a brainstorming session

Designing a clinical trial is a highly interactive and iterative process. The study design team leader runs a series of design meetings with a variety of contributors to brainstorm ideas for the trial goal (ex. reduce pain) and to figure out considerations like patient population, dosage amounts, geographical location, etc.

It is very important that the discussions at these meetings are fully documented so that the rationale for settling on a certain option for patient population/dosage etc can be referenced at a much later stage of the clinical trial process when the study design has to be defended during the formal reporting of study results.

There will be occasions when design discussions occur outside of a formal design meeting and these also need to be captured somehow. There is also often the need to reference/attach journal articles/industry guidelines etc. It is very difficult for the study design team leader to capture the discussions (usually very wide ranging) in real time while also being a key contributor to the brainstorm discussions. The study design team leader also needs to be able to sort, categorize and summarize the information after each meeting. In the past, we tried building a tool to help study design team leader capture and record information from these clinical trial design brainstorming sessions. The tool failed because it was too complicated. It prevented the study design team leader from quickly and easily capturing information in the chaotic environment of a design trial meeting. We want a solution that lets the study design team leader actively participate in the meetings (like the leader of a fun brainstorm) but also makes it easy to capture all the information so it can later be sorted and summarized.

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