Usability Studies for Point of Care Testing

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Drouville, *In the fish tank*

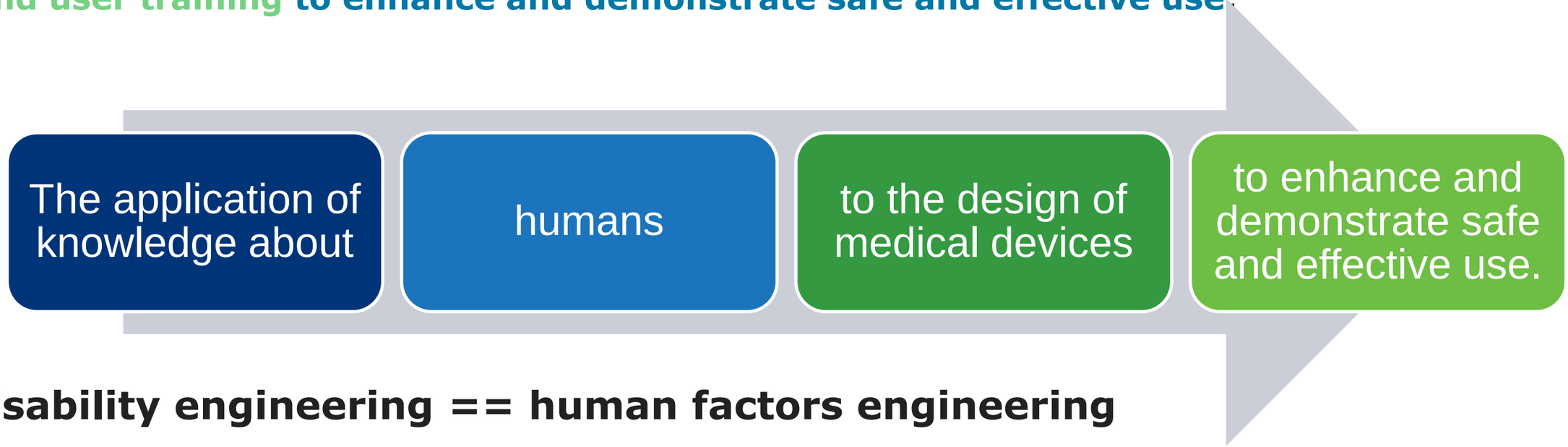
Drouville is a patient, graphic designer and artist from Argentina who has survived multiple myeloma and a relapse.

Agenda

- What is Usability?
- Why are Usability Studies performed for IVDs?
- Regulatory expectations for Usability Testing
  - FDA Expectations
  - EU Expectations

What is Usability?

- **The application of knowledge about human behavior, abilities, limitations, and other characteristics of medical device users to the design of medical devices including mechanical and software driven user interfaces, systems, tasks, user documentation, and user training to enhance and demonstrate safe and effective use.**

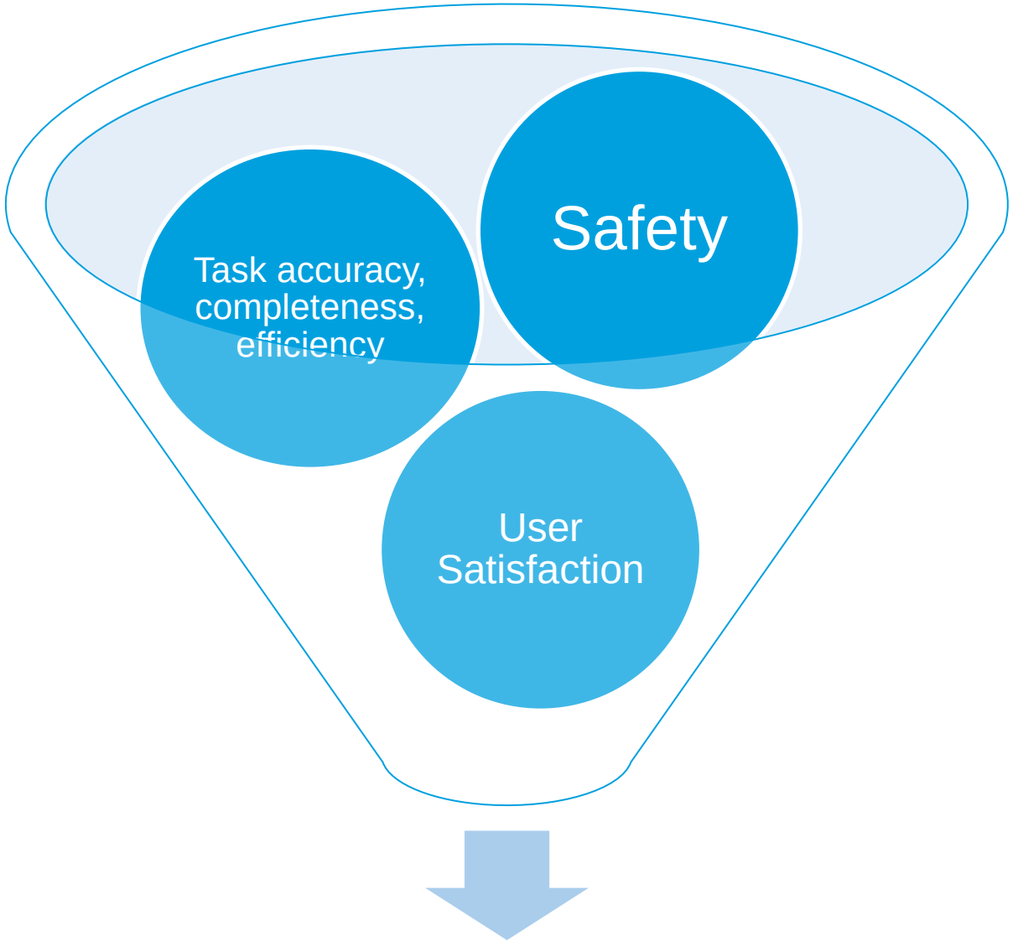


- **Usability engineering == human factors engineering**

Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff, February 2016

Usability is… a Human factors engineering approach

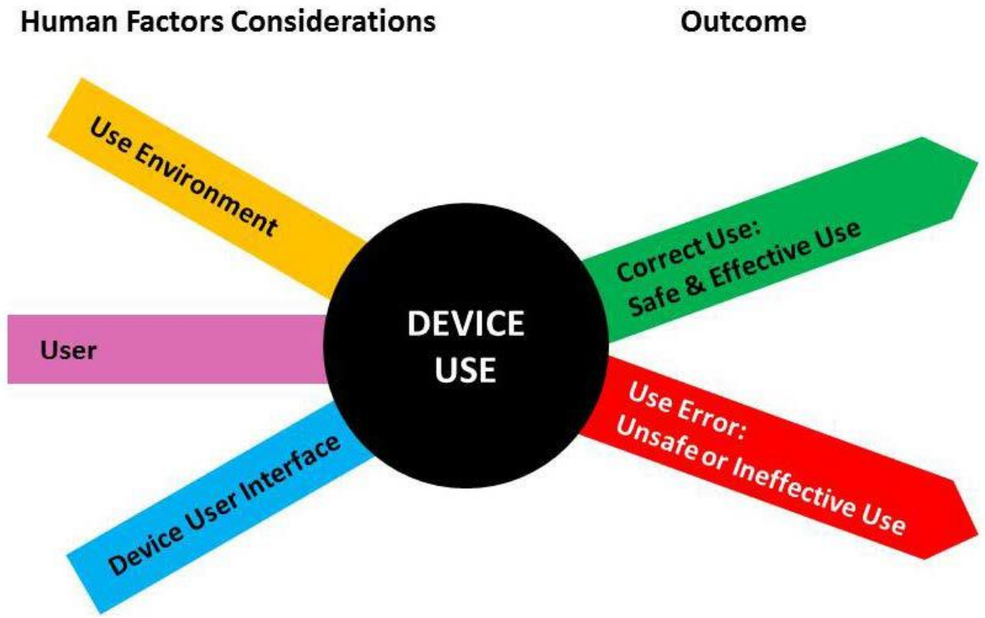
- HFE gives engineers an opportunity to actually use or test a product that they developed and designed on actual end users



IEC 62366-1:2015-02+AMD1:2020-06, Medical Devices – Part 1: Application of usability engineering to medical devices

Usability is… linked with Risk Assessment

- Usability relates to safety
- Eliminating or reducing design-related problems that contribute to or cause unsafe or ineffective use is part of the overall risk management process



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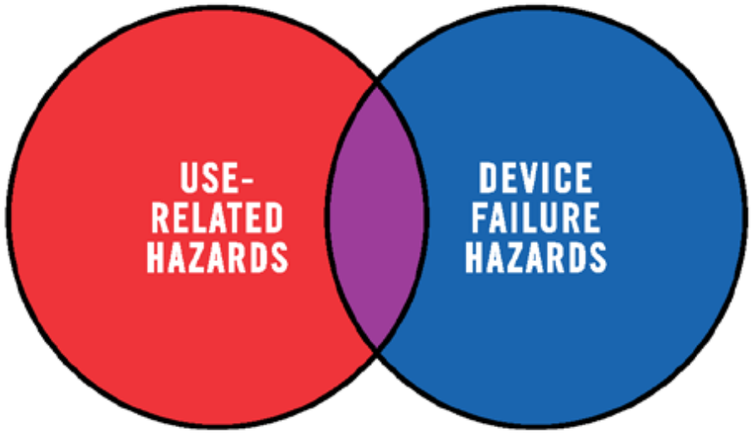
Usability is… linked with Risk Assessment



- Device failure hazards not necessarily dependent on how a user interacts with a device
- Use-related hazards might result from aspects of the user interface design that cause the user to fail to adequately or correctly perceive, read, interpret, understand or act on information from the device.
- These are not the fault of the user – use error but not user error

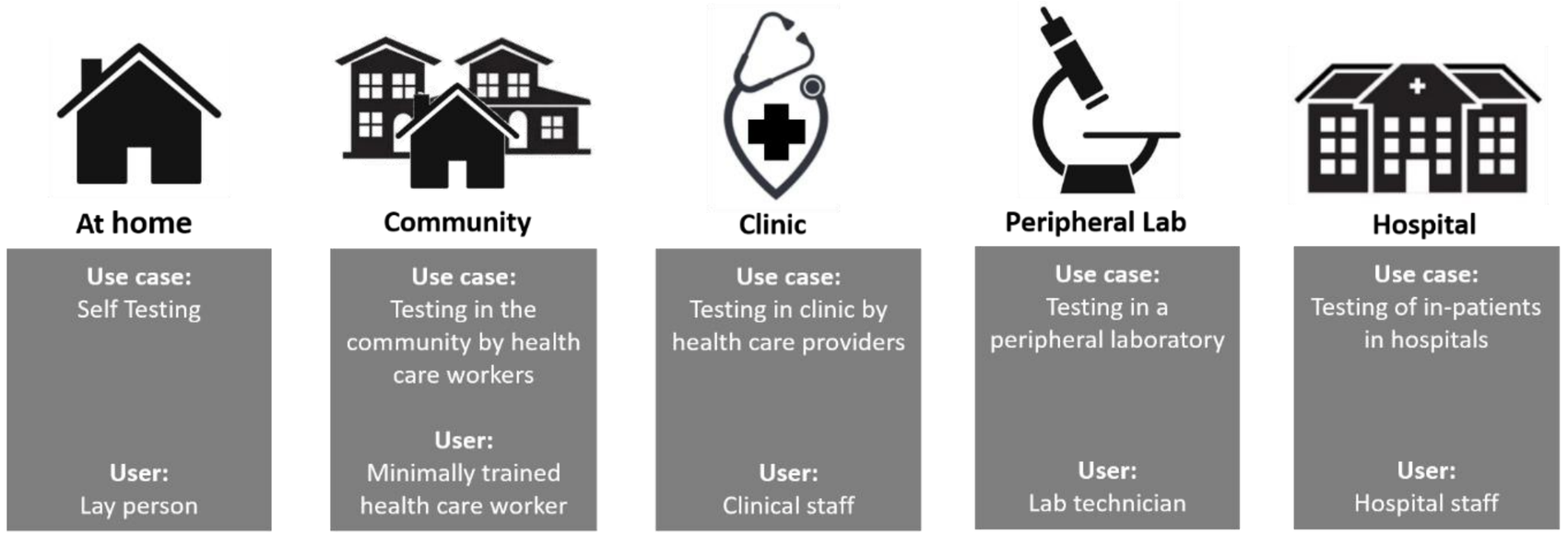
Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff, February 2016

Usability is… guided by Standards

- **IEC 62366-1:2015-02+AMD1:2020-06,** Medical Devices – Part 1: Application of usability engineering to medical devices
- **IEC 62366-2:2016,** Medical Devices – Part 2: Guidance on the application of usability engineering to medical devices
- **ISO 14971: 2019** Medical Devices – application of risk management to medical devices
- **ISO 20417:2021** Medical Devices – Information to be supplied by the manufacturer
- **CLSI POCT4-A2 Vol. 26 no. 30**, Essential Tools for Implementation and Management of a Point-of-Care Testing Program, 3rd Edition (professional users' responsibilities, test methods, safety, disposal, calibration and documentation)
- **ISO/TS 22583:2019,** Guidance for supervisors and operators of point-of-care testing (POCT) devices
- **DIN EN ISO 22870:2017-04,** Point-of-care testing (POCT). EN ISO 15189:2022 Medical Laboratories – Requirements for quality and competence
- **DIN ISO 18113-4: 2022,** In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 4: In vitro diagnostic reagents for self-testing
- **ISO 18113-5: 2022,** In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 5: In vitro diagnostic instruments for self-testing
- **DIN EN 13532:2002-08,** General requirements for in vitro diagnostic medical devices for self-testing.

Why are Usability Studies done for POCTs?

- Address risks introduced by user populations, use environments, user interfaces unique to Point of Care Tests



https://starfishmedical.com/blog/developing-a-diagnostic-product-for-use-outside-a-laboratory/

Why are Usability Studies done for POCTs?

- Usability testing is conducted to demonstrate that the device can be used by the intended users without serious use errors or problems, for the intended uses and under the expected use conditions.[1]

Usability Engineering Effort and Methods[2]

- Complexity of user interface
- Severity of harm with use of device
- Use specification

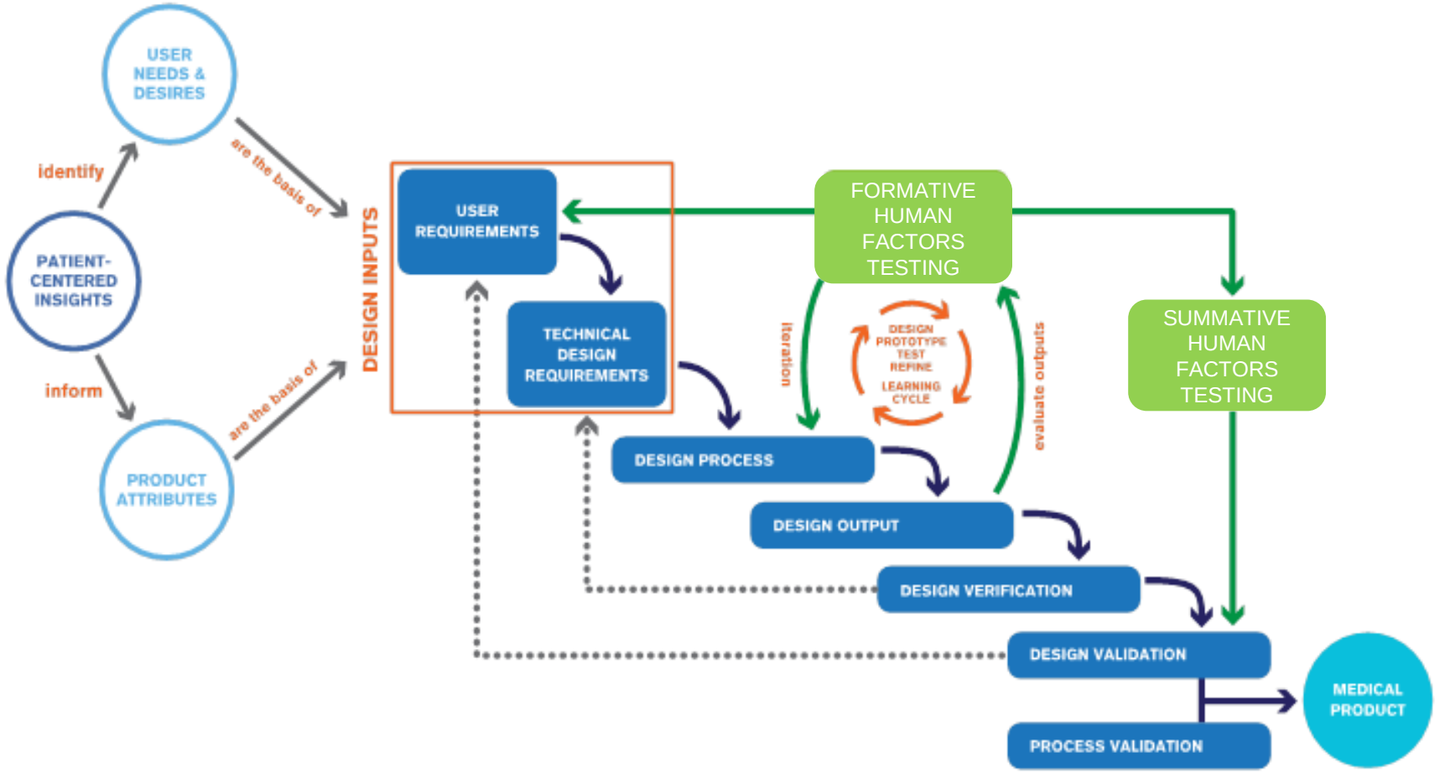
POCTs[3]

- Intended user, use environments
- Product Labeling
- Contamination, biohazard, and disposal
- Shelf life and packaging
- Data handling, interpretation, and storage

[1] Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff, February 2016
[2] IEC 62366-1:2015-02+AMD1:2020-06, Medical Devices – Part 1: Application of usability engineering to medical devices
[3] https://starfishmedical.com/blog/developing-a-diagnostic-product-for-use-outside-a-laboratory/

Regulatory Expectations for Usability Testing

- HFE takes place within device development Quality System (e.g. design controls)



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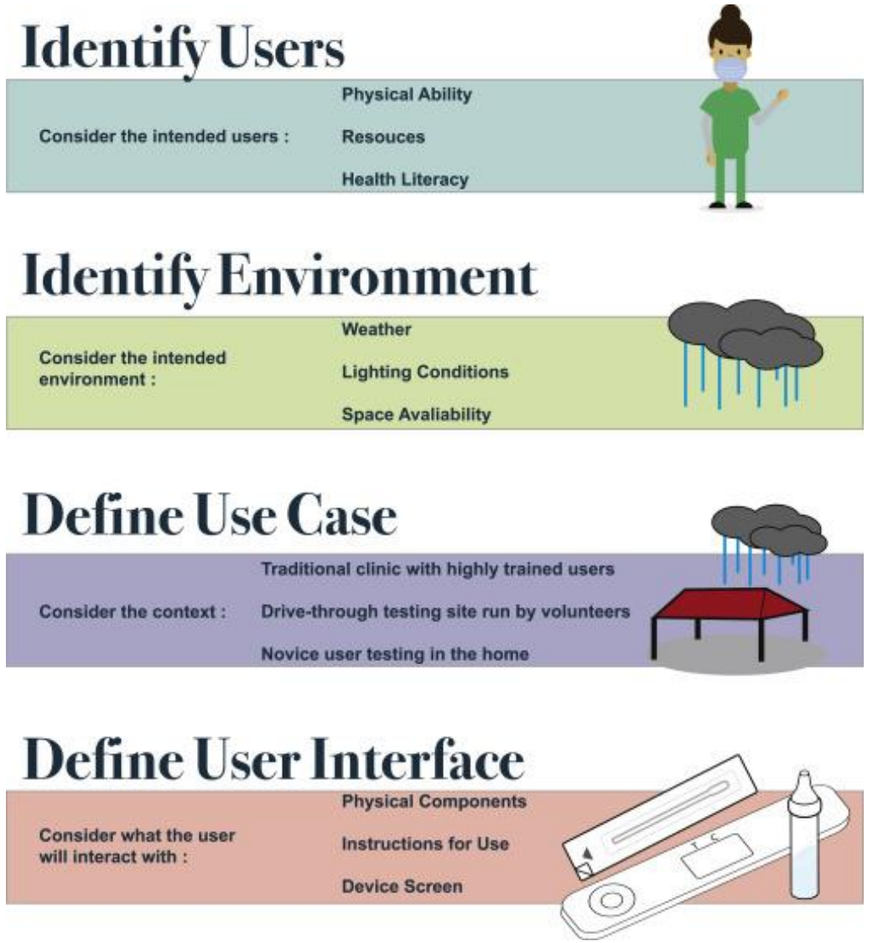
Usability Test: Features

Establish product

- Intended users/use environment
- User interface:
  - Instructions for Use and other labeling
  - Packaging
- Training



Farmer, et al. , Don’t forget about human factors: Lessons learned from COVID-19 point-of-care testing, Cell Reports Methods, Volume 2, Issue 5, 2022, 100222, ISSN 2667-2375, https://doi.org/10.1016/j.crmeth.2022.100222.

Usability Test: Features

Establish product

- Intended users/use environment
- Instructions for Use and other labeling
- Packaging
- Training

Task identification

- Use timeline/ journey: specimen collection, handling, storage, running test, interpreting results

https://www.abbott.com/corpnewsroom/diagnostics-testing/BinaxNOW-what-you-need-to-know.html, accessed 9/19/2023

Usability Test: Features

Establish product

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Task identification

- Use timeline/ journey: specimen collection, handling, storage, running test, interpreting results

Data collected

- Observational data
- Knowledge tasks, user comprehension
- Interview data

Usability Test: Data and Analysis

Aggregate and analyze data

Determine root cause of any use errors

Predetermined acceptance criteria?

Determine if further improvement is necessary

Documentation

Evaluate residual risk

FDA Approach to Usability Testing

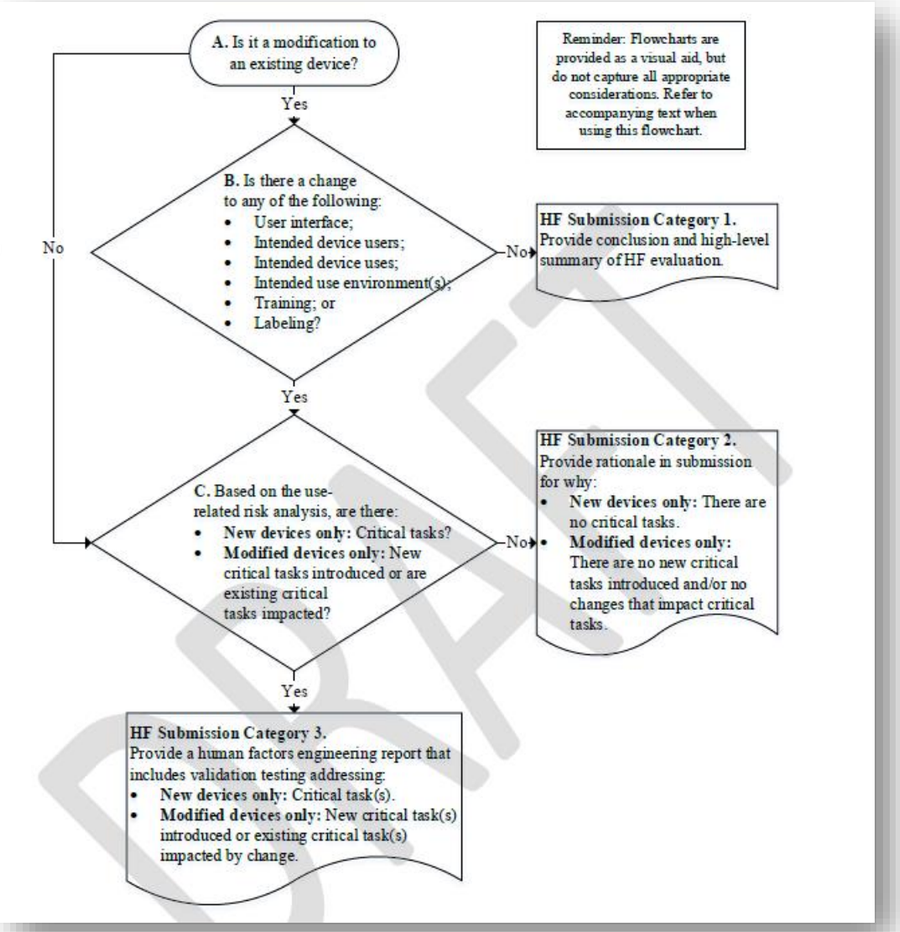
- Usability testing may be required to support 510(k), PMA, CLIA waivers [1,2]
- Risk based approach: Focus on critical task identification and categorization
  - User tasks categorized based on severity of potential harm that could result from use errors, as identified in risk analysis[2]
  - FDA doesn't prescribe risk analysis approach
- Does not differentiate devices used by trained healthcare professional vs patient or caregiver

[1] Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices, Guidance for Industry and Food and Drug Administration Staff, February 2020

[2] Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff, February 2016

FDA Approach to Usability Testing

- Usability content in marketing application determined by *critical tasks*[1]
  - *A user task which, if performed incorrectly or not performed at all, would or could cause serious harm to the patient or user, where harm is defined to include compromised medical care.*



[1] Content of Human Factors Information in Medical Device Marketing Submissions, Guidance for Industry and Food and Drug Administration Staff, December 2022

FDA Approach to Usability Testing

- Prescribed Usability Report Format
- CDRH Review of Usability Content
  - OPEQ
    - Office of Health Technology 7 (OHT 7: In Vitro Diagnostics)
    - Division of Health Technology 3 C (Drug Delivery and General Hospital Devices and Human Factors)

Table A-1. Outline of HFE/UE Report

Sec.	Contents
1	**Conclusion** The <device> has been found to be safe and effective for the intended users, uses and use environments. • Brief summary of HFE/UE processes and results that support this conclusion • Discussion of residual use-related risk
2	**Descriptions of intended device users, uses, use environments, and training** • Intended user population(s) and meaningful differences in capabilities between multiple user populations that could affect user interactions with the device • Intended use and operational contexts of use • Use environments and conditions that could affect user interactions with the device • Training intended for users
3	**Description of device user interface** • Graphical representation of device and its user interface • Description of device user interface • Device labeling • Overview of operational sequence of device and expected user interactions with user interface
4	**Summary of known use problems** • Known use problems with previous models of the subject device • Known use problems with similar devices, predicate devices or devices with similar user interface elements • Design modifications implemented in response to post-market use error problems
5	**Analysis of hazards and risks associated with use of the device** • Potential use errors • Potential harm and severity of harm that could result from each use error • Risk management measures implemented to eliminate or reduce the risk • Evidence of effectiveness of each risk management measure
6	**Summary of preliminary analyses and evaluations** • Evaluation methods used • Key results and design modifications implemented in response • Key findings that informed the human factors validation test protocol
7	**Description and categorization of critical tasks** • Process used to identify critical tasks • List and descriptions of critical tasks • Categorization of critical tasks by severity of potential harm • Descriptions of use scenarios that include critical tasks
8	**Details of human factors validation testing** • Rationale for test type selected (i.e., simulated use, actual use or clinical study) • Test environment and conditions of use • Number and type of test participants • Training provided to test participants and how it corresponded to real-world training levels • Critical tasks and use scenarios included in testing • Definition of successful performance of each test task • Description of data to be collected and methods for documenting observations and interview responses • Test results: Observations of task performance and occurrences of use errors, close calls, and use problems • Test results: Feedback from interviews with test participants regarding device use, critical tasks, use errors, and problems (as applicable) • Description and analysis of all use errors and difficulties that could cause harm, root causes of the problems, and implications for additional risk elimination or reduction

FDA Approach to Usability Testing

- EUA Templates for Molecular and Antigen Diagnostic Tests for Home Use
- Performance Evaluation to include Usability Study
  - Minimum 30 participants (15 self/15 caregiver), varying education levels, excluding medical/lab/self collection experience
  - Entire workflow performed by each participant using the kit
  - Quick reference instructions only
  - Participants to be observed, all difficulties noted
  - Data collected: User questionnaire, observation of packaging errors, sample adequacy
  - Pre-defined acceptance criteria and defined strategy to mitigate risk of errors identified in the study
  - User comprehension (of test results or critical elements)

https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas

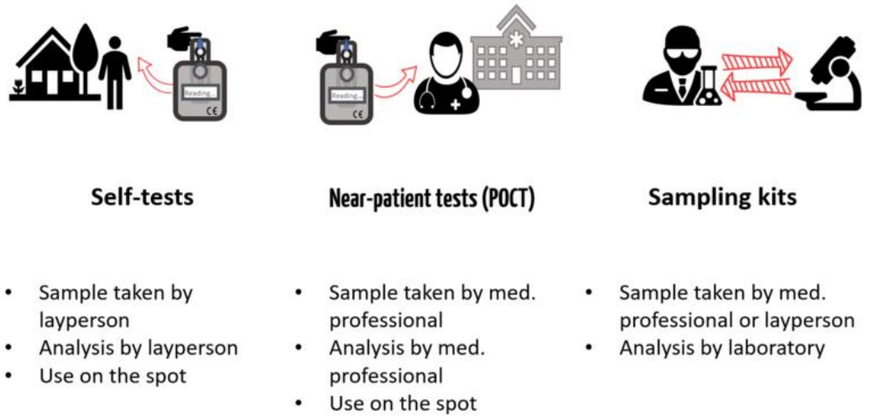
https://www.fda.gov/media/140615/download?attachment

FDA Guidances

Guidance	Date	Center	Notes
Applying Human Factors and Usability Engineering to Medical Devices	February 2016	CDRH	Supersedes List of Highest Priority Devices for Human Factors Review (2016) Will be updated based on comments on below
Content of Human Factors Information in Medical Device Marketing Submissions	December 2022	CDRH	
Safety Considerations for Product Design to Minimize Medication Errors	April 2016	CDER	
Application of Human Factors Engineering Principles for Combination Products: Questions and Answers	September 2023 (Final)	CDER	Supersedes Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development
Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications	August 2019	CDRH CBER	Supersedes Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approvals and De Novo Classifications (2016)
Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices	February 2020	CDRH CBER	

EU Approach to Usability Testing

- Usability engineering concepts embedded in EU Regulation
  - Reduce risks related to use error
  - Establish performance with intended users, use environments
  - Instructions for Use appropriate for user
  - Presentation of results appropriate for user



https://www.johner-institute.com/articles/health-care/and-more/self-tests-and-near-patient-tests-what-eu-law-says/, last accessed 9/23/2023

EU Approach to Usability Testing

- **EU 2017/746 IVDR Article 1 General Safety and Performance Requirements:**

5. Eliminate or reduce risks related to use error, considering
   - Ergonomic features
   - Use environment
   - Intended user: knowledge, experience, education, training, medical and physical conditions

9.4. Device performance established under normal conditions, i.e.
   - Being used by laypersons for **self-test** devices
   - Being used in relevant environment for **near-patient** devices

EU Approach to Usability Testing

- **EU 2017/746 IVDR Article 1 General Safety and Performance Requirements:**

19. Protection against risks posed by **self-test** or **near patient** devices

- Perform appropriately taking into account skills of user and influence of use environment
- Easy to understand instructions for interpreting result
- Near-patient testing instructions specify level of training/experience of user
- Ensure device can be used safely during all steps of use
- Reduce risk of error by intended user in handling device and specimen, and interpretation of results
- User can verify correct performance and is warned if valid result not provided

EU Approach to Usability Testing

- **EU 2017/746 IVDR Article 1 General Safety and Performance Requirements:**

20.4.2. **Self-test** device IFUs must contain

- Sufficient information to enable the user to use the device and to understand the result(s) produced by the device.
- An intended purpose that is comprehensible for laypersons.
- A presentation of results that is comprehensible for laypersons.
- Information on actions dependent on the test result (e.g., intervention (such as quarantine), recommended action (avoid certain allergens) or discharge (negative test result and therefore no restrictions))
- Information on restrictions (for example, age, sex, menstruation, infections, exercise, fasting, diet, or taking of medication)
- Additional information, some of which is member state-specific

Summary from https://www.johner-institute.com/articles/health-care/and-more/self-tests-and-near-patient-tests-what-eu-law-says/ last accessed 9/19/2023

EU Approach To Usability Testing

- **Conformity Assessment**
  - Self-testing or near-patient testing:

QMS/Technical Documentation	Type Examination
Description of the **design aspects that make them suitable** for self- or near-patient testing (Annex II 3.1(e) IVDR)	Data showing the **handling suitability of the device in relation to its intended purpose** for self-testing or near patient-testing (Annex X 2 IVDR)
Test reports including **results of studies carried out with intended users** (Annex IX 5.1 IVDR)	Test reports, including **results of studies carried out with intended users** (Annex X 2 IVDR)

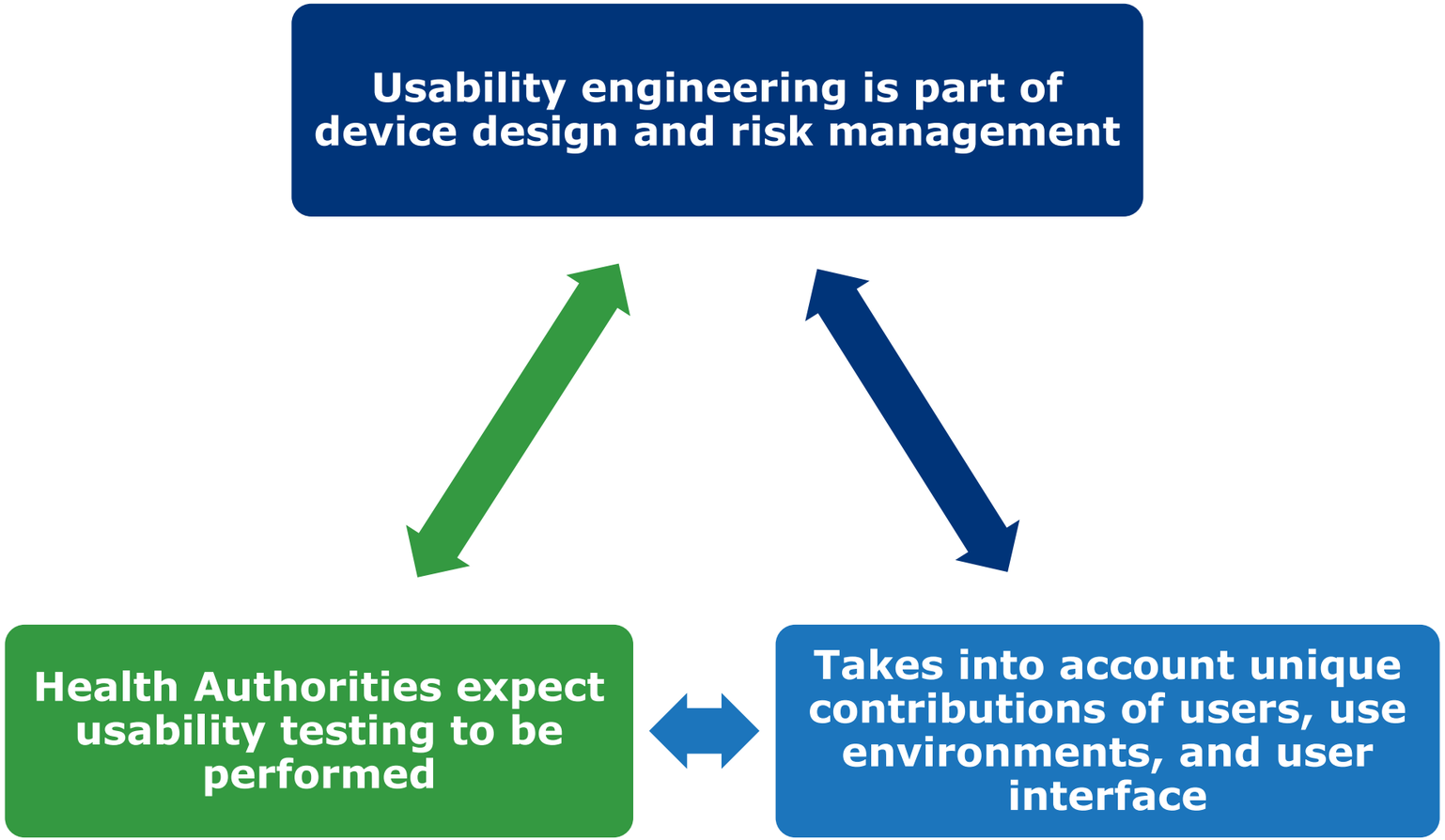
- **Summary of Safety and Performance**
  - Template includes section on self-testing devices for patients or lay persons

EU 2017/746 IVDR
MDCG 2022-9 Summary of safety and performance Template May 2022

Comparison of Approaches

US	EU
Based in Risk Management: focus on critical task identification	Based in Risk Management (ISO 62366, 14971)
Requirements per Guidances	Requirements per EU IVDR
Requirements not specifically differentiated by intended user	Self-test vs near-patient test requirements specified in IVDR
Must incorporate intended users, use environments, established product	Must incorporate intended users, use environments, established product

Key Takeaways

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