INVIDA® In Vitro Inhaled Drug Analysis

TEST SERVICES

Accelerated generic drug development and *In Vitro* bioequivalence

proveris®
LABORATORIES

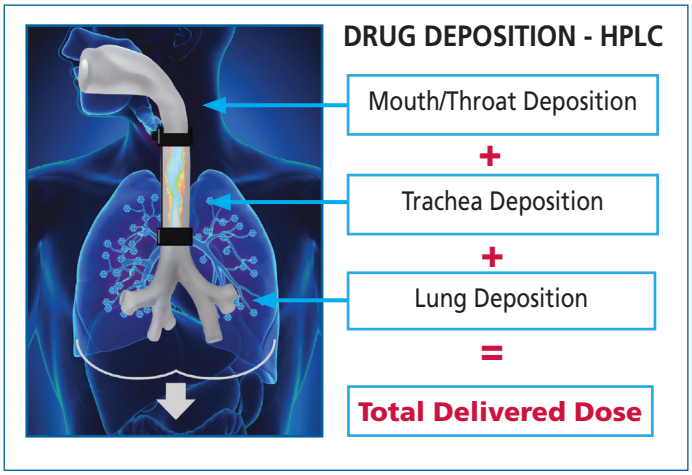
To reduce the risk and cost of developing generic orally inhaled products, the industry needs a tool that can rapidly evaluate product performance and equivalence against the reference product. Proveris Laboratories offers human-realistic, *In Vitro* Inhaled Drug Analysis (INVIDA) services to accelerate generic orally inhaled product development through submission. Leveraging Proveris's expertise in OINDP testing we can expedite candidate screening and performance assessments, resulting in confident clinical trials through an *in vitro* weight of evidence approach.

Using Human-Realistic Conditions for Rapid Indication of Bioequivalence

INVIDA is the complete rapid screening and bioequivalence *in vitro* service that evaluates drug candidates, in their native form, under human-realistic conditions.

Quantitative regional deposition and delivered dose using human-realistic respiratory models, representative breathing profiles, and proprietary technologies provide the best indication of *in vivo* performance in a targeted demographic.

Qualitative drug flow mapping enables respiratory drug particle visualization as it travels through the respiratory tract model.



APPLICATIONS

- **Screening of candidates** allows selection of the most promising candidates that demonstrate equivalent performance to the reference product.
- **Performance assessment after formulation changes** allows you to validate performance and maintain equivalence.
- **Extensive data generated** during these projects complement other approaches for bioequivalence and supports Clinical Biowaiver and high confidence clinical endpoint studies.

Partnering with Proveris Laboratories provides the speed to knowledge needed to make informed decisions fast.

Pressurized Metered Dose Inhalers

Breath Actuated Inhalers

Dry Powder Inhalers

Soft Mist Inhalers

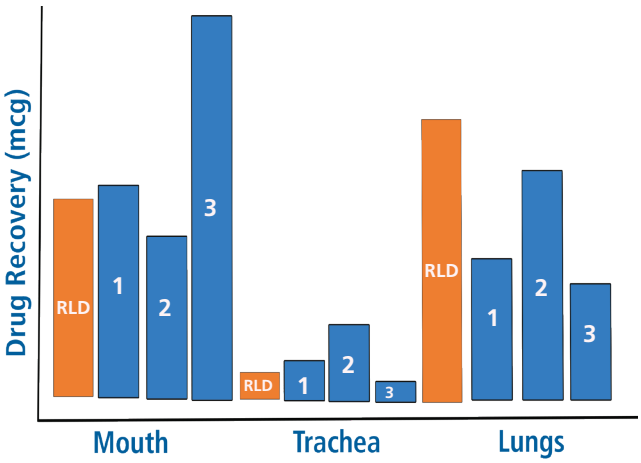
Device Screening

Rapid screening is key to accelerated generic product development and market entry. INVIDA can screen more than 20 generic candidates for equivalence in one day.

Generic inhaled drug approval depends on equivalent deposition of drug in the lungs. Eliminating candidates that do not show equivalent deposition profiles allows you to choose the best candidates up front, reducing timelines and helping avoid late-stage failures.

Studies with INVIDA may identify multiple high-quality candidates from distinct manufactures, giving you a second source and flexibility to manage unforeseen outcomes.

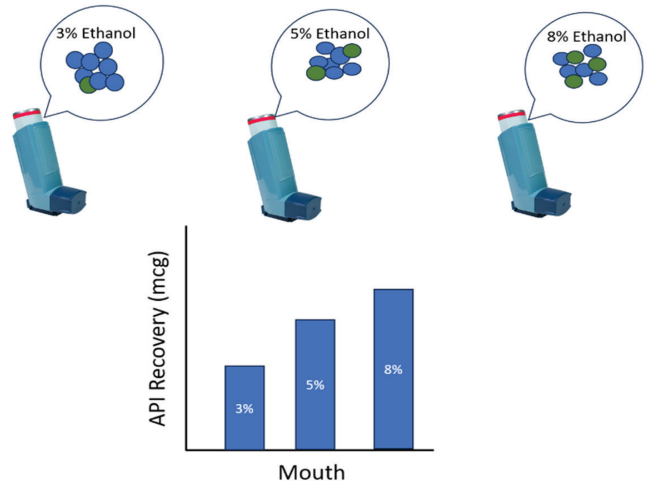
Regional Deposition of RLD and Candidates (1,2,3)



Formulation to Reformulation

Changes made to formulation composition can influence product performance, and traditional methods for evaluating the effect of incremental changes are time consuming and expensive.

After making a change to candidate formulation, a performance assessment with Proveris Laboratories will help avoid unexpected results and maintain equivalence to the reference product. The speed of data generation means no delay in decision making.

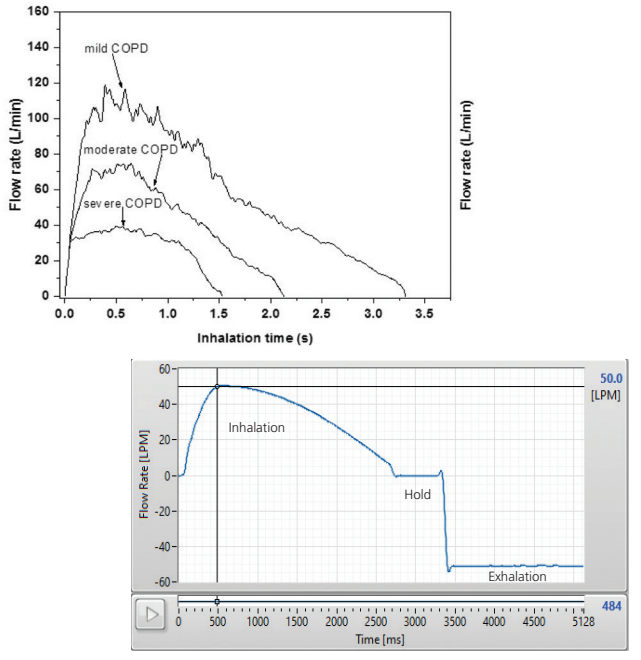


Proprietary Technologies

The INVIDA process is a complete drug development and bioequivalence study. Proprietary technologies enable testing on the full range of human breathing, including disease states, for the most accurate indication of in vivo performance.

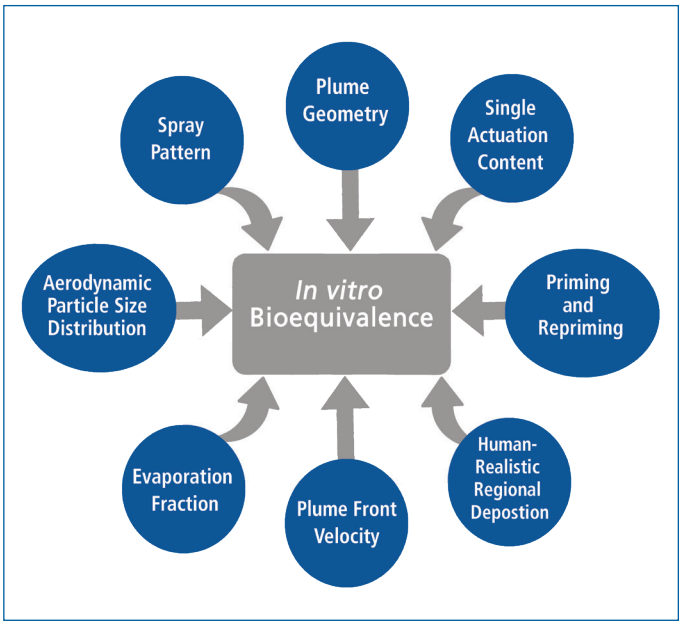
True human flow rates are made possible with proprietary low resistance filters. This allows for the study of drug particles in their native form, not after being altered by sheer forces.

Proveris Laboratories' fully programmable breathing simulator results in the most human-realistic volumes that enable breath coordination and misuse studies to de-risk clinical trials.



Weight of Evidence for Bioequivalence

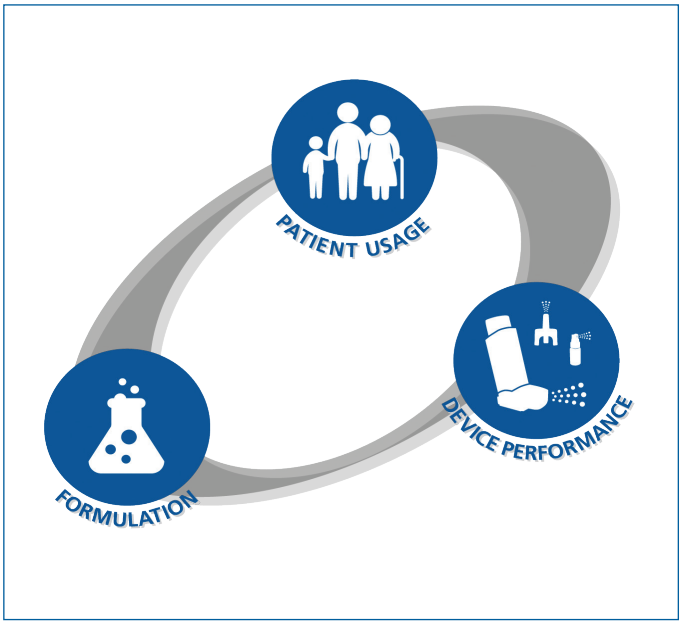
The FDA refers to weight of evidence as a systematic approach in which investigators look at all relevant evidence to make an assessment or determination. Data generated by Proveris Laboratories for Bioequivalence satisfies regulatory efforts by leveraging traditional tests and new technologies to build a comprehensive story of in vitro equivalence. Bioequivalence with Proveris Laboratories can help achieve clinical biowaivers and provides you with the most equivalent candidate for clinical endpoint studies, dramatically reducing risk, time, and cost.



Proveris by Design™

All projects with Proveris Laboratories use Proveris by Design, a proven, systematic approach that has been shown to eliminate late-stage failures, shorten timelines, and reduce cost while maintaining high quality.

Proveris by Design for bioequivalence is a thorough evaluation of equivalence where all decisions are justified by data. The Proveris by Design process provides the necessary product understanding for continued commercial product support.



A Trusted Partner for Over 25 Years

Proveris Laboratories has been a proven partner with innovator and generic companies around the world for over 25 years. We work with you to find the most appropriate and efficient path for your product to reach the market. The industry leader in spray characterization, instrumentation, and service, combined with driving new innovative technologies to support recent regulatory advancements to reduce clinical endpoint studies, Proveris is the right choice for your OINDP development needs.

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