FAQs: Creating an FDA-Ready Moderator's Script for your Human Factors Validation Study

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When considering the labeling, it may be possible to use "near final" labeling. Is it possible to perform Human Factors (HF) testing using the Instructions for Use (IFU) without the final clinical trial results since those results would be less likely to facilitate how the product is used?

Yes—as long as that data doesn't change the instructed procedures or injection sites, you don't need the final clinical trial results. Everything related to use of the product is already developed.

Is independent or third-party moderation required, or can a sponsor perform the moderator role themselves?

There is no formal requirement from the FDA about who executes or moderates a validation study. However, for best results, an HF validation should be designed, carried out, and reported by HF professionals. If the sponsor organization has an internal HF professional, they can moderate the study.

How do you disposition unanticipated events if they occur in your study analysis and report?

Unanticipated events are still a use error, but they require more explanation of the reasoning and context. The FDA also wants to see these unanticipated use errors added to the URRA.

How would you design a validation study for technology that is meant to be used by a team (i.e., multiple users working interdependently and synchronously)?

The design will depend on the complexity of the product. Highly complex products with multiple users involved will be very time-consuming since there are many scenarios and tasks to cover. It is generally most effective to have separate scripts and sessions for the different groups involved, especially when their roles do not overlap. If the roles overlap and coordinate, then a team session is required, though you should have separate observers and metrics for each team member.

Regarding the final subjective question ("Do you think you could safely and successfully prepare and dose with this product if you needed to?"), are participants actually comfortable saying "no"?

Yes, participants do occasionally say "No." When they do, it is important to document their reasoning.

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What kind of language could a moderator use to prepare a participant for placing the injection pad, so the use scenario is uninterrupted at the point of choosing an injection site?

The first step is to ensure that your setup for the injection pad is easy for the participant to use on their own, like a Velcro belt that the injection pad sticks to.

With that setup, the moderator can instruct the participant to use the injection pad when they are ready to inject. The moderator should explain that they should first put the belt over their chosen area and then stick the pad onto the belt.

There are often conflicting opinions around scoring knowledge tasks. If the participant's response to a knowledge task is, "I don't know," do you automatically score that as a use error before asking them to look in the provided materials or IFU?

You might want to review the latest (2025) version of ANSI/AAMI HE-75 which discusses this issue. Try prompting the participant to answer based on the product materials instead of immediately coding it as a use error and moving on. It is important to note their initial answer in the report though, and the debrief should include discovery to understand their reasoning. Was the participant reluctant to look for the answer? Did they skip the step or information because it was too much content or difficult to understand? It is important to keep asking questions to determine the root cause.

Which script format is best in situations where there is a designated note taker, and the moderator does not log data?

Our recommended format lists prompts on the left and includes the use errors on the right. Inclusion of the use errors is valuable to a moderator because they need to know what constitutes perfect performance. Anything other than that for each subtask warrants a debrief, and the moderator will only be aware of that if they have a reminder of the use errors for every task. Even though the moderator is not the official data logger, they must be able to track use errors for debriefing purposes.

Has the FDA provided feedback on performing the debrief after simulated use, knowledge tasks, and subjective feedback are completed vs. performing a debrief after each of those activities?

Yes—they overwhelmingly prefer individual debriefs after completion of each section.

If the product does not have critical tasks, is it okay to have less than 15 users per group?

If there are no critical tasks, a validation study may not be required—refer to recent guidance to determine if that is the case. If a validation study is required, you still need 15 users per individual subgroup. The critical or non-critical task distinction does not impact the number of users the FDA wants to see in a validation study.

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