Facing unmet needs in nebulized therapies – the journey of Kolibri -

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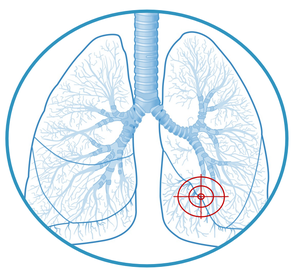
Introduction: Despite notorious evolution, nebulized therapies continue to face important unmet needs, particularly when considering the following three important concepts:



1. **Uncontrolled particle deposition** remains a limitation for effective targeted drug delivery into the lungs. The **breathing maneuvre** has a significant impact on deposition, especially when smaller airways are targeted. Therefore, drug delivery is frequently **uncontrolled** or not tailored to the targeted deposition areas due to a large variability in the inhalation maneuvre of nebulizer users. This leads to **lack of efficacy** in pulmonary drug deposition and consequently to **higher risks and costs**.

2. **High risks in clinical development** are associated to the inability to monitor **high influential parameters** on drug deposition, adding difficulty and complexity to clinical trials. Inefficient management of clinical/device data also poses a challenge to effective study monitoring. In addition, the considerable results variability often require **costly study repetitions** for dose finding and further safety evaluations, thereby increasing overall expenses.

3. **The patient´s needs** include:
   - improving the nebulizer´s **usability** by optimizing its assembly, use and cleaning process;
   - a device that provides **feedback and guidance** for the patient to achieve an **optimal inhalation maneuvre**;
   - an **alleviation in the disease burden,** by simplifying the interaction with the nebulizer and facilitating therapy adherence and compliance,

Overall, it´s crucial to find a **balance** between treatment effectiveness and patient engagement.

Results: Focused on these challenges, Pulmotree developed Kolibri, a connected mesh nebulizer, whose technology is hereby described.

User-specific Customization
for medication, patient group and market strategy

Haptic and digital Inhalation feedback
for optimized lung deposition

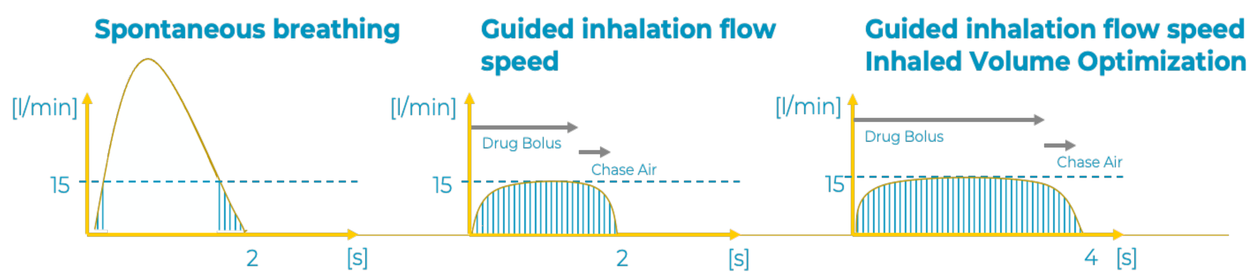
Intelligent Administration System (INAS)
for breath-triggered aerosol generation and targeted drug deposition

Automatic data transfer to users, physicians and CROs, with the Pulmotree Connect

Key- & Lock-System
for product protection and easy handling

Kolibri as a nebulizer platform can be **customized** according to each drug-device combination, due to a **tailored aerosol generator** that produces optimal aerosol particles.

Additionally, an **unique inhalation technology** guides the patient through **haptic and digital feedback** to achieve the ideal inspiration maneuvre. For optimized lung deposition, the breath-triggered aerosol generation and the **INAS technology** only administer aerosol in the therapeutically useful phase. By analysing the patient´s behaviour, INAS trains the patient to perform the desired inhalation maneuvre.



Remote monitoring is possible due to **automatic data transfer** on inhalation, adherence and device status, while using a centralized interface platform and a mobile app.

A **key- & lock-system** protects the product on the market and also protects the patient of interchangeability with other medications.

For an enhanced **patient's experience and usability**, Kolibri is a hand-held small portable device of simple assembly and cleaning, with a modern design that alleviates the treatment's onus.

Conclusion: Kolibri´s technology presents solutions to unanswered challenges and aims to drive progress in nebulized therapies. Furthermore, by providing **new patient-side parameters** generated during nebulization, important **inputs** would be available for **lung deposition models**. These future developments can mark a significant advancement in personalized respiratory medicine, fostering further knowledge and pushing evolution in inhaled therapies.