INVIDA™

IN VITRO INHALED DRUG ANALYSIS PLATFORM

A new paradigm for inhaled drug analysis: Testing under human realistic conditions determines true product performance and enables predictive *in vivo* correlation.

proveris®
LABORATORIES

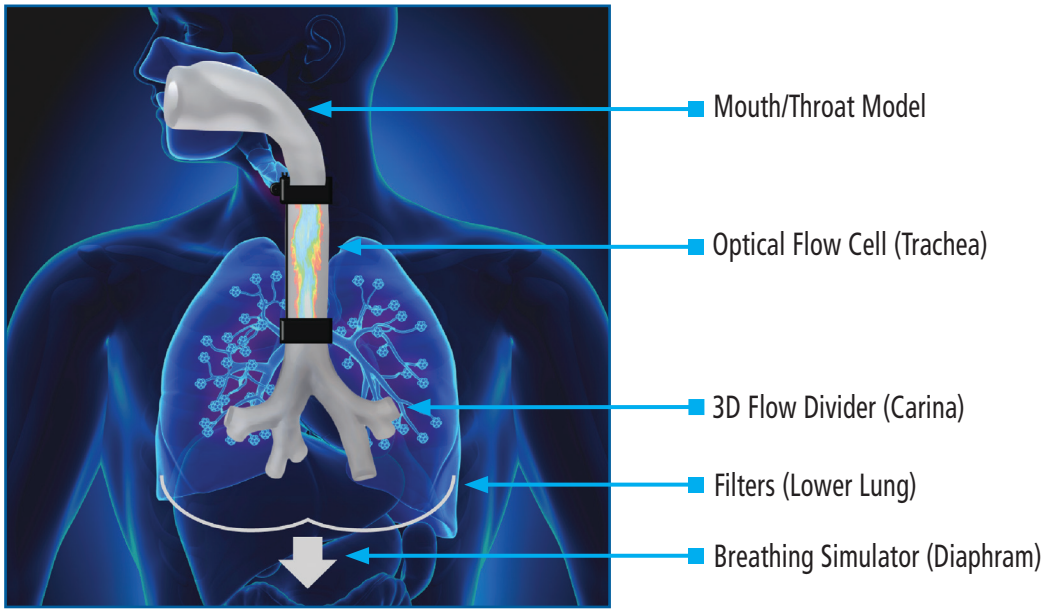
Successful drug development depends on *in vivo* performance and bioequivalence

Inhalation drug development is a complex relationship between device design, particle engineering, formulation, and inspiratory flow. Current technologies do not provide enough information to accurately evaluate these relationships, creating knowledge gaps that raise more questions than answers. Delaying product development, impacting clinical studies, and the ability to achieve bioequivalence. The result, rapidly increasing development costs and significant delays in product approvals.

Introducing *INVIDA*... *In Vitro* Inhalation Drug Analysis Platform

Proveris Scientific's new *INVIDA* Platform can accelerate product development and approvals by providing the information necessary for predictive clinical outcomes and bioequivalence. This innovative new technology measures the aerosol dispersion and regional deposition of inhaled drugs under simulated human-realistic conditions. Enabling scientists to better understand their product's performance through visual mapping within the respiratory tract and quantitative measurements of drug deposition that are more predictive of *in vivo* performance.

- Simulates drug dispersion and deposition under human-realistic respiratory conditions
- Visually maps drug flow through the respiratory tract
- Quantifies regional deposition in mouth/throat, trachea, and lower lung
- Unrivaled approach to *in vivo / in vitro* correlation (IVIVC)



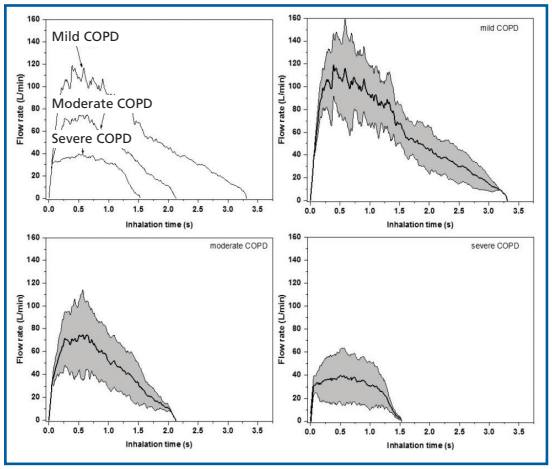
Accelerate development and release through better:

✓ Predictive Clinical Assessment	✓ Bioequivalence Studies and IVIVC
✓ Toxicology / Exposure Studies	✓ Formulation Characterization, Screening
✓ Device Design, Characterization, Screening	✓ Particle Engineering / Characterization

One platform — multiple answers:

1. Human-realistic testing conditions

- Simulates respiratory tract geometry under realistic and controlled conditions
- Breathing simulator replicates complete breathing cycle: inhalation, hold, exhalation
- Multiple profiles for normal, diseased, and lung left/right imbalances
- Controlled temperature and humidity to simulate respiratory environment



Restricted breathing capacity across patients with mild to severe COPD.*

DRUG DEPOSITION - HPLC

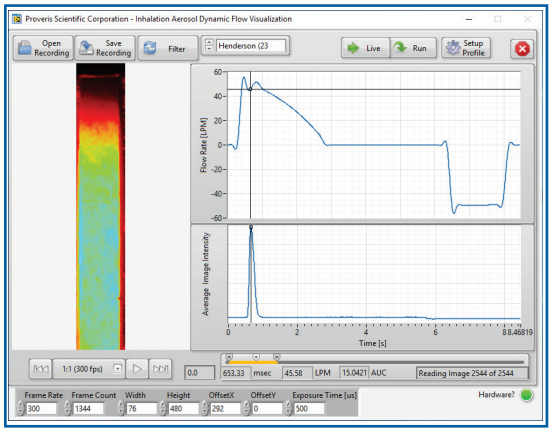
Mouth/Throat Deposition
+
Trachea + Primary Carina Deposition
+
Left/Right Bronchi Deposition
+
Left/Right Deep Lung (Iveolar) Deposition
=
Total Delivered Dose

2. Regional drug deposition analysis

- Replicates actual *in vivo* drug deposition through inertial impaction, sedimentation, and diffusion**
- Quantify actual drug deposition in each region**
- Rapid analysis allows for expanded method evaluation and screening
- Determine critical influencing factors
- Predictive PK correlation

3. Informed decisions through real-time assessments

- Visual mapping of drug dispersion in real time throughout the complete breathing cycle
- Quantitative lower lung deposition data irrespective of fine particle mass**
- Time correlated flow monitoring accurately confirms conditions are achieved
- Integrated data analysis and management



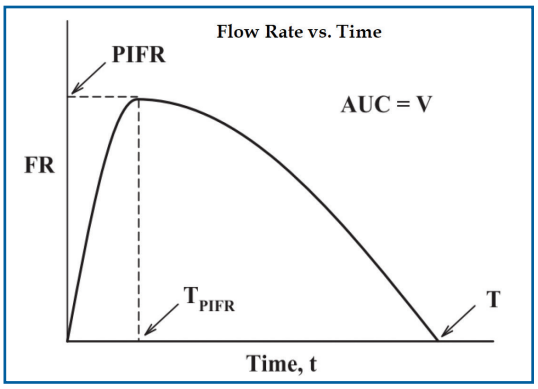
Example data for time synchronized plume visualization coupled with real-time flow monitoring under human realistic breathing profile.

** Reprinted from Simulation of Airway Deposition of an Aerosol Drug in COPD Patients (p. 6). Pharmaceutics, 2019. MDPI Open Access Journal © 2019.*

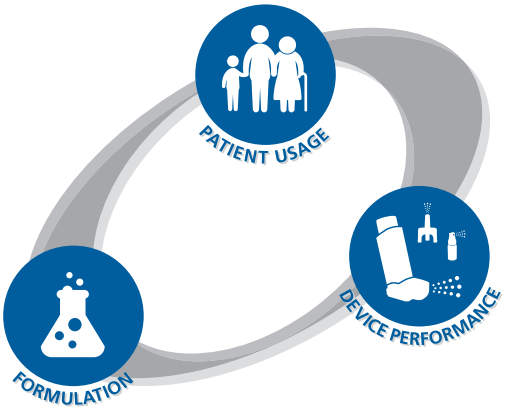
*** Traditional methods are not humanly realistic and fail to predict actual performance.*

The power of *INVIDA*

- Rapid insight into actual product performance under controlled conditions
- Accurate characterization of your product's critical performance parameters by Quality by Design (QbD)
- Supports IVIVC / PK and Bioequilvence studies through predictive regional deposition
- Reduces development time through data-driven decision making



Key parameters influencing the performance of breath-actuated and dry powder inhalers.



Proveris Laboratories as your development partner

For over 20 years Proveris has assisted companies in the development, optimization, submission, and compliance of orally-inhaled drug products. Our proven team of experts has helped shorten development times by providing critical insight and information to product device design, formulations screening, and now a new tool for IVIVC studies.

Services offered

- Optimization of Device / Formulation / Particle Engineering
- Determination of performance under different breathing profiles (healthy *vs* diseased)
- Regional drug deposition analysis
- Total dose content
- Flow visualization
- Evaluate device resistance and flowrate to actuate
- Support for IVIVC studies

Device types:

- Dry Powder Inhalers
- Pressurized Metered Dose Inhalers
- Breath Actuated Inhalers
- Soft Mist Inhalers
- Nebulizers

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