

## Introduction

Throughout the product development cycle, it is important to conduct usability research. In the US, this process is mandated and detailed by the FDA. Early in the process, you need to confirm confidence in your design via user preference testing. Later, you may conduct formative studies to ensure your design properly mitigates risk or to discover new risks. Finally, conduct summative testing to ensure the device is safe for its intended users in their intended environment.

For an FDA submission or US-based device, this process is straightforward. However, what if you are designing a device that will seek initial clearance in the US, then will transition to international markets? Language barriers, long-distance logistics, and various unknowns can result in disastrous outcomes. Best practices are presented for lab-based testing in addition to contextual inquiry field research.

## Actors

### Protocol Author

- Possesses a thorough understanding of the device being tested as they will act as the main point of contact and likely product expert.
- Flexible schedule to collaborate with stakeholders in various time zones.
- Strong communication skills to ensure the rest of the study stakeholders understand the protocol discussion guide, device functions, and study objectives.

### Simultaneous Interpreter

- Must have a thorough understanding of the device's functions discussion guide and the testing protocol.
- Acts as the research team's liaison while executing the study because they have the best knowledge of the participant's native language and the research team's native language.
- Has a background or experience with medical devices and medical technology
- Has experience working with the Moderator and is familiar with their moderation style.

### Moderator

- To ensure participants' comfort and ensure high-quality data, the moderator must speak the participants' native language.
- Has a background or experience with medical devices and medical technology.
- Understands the difference between market research and usability testing, and ensure the protocol and discussion guide is executed according to best practices.

### Data Collection Technology

- If conducting a standard lab-based usability study, the amount of data collected should be maximized.
- Recording the simultaneous interpreter, moderator, and room audio can be mixed together on different audio channels for a more detailed review later.
- Multiple camera angles should be utilized to ensure the participants full interactions are recorded and can be combined in a compilation video at a later time.
- Multiple cameras and microphones simultaneously recording can create massive amounts of data. Have a plan to backup and transport the data.

### Logistics Facilitator

- Manages required travel, accommodations, and facility logistics.
- Has a strong understanding of international shipping, customs, and visa policies.
- Must be intimately familiar with any prototypes that are being shipped, specifically dimensions, materials, and fragility.
- Collaborates with the research facility to ensure delivery of any study stimuli.

### Study Facilitators (Note Taker)

- Has an in-depth knowledge of video and audio recording technology for data collection.
- Will need a thorough understanding of the study stimuli's components, and have resources available to repair any prototypes that may fail.
- Must have the authority and experience to make emergency decisions and take action. Any assistance is likely many time zones away.

## Language & Regional Challenges

### Recruitment Agency Selection

- Selecting an appropriate recruitment partner is one of the most crucial elements of a successful international usability study.
- The recruitment partner should have experience conducting usability studies and medical device research.
- It can be beneficial to locate a recruitment partner who also has experience conducting pharmaceutical

research as they may be more privy to local laws and regulations pertaining to clinician compensation.

- The recruitment partner can help arrange study facilities and ensure appropriate resources are available for a successful study.
- The recruitment agency will be your best resource to identify and characterize your targeted users in the region.

### Simultaneous Interpreter & Native Speaking Moderator

- As they are executing the study, your moderator-interpreter team are a critical part of any international usability study.
- The relationship between the moderator and simultaneous interpreter is crucial for success. They must have experience working together to ensure the study is interpreted accurately.

- The simultaneous interpreter will act as your liaison to the participants.
- The Interpreter and moderator must be intimately familiar with the study protocol and discussion guide to ensure everyone stays in sync throughout the study sessions.

### Man Behind The Curtain - Prototype Operations

- Typically, study stimuli will require input from the study facilitators to offer the most immersive experience for the participants.
- Study facilitators must create a system of communication between the moderator and themselves to operate

the prototype or study stimuli in sync with the study; language barriers may make this difficult.

- Radios and hands-free ear pieces can be used for the simultaneous interpreter to communicate with the study facilitators discretely and efficiently.
- Reserve at least one full day to practice/ pilot study.

## Experience

BlackHägen Design has completed hundreds of international studies across the globe. By completing usability research and contextual inquiry in 20

countries across Asia, Europe, and the Americas BH has intrinsic knowledge and skills applicable to medical device development in international markets.

