Advancing Scientific Development with Collaborations

15+ FDA grants and $5M+ in funding
& new feature developments since 2014

Ongoing FDA Collaborations

Long-Acting Injectibles
Validating *IVIVC* methods for LAIs by enhancing PBPK models to predict formulation behavior, supporting generic drug development.

Virtual Bioequivalence
Establishing best practices for conducting virtual BE using GastroPlus®.

Oral Modified-Release Tablets
Developing a digital-twin of the tiny-TIMsg *in vitro* system to predict MR formulation PK accross multiple strength using PBPK-based IVIVE.

Dermal PBPK Model
Develop and validate a dermal PBPK tool to predict formulation evolution during application, addressing challenges like solvent evaporation and permeability enhancers, by enhancing the TCAT™ model.

Locally-Acting in GI Tract
Develop PBPK models to predict local GI concentrations and establish IVIVR/IVIVC, linking local and systemic exposure for patients with gastrointestinal pathologies, where plasma concentration alone is insufficient.

Pulmonary Absorption
Predict and enhance the PCAT™ model to include pathophysiologies and develop an IVIVR for lung permeability.

Oral Cavity Route
Develop an *in silico* modeling platform informed by dynamic *in vitro* oral cavity permeability data to establish biowaivers for oral cavity drug products.

2024 Achievements

Ophthalmic Products
Applying the OCAT™ model to predict human eye pharmacokinetics and pharmacodynamics, leveraging preclinical data to support bioequivalence (BE) evaluations.

Dermal Drug Products
Using PBPK models to predict skin permeation and and support the BE assessment of dermal drug products in patients.

NEW! Grants & Collaborations

- From Bench to Bioequivalence: *In vitro* Mechanistic Understanding of Amorphous Solid Dispersions (ASD) Drug Products in Simulated Gastrointestinal Conditions.
- Development of PBPK Model-Based Mechanistic *IVIVCs* for Long-Acting Injectable (LAI) Suspensions

GastroPlus®

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