> **This would never happen in my hospital**

Bold Insight

THE IMPORTANCE OF ADJUSTING YOUR SIMULATED-USE ENVIRONMENT BASED ON HCP PARTICIPANT FEEDBACK

Kaitlin Carter, Director • Coleen Long, Director • Jonathan Carlson, Collaborator

Early formative studies, although they usually involve smaller sample sizes, can reveal important indications of study artifacts. These indications may be amplified in larger validation studies that include health care practitioners.

Considerations for study design and simulated-use setup can help decrease the incidence of study artifacts. This approach increases the validation study's acceptability during FDA submission by ensuring that the usability data produced is both complete and accurate.

Test plan
Build a usability test plan starting with a base of best practices and prior experience.

Formative studies
Conduct formative studies and monitor for trends in study artifact, asking for participant feedback as time allows.

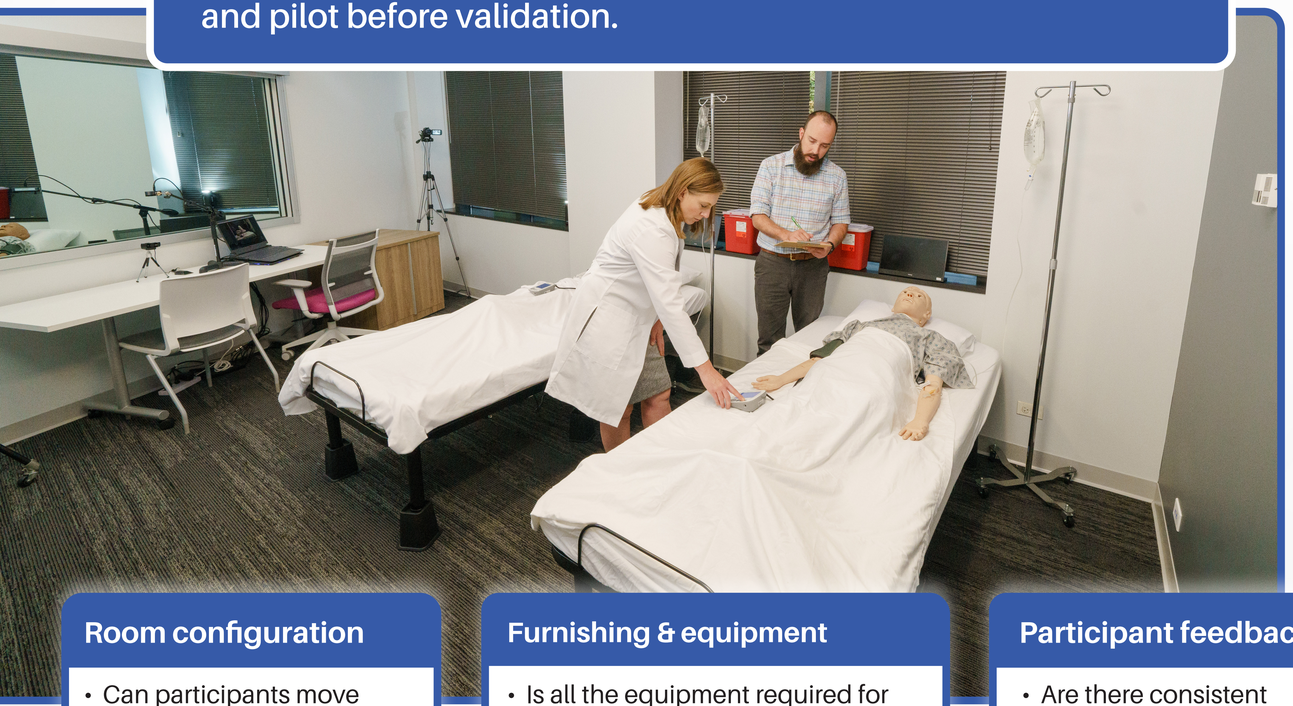
Validation plan
Integrate observations of study artifact and and feedback while planning the validation study.

Live pilots and pre-validation
Evaluate study changes based on identified study artifacts prior to formal validation.

Validation studies
Conduct validation studies informed by the findings surrounding study artifacts.

Repeat
Compile all learnings from the completed studies to build on existing best practices to support future product validation.

In our 20 year history of usability study participant feedback, there are key components of simulated use to listen for, update, and pilot before validation.



Room configuration
- Can participants move freely?
- Is there too much or too little space in between furniture?
- Is it distractingly different from their normal work set up?

Furnishing & equipment
- Is all the equipment required for the workflow present (i.e., sinks for handwashing)?
- Can participants access telephones to call for support?
- Are furnishings consistent with the intended-use environment (i.e., home environment)?

Participant feedback
- Are there consistent themes on what needs to be updated?
- Is there variation depending on facility type?

CASE STUDY

What happens when you need to test multiple variations of device use within one session?

Pre-summative testing revealed a high incidence of test artifacts due to our attempt to evaluate multiple modes and alarm states of a medical device in a way that did not align with its actual use with a single patient. Participant feedback during follow-up questioning and root-cause probing helped us better understand these test artifacts.

Based on the findings from pre-summative, the following changes were made for summative:

- The concept of caring for multiple patients was introduced.
- Additional personal and clinical context was provided with each simulated-use scenario to fully flesh out the test environment and reduce the pressure of feeling tested.
- Bedside simulated environment fidelity was increased.

- A **30% reduction** in test artifacts when evaluating alarm states.
- A **50% reduction** in test artifacts related to room configuration.