Tailoring the Usability Engineering Process

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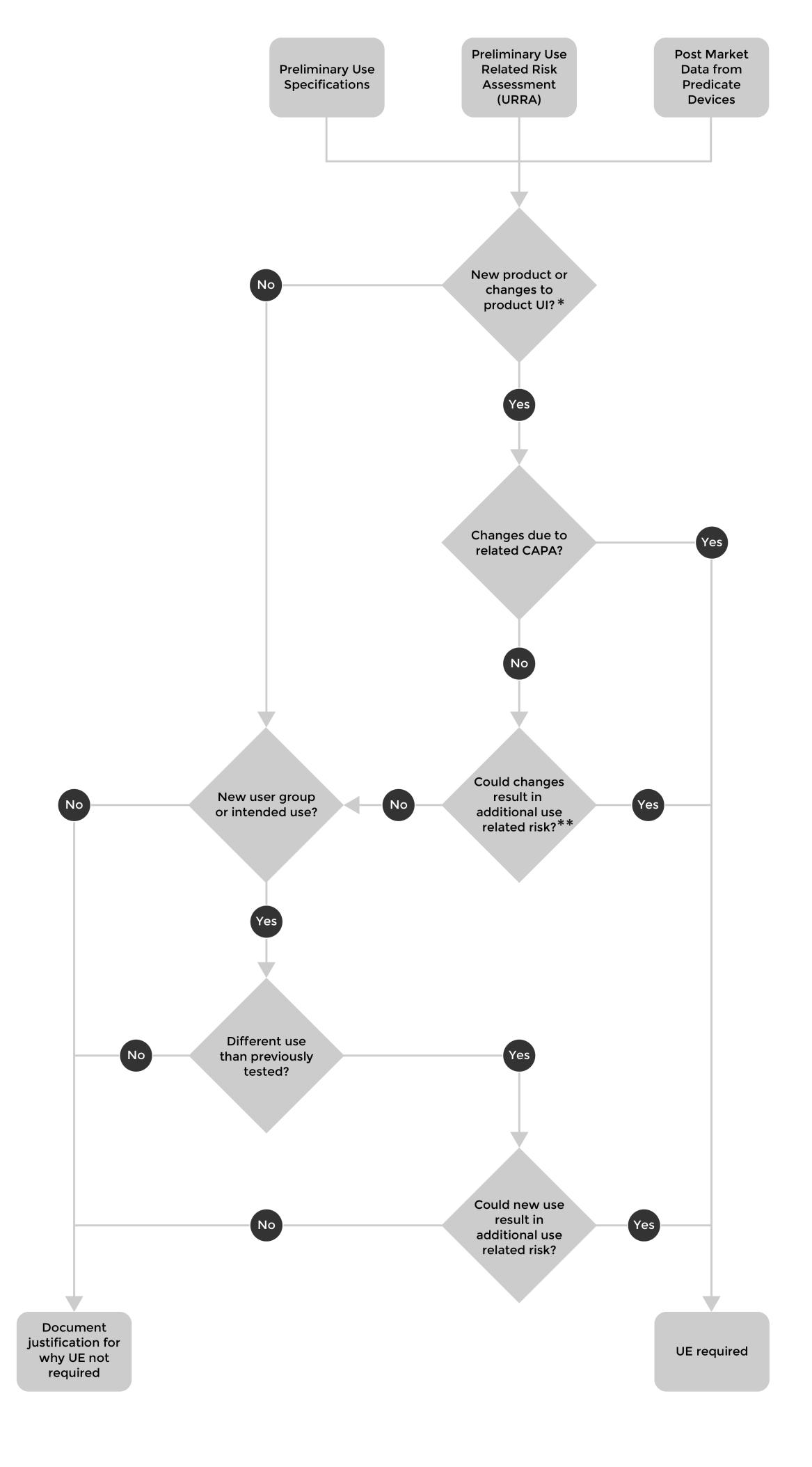
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What is Tailoring the UE Effort?

Tailoring the Usability Engineering (UE) Effort refers to:
• Determining whether formal UE activities are required
• If so, what type, to what extent, and when should they be performed

Activities that can be Tailored

Tailoring the UE effort can affect the following activities
• User Research
    • How much (if any) and what types of research are recommended
• Formative Activities
    • How many and what type of formative activities are recommended

Is Usability Engineering Required?

Preliminary Use Specifications → Preliminary Use Related Risk Assessment (URRA) → Post Market Data from Predicate Devices

New product or changes to product UI *
- No
- Yes → Changes due to related CAPA?
    - Yes
    - No → New user group or intended use?
        - No → Could changes result in additional use related risk? **
            - Yes
            - No → Different use than previously tested?
                - No
                - Yes → Could new use result in additional use related risk?
                    - No → Document justification for why UE not required
                    - Yes → UE required

Tailoring User Research

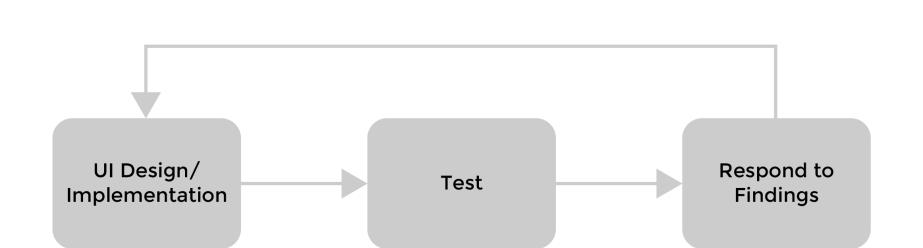### User research is used to help identify and understand
• How the device is used (intended uses, medical indications)
• Who uses the device and how (user profiles/user groups)
• Aspects of the use environment that impact device use
• Known issues, pain points, etc. with predicate devices

User Research Activities may include
• Contextual Inquiry
    • Observing users within clinical context and/or using predicate device
    • Use error modalities
• User Preference Studies
• Interviews

Factors used to Tailor User Research
• Novelty of Device
    • If there is not a direct predicate device, you may want to observe users interacting with similar or supporting devices
• Knowledge of Device Use and Users
    • Doing upfront user research will help avoid surprises later in the UI development process
    • Don't assume you know your user
        • Even if you've been developing similar products for some time, user needs and perceptions change with new developments in technology

Tailoring Formative Evaluations

Formative Evaluations are used to
• Inform the design of the device user interface
• Assess the effectiveness of use-related risk mitigations
• Determine training requirements and inform the design of the labeling and training materials
• Inform the design of the human factors validation testing

Formative Evaluations may include
• User Preference Studies
• Guided Interview
    • Moderator walks participant through a prototype
• Simulated-Use Testing

Iterative Development / Testing Cycle
Formative evaluations are part of an iterative User Interface Development Cycle

UI Design/Implementation → Test → Respond to Findings

Iterations continue until a confidence level is achieved that
• Risk Mitigations for use related hazards and potential Use Errors are effective
• The final usability objectives will be met when the summative evaluation is conducted

Tailoring Factors

Number of User Groups and/or Intended Uses
If the device is used differently by various users or for different intended uses
• May need different discussion guides for different user groups or intended uses
    • Adult vs. Pediatric
    • Nurse vs. Anesthesiologist
    • Geographic differences in use
    • Etc.

Complexity / Scale of the User Interface
The complexity or amount of functionality of the user interface may drive the need for additional formative evaluations
• UI may be developed over many months
    • Test incrementally as functionality is developed
        • Helps identify risks and potential use errors sooner
• May be too much functionality to test in a single test session
    • Test different use scenarios in separate sessions to avoid overtaxing participants

Severity of Potential Harm
Higher severity of harm may require more iterations to reach the desired level of confidence prior to conducting the summative test

IFU / Training Materials
If IFU and/or training are used to mitigate risks, they should be tested prior to the summative
• May be part of other formatives or separate test

Extent / Impact of UI Modifications
Whether developing a completely new UI or making major or minor modifications to an existing UI
• Minor change
    • Must test any new functionality
• New feature
    • Must test menu or control changes that affect critical or essential tasks
• Extensive changes to look and feel, menu structure, workflow, etc.
    • May need to retest entire system

Extent of previous UE Activities
If modifying legacy products where there is no evidence of formal UE activities (User Interface of Unknown Provence, or UIOUP)
• High severity of harm and/or post market feedback (use safety issues) could drive the need to test unchanged parts of UI
    • May need to test some or all critical and essential tasks
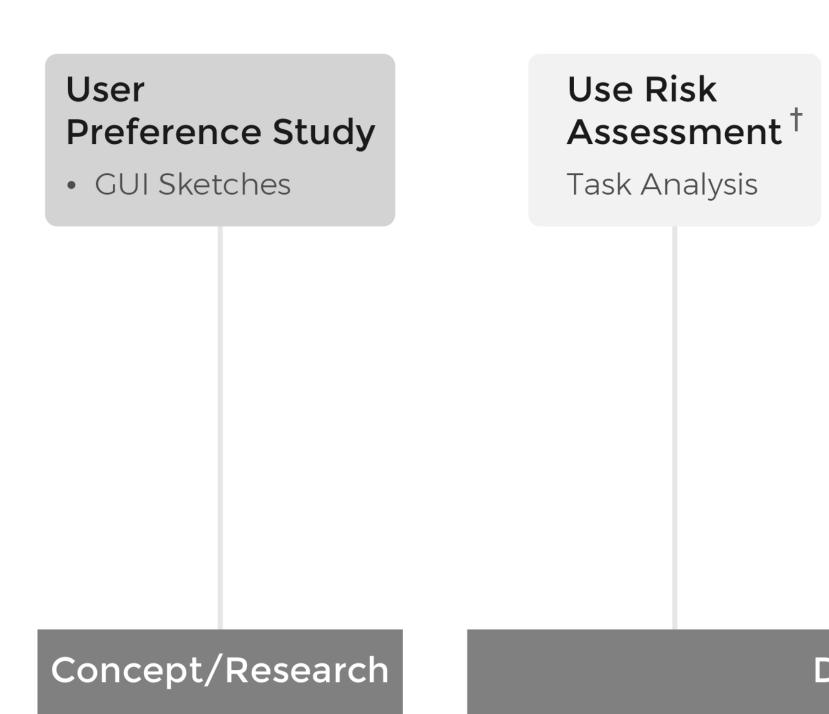   • Therefore, a task analysis is required

References

• FDA Guidance: Applying Human Factors and Usability Engineering to Medical Devices, 3 Feb 2016, p17
• AAMI/IEC 62366-1:2015, p26

Example 1 - A "Simple" Change

Use Related Risk	Physical User Interface	GUI	Users/Intended Use	IFU/Training
• Risk related to selecting wrong feature • Risks related to using new feature incorrectly	• No changes	• Adding a new feature • Minor menu changes to access new feature	• Feature is used in the same way by all users for all intended uses	• Training/IFU NOT used as risk mitigation for new feature

User Preference Study
• GUI Sketches

Use Risk Assessment †
Task Analysis

Formative 1 Simulated Use Study
• Near production equivalent HW/SW
• Evaluate all critical and essential tasks

Summative Pilot Simulated Use Study
• Verify all use related risk mitigations are effective
• Verify summative test design
• Same rigor as summative with smaller sample size

Summative Evaluation †
(HF Validation Testing)

Concept/Research	Development	Verification	Validation

† These activities are required and not subject to tailoring

Example 2 - Complex New Product

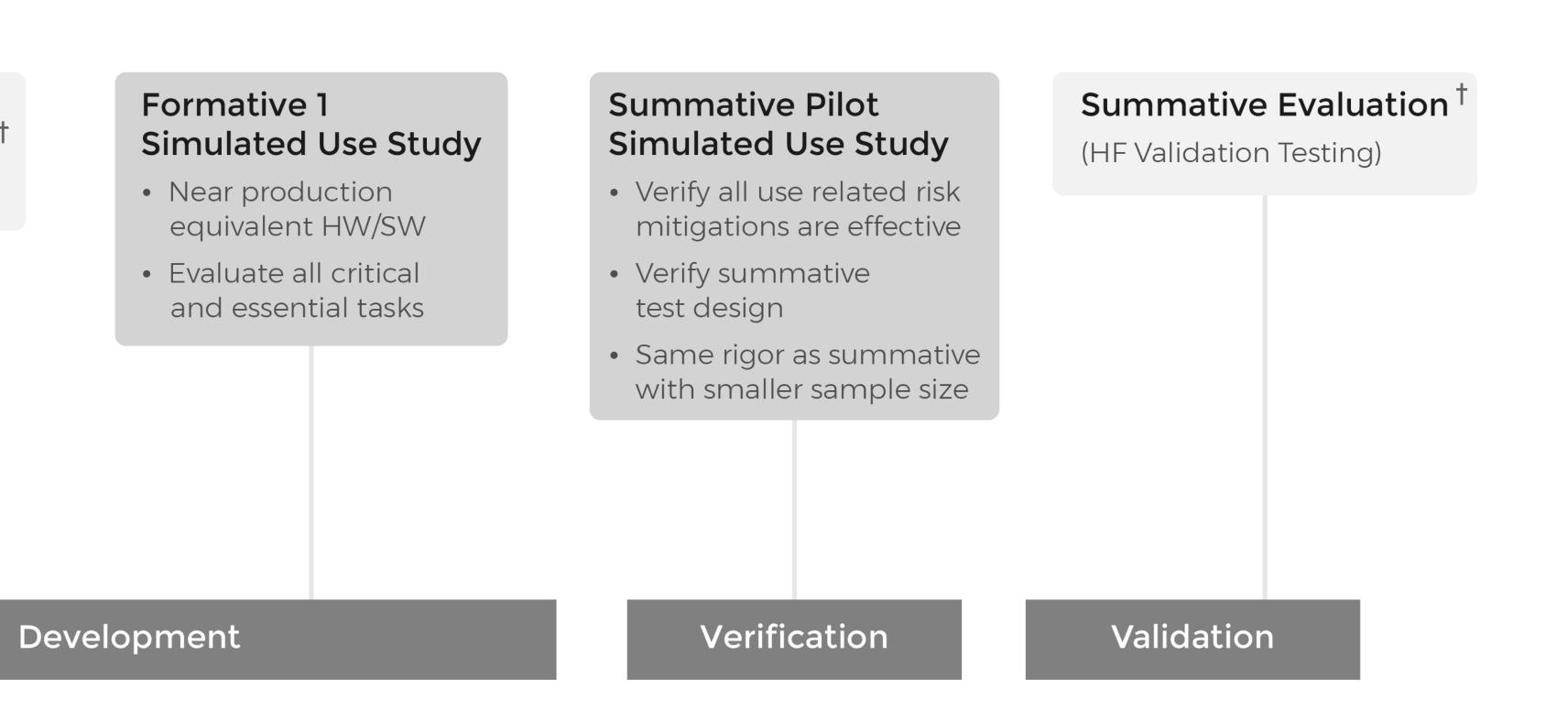| Use Related Risk	Physical User Interface	GUI	Users/Intended Use	IFU/Training
• Large number of risks related to use of physical UI and GUI	• Connectors, mounting • Physical buttons/knobs	• Complex touch screen interface • Multiple levels of menus & dialogs	• Device used differently by different user groups and/or for different intended uses	• User will receive training • Training/IFU used as risk mitigation

Formative 3 Simulated Use Study
• Near Production Equivalent HW/SW Prototype
• Evaluate all critial and essential tasks
• Evaluate preliminary IFU and training

Formative 1 Cognitive Walkthrough
• Partially Functional 3D Printed Physical Model
• Prototype GUI Wireframes

Contextual Inquiry

User Preference Study
• 3D Printed Static Prototype
• GUI Sketches

Use Risk Assessment †
Task Analysis

Formative 2 Simulated Use Study
• Updated Physical Device Prototype
• Rapid Prototype Interactive GUI Prototype
• Evaluate high-level layout and navigation, "core" functionality

Pre Summative Simulated Use Study
• Verify all use related risk mitigations are effective
• Verify summative test design
• Same rigor as summative with smaller sample size
• Include IFU and Training

Summative Evaluation †
(HF Validation Testing)

Concept/Research	Development	Verification	Validation

† These activities are required and not subject to tailoring

*   Includes hardware, software, IFU, packaging, & labeling
** Use related risk resulting in high severity of harm