GDUFA

June 3rd, 2025

A Taxonomy for Categorizing User Interface Design in Medical Device Development

Human Factors Application, Development Opportunities, and Potential Integration of AI and Machine Learning

MEGAN CONRAD, PHD

University of Detroit Mercy

MARYBETH PRIVITERA, PHD

University of Cincinnati

Goals

Introduce Taxonomy for identifying UI design features

Discuss research and development considerations for using taxonomy necessary to improve / enhance ANDA HF submissions

FDA Funded Research - U01FD007360

Development of a Combination Product Taxonomy and Comparative Human Factors Testing Method for Drug-Device Combination Products Submitted in an ANDA

MEGAN CONRAD, PHD

University of Detroit Mercy

MELISSA LEMKE, MS

University of Wisconsin at Milwaukee

MARYBETH PRIVITERA, PHD

University of Cincinnati

MOLLY STORY, PHD

Human Spectrum Design

MOLLY LAIRD, PHD

HS Design

PROCESS for seeking approval of a generic DDCP

Demonstrate INTERCHANGEABILITY through CUHF Study

Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA: Draft Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Andrew LeBoeuf, 240-402-0503.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

January 2017
Generics

The CUHF Process

Comparative Analysis

Comparative Task Analysis

- Differences in user interaction (No/minor/other)

Physical Device / Labeling Comparative Analysis

- Critical Design Attributes
- Product Differences (No/Minor/Other)

Comparative Use Human Factors Study

Plan Product Testing

- Populations
- Environment
- Protocol

Test Products (RLD/Generic)

- Success/Use Error

Evaluate Experimental Data

- Pass/Fail (No/Minor Difference)

Analyze Statistical Data

- Use Error Rate within Non-inferiority margin

CHALLENGES for implementing CUHF Studies

CUHF Challenges (2017 draft guidance)

HF Methodology w/ Use Error Rate

Focus on Generic comparable to RLD

Challenging Statistical Methods

Difficult to Define "Minor" vs "Other"

ELSEVIER

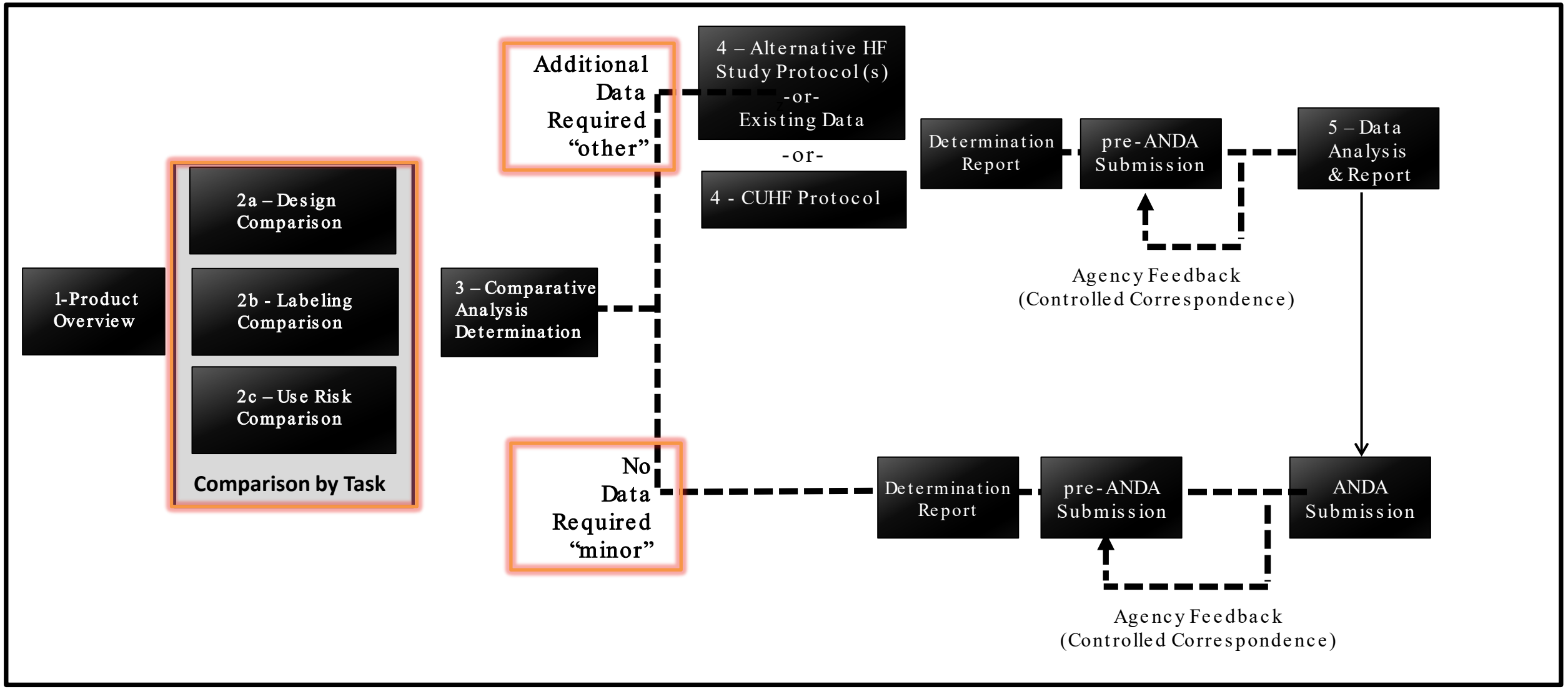
Human Factors in Healthcare
Volume 7, June 2025, 100099

Survey analysis on comparative use human factors processes

Megan O. Conrad [a], Mary Beth Privitera [b], Molly E. Laird [c], Melissa R. Lemke [d], Molly Follette Story [e]

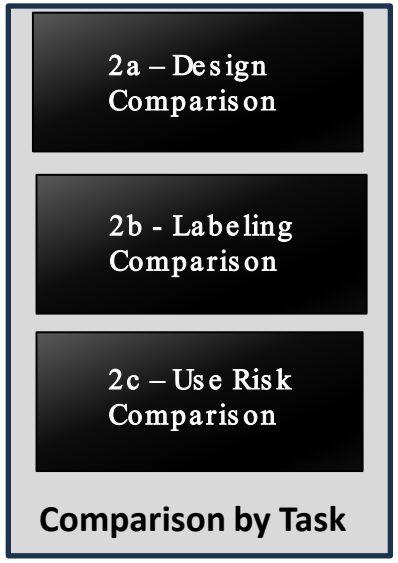
Challenging and Unfamiliar Methods!

Human Factors Process for Determining CUHF and Submitting ANDA



Scientific Challenge

Human Factors Process for Determining CUHF and Submitting ANDA



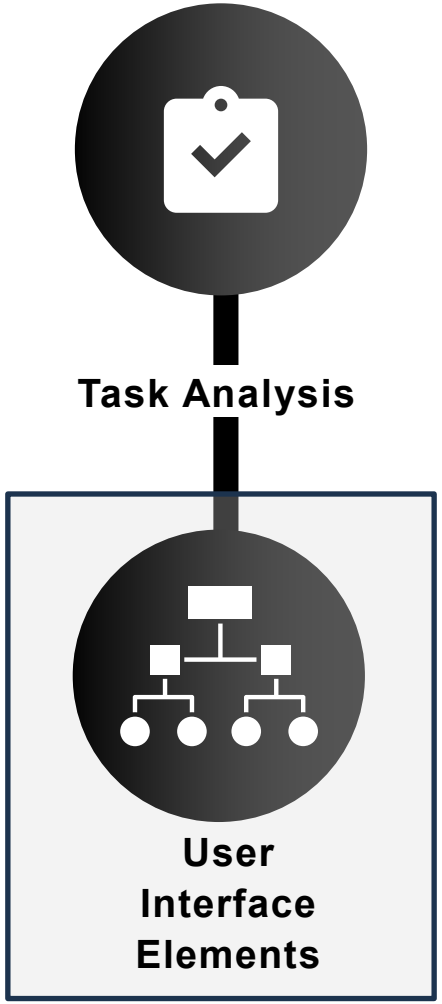
Scientific Challenge

ANDA procedures currently lack a common procedure/language for comparing UI design features between a proposed generic and its RLD.

Solution

Standardized tool identifying differences in UI design attributes of proposed generic DDCPs in preparation for ANDA submissions

Link User Interface Elements to Task



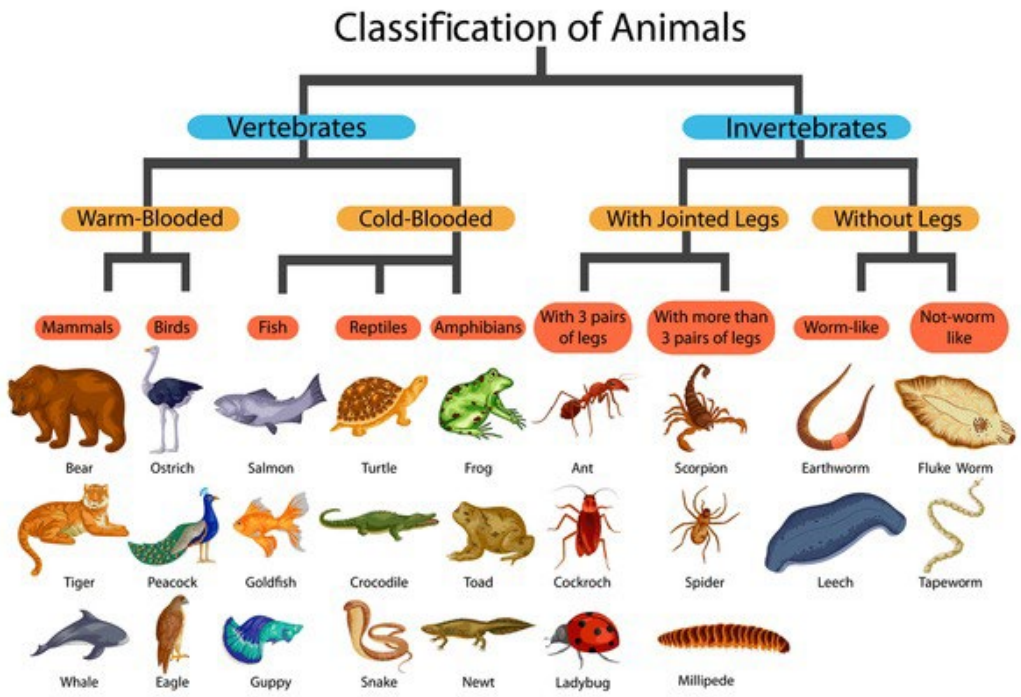
USER INTERFACE influences PRODUCT DELIVERY

Are these the same? Are they substitutable?

…..not as easy as ketchup.

How do we link DESIGN (attributes) to TASKS?

Taxonomy of design:
A method for organizing subject-specific concepts and creating a vocabulary for those concepts



User Interface

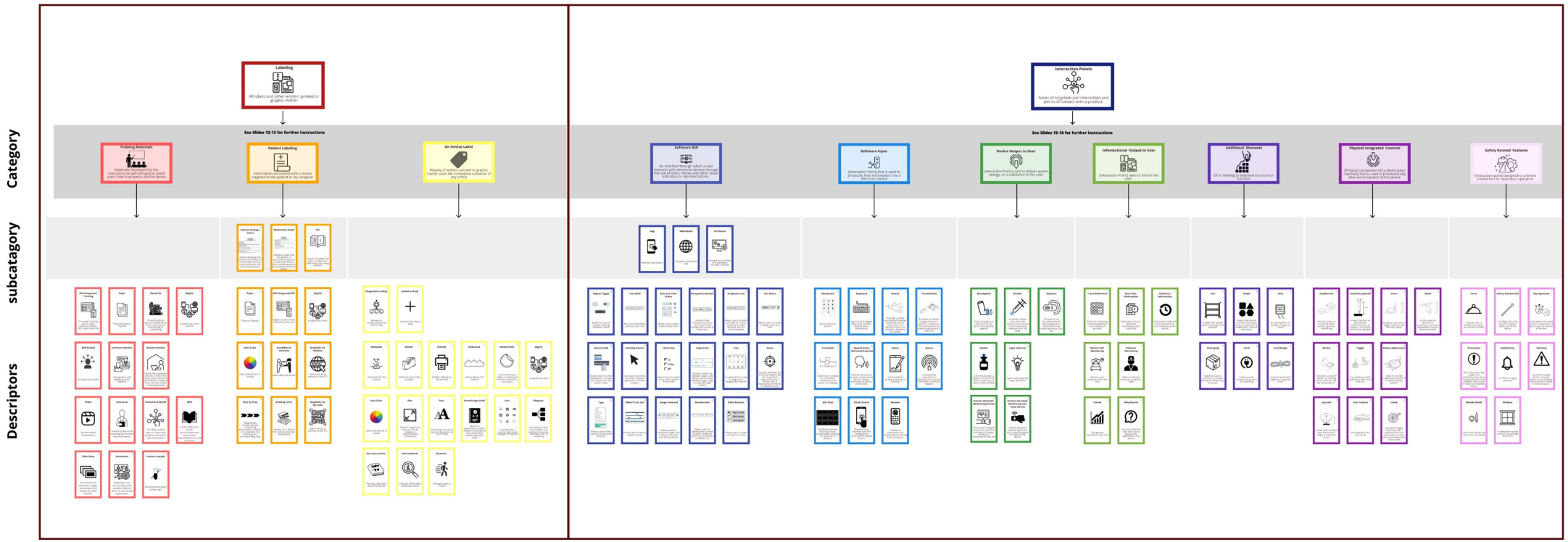
Labeling

All labels and other written, printed or graphic matter

Interaction Points

Areas of targeted user interaction and points of contact with a product.

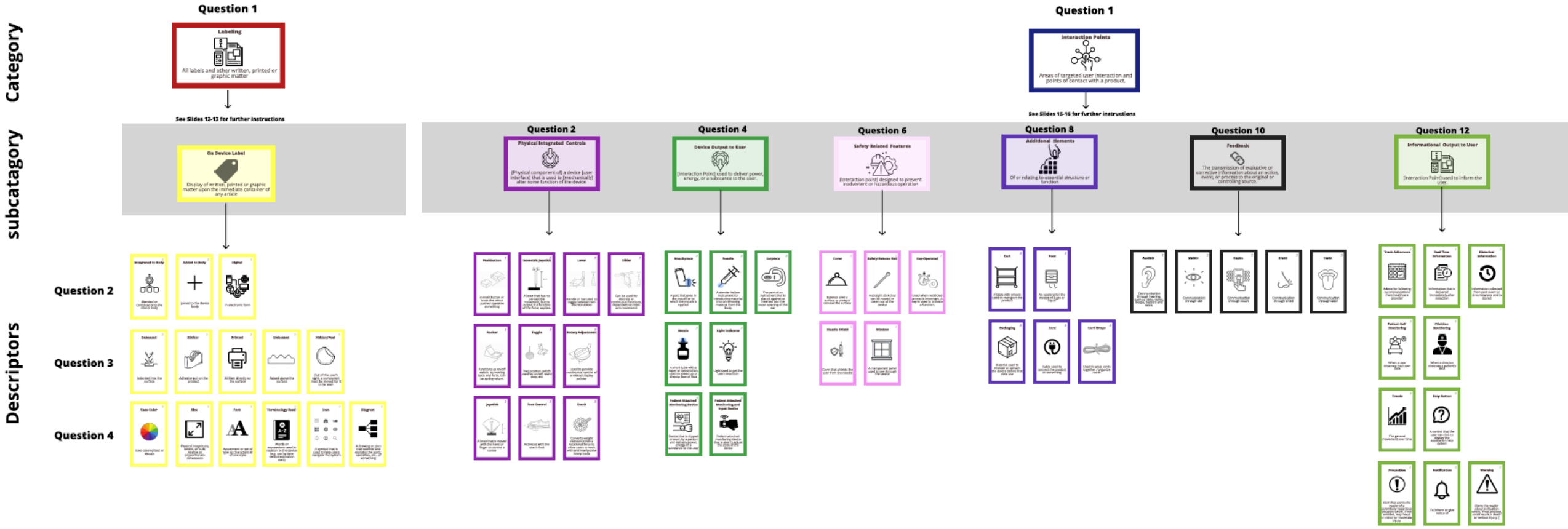
Medical Device UI Design Taxonomy*



Labeling **Interaction Points**

*** Developed using literature review on product design attribute descriptions, AAMI ANSI HE 75 design nomenclature.**

Taxonomy for Classifying the User Interface Design Components of DDCPs



A systematic process for comparing generics to RLDs

Comparison of Task and Design

Instructions on using Design Feature Taxonomy

1. Use Taxonomy to identify & classify design

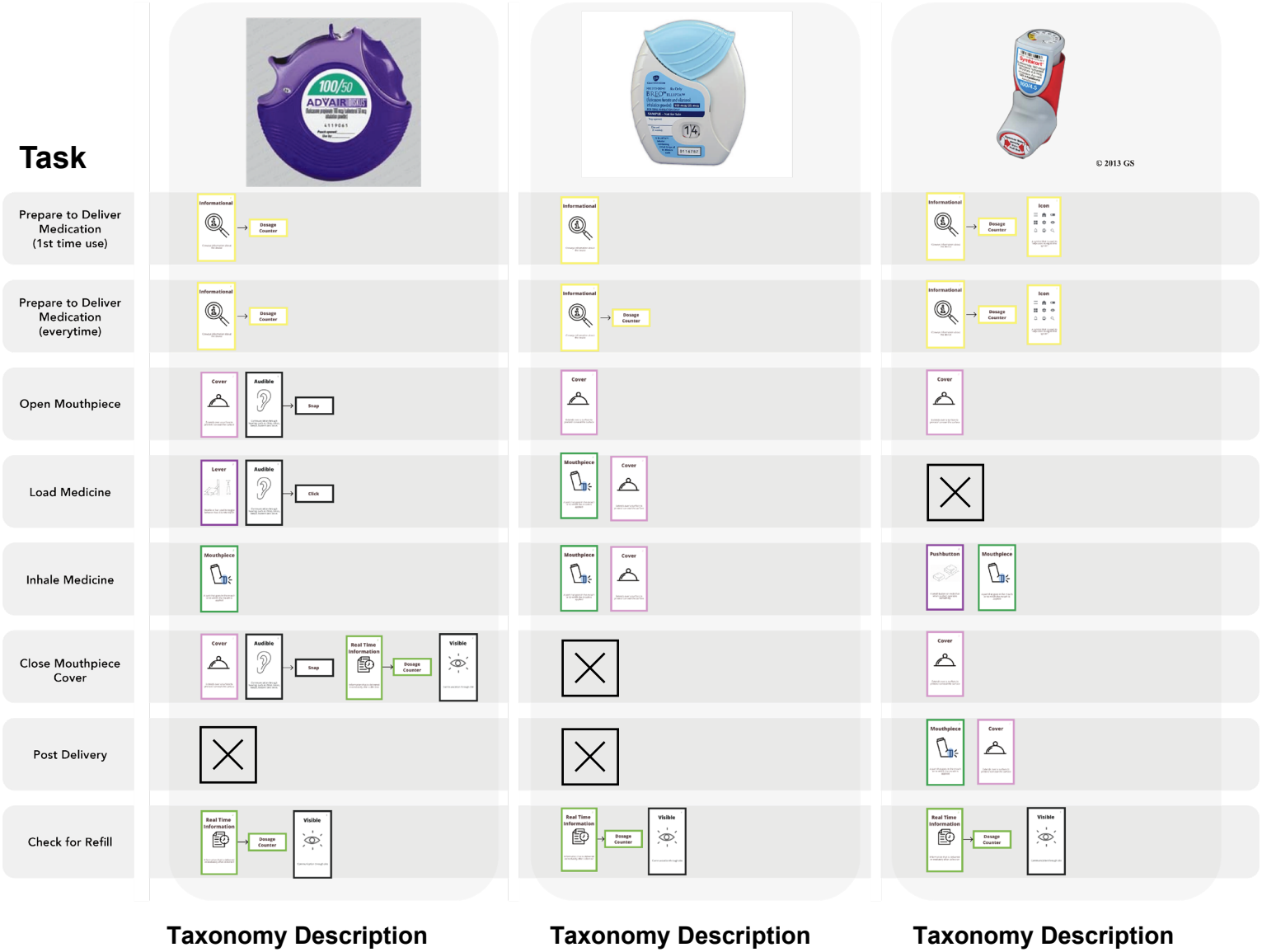
2. Use Task Analysis to relate design features to tasks

3. Conduct Risk Analysis [using TA]

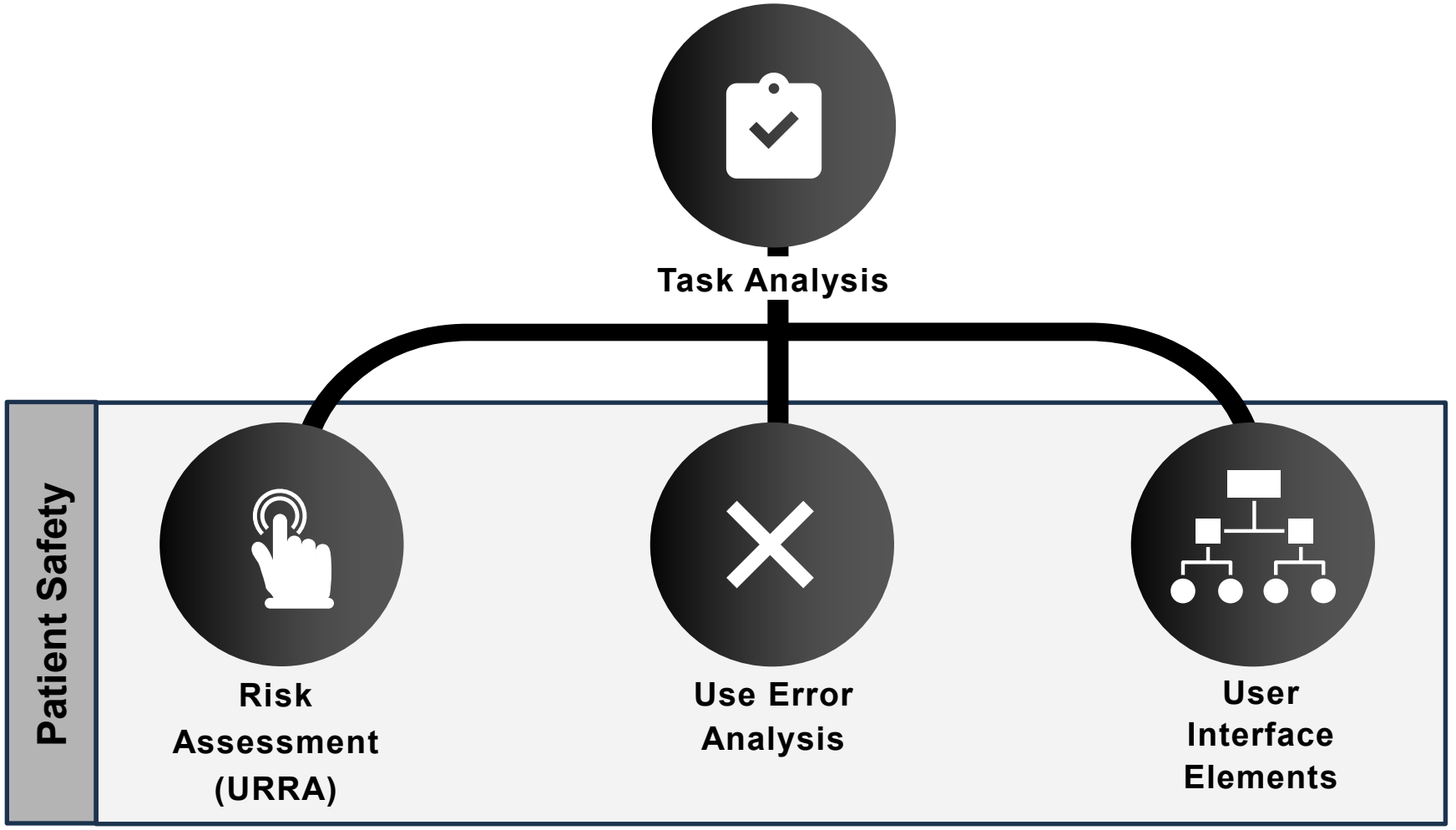
4. Compare RLD to Generic based on taxonomy to determine design differences

   Minor difference = change within a sub-category

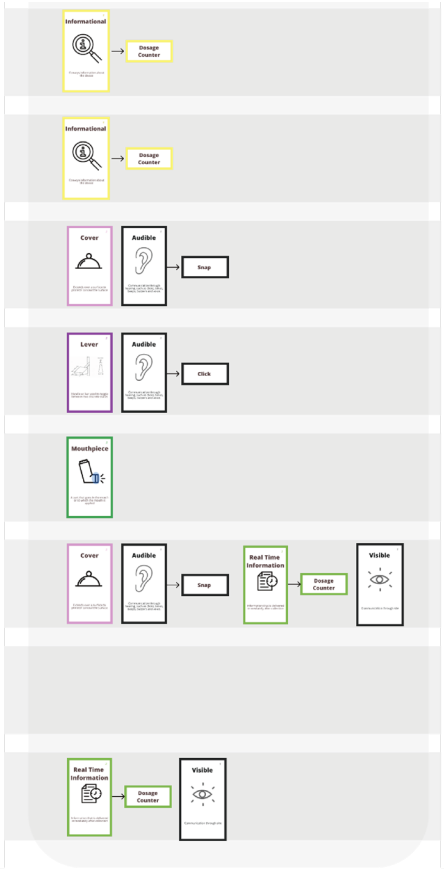
   Other difference = change in design feature identification (e.g., IFU is printed on device rather than paper handout)



Task Analysis can link DESIGN features, potential USE ERRORS, and associated RISK



Common Task Analysis: Links UI Taxonomy to Potential Use Risk

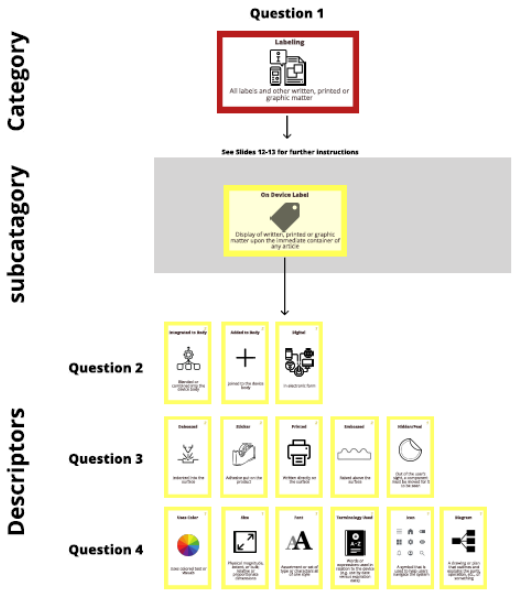


URRA –Use Related Risk Analysis

Task ID	Subtask	Potential use errors	Clinical consequences/	Crticial Task?
3	3.1 Hold the DISKUS in one hand and place the thumb/finger of your other hand in the thumb grip.	Does not place thumb/finger on thumb grip	Delay of therapy	N
	3.2 Push the thumb grip away from you as far as it will go until the mouthpiece shows and cover snaps into place	Does not rotate thumb grip		
		Insufficient rotation of thumb grip; doesn't engage cover latch		
4	4.1 Hold DISKUS in a level, flat position.	Does not hold device horizontally (parallel to ground)	No dose administered	Y
	4.2 Slide the lever until you hear the click	Does not slide the lever away from the mouthpiece as far as it can go	No dose administered	
		Closes the diskus	Repeated loading over-dosing	
		Moves lever once pushed down	Repeated loading over-dosing	

Taxonomy Evolution

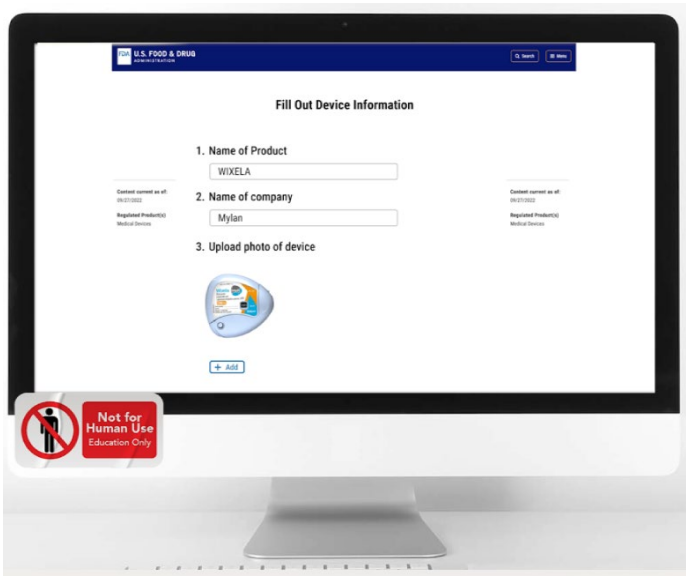
Card Sorting



Spreadsheet

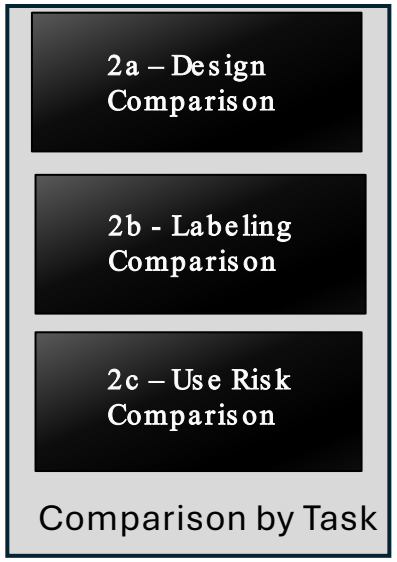
Task Analysis					User Interface
Task #	Task	Sub Task	Group	Category	Subcategory & Descriptors
1.1	Install batteries	Remove monitor from case	Interaction_Points	Fundamental_Elements	Packaging
1.2		open door on back of device	Interaction_Points	Safety_Related_Features	Cover
			Interaction_Points	Physical_Integrated_Controls	Other
			Labeling	On_Device_Label	Icon
			Labeling	On_Device_Label	Embossed
		Insert batteries	Interaction_Points	Fundamental_Elements	Other
		Replace Cover	Interaction_Points	Safety_Related_Features	Cover
			Interaction_Points	Safety_Related_Features	Cover
2.1	Apply Cuff	Insert cuff air plug into the left side of monitor unit	Interaction_Points	Fundamental_Elements	Cord
			Labeling	On_Device_Label	Embossed
2.2		Remove thick clothing from arm			
2.3		Sit in quiet place, with arm supported and legs uncrossed			
2.4		Fasten cuff to left arm with the middle of the cuff at the level of your heart	Labeling	On_Device_Label	Printed
			Labeling	On_Device_Label	Use_Instructions
			Labeling	On_Device_Label	Use_Instructions
			Interaction_Points	Physical_Device_Output	Patient_attached_monitoring_device
3.1	Take Blood Pressure	hold start/stop button to turn on and pressurize	Interaction_Points	Physical_Integrated_Controls	Pushbutton
			Labeling	On_Device_Label	Printed
3.2		Sit still and allow device to pressurize			
3.3		Once done pressurizing, remove cuff from arm	Interaction_Points	Physical_Device_Output	Patient_attached_monitoring_and_input_device

Interactive Software Tool



Research Need

Human Factors Process for Determining CUHF and Submitting ANDA



Proposed Research Initiative

Develop a user-friendly, web-based taxonomy for comparing UI design features between the generic and RLD

Incorporate ML and AI as a tool to further understand and improve patient safety

Vision for further FDA supported RESEARCH and DEVELOPMENT

FDA U.S. FOOD & DRUG ADMINISTRATION

Search Menu

Fill Out Device Information

1. Name of Product

WIXELA

Content current as of:
09/27/2022

Regulated Product(s)
Medical Devices

2. Name of company

Mylan

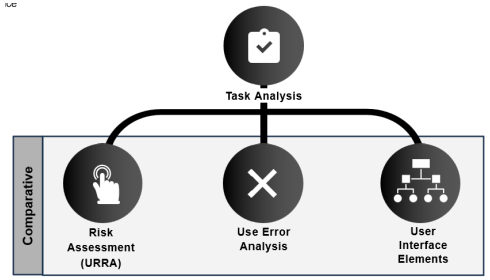
Content current as of:
09/27/2022

Regulated Product(s)
Medical Devices

3. Upload photo of device

+ Add

The CUHF Process



Comparative Analysis

Create URRA
- Task Analysis
- Critical Tasks WRT risk
- Set Success Criteria per Task

Comparative Task Analysis
- Differences in user interaction (no/minor/other)

Physical Device / Labeling Comparative Analysis
- Critical Design Attributes
- Product Differences (No/Minor/Other)

Link Design Differences to Critical Tasks
- Critical tasks and corresponding design differences

Comparative Use Human Factors Study

Plan Product Testing
- Populations
- Environment
- Protocol

Test Products (RLD/Generic)
- Success/Use Error
- Close Call/ Difficulties
- Root Cause of UE/CC/D

Evaluate Experimental Data
- Pass/Fail (No/Minor Difference)
- S/UE/CC/D
- “Other” Differences

Analyze Statistical Data
- Use Error Rate within Non-inferiority margin
- Root Cause Analysis

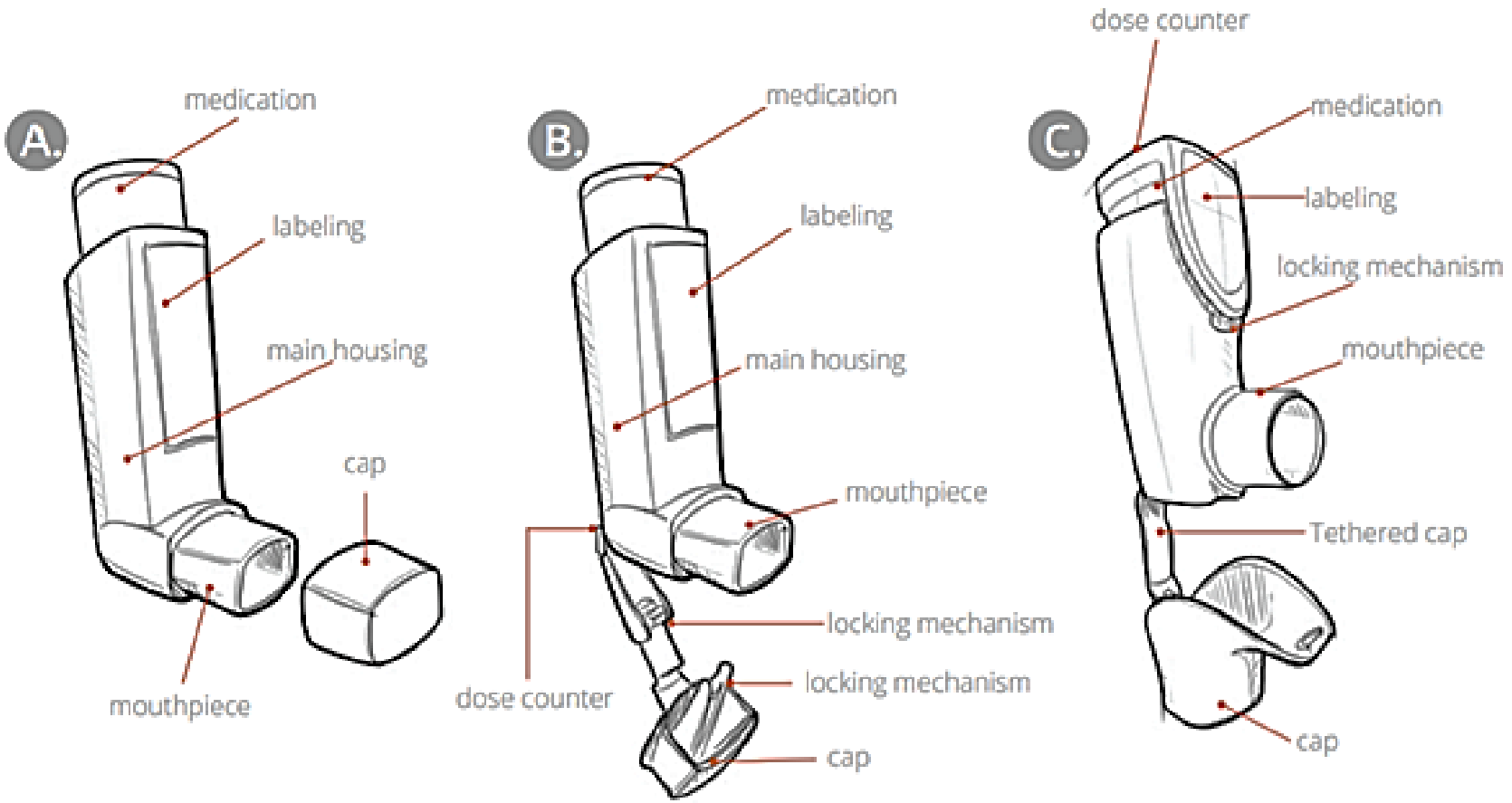
Not required in current draft guidance

Research Need

How can AI and ML enhance the vision?

Applications for AI and ML

1) **Detect** UI Design Differences



Research Need

Applications for AI and ML

2) Re-structure taxonomy **Categorization/Classification** by identifying patterns in data:

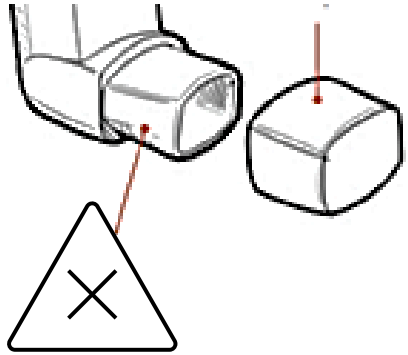
Device/Category	Technology	Regulatory Path	Anatomical App	Context of Use
Diagnostic	Mechanical	NDA	Neurological	Hospital based
Therapeutic	Electronic	ANDA	Cardiovascular	Wearable
Monitoring	Software Driven	Etc.	Orthopedic	Implantable
Assistive	Hybrid		Etc.	Etc.
DDCP	Etc.			
etc.				

Research Need

Applications for AI and ML

3) Learn and **Predict** possible difficulty and hazards associated with design

Link UI Design Feature to Potential Risk



Link User Population to Difficulty with UI Design

Challenges

Source data – Sponsors must agree to submission

Data volume – Will take time to gather sufficient data set

Data quality – Consider rare user-populations, low-frequency device use, context of use

Research Need

Taxonomy Research and Development can lead to… future use with AI and ML

Advantages to Industry

- Taxonomy **guides innovation** while **ensuring compliance** and reliability
- **Repeatable methodology** leading to SOPs for HF ANDA submission
- **Common language** for device designers, manufacturers, HF experts and regulators

Advantages to Regulators

- Improved **quality** & **efficiency** of reviews with consistent method for ANDA submission comparing UI device characteristics
- Taxonomy acts as **training tool** for reviewers related to UI design
- Potential to link to **adverse event reporting** (FAERS and MAUDE databases)
- Opportunity to integrate **real world evidence**

Thank you!

MEGAN CONRAD, PHD

University of Detroit Mercy

MELISSA LEMKE, MS

University of Wisconsin at Milwaukee

MARY BETH PRIVITERA, PHD

University of Cincinnati

MOLLY STORY, PHD

Human Spectrum Design

MOLLY LAIRD, PHD

HS Design