Employing a Remote Usability Testing Method to Conduct Summative Usability Testing

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Introduction

Summative usability testing

The FDA today mandates that companies provide summative usability testing data to validate the product's use safety as part of a 510(k) submission. The FDA expects that the testing will be conducted with representative users in a representative environment (real or simulated) with a production-equivalent version of the device. Further, the FDA expects an adequate sample size of representative users evaluate the product in order collect a sufficient amount of data.

Testing challenges

- Participant databases are often depleted by individuals participating in previous formative testing.
- The "density" of qualified participants can be low for some user backgrounds and necessitate travel to distant metropolitan areas. This leads to higher testing costs and longer testing efforts.
- The time available to complete summative testing can be constrained by a company's goals to reduce time-to-market.

A solution

Remote usability testing alleviates the need for participants and test administrators to be co-located. Conducting summative testing remotely using internet-based desktop-sharing tools provides benefits such as:

- Nationwide access to larger user populations from which to recruit qualified test participants.
- Lower testing costs by foregoing travel expenditures.
- Greater schedule flexibility for users and the test administration team.
- Expedited testing timeline due to reduced testing duration.
- A more representative environment for users to evaluate an office-based software product.

Evaluated product

Ivenix Infusion System

We (the authors) conducted a summative usability test of Ivenix Infusion System. One element of the system that could result in hazardous outcomes from potential use errors is a computer-based drug library editing tool that serves as a dose error reduction system for using a large volume infusion pump. The tool is a browser-based application that resides on the server and modifies a database containing the infusion pump's drug library (i.e., smart pump). A drug library contains drug dosing information that is downloaded to the pump and is used to alert users (e.g., nurses) regarding unsafe infusion therapy.

Representative users and use unvironment

Clinical pharmacists (not to be confused with retail pharmacists), among other things, supervise medication administrations to patients such as medications administered via infusion pumps. Within a hospital or sometimes a hospital system, there is one clinical pharmacist who is responsible for maintaining the drug library for infusion pump fleet. They typically work in an office environment situated within an acute-care hospital.

Background

Participants

We (the authors) conducted a summative usability test with 26 clinical pharmacists from 17 cities across the U.S.

Informed consent / Non-disclosure / permissions

Recruited participants read and electronically signed an informed consent and non-disclosure statement. They provided permission to record their voice and onscreen interactions.

Procedure

We conducted two sessions remotely with each participant using a web-based screen sharing service (i.e., GoToMeetingTM) The first 2-hour session consisted of an interactive training session with the participant followed by a second 3-hour session to evaluate the application conducted one to seven days later.

Desktop sharing

A desktop-sharing service enabled the test administrators in one location to conference with a participant in a second location while they shared a mouse cursor and interacted with the software application in a third location. Specifically, test administrators were able to use the desktop-sharing and teleconference features to talk, listen, and observe user interactions (i.e., cursor movements) by the participant with the application running on a remote computer.

Product support

The desktop-sharing service also enabled Ivenix's product specialist to view the participant's display and facilitate real-time support in the event the participant requested help. This interaction was representative of the Ivenix's product support plans.

Benefits

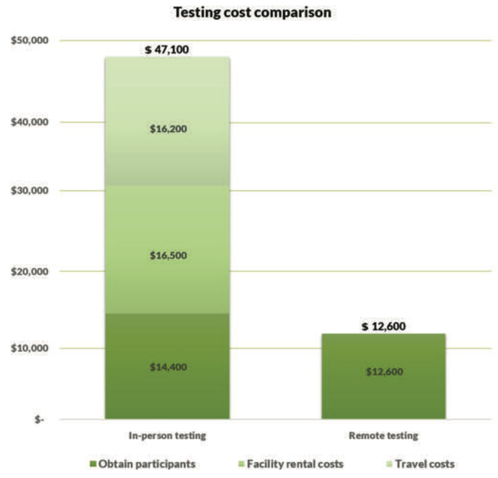
Remote summative usability testing shares many of the advantages that in-person testing offers but on a larger scale, especially considering the larger amount of participants needed for summative usability testing as compared to formative usability testing.

Lower costs

Remote usability testing allowed the testing team to save on costs associated with:

- Obtaining participants (recruiting and honoraria).
- Renting facilities for testing and training.
- Traveling (e.g., lodging, transportation, meals).
- Shipping test materials.

When compared to the costs associated with in-person testing, our team was able to save approximately $34,500 because of our remote usability testing approach.



Representative environment

By participating remotely, pharmacists were able interact with the system while working on their normal computer in their hospital office work environment that included natural conditions and distractions.

Geographically-diverse participants

Participants were recruited from across the country and, therefore, represented a geographically diverse test cohort, and perhaps had more diverse backgrounds, as compared to pharmacists that might have participated if testing was conducted in a select number of metropolitan areas.

Enhanced data collection

During a remote test session, the two test administrators performed some data analysis offline while observing the session. It is our opinion that working offline helped ensure the data collection was more thorough and complete as compared to an analysis conducted retrospectively.

Prerequisites

The tools used to conduct remote summative usability testing were similar to tools used to conduct other usability testing remotely.

Hands-free communication

Participants were required to have a means to communicate with the test administrators using a headset or speakerphone while simultaneously using a keyboard and mouse with two hands.

Display screen resolution

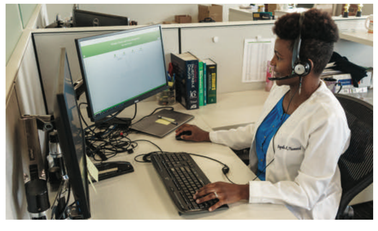
To ensure the software user interface would be displayed properly and to be consistent with the product's intended display screen, participants were required to use a display having HD screen resolution (720p) or higher.

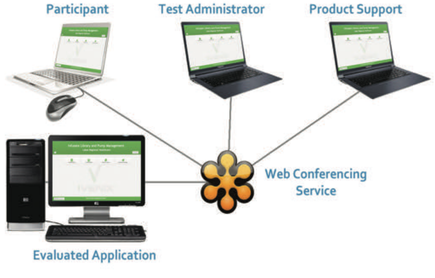
Informed consent and non-disclosure acknowledgment

We used an electronic signature service (e.g., RightSignature™) to allow participants to read Informed consent and non-disclosure documents and obtained their acknowledgment via an electronic signature.

Desktop-sharing teleconference service

A platform-independent desktop-sharing teleconference service is at the heart of conducting remote usability testing. We required a robust, easy-to-use, and lightweight service (e.g., GoToMeeting) such that we would be less likely to encounter technical problems that would prevent us from conducting scheduled sessions. We did not require web camera use to protect participants' privacy and minimize bandwidth use.





Challenges

Technical issues

Conducting testing remotely inhibits administrators' ability to troubleshoot technical problems (e.g., incompatible hardware, unreliable or insufficient internet bandwidth). As such, it is important to allow sufficient time during each test session to solve unexpected issues to not take time away from the evaluation. As an aide to troubleshooting, it is helpful to establish voice communication that is independent of the meeting service.

System latency

A couple of participants remarked about the latency they experienced while manipulating the mouse. During a test session, participants would use their desktop's mouse to control the mouse cursor on the evaluated application. If latency was present due to limited bandwidth, a participant might overshoot the intended button target and end up mis-clicking and need to adjust the mouse's position over the button. This was perceived as a minor inconvenience and did not appear to alter the test's findings.

Pre-test requirements

To not burden participants with printing, signing, scanning, and then emailing back a signed copy of the informed consent document, use of a service that enables participants to sign electronically helped streamline pretest requirements that might otherwise postpone testing.

Preparation and practice

Before employing remote testing for summative usability testing, the method should be utilized in formative testing to gain experience solving technical issues, communicating with participants, and collecting data. For example, we could not rely on observations of participant's facial expressions to document difficulties. Instead, we interpreted cues such as audible sighing, cursor motions, and unproductive interactions with the software as signs that the participant was experiencing difficulty completing a use scenario.

Confirming the participants' experience

During each test session, we relied on participants to attest the application's user interface was displayed and they could read it without difficulty. However, we were not able to directly observe if their screen displays were adjusted properly to confirm if font sizes, button sizes, colors, or screen contrast was sufficient and intended.

Conclusion

Compelling advantages

Remote usability testing can offer advantages to participants and test teams such as an expanded participant database, convenience, geographic diversity of participants, lower cost, and efficient scheduling that make it an appealing approach for conducting summative usability testing.

Well suited for stand-alone medical device software

Although we know of no opinion or guideline from the FDA regarding the use of remote usability testing for collecting summative usability data, we assume that it is acceptable because it satisfies the expectations for use by representative users in a representative environment. As such, remote summative usability testing appears to be well suited for collecting test data for stand-alone medical device software products such as:

- Software tools that provide decision support or configures a medical device.
- Websites or mobile software apps that provide diagnoses or decision support.
- Telehealth and telecare systems with connected monitoring devices.