Human Ability Designs

We Muddled Our Way Through Comparative Use Human Factors (CUHF): Now what?

Melissa R. Lemke, MS

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Human Ability Designs

Melissa Lemke

Human Ability Designs

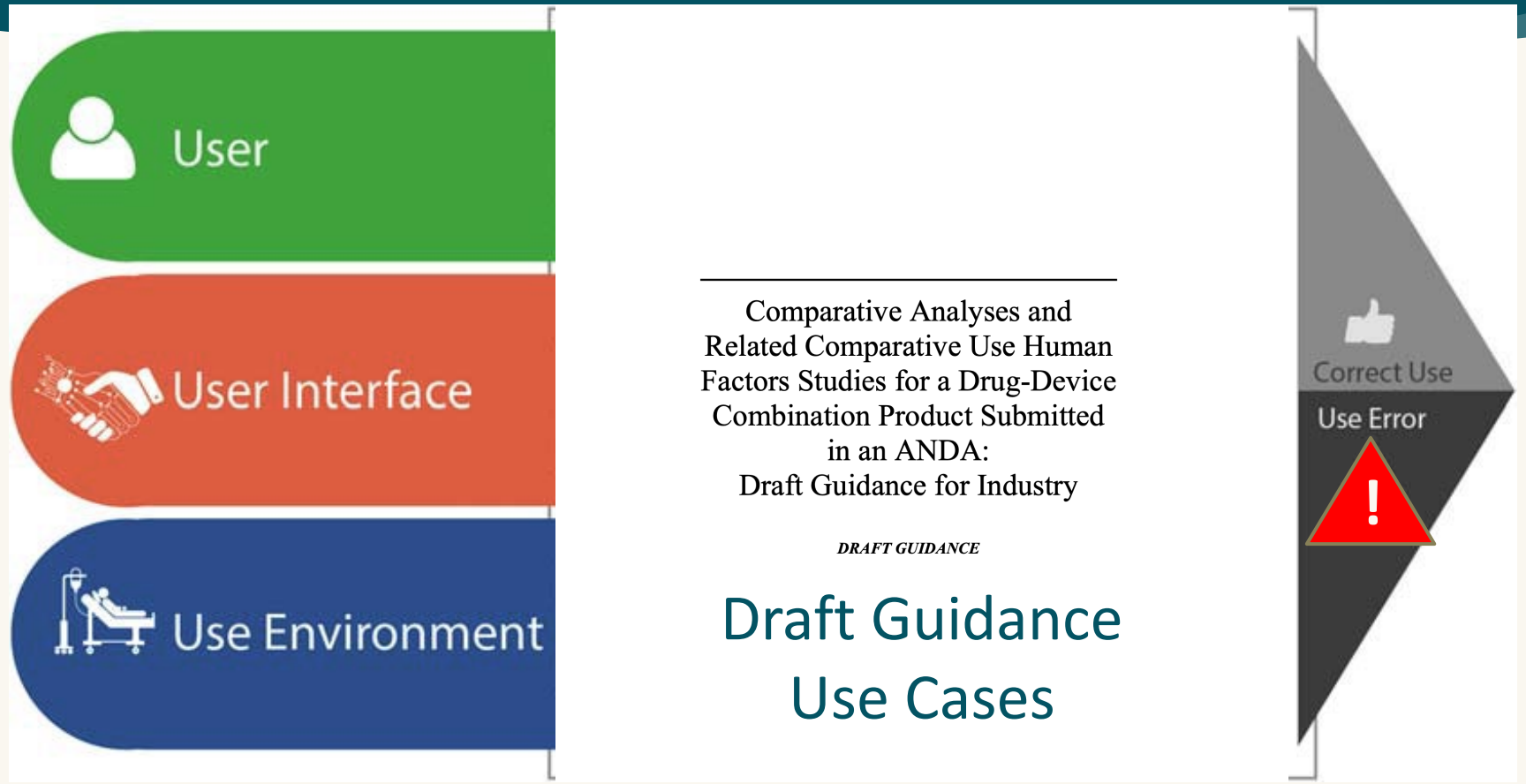
https://www.linkedin.com/company/human-ability-designs

- Regulatory **human factors engineering (HFE) advising and training** for designers and developers of medical and drug delivery devices
- Human Factors Pre-FDA Reviews, HFE Training, SME on call
- Led by Melissa Lemke, biomedical engineer and HFE with 21 years in the industry, AAMI HF instructor, Instructor at UW-Milwaukee and University of Cincinnati
  - Lay caregiver turned professional HFE
  - **100% first time regulatory success** designing and implementing HF science to bring hundreds of safe & effective client products to the market

Industry Perspectives: Vignettes from Interview Data and Client Projects

Disclaimer: The information contained in this presentation is to be used only as examples for teaching purposes. The information is based on factual information, but due to confidentiality agreements the vignettes do not contain actual client information. Opinions formulated by the author are intended to stimulate discussions and improvements with the FDA CUHF method and HF submissions for FDA generic product market submissions.

Human Factors of the Generic DDCP Draft Guidance



Excerpted and Adapted from Privitera, *Applied Human Factors in Medical Device Design*. FIG. 1.1 Major HF components of a device-user system interactions which result in device use outcomes. *Adapted from FDA/CDRH, 2016 Guidance.*

CUHF Users – Diverse Expert Stakeholders

- FDA Regulators - pre ANDA and ANDA reviewer teams
- Consultants – HF Experts, Statisticians, etc.
- Pharma Companies – Drug Developers, Regulatory, Quality, Risk Management, etc.
- Device Developers – Engineering, Designers, Platform Device Developers, etc.
- Collectively:
  - Confusion with CUHF draft guidance requests
  - Experimentation with novel HF methods for ANDA
  - Frustration with regulatory approval delays and methodology challenges

CUHF as a User Interface – Draft Guidance (Jan 2017)

Novel Features in ANDA Guidance:

- Comparative / Threshold Analysis
- Statistics for HF evaluations of med products - Non-inferiority
- Approved generic = Same clinical effect and safety profile as RLD
- External critical design attributes
- No mention of URRA
- Minor & Other design differences
- Use error rates

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

https://www.fda.gov/media/102349/download

CUHF Use Environment – Generic DDCP Development

- Drug and device patents last 20 years and create competitive market
- Competitive drug development landscape prevents collaboration and publishing of HF data
  - Pre- and post market use-safety data are limited
- ANDAs require proof that the generic drug is bioequivalent to the RLD (no preclinical and clinical trial data required)
  - Dosage, form, strength, route of administration, quality, performance characteristics, and intended use
- HF budgets are significantly less than clinical study budgets

CUHF Use Cases – Generic DDCP Development

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

Draft Guidance Use Cases

- Comparative Analysis during **early design** to guide development and determine if ANDA pathway is feasible
  - ANDA is <u>not</u> for seeking to innovate or improve RLD
  - Sponsor rarely has access to or 'right to reference' RLD HF documentation (e.g., task analysis, URRA, HF validation data, etc.)
  - Industry goal is to avoid (or minimize) design differences
- ANDA also requires **HF Validation Study** for proposed generic (per CFR 820.30), which could be usable as justification for no CUHF
- **URRA** is important piece of ANDA regulatory submission to identify critical tasks, which could help standardize FDA reviews
- Comparative Analyses may identify '**other design differences**' that require CUHF data
  - Industry goal is to avoid (or minimize) identification of other design differences
  - Experienced and novice HF professionals have difficulties in categorization and justification of other design differences

Industry Realities – CUHF Challenges

From: Privitera, Applied Human Factors in Medical Device Design. FIG. 11.6 Interviewer who is actively listening to participant. *Photo provided by HS Design.*

Human factors method	Cost range	Considerations
Contextual inquiry	$50,000–$250,000+	# of site visits, costs associated with p access, honoraria
Task analysis	$5,000–$15,000+	# of iterations/revisions, level of deta
HF in design	$5,000–$15,000+	Uniqueness of user interface, complex
Formative studies	$5,000–$75,000+	User involvement, # of formative stuc recruiting, location, travel, honoraria
Use risk analysis	$5,000–$40,000+	# of iterations/revisions, level of deta
Known use error analysis	$2,500–$60,000+	# of incidents reported, # of varying c findings
Summative study	$60,000–$250,00+	# of distinct user groups, costs associa location, travel, honoraria, residual ri

From: Privitera, Applied Human Factors in Medical Device Design. TABLE 3.1 Cost estimates for human factors activities.

From: https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers

Challenging Methods

- Participant recruitment – Adolescents, Experienced
- RLD Procurement – Cost, Supply-chain, Legal
- Statistics – Meaningful delta for NI statistics, Rates versus Risk (potential harm)
- Simulated use testing method – RLD contains actual drug

HF Budget Constraints

- N=65-85 participants per user group means high study fees
  - Site rental
  - Participant recruitment and incentives
  - RLD and proposed generic
- HF Validation Study: ~$250,000 CUHF Study ~$1,000,000

Delays to Market

- FDA controlled correspondence to gain alignment can take years
- Recruitment challenges – especially RLD experienced users
- CUHF data collection and analysis

Let's Shift our Focus to Potential HF Solutions!

Dr. Megan O. Conrad

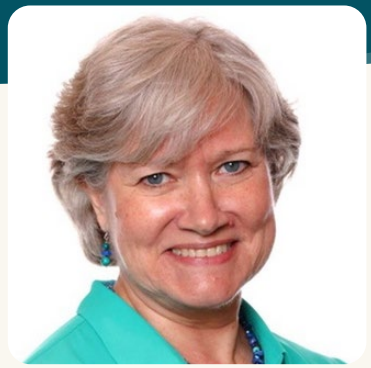
Dr. Megan Conrad leads our FDA collaborative grant as the PI at University of Detroit Mercy. Dr. Conrad is an Associate Professor in the Dept. of Mechanical Engineering who leads the Biomedical Design Program and Center for Assistive Technology.

Melissa R. Lemke, MS

Melissa Lemke provides HF regulatory advising for FDA and international human factors engineering programs along with outcomes based training for product design and development teams of medical devices and combination products.

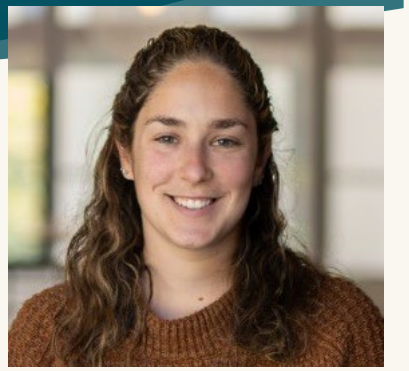
Dr. Mary Beth Privitera

Dr. Mary Beth Privitera is Professor of Biomedical Engineering at the University of Cincinnati and Principal Design and Human Factors Expert at Sentiar who has worked globally in the medical device industry since 1988.



Dr. Molly F. Story

Human Spectrum Design provides consulting on human factors for medical devices and combination products, particularly to satisfy FDA requirements, minimize use-related risk, and provide a superior user experience.



Dr. Molly Laird

Dr. Molly Laird is a Human Factors Engineer at HS Design, which is a full service user centered design firm specializing in Medical and Digital Health product and user interface design.

Our FDA Funded CUHF Research (2021 – 2024)

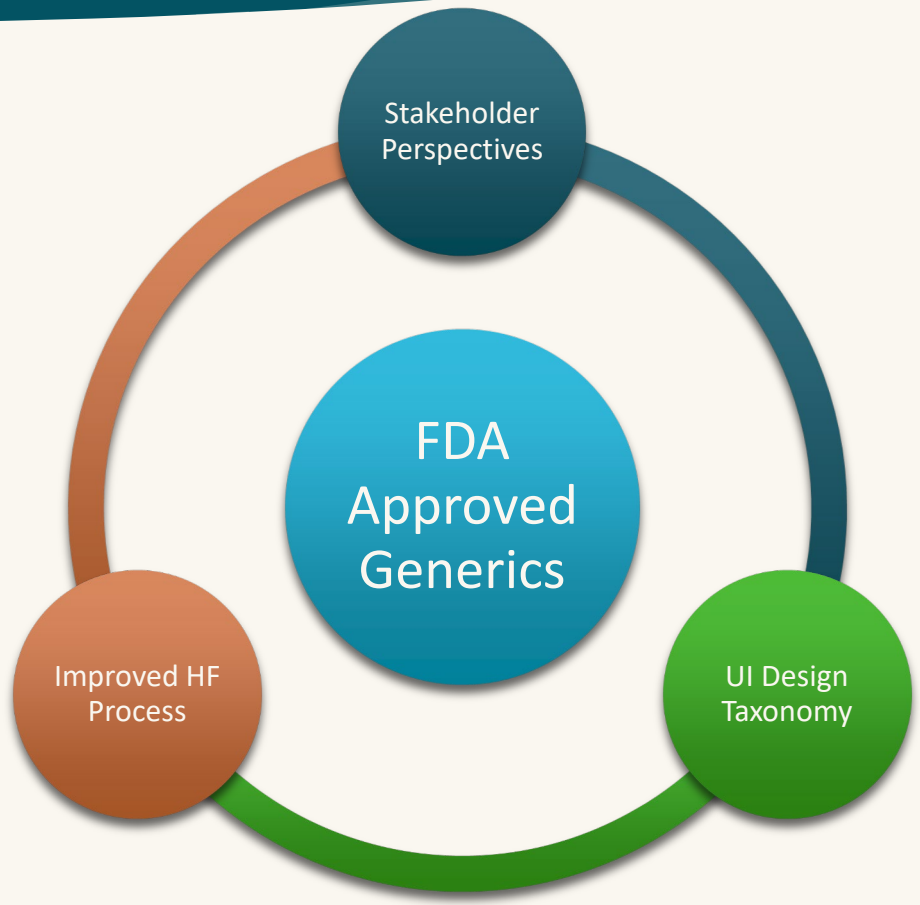
FDA Grant Number 1U01FD007360-01

Develop an Improved Comparative Use Human Factors (CUHF) Method

To identify and analyze user interface (UI) design differences that may impact substitutability of an RLD and proposed generic drug device combination product (DDCP) for clearance through the FDA ANDA pathway.

Key Advancements

- Literature Review & Stakeholder Survey/Interviews
- UI Design Taxonomy
- Different Statistical Method and Case Study Evaluation

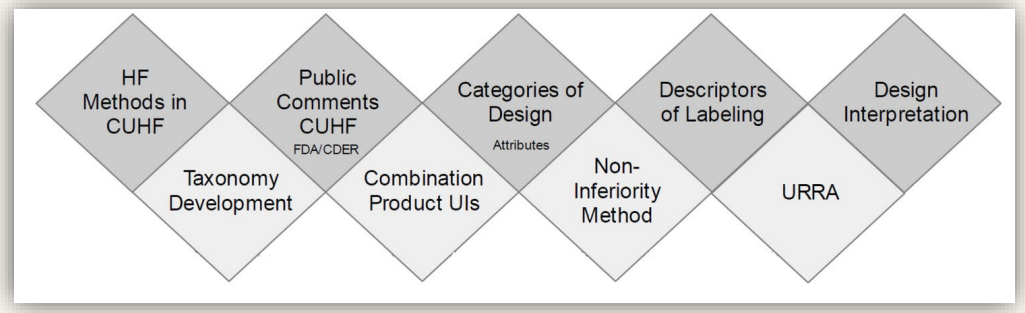


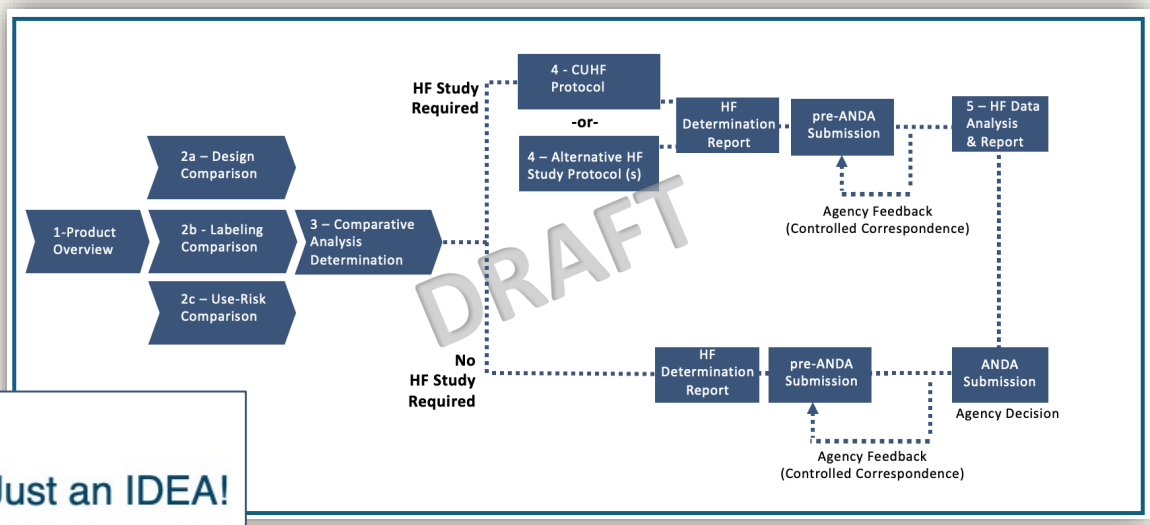
Our Team's Key Outputs (2021 – 2024)

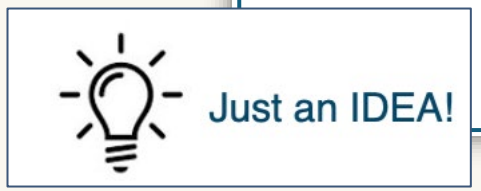
Aim 1 - Developed body of knowledge of key stakeholder perspectives of existing strategies

Aim 2 - Developed visual taxonomy to systematically analyze UI design attributes and identify minor and other design differences

Aim 3 - Developing improved CUHF method that relates to UI design differences that have the potential for introducing use errors on critical tasks that could result in harm or compromised medical care







Thank you!

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