

# A Novel HF User Characteristics Approach for a New Platform-Based, Breath-Triggered Nebulizer

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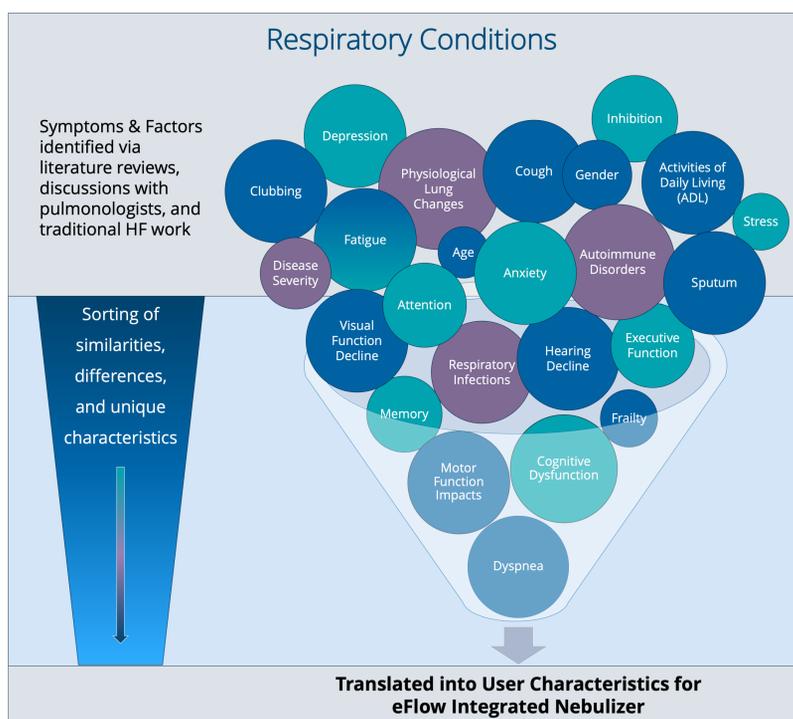
## Background

- A platform approach uses a shared, core nebulizer technology that can be adapted for different therapeutic areas.
- However, this creates unique Human Factors (HF) challenges, as the device design must account for diverse patient groups before the final drug, indication, or partner is known.
- Limited data-sharing, due to proprietary and confidential data between device and pharma companies, often results in repeat, time-consuming and costly usability studies, even if similar issues have already been addressed.
- Regulators, such as the FDA, increasingly expect manufacturers to outline how a new platform-product differs from similar devices or earlier platform versions to support a focused and efficient review.
- PARI desires to facilitate HF data-sharing and provide a strong basis for leveraging user characteristics as a scientific pathway to improve efficiencies and usability testing methods.

## Objectives

- Ensure the eFlow<sup>®</sup> Integrated (Figure 3) meets a diverse target respiratory population's needs.
- Gain a deeper understanding of use errors and their root causes and introduce effective design mitigations early on.
- Establish a core list of characteristics a panel of pulmonologists report on their respiratory patients.
- Identify if user characteristics can enable deeper insights into the test individual and user population.
- Identify common and unique disease characteristics through literature, with an initial focus on a set of representative diseases (Figure 1).
- Investigate optimal, validated assessment tools for cognitive domains that are useful in an HF setting.
- Reduce the risk of regulatory complications and delays by enabling pharma companies to leverage existing device usability data.

Figure 1: User Characteristics Identification



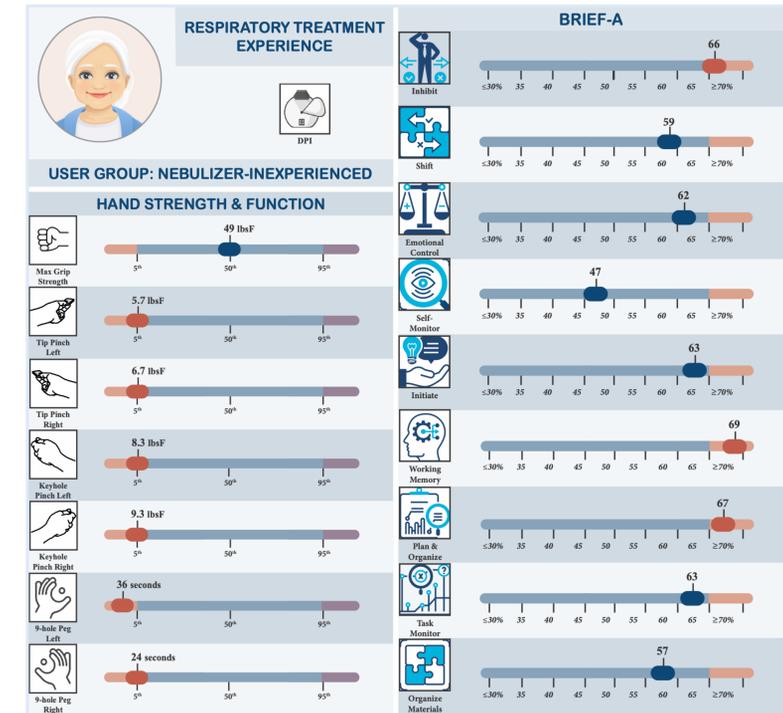
## Materials and Methods

- Literature reviews and expert interviews were conducted with pulmonologists, allowing researchers to map shared and divergent functional patient characteristics across respiratory indications, and providing initial evidence that respiratory diseases share a broad set of patient capabilities.
- Symptoms and related factors were filtered to establish user characteristic categories and develop tools to assess study participants.
- User Characteristics Assessment (UCA) was incorporated into the traditional workflow of HF simulated-use study design – an additional evaluation of individual test participants prior to the actual simulated use within the test session, including:
  - Physical parameters (hand size, grip strength, dexterity)
  - Cognitive function (MMSE-2:SV and BRIEF-A)
  - Quality of life (SGRQ)
- Systematic measurements were conducted using validated tools of user characteristics within formative studies to ensure the device design adequately reflected the needs of the intended population and to steadily build up a data-set with UCA to strengthen the outcomes of the literature research (Figure 2).
- Design iterations and interventions were informed by a thorough root cause analysis conducted during user testing, taking user characteristics into account

## Results

- UCA supports improved design decisions through a comprehensive understanding of relevant user capabilities and limitations, allowing deeper insights for root cause analyses:
  - Even with a small sample size, formative testing captured a wide range of hand dimensions, strength levels, and dexterity parameters, indicating the cohort reflected the variability of the respiratory population.
  - Insights into physical impairments and dexterity challenges led to several iterations of the device design.
  - Users with chronic respiratory conditions showed greater cognitive impairment than expected based on literature and measured characteristics.
  - Early identification of these cognitive limitations allowed targeted design changes, which included refinements to component presentation to better support users with reduced executive function.
- Additional benefit observed in practice was the reduction of test-related anxiety among participants, potentially leading to more reliable assessment outcomes.
- Previously generated UCA-based usability data from PARI can be shared transparently with pharmaceutical partners and used as supportive evidence in regulatory submissions.
  - Certain use scenarios may not require re-validation if documented evidence shows these steps were already evaluated with representative users.

Figure 2: UCA Sheet Excerpts



## Conclusion and Key Findings

- The UCA approach supported evidence-based design decisions for the eFlow<sup>®</sup> Integrated (Figure 3); it allows for streamlined combination product development:
  - Deeper root cause analysis:** Use errors assessed more accurately—generalizable issue affecting the entire target user population versus attributable to an individual case.
  - Improved design interventions:** Design decisions and risk mitigations are made in a more targeted manner.
  - Existing UCA-based usability data can be transparently shared:** Study results used as supportive evidence in regulatory submissions of combination products. Certain device-related use scenarios may not require re-validation.
  - Redundant testing minimized:** Approach enables more efficient resource allocation by focusing efforts on combination product-specific risks that truly matter for patient-centered outcomes.
  - Efficient regulatory reviews:** Comparative justification enables authorities to conduct a more efficient and focused review by identifying product-specific risks, novel features, and relevant regulatory considerations.

Figure 3: eFlow<sup>®</sup> Integrated



## Next Steps

- Select additional respiratory diseases for literature review.
- Expand UCA dataset.
- Explore further verification methods