WHEN AND HOW TO DO USABILITY TESTING TO MEET FDA & CE REQUIREMENTS
Product Design, Development, and Strategy Since 1976
IN THE LAST 5 YEARS

500+ HOSPITALS STUDIED

1500+ CLINICIANS SHADOWED

45 PRODUCTS CLEARED BY THE FDA

30 PRODUCTS IN DEVELOPMENT AND CLINICAL TRIALS
HUMAN FACTORS ENGINEERING

3 SUMMATIVE STUDIES
11 FORMATIVE STUDIES
335 PATIENTS, CAREGIVERS & HEALTH CARE PROVIDERS IN 2013 ALONE
We will focus on Formative and Summative Testing and how it integrates into the development process

...looking at it from a device manufacturer’s point of view

Human Factors Engineering includes all “User Interface”:
• Physical components
• Graphical User Interface (GUI)
• Labeling (IFUs, packaging) and training material
• Application specification
• Frequently used functions
• Identification of hazards related to usability
• Identification of characteristics related to safety
• Identification of known or foreseeable hazards

• Primary Operating Functions
• Usability Specification
• Usability Validation Plan
• User interface design and implementation
• Usability Verification
• Usability Validation
• Preliminary Analysis
   Aspects of users, device use, environments, user requirements, and preliminary risk analysis

• Formative Testing
   Applying early iterative test and evaluations to optimize device usability

• Summative Testing
   Formal simulated use validation testing with a production level device

• Human Factors Report
FREQUENTLY ASKED QUESTIONS

- Why do we have to do that?
- When do we need to do that?
- What do you test?
- How many people do we need to test?
- How often?
- How much would that cost?

- Because FDA requires it!
- As part of IEC 60601-1-6, IEC 62366 is required in your submission
  ...but also
  - You’ll have a safer product
  - Improve usability of your device
  - Mitigate risk of lawsuits related to misuse
  - Reduce training
Understanding the risks and usability challenges of your device

- New device vs. Minor changes
- Complex UI vs. Simple UI
- Life-sustaining vs. Non life-sustaining
Assuming that you already have:

- Ethnographic Research (Contextual Inquiry)
- Market Research
- Complaints Analysis
- Competitive Analysis
- Customer Requirements
Assuming that you already have:

- Task Analysis
- User Profiles
- Use Environment
- Heuristic Review
- Hazard Analysis
- Usability Objectives
Exploratory Phase

- Cognitive Walkthroughs
- Partial System Testing
- Think Aloud Protocol
- Self-exploration
Outcomes...

- Inform the Industrial Design and Engineering teams
- Inform the User Experience team
- Confirm design direction
- Highlight fundamental usability issues
- Initiate the labeling process
From previous phases
• Update documentation

During this phase
• Usability Specifications
• Risk Analysis (uFMEA)
Verification Phase

- Formative Testing
- Partial System Testing
- Expert Reviews
Preparation for Formative Testing

• Protocol
  • Detailed description of the procedure, training, and tasks
  • Based on risk assessment
### Logistics

- **Screener**
- **Recruitment**
  - Minimum of 5-8 users per user group
- **Identified in your Usability Specification**
- **Testing facility**
- **Material needed during testing**

### Dry-runs
During Formative Testing

- Dry-runs
- Moderator and Note-Taker
- Video capture
- Consistency during testing
- Get ready to fix your prototype or have spare units
**After Formative Testing**
- Consolidate data
- Look for trends
- Review videos
- Outline your report
- Write report and recommendations

**Outcome...**
- Capture information for the development teams
- Document usability testing in the Usability Engineering File
WHAT IS A USE ERROR?

Attention Failure - Intrusion, miss-ordering, reversal, mistiming, or omission

Memory Failure - Omitting a planned action, losing your place, or forgetting intention

Rule Based - Misapplication of a good rule or application of a bad one

Knowledge Based - Routine violation, well-meant “optimization”, shortcut (workaround), or improvisation in unusual circumstances

Following Good Practice use of accompanying documents, professional knowledge, maintenance, training, and calibration

Action that is contraindicated, inadequately trained or unqualified use, exceptional violation, reckless use, or sabotage
Validation Phase

- Summative Testing including:
  - Production level devices
  - Training and Labeling
Preparation for Summative Testing

- **Protocol**
  - Detailed description of the procedure, training, and tasks
  - Based on tasks analysis and use-related risks
  - Incorporating findings from previous studies
  - Define what success is
  - You don’t need to test everything
  - Training Decay
• **Logistics**
  • Screener
  • Recruitment
  • Identified in your Usability Specifications
  • At least 15 users per user group (over recruit!)
  • Must be U.S. Residents
  • Testing facility
  • Material needed during testing

• **Dry-runs**
During Summative Testing

- Dry-runs
- Moderator and Note-Taker
- Video capture
- Consistency during testing
- Realistic use condition, not clinical
- Avoid bias inducing questions
During Summative Testing cont.

• Essential and Safety Critical Tasks:
  • Essential – necessary for successful use
  • Safety Critical - tasks that if omitted or were not completed, would have a NEGATIVE clinical impact
After Summative Testing

• Consolidate data
• Analyze use errors and failures
• Identify true residual risks

You’re always going to have residual risks. You just need to prove that you did something about it.

Outcome...

• Summative Usability Report

To be included in your Usability Engineering File
• Do not lead participants
• Careful with your own body language and facial expressions
• Talk only to clarify and to run the testing session
• Let participants fail, do not interrupt
• If participant ask “can I do that?” your answer should be “what would you do if I wasn’t here?”
• Ask open ended questions without proposing an answer
Ex: “How do you feel?” instead of “do you feel frustrated?”
• No prior dry-runs of the testing session
• Leading or helping the participant during the tasks
• Talking too much and not watching carefully
• Getting tired of repeating the protocol
• Rushing the participant
• Making the participant feel inferior (not being empathetic)
• Not making the session relaxed, friendly, or interactive