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WORLDWIDE GUIDE TO HUMAN FACTORS

SEPTEMBER 16, 2021

BRYANT FOSTER
ANDERS ORN

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MEDICAL DEVICE QUALITY IS ALL WE DO, AND WE'RE ALWAYS AHEAD OF THE GAME.

75
years industry experience

275k
podcast listeners

#1
blog and podcast in the industry

114k
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THE WALL STREET JOURNAL.
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"Best eQMS I have ever used..."

This is the easiest eQMS I have used in the 20 years I have been in the Medical Device Industry. ***It is simple, intuitive and easy to use...*** We are successfully implementing a Quality Culture.

- Director of Regulatory Affairs & Quality Assurance

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"Demystifying QMS and Regulatory Requirements"

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"Makes your QMS Simple and Effective"

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PRESENTERS

BRYANT FOSTER, MS
VP, Human Factors

ANDERS ORN, MS
Sr. Human Factors Scientist

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PRODUCT EXPERIENCE

Cardiac

Cardiac surgery devices
Artificial organs
Catheter delivery systems
Pacemakers/defibrillators
Vascular devices
Blood flow meters

Diagnostics

Imaging systems
Biosensors
Kinematic analysis
In vitro diagnostics
Image analysis
Biopsy systems

Combination Products

Injection devices
Infusion pump
Autoinjectors
Drug delivery devices
Pre-filled syringes
Medication dispensing

Electronic Medicine

Electronic medicine records
Telemedicine platforms
Health-related mobile apps
Wearable devices
Robotic surgical systems

Monitoring

Glucose meter
Monitors and pumps
Remote patient monitoring
Patient monitors
At-home diagnostics

Therapy Assistance

Wheelchair accessible vehicles
Assistive walking devices
Negative pressure wound therapy
Pain treatment
Therapeutic devices

Training & IFU

Training programs
Reprocessing procedures
Instructions for use (IFU)
Online education software
Clinician training

And More…

Hemophilia products
Rare diseases
Home infusion
Reproductive health
Ophthalmologic devices
OTC products

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AGENDA

- Definitions
- Who should employ human factors engineering
- The human factors process
- Human factors across markets (US, EU, UK, International)
- Reports
- Questions from audience

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WHO SHOULD EMPLOY HFE/UE?

- If the result of a use error could result in harm to the patient or user, you should employ HFE/UE.
- Risk, risk, risk

Market	Regulation	HFE/UE Guidance
US	ANSI/AAMI/ISO 14971*	Applying Human Factors and Usability Engineering to Medical Devices (2016)
EU	EU Medical Device Regulation (MDR)	IEC 62366-1 Part 1: Application of usability engineering to medical devices IEC TR 62366-2 Part 2: Guidance on the application of usability engineering to medical devices
UK	UK Medical Device Regulation (MDR)	Guidance on applying human factors and usability engineering to medical devices including drug-device combination products in Great Britain (2021)
China, South Korea, Australia, Canada		

DEFINITIONS

Human factors / usability engineering

The application of knowledge about human behavior, abilities, limitations, and other characteristics of medical device users to the design of medical devices to achieve adequate usability of all parts of a user interface. Human factors engineering and usability engineering are synonymous. (FDA)

DEFINITIONS

Usability testing

Method used to evaluate a product's usability, which usually employs simulated-use of the device in question.

DEFINITIONS

Validation / Summative Usability Testing

Usability testing conducted at the end of the device development process to identify use errors that would or could result in serious harm to the patient or user. Human factors validation testing is also used to assess the effectiveness of risk management measures. (FDA)

DEFINITIONS

Critical task

A user task which, if performed incorrectly or not at all, would or could cause serious harm to the patient or user, where harm is defined to include compromised medical care. (FDA, MHRA)

DEFINITIONS

Use error

User action or lack of action while using the medical device that leads to a different result than that intended by the manufacturer or expected by the user. (IEC 62366-1, MHRA)

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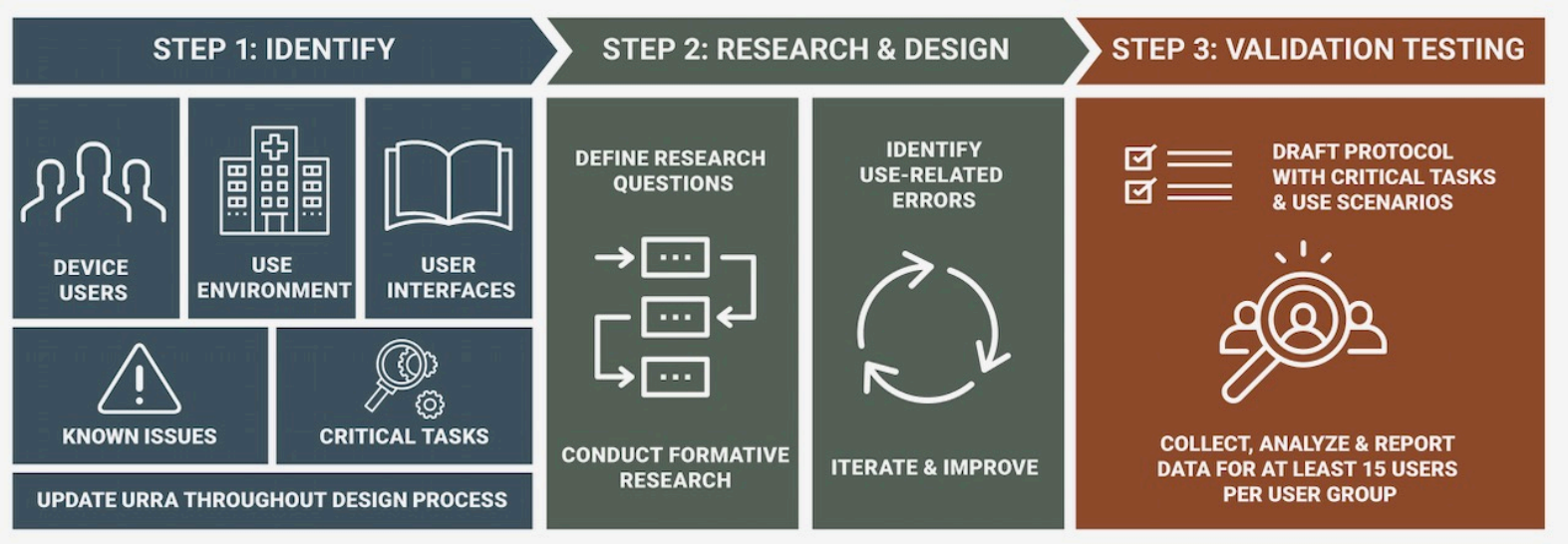
HUMAN FACTORS PROCESS



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IDENTIFY DEVICE USERS

Who:

- Purchases the device?
- Receives the device?
- Unpacks the device?
- Sets up the device?
- Uses the device?
- Cleans/reprocesses the device?
- Disposes of the device?

Characteristics:

- What physical limitations do they have?
- What cognitive limitations do they have?
- What is their level of education and training?
- What is their emotional state when using the device?

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IDENTIFY DEVICE USERS

Objective

Identify the abilities and limitations of the device's users so that the device may be designed for those users.

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IDENTIFY DEVICE USE ENVIRONMENTS

Where is the device used?

- Home vs. clinical
- Lighting
- Noise(s)
- Temperature
- Distractions
- Cleanliness
- Space

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IDENTIFY DEVICE USE ENVIRONMENTS

Objective

Identify the characteristics of the use environment that could impact the safety, effectiveness, and usability of the device.

IDENTIFY DEVICE USER INTERFACE

Anything the user sees, touches, hears, smells, or otherwise interacts with.

- Physical device
- Instructions for use (IFU)
- Labeling and packaging
- Screens
- Buttons
- Training

IDENTIFY DEVICE USER INTERFACE

Objective

Identify the characteristics of the user interface that could impact the safety, effectiveness, and usability of the device.

IDENTIFY KNOWN USE ISSUES

Primary research:

- Interviews with device users
- Observational research with device users
- Interviews with trainers

Secondary research:

- Literature
- Internal complaint logs
- Databases

6.2 Identification of Known Use-Related Problems

When developing a new device, it is useful to identify use-related problems (if any) that have occurred with devices that are similar to the one under development with regard to use, the user interface or user interactions. When these types of problems are found, they should be considered during the design of the new device's user interface. These devices might have been made by the same manufacturer or by other manufacturers. Sources of information on use-related problems include customer complaint files, and the knowledge of training and sales staff familiar with use-related problems. Information can also be obtained from previous HFE/UE studies conducted, for example, on earlier versions of the device being developed or on similar existing devices. Other sources of information on known use-related hazards are current device users, journal articles, proceedings of professional meetings, newsletters, and relevant internet sites, such as:

- FDA's Manufacturer and User Facility Device Experience (MAUDE) database;
- FDA's MedSun: Medical Product Safety Network;
- CDRH Medical Device Recalls;
- FDA Safety Communications;
- ECRI's Medical Device Safety Reports;
- The Institute of Safe Medical Practices (ISMP's) Medication Safety Alert Newsletters; and
- The Joint Commission's Sentinel Events.

All known use errors and use-related problems should be considered in the risk analysis for a new device and included if they apply to the new device.

FDA, 2016

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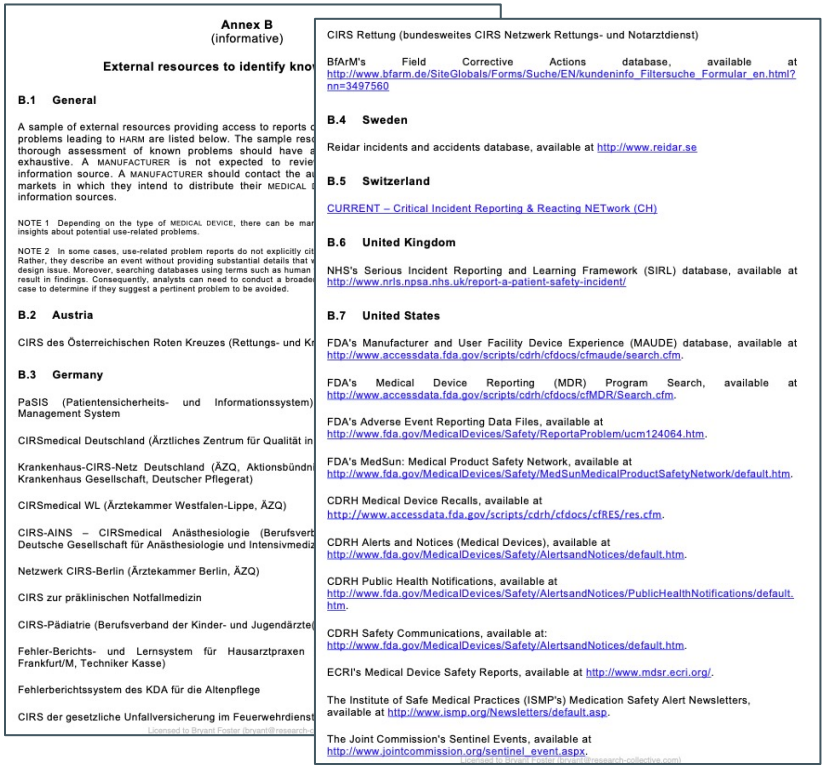
IDENTIFY KNOWN USE ISSUES

Primary research:

- Interviews with device users
- Observational research with device users
- Interviews with trainers

Secondary research:

- Literature
- Internal complaint logs
- Databases



Annex B
(informative)

External resources to identify kno

B.1 General

A sample of external resources providing access to reports o problems leading to HARM are listed below. The sample rese thorough assessment of known problems should have a exhaustive. A MANUFACTURER is not expected to revie information source. A MANUFACTURER should contact the au markets in which they intend to distribute their MEDICAL D information sources.

NOTE 1 Depending on the type of MEDICAL DEVICE, there can be mar insights about potential use-related problems.

NOTE 2 In some cases, use-related problem reports do not explicitly cit Rather, they describe an event without providing substantial details that v design issue. Moreover, searching databases using terms such as human result in findings. Consequently, analysts can need to conduct a broade case to determine if they suggest a pertinent problem to be avoided.

B.2 Austria

CIRS des Österreichischen Roten Kreuzes (Rettungs- und Kr

B.3 Germany

PaSIS (Patientensicherheits- und Informationssystem) Management System

CIRSmedical Deutschland (Ärztliches Zentrum für Qualität in

Krankenhaus-CIRS-Netz Deutschland (ÄZQ, Aktionsbündni Krankenhaus Gesellschaft, Deutscher Pflegerat)

CIRSmedical WL (Ärztekammer Westfalen-Lippe, ÄZQ)

CIRS-AINS – CIRSmedical Anästhesiologie (Berufsverb Deutsche Gesellschaft für Anästhesiologie und Intensivmediz

Netzwerk CIRS-Berlin (Ärztekammer Berlin, ÄZQ)

CIRS zur präklinischen Notfallmedizin

CIRS-Pädiatrie (Berufsverband der Kinder- und Jugendärzte(

Fehler-Berichts- und Lernsystem für Hausarztpraxen Frankfurt/M, Techniker Kasse)

Fehlerberichtssystem des KDA für die Altenpflege

CIRS der gesetzliche Unfallversicherung im Feuerwehrdienst

CIRS Rettung (bundesweites CIRS Netzwerk Rettungs- und Notarztdienst)

BfArM's Field Corrective Actions database, available at http://www.bfarm.de/SiteGlobals/Forms/Suche/EN/kundeninfo_Filtersuche_Formular_en.html?nn=3497560

B.4 Sweden

Reidar incidents and accidents database, available at http://www.reidar.se

B.5 Switzerland

CURRENT – Critical Incident Reporting & Reacting NETwork (CH)

B.6 United Kingdom

NHS's Serious Incident Reporting and Learning Framework (SIRL) database, available at http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/

B.7 United States

FDA's Manufacturer and User Facility Device Experience (MAUDE) database, available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.

FDA's Medical Device Reporting (MDR) Program Search, available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMDR/Search.cfm.

FDA's Adverse Event Reporting Data Files, available at http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/ucm124064.htm.

FDA's MedSun: Medical Product Safety Network, available at http://www.fda.gov/MedicalDevices/Safety/MedSunMedicalProductSafetyNetwork/default.htm.

CDRH Medical Device Recalls, available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm.

CDRH Alerts and Notices (Medical Devices), available at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/default.htm.

CDRH Public Health Notifications, available at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/default.htm.

CDRH Safety Communications, available at: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/default.htm.

ECRI's Medical Device Safety Reports, available at http://www.mdsr.ecri.org/.

The Institute of Safe Medical Practices (ISMP's) Medication Safety Alert Newsletters, available at http://www.ismp.org/Newsletters/default.asp.

The Joint Commission's Sentinel Events, available at http://www.jointcommission.org/sentinel_event.aspx.

IEC TR 62366-2

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IDENTIFY KNOWN USE ISSUES

Objective

Learn from the mistakes of previous versions of the device or similar devices of other manufacturers.

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IDENTIFY CRITICAL TASKS

1. Identify all device tasks
2. Identify use-related risks and associated harm for each device task
3. Assign severity level for each use-related risk
4. Select a subset of tasks based on severity to be included in validation/summative usability testing

Example

Task	Use-related risk	Harm	Severity of harm
Remove needle protector	Accidental needle stick	Solution delivered to user	3 - Serious
	Contaminate needle	Infection	3 - Serious
	Damage needle	Pain	2 - Marginal
Insert needle into skin	Accidental needle stick	Solution delivered to user	3 - Serious
	Incorrect insertion angle	Pain	2 - Marginal

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IDENTIFY CRITICAL TASKS

Objective

- Identify which tasks have use-related risk.
- Identify which tasks you need objective usability data for in order to evaluate the device's safety and effectiveness.

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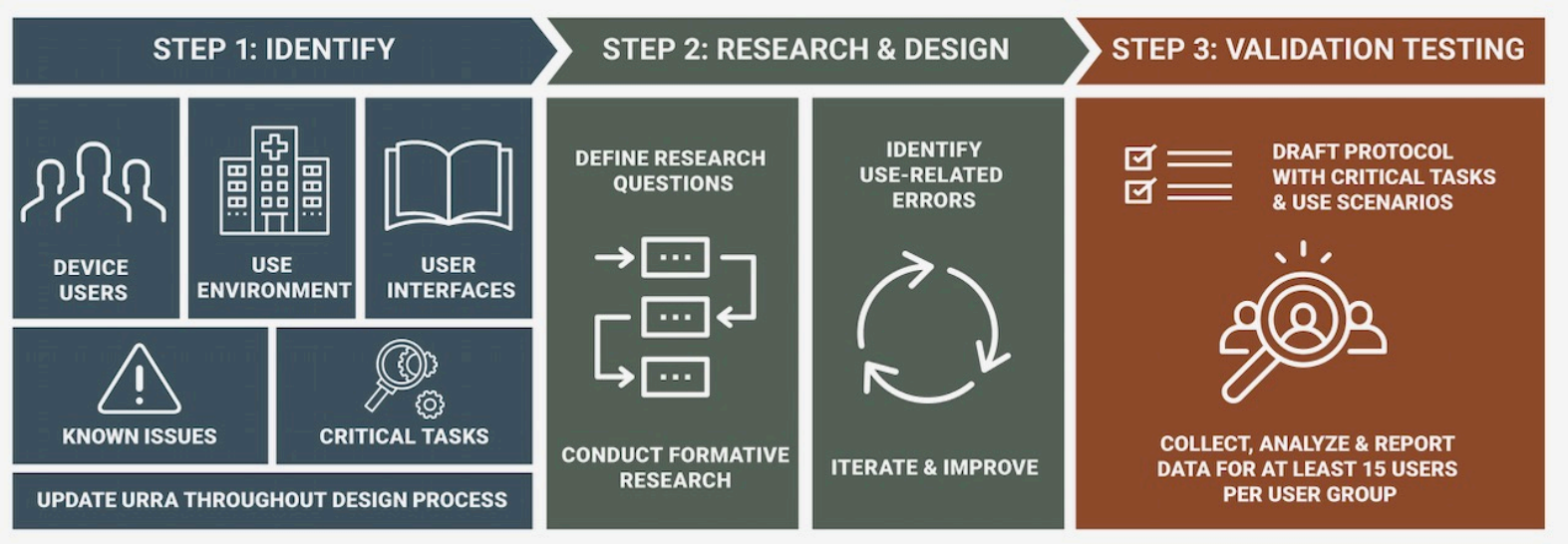
HUMAN FACTORS PROCESS



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CONDUCT FORMATIVE RESEARCH

- Identify part(s) of user interface under evaluation
- Identify research questions
- Select research method (i.e., usability test, interviews, heuristic evaluation)
- Sample size (5-7 participants will do)
- Learn everything you can

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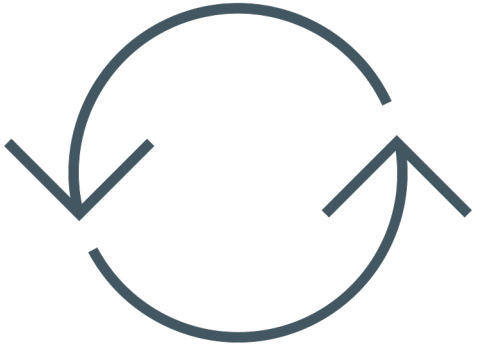
ITERATE AND IMPROVE

- Focus on critical tasks
- Build confidence for validation / summative usability testing
- Perfect the validation / summative usability study protocol



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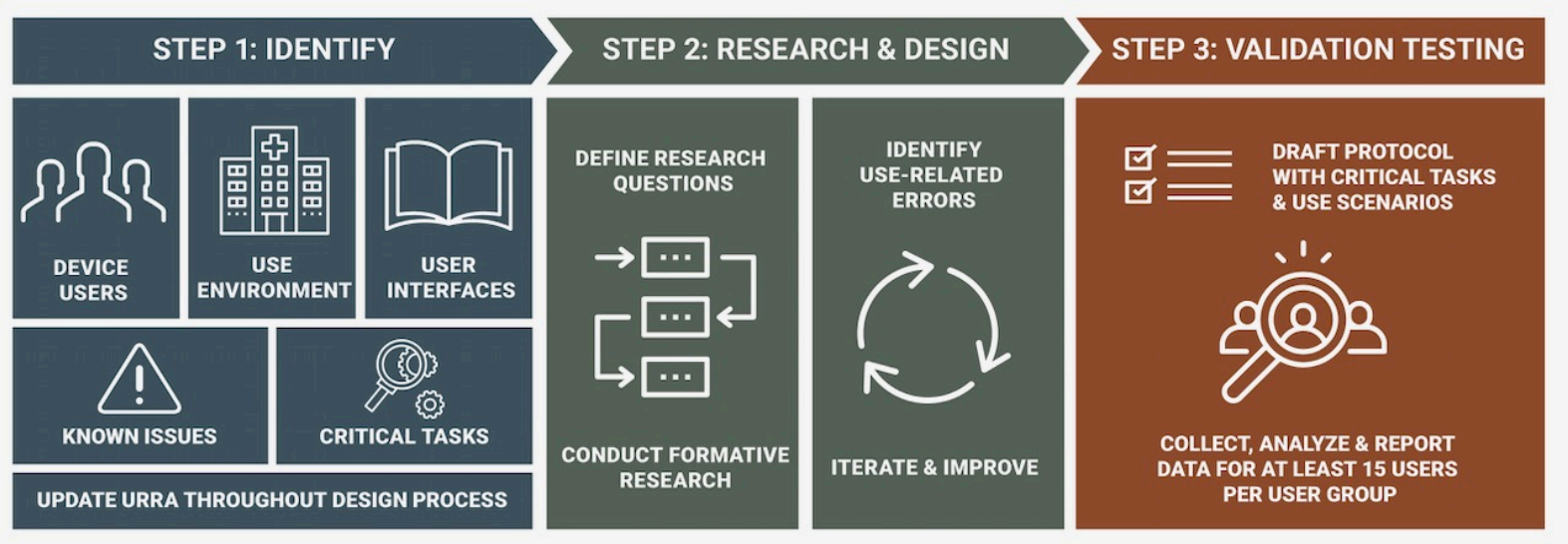

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VALIDATION USABILITY STUDY

Goal:

Obtain objective evidence that the user interface can be used safely

Important details:

- Entire user interface is evaluated in its final form
- Simulated study environment
- Training is representative of real world and includes a decay period
- All critical tasks are evaluated via simulated-use tasks or open-ended comprehension questions
- No bias or hints to the participants!
- Determine root causes of use errors, difficulties, and close calls
- 15 participants per user group

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COMPARING MARKETS

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COMPARING MARKETS: IDENTIFY

HFE/UE Activity / Topic	FDA Guidance	IEC 62366-1, -2	MHRA Guidance
Identify intended users	✓	✓	✓
Identify intended uses	✓	✓	✓
Identify intended use environments	✓	✓	✓
Define training, if any	✓	✓	✓
Create a use specification document	Does not mention a specific use specification document	✓	✓

COMPARING MARKETS: IDENTIFY

HFE/UE Activity / Topic	FDA Guidance	IEC 62366-1, -2	MHRA Guidance
Describe the user interface, including technical requirements	Does not mention technical requirements, only a description	Does not mention description of user interface, only technical requirements	✓
Create user interface specification document	Does not mention a specific UI spec document	✓	✓
Identify known use-related issues	✓	✓	✓
Identify use-related hazards	✓	✓	✓
Define “critical” tasks	✓	✓	✓

COMPARING MARKETS: FORMATIVE RESEARCH

HFE/UE Activity / Topic	FDA Guidance	IEC 62366-1, -2	MHRA Guidance
Create a user interface evaluation plan	Does not mention a user interface evaluation plan	✓	✓
Sample validation/ summative evaluation protocol	Does not provide a sample protocol*	✓	Does not provide a sample protocol*
Conduct formative evaluations	✓	✓	✓
Revise use-related issues	✓	✓	✓

*Formative and validation / summative protocols are still needed

COMPARING MARKETS: VALIDATION STUDY

HFE/UE Activity / Topic	FDA Guidance	IEC 62366-1, -2	MHRA Guidance
Validation / summative usability study	✓	✓	✓
Simulated use environment	✓	✓	✓
Include representative users	✓	✓	✓
Sample size: 15 participants per user group	✓	Does not commit to a 15-participant requirement, but suggests 15 may be sufficient	✓
Tasks / hazard-related scenarios under evaluation	Only critical tasks required	All hazard-related scenarios OR a subset of highest severity (critical tasks only)	Critical tasks AND essential tasks

COMPARING MARKETS: VALIDATION STUDY

HFE/UE Activity / Topic	FDA Guidance	IEC 62366-1, -2	MHRA Guidance
Finalized design	✓	✓	✓
Validate instructions for use (IFU)	✓	✓	Specifies a specific study evaluating the IFU in addition to validation/summative
Training decay period of at least 1-hour	✓	Does not specify a minimum training decay period length	✓
Evaluate residual risk after validation / summative study	✓	✓	✓
Post-market surveillance	Does not mention post-market surveillance	✓	✓

COMPARING MARKETS: REPORTS

FDA Guidance Deliverable: Human Factors and Usability Engineering Report

1. Conclusion
2. Descriptions of intended device users, uses, use environments, and training
3. Description of device user interface
4. Summary of known use problems
5. Analysis of hazards and risks associated with use of the device
6. Summary of preliminary analyses and evaluations
7. Description and categorization of critical tasks
8. Details of human factors validation testing

COMPARING MARKETS: REPORTS

IEC 62366-1 & IEC TR 62366-2 Deliverable: Usability Engineering File

1. Use specification
2. User interface characteristics related to safety and potential use errors
3. Known or foreseeable hazards and hazardous situations
4. Hazard-related use scenarios
5. Hazards or hazardous situations
6. User interface specification
7. User interface evaluation plan
8. Formative evaluation usability test report(s)
9. Summative evaluation test protocol
10. Summative evaluation test report

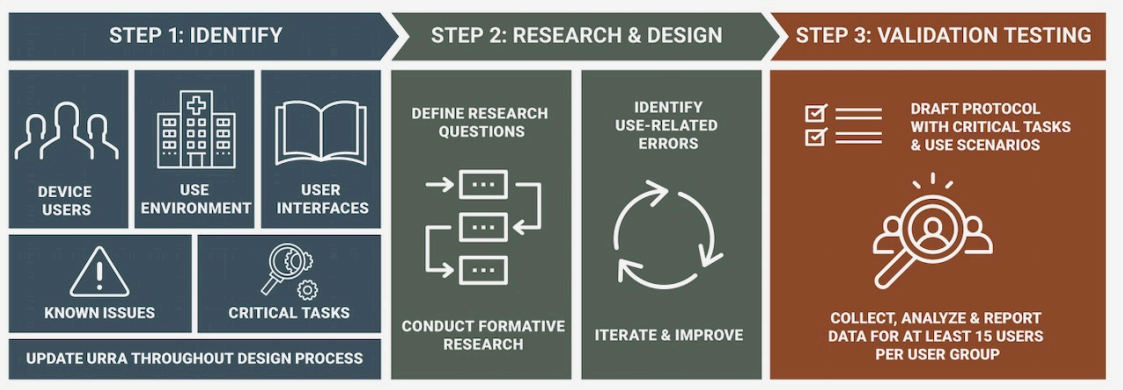
COMPARING MARKETS: REPORTS

MHRA Guidance Deliverable: Human Factors Summary Report

1. Intended device users, uses, environments, and training
2. Description of the device user interface
3. Summary of known use problems (device under consideration and other related devices in market)
4. User task selection and prioritization (based on the risk management file)
5. Summary of formative evaluations
6. Results of summative usability testing (including manual validation
7. Benefit-risk status of the device from the risk management file
8. Conclusions

CONCLUSIONS

- The human factors process is largely the same, regardless of market. The guidances are largely harmonized.
- When in doubt, use IEC 62366-1 and IEC TR 62366-2.



RESOURCES

AAMI TIR59: 2017 Integrating human factors into design controls

ANSI/AAMI HE75:2013 Human Factors Engineering – Design of Medical Devices

ANSI/AAMI/IEC 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices

ANSI/AAMI/IEC 62366-2:2016 Medical devices – Part 2: Guidance on the application of usability engineering to medical devices

Faulkner, L. (2003). Beyond the five-user assumption: Benefits of increased sample sizes in usability testing. Behavior Research Methods, Instruments, and Computers, 35(3), 379-383

U.K. Medicines & Healthcare products Regulatory Agency, 2021, Guidance on applying human factors and usability engineering to medical devices including drug-device combination products in Great Britain

U.S. Food and Drug Administration, 2016, Guidance for Industry and FDA Staff: Applying Human Factors and Usability Engineering to Medical Devices

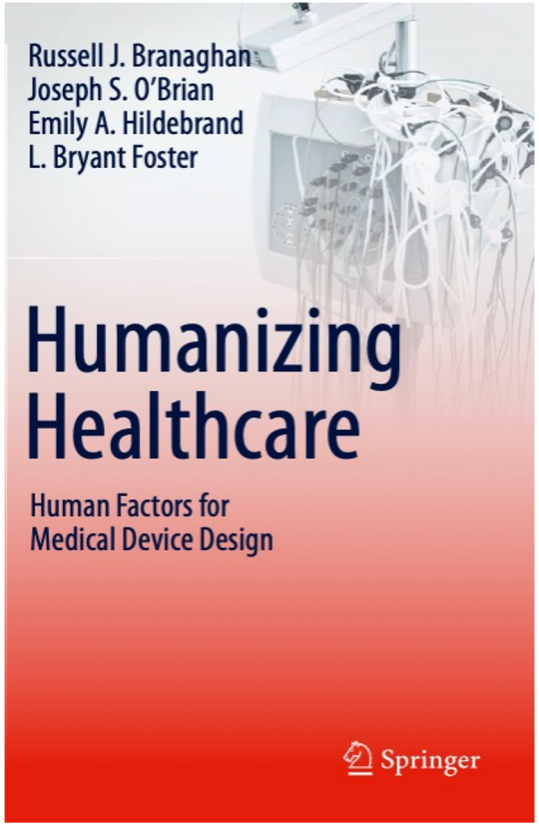
RESOURCES

Russ Branaghan, Bryant Foster, Emily Hildebrand and Joe O'Brian, from our team, recently co-authored a book, *Humanizing Healthcare*

A comprehensive guide to human factors engineering principles, guidelines, and design methods for medical device design

Email: book@research-collective.com

The book can also be purchased from Amazon using the following link: https://www.amazon.com/Humanizing-Healthcare-Factors-Medical-Device-dp-3030644324/dp/3030644324/ref=mt_other?_encoding=UTF8&me=&qid=



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THANK YOU

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