



Safety Considerations for Patient Instructions for Use to Minimize Medication Errors

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- The views and opinions expressed in this presentation represent those of the presenter, and do not necessarily represent an official FDA position.
- The labeling examples in this presentation are provided only to demonstrate current labeling development challenges and should not be considered FDA recommended templates.
- Reference to any marketed products is for illustrative purposes only and does not constitute endorsement by the FDA.

Overview of Presentation

- Best practices for developing patient instructions
 - Instructions for Use (IFU) and Quick Reference Guide
- Review from patient labeling team perspective
- Review from the medication error team perspective
 - Role of human factors (HF) validation studies
- DMPP and DMEPA integrated review process

Labeling to Minimize Medication Errors

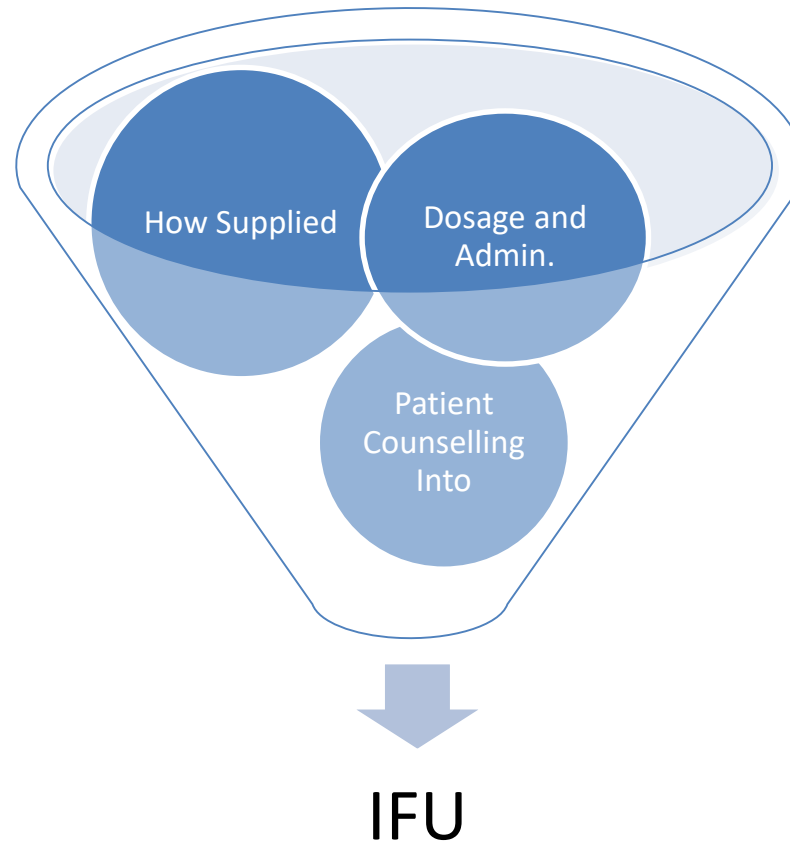
- Best practices in labeling development for drugs with complex dosing and delivery
 - Use of proactive risk assessments by industry to inform design of labeling and improve clarity and safe use
- Greater awareness on the content and format for ***all*** labeling on the appropriate use of drugs
 - Attention in FDA and Industry has moved beyond the prescribing information to focus on the accompanying patient information, carton and container labels, instructions for use



Patient Instructions for Use (IFU)

- Developed by manufacturers, approved by FDA
 - Part of FDA-approved labeling
- May be referenced in an FDA-approved Medication Guide or Patient Package Insert
- Creation recommended for products that have:
 - Complicated dosing instructions
 - A device component that a patient or caregiver must use to administer the drug
- Typically uses visuals and text to help the patient use the product properly
- Quick Reference Guide (QRG) is an abbreviated version of the IFU

Creation of IFU information



DMPP Patient Labeling Review Process

- Patient Labeling Review Team performs a review to ensure the IFU:
 - Uses simple words and concepts
 - Does not include unnecessary or redundant information
 - Meets all applicable Regulations and is consistent with FDA Guidance
 - Is consistent with the proposed prescribing information where applicable

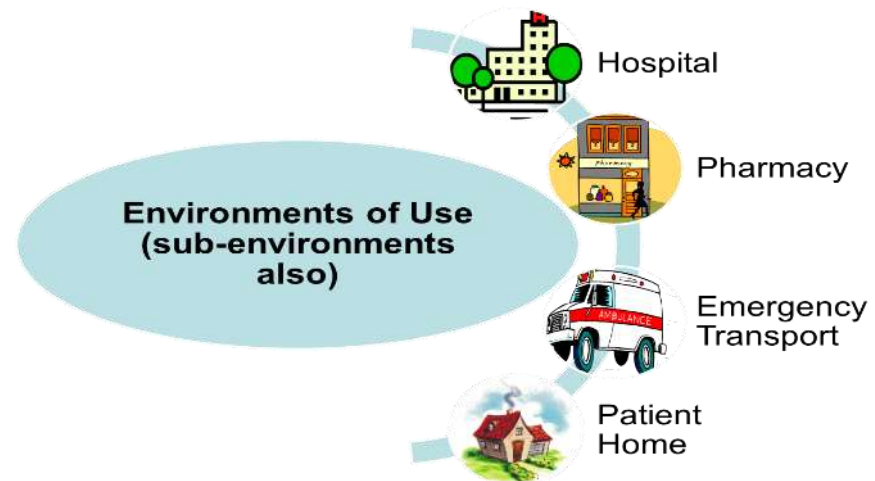
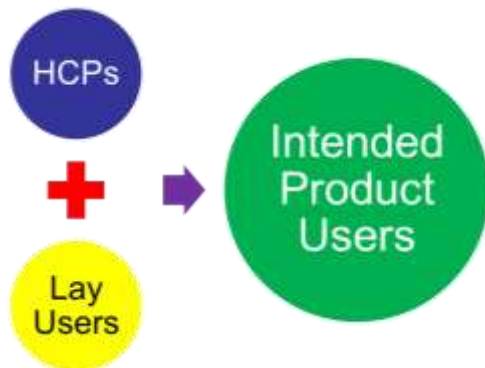
DMEPA Patient Labeling Review Process

- Ensure the IFU for patients and/or caregivers are clear and consistent with Dosage and Administration section
- Review information and graphics regarding:
 - How to use the product
 - How to maintain the product
 - What to do when problems arise
- Ensure that there are no error-prone abbreviations or symbols*
- Ensure the IFU incorporates results and feedback from HF validation study, if applicable

*ISMP's List of Error-Prone Abbreviations, Symbols, and Dose Designations [Internet]. Horsham (PA): Institute for Safe Medication Practices. 2015. Available from: <http://www.ismp.org/tools/errorproneabbreviations.pdf>

Human Factors Studies

- Conducted to demonstrate that intended users of a product can safely and effectively use the product (perform essential and critical tasks) for the intended uses in the expected use environments



Human Factors Studies

- Data is analyzed to identify use-related hazards related to product design and labeling
- Allows manufacturers to make revisions prior to marketing to avoid introducing a product or labeling that could confuse HCPs or patients/caregivers

HF Studies and Labeling Design

- Implementing HFE in the design process can improve instructional materials
 - Iterative nature of formative studies can inform labeling development
 - Labeling used in the human factors validation testing should represent the final designs
 - Optimize patient understanding of key information conveyed in labels or labeling

HF Studies and Labeling Design

- Participant performance or subjective feedback in the HF studies may identify vulnerabilities in the labeling
 - If the results of HF validation testing include use errors on critical tasks or participant feedback indicating difficulty with critical tasks, then additional revisions and mitigations may be necessary
 - Provide additional data demonstrating that the additional mitigations were effective in reducing the risks to acceptable levels
- Labels and labeling are part of the product user interface
 - Do not replace the need for good product design

User Interface in HF Study

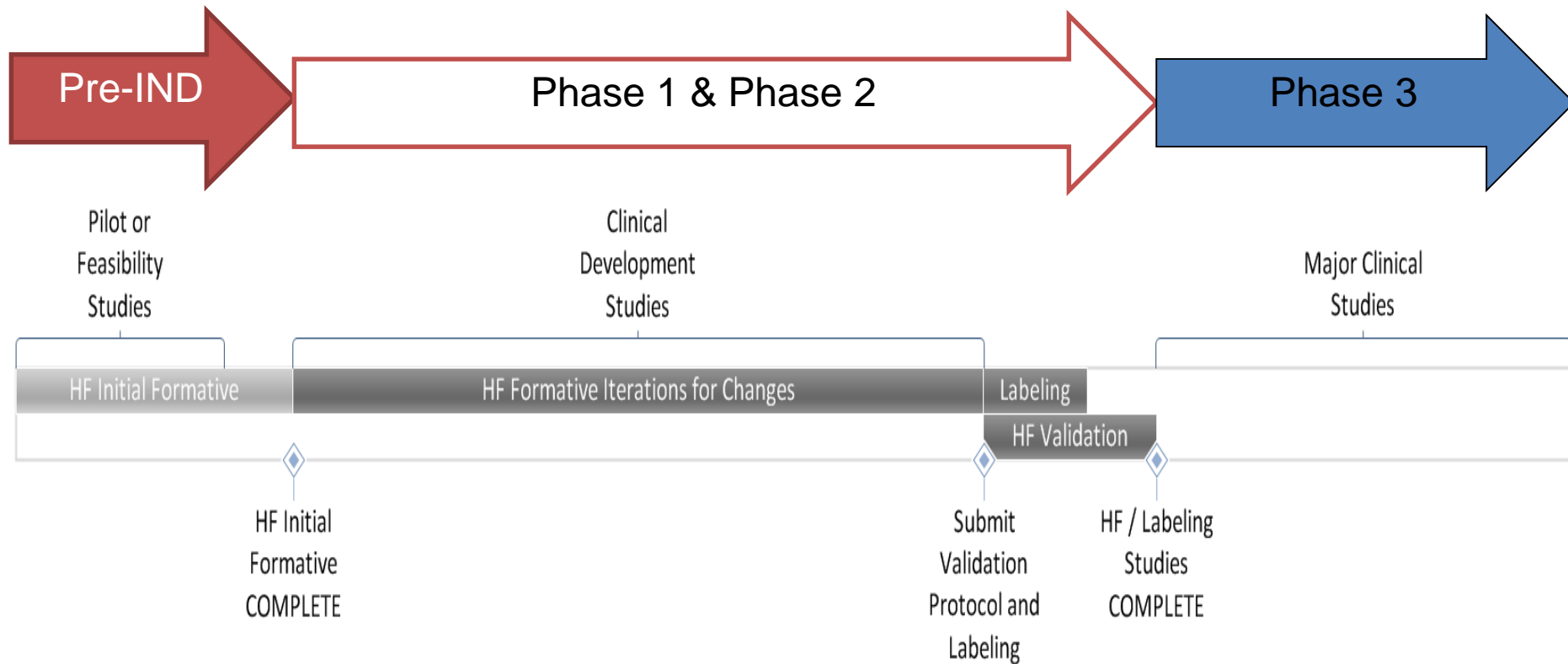
All components of a product with which a user interacts.

E.g.,

- Labels
- Packaging
- Delivery device constituent part, and any associated controls and displays
- Instructions for Use



HF Study Timeline Considerations



*Note: Timeline for illustrative purposes only; alternate timelines may be acceptable

IFU Changes Based on HF Studies

Formative Study No.	Summary of Methods	Summary of Key Results	Summary of Changes Made to IFU
Study #1 – Evaluation of IFU	15 study participants reviewed the IFU, and were then asked to administer a simulated injection using the IFU.	3 patient participants did not select one of the approved injection sites (thigh or abdomen) and selected the arm, which can be used for caregiver administration. Patient participants indicated that the IFU can be further improved by including a graphic which labels the appropriate injection sites for self-administration and caregiver administration.	IFU was updated to provide additional graphics and clarify that the arm should be used as an injection site if the drug is being administered by a caregiver.

DMPP and DMEPA Integrated Review

Process for Patient Labeling



- DMPP and DMEPA work to coordinate the efforts during the application review to consider the HF data supporting IFU content, layout and design
- To facilitate the use of HF studies in drug development, DMPP and DMEPA adapted their review processes to allow for early review of IFU materials in the IND phase
- DMPP and DMEPA perform initial independent reviews of the IFU and/or QRG
- DMPP and DMEPA align recommendations before finalizing each review and provide an integrated set of recommendations for the Sponsor

Additional Resources

- Draft Guidance for Industry – Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors;
<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm349009.pdf>
- Guidance for Industry – Label Comprehension Studies for Nonprescription Drug Products;
<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm143834.pdf>
- Guidance for Industry – Formal Meetings Between FDA and Sponsors or Applicants;
<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm153222.pdf>

Additional Resources

- Draft Guidance for Industry – Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development;
<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM484345.pdf>
- Guidance for Industry and FDA Staff – Applying Human Factors and Usability Engineering to Medical Devices;
<https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm259760.pdf>
- Draft Guidance for Industry – Safety Considerations for Product Design to Minimize Medication Errors;
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM331810.pdf>

