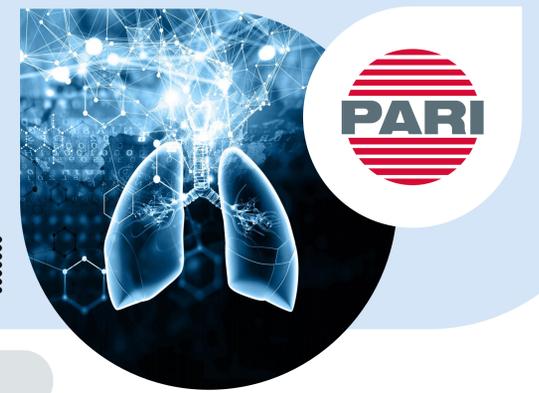


From Continuity to Competitive Edge – How Long-Term Collaboration Drives HF Program Success



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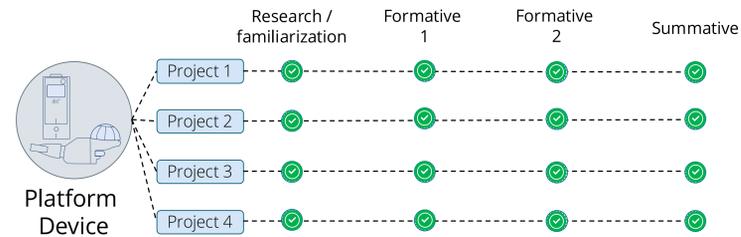
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Background

- PARI's drug-device combination products rely on a nebulizer platform used across **multiple inhaled drug development projects**; however **proprietary data** is typically **locked within individual projects** sponsored by the pharmaceutical partner.



- Nebulizers show a more **unique use error pattern** than autoinjectors or pre-filled syringes, due to **multiple assembly steps** and **hygienic procedures**. While these preparation steps are more vulnerable to use difficulties, they must be interpreted distinctly as they have no direct impact on dosing success and are known to resolve over time.
- Valuable knowledge** on device-related use difficulties and mitigation measures **may remain locked** within individual partnerships, as certain **project-specific data is proprietary**. Instead of repeatedly relearning the same insights, these learnings should be shared and built upon across projects.
- This ensures **focus on the right measures**, enabling pharmaceutical companies to develop a robust and strong combination product design by incorporating former learnings from the start.

Objectives

- Optimize the human factors process** for combination products with platform **nebulizers**.
- Streamline submission processes** for pharmaceutical companies to **reduce the risk** of unnecessarily **extended timelines** for the overall program, **regulatory rejections** and **costly rework**.
- This includes:**
 - Leverage former learnings** within the HF process by using **consistent teams** and **publicly available data** while respecting confidentiality obligations with different pharmaceutical partners at any time
 - Incorporate **efficient test setups** to allow for **repeated testing**.
 - Apply a **reasonable view** on **critical** versus **non-critical use errors**.

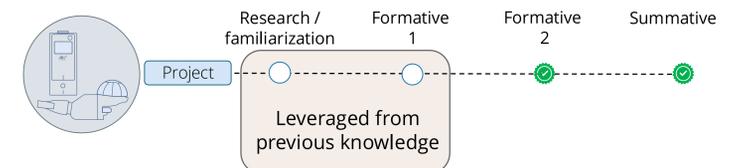
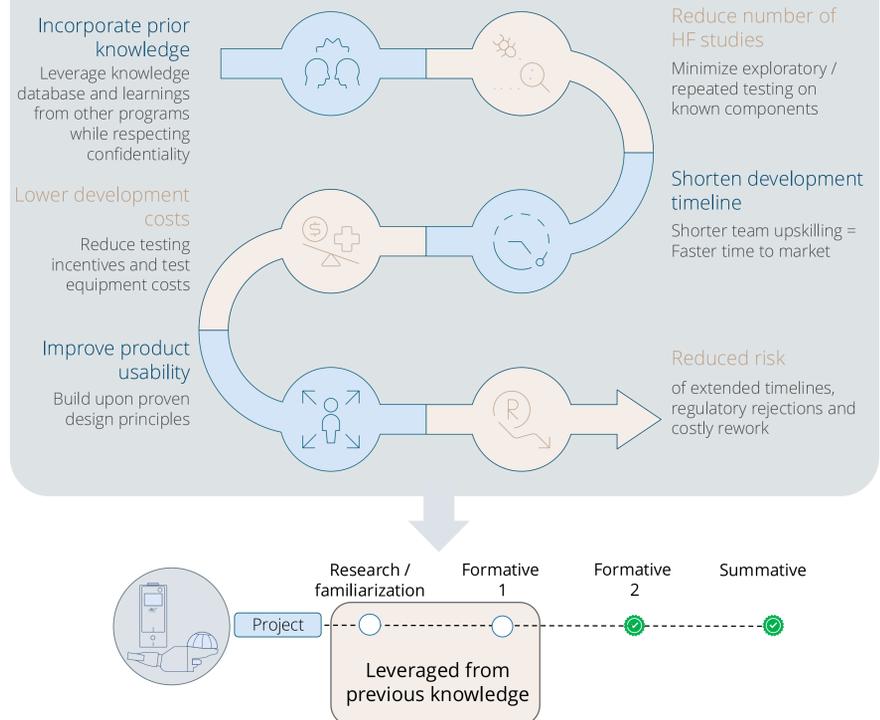
Materials and Methods

PARI and PDD have a long-standing collaboration in supporting pharmaceutical companies with implementing PARI's eFlow Nebulizer System into combination product design, providing guidance, advice and practical experience gained through their joint work.

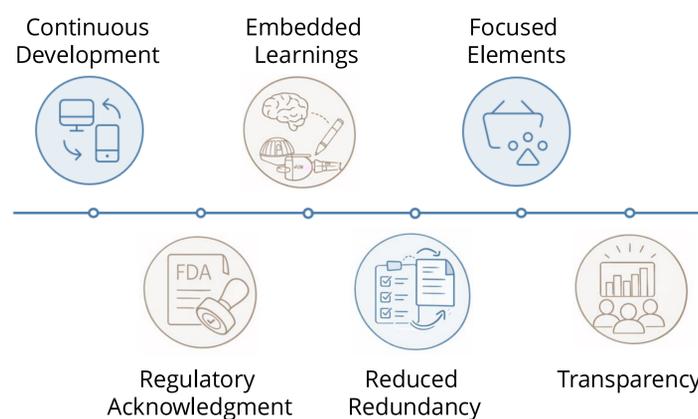
Leveraging elements of the study design without breaching confidentiality:

- Expedient Moderation Techniques & Language:** Established moderation guides allow for a naturalistic progression of product use and more authentic user engagement and limit the need for moderator training and intervention.
- Proven Sequence of Use Scenarios:** Ensures smooth test flow, avoids unnecessary study artefacts.
- Grouping Cleaning & Disinfection Scenarios:** Smart grouping reduced max test durations from 120 minutes plus to 60-90 minutes.
- Incorporate FDA Input - Knowledge-based assessments:** Avoids leading language, ensures validity of answers.
- Incorporate Learnings from Former User Studies:** Streamlining risk assessment activities and actions that can be applied universally to the platform product.
- Robust instructions and effective labeling strategies:** Seamless integration into combination labeling, labeling strategies that are effectively recognized by the user and were reviewed by FDA.
- Apply known strategies for co-packaging of drug & device:** Ensures successful user experience, guide patients through first exposure, avoiding first-time use difficulties.

Streamlining Nebulizer System Implementation



Results



- Regulatory bodies** acknowledge the continuous development of the platform across programs, which is reflected in **fewer comments in reviews**, **consistent feedback** on the study protocol, and **requested comparisons** with existing platform devices.
- Learnings are embedded into risk management strategies, enabling the **design of mitigations independent of past liabilities** and **reducing the need for redundant formative testing**
- Project timelines are shortened** by focusing on the combination-product specific elements.
- Authorities gain transparency** that prior experience has informed a **robust combination product design**, underlining the nature of an iterative human factors engineering process.

Conclusion and Key Findings

