

Usability (Human Factors) Studies

Designing for safety, usability, and compliance

We help you evaluate how real users interact with your device, from early design to final validation. Our studies uncover use-related risks, refine design, and deliver regulator-ready evidence aligned with FDA, IEC 62366, and EU MDR.

Human Factors Expertise

- Theories, models, and data that describe, explain, predict, and attribute causation to Perception
 - Memory (how we store it)
 - Attention (how we focus on it)
 - Decision Making (how we use it + knowledge)
 - Expectation (impacts what we see)
 - Actions (effective or ineffective, safe or unsafe)
- Appropriate Research Methods to gather data to inform requirements, to make design decisions, to make development decisions to improve safety and usability and the user experience

Our Services

• Formative & Summative Evaluations

- Protocol Design
- Participant Recruitment & Scheduling
- Test Facilities & Environment Simulation
- Study Moderation
- Data Analysis & Reporting
- Actionable Design Recommendations
- Residual Risk Analysis
- Summary HFE/UE Report or Usability Engineering File (UEF)

• Human Factors Documentation

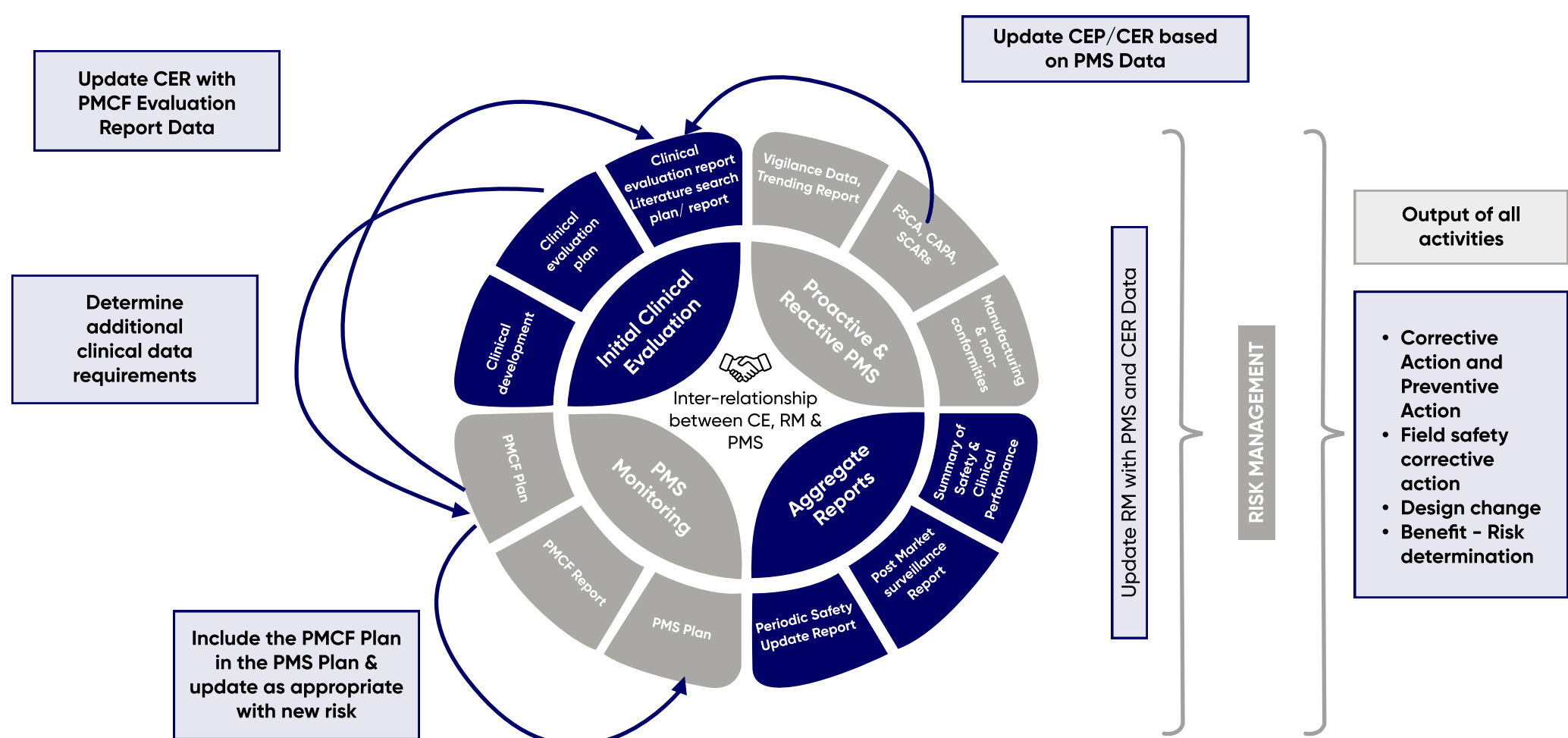
- Usability Plan
- Gap Analysis (in relation to international standards and regulatory guidance)
- Use Specification
- Identification of Known Use-Related Problems
- Task Analysis
- Hazard Analysis
- Risk Analysis (URRA)

USABILITY (HUMAN FACTORS) STUDIES

HF Experience on devices:

Beds & Surfaces, Patient Monitoring, Care Communication, Patient Handling (Lifts), Respiratory Therapy, Surgical System and Devices, Software as a Medical Device (e.g., Clinical Decision Support), Digital Therapeutics, Medication Delivery (Infusion Pump, Syringe Autoinjector, Transdermal Patch, Inhaler etc), Imaging, In Vitro Diagnostics, Pharmacy Compounding, Ultrasound Therapy

Impact Assessment on other Linkage System



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