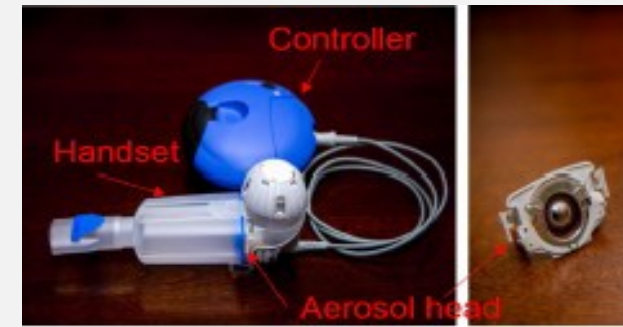




RATIONALE

- Effective inhaled therapy depends on reliable interaction between the user, the drug, and the device.
- Proper alignment of these elements is essential to ensure consistent, safe, and effective treatment delivery.
- Early engagement with patients, care partners, and health care professionals (HCPs) supports design decisions that are clinically sound, practical, and accessible.
- Human-centered insights enable design solutions that genuinely support those relying on the device.
- This study summarizes insights from an IRB-approved usability study evaluating the eFlow[®] Nebulizer System (PARI Pharma GmbH, above), to deliver the AP01 solution (inhaled pirfenidone), that is currently being investigated in the Phase 2b MIST Study (NCT06329401) for progressive pulmonary fibrosis (PPF).¹



eFlow Nebulizer System designed for the delivery of AP01

METHODS

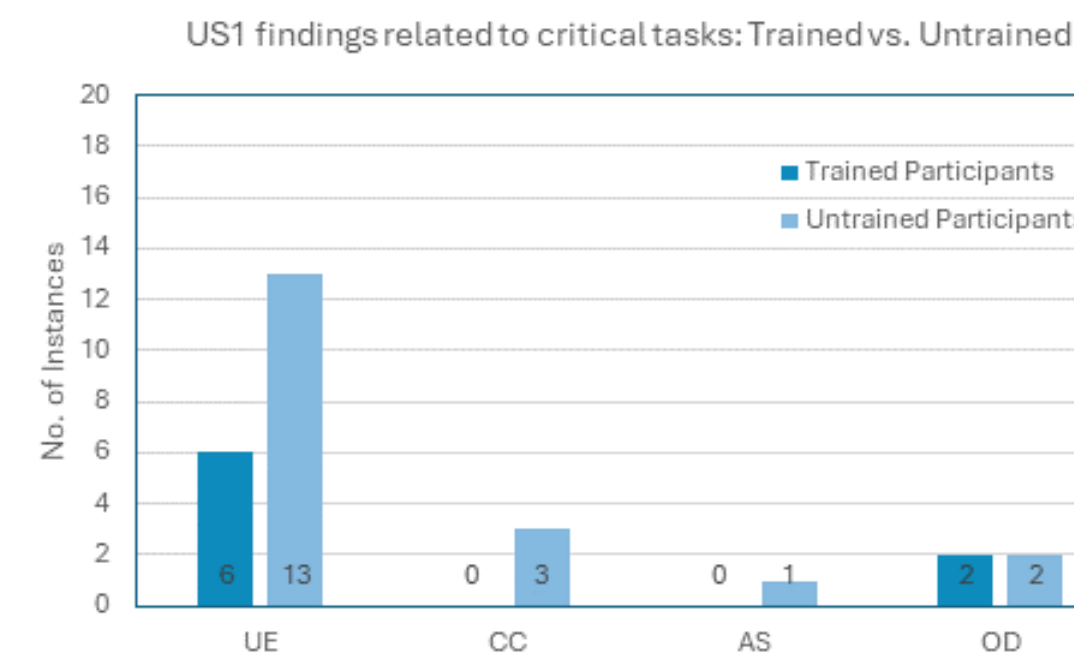
Usability Study Overview

Study item(s)	<ul style="list-style-type: none"> - eFlow Nebulizer System including controllers, connection cords, power adapters, batteries, and handset components - Placebo medication - Nebulizer maintenance solution - Printed Instructions for Use (IFU)
Participants	<ul style="list-style-type: none"> - 6 patients living with idiopathic pulmonary fibrosis (IPF) - 6 caregivers providing care to someone with a lung condition - 6 HCPs (i.e., pulmonologists, registered nurses, and respiratory therapists) with experience treating patients with IPF and training patients to use nebulizers
Training	A nurse trainer provided training to half of the participants in each user group (i.e. 3 patients, 3 caregivers, and 3 HCPs)
Training session duration	45 minutes
Training decay period	1 hour to 1 overnight
Test session duration	2 hours
Evaluation activities	<ul style="list-style-type: none"> - The following use scenarios (US) and knowledge tasks (KT) were selected for evaluation purposes: <ul style="list-style-type: none"> o US1: Prepare nebulizer for use and administer treatment o US2: Clean and store nebulizer system o US3: Perform weekly aerosol head maintenance o US4: Disinfect nebulizer system o Knowledge Tasks: Warning interpretation
Data collection and analysis	<ul style="list-style-type: none"> - All critical tasks were evaluated in terms of use errors (UE), instances of moderator assistance (AS), close calls (CC), and operational difficulties (OD). - Open-ended questions were asked to collect participants' subjective assessments of the root cause(s) associated with such events. - Participants' feedback on the product's use-safety and usability, and the label clarity and effectiveness were collected. - After the test sessions, performance data were analyzed and improvements to the usability and labeling were recommended.

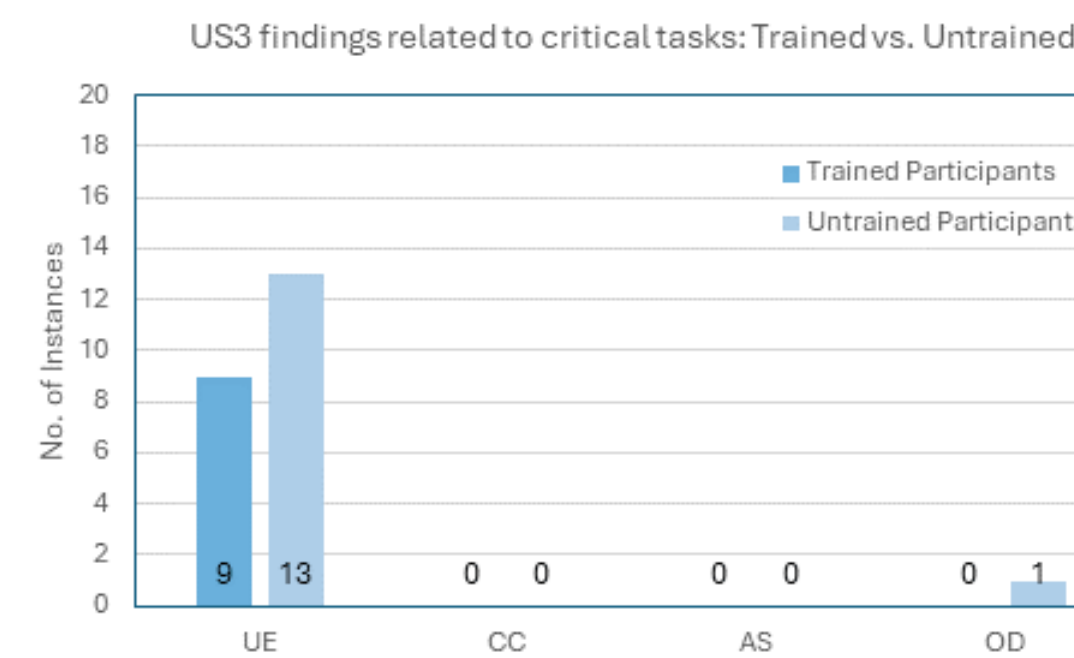
RESULTS

Task	Definition
Critical task	A user task which, if performed incorrectly or not performed at all, would or could cause harm to the patient or user
Use error (UE)	A user action or lack of action that differed from what the manufacturer intended and resulted in an outcome that (1) was not what the user expected; (2) was not caused solely by device failure; and (3) did or could result in harm
Close call (CC)	Instances in which a user has difficulty or makes a use error that could result in harm, but the user takes an action to "recover" and prevents the harm from occurring
Moderator assistance (AS)	Cases in which the moderator provides information to help a participant perform one or tasks
Operational Difficulty (OD)	Cases in which a participant appears to struggle to perform a task

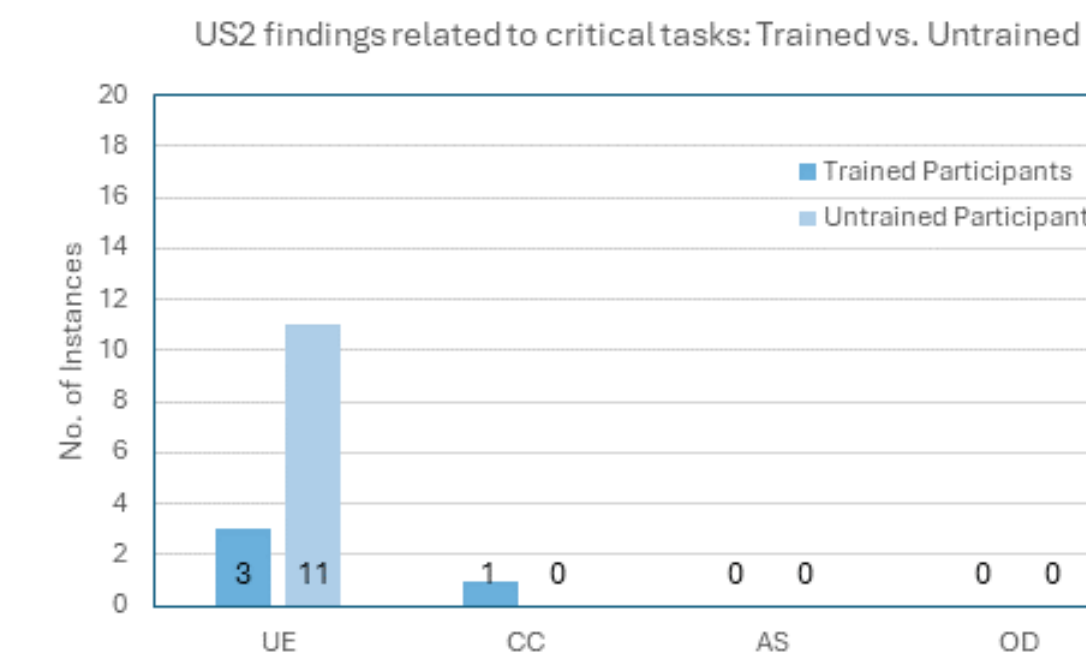
Use Scenario 1: Prepare nebulizer for use and administer treatment:



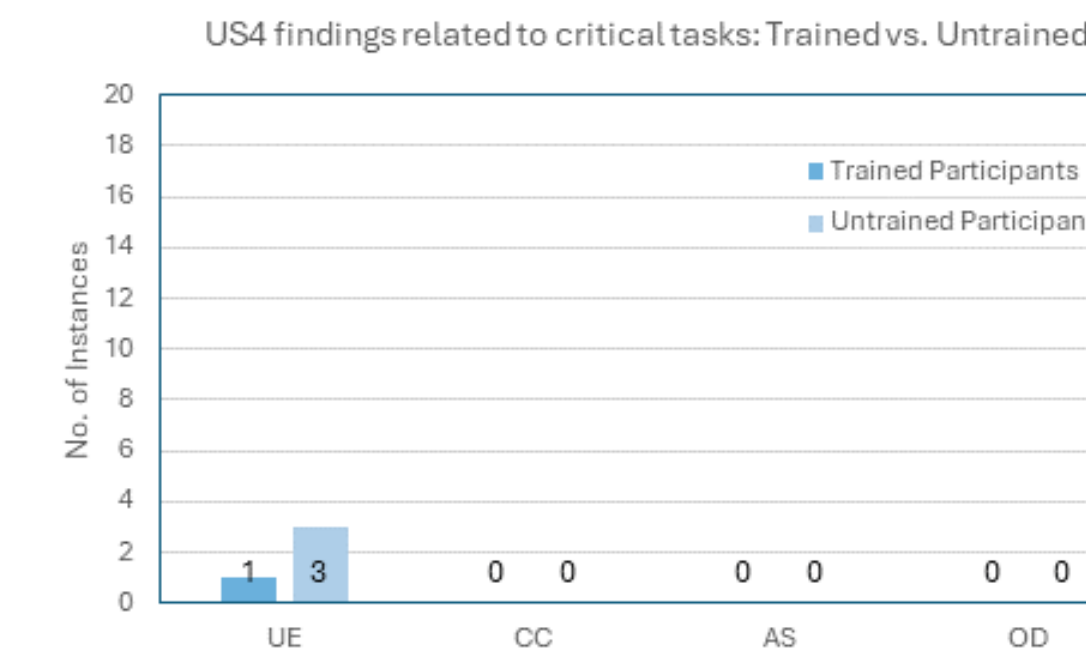
Use Scenario 3: Perform weekly aerosol head maintenance:



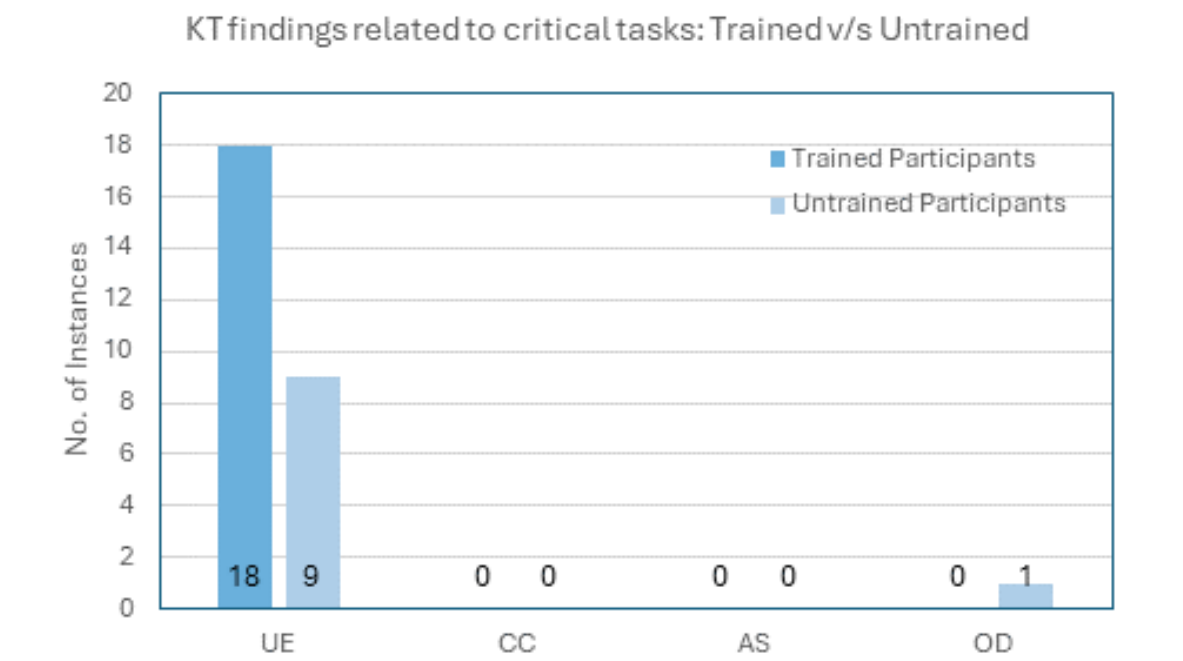
Use Scenario 2: Clean and store nebulizer system:



Use Scenario 4: Disinfect nebulizer system:



Knowledge Tasks: Warning interpretation



KEY FINDINGS

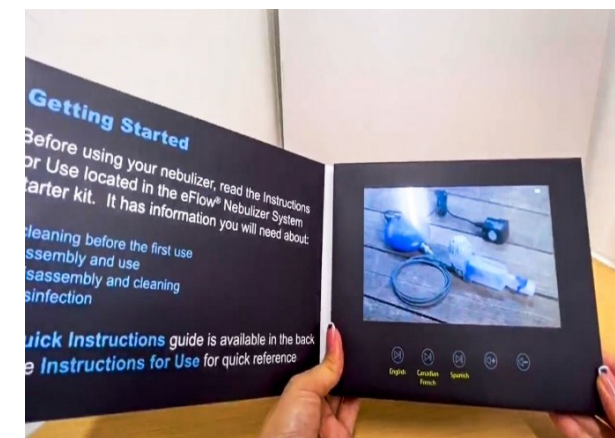
- Training reduced use errors and improved performance with the product.
- Many participants referred to the IFU minimally or not at all when performing tasks, leading to common use errors.
- High frequency of use errors in the warning interpretation knowledge task suggested the need for IFU revision.
- Despite some interaction challenges, all participants expressed the view that the eFlow Nebulizer System is safe for use as is.



Depiction of eFlow nebulizer use

CONCLUSION

Engaging potential end-users in this study generated essential insights into both the usability of the eFlow Nebulizer System and the clarity of its instructional materials. Findings from this study led to updates to the IFU and the creation of an instructional video (right) to improve usability of the eFlow Nebulizer System in an effort to support safer, more effective use and promote strong adherence during clinical studies evaluating AP01.



eFlow Nebulizer System

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