

Model-Informed Formulation Development

Connecting formulation science with predicted human performance.

Corealis Pharma and PhinC Modeling combine oral solid dose formulation expertise with PBBM/PBPK predictive modeling to help sponsors focus experiments, understand formulation risks earlier and make more informed decisions before advancing to the clinic.

DEVELOP SMARTER. | PREDICT EARLIER. | REDUCE RISK.

FROM MOLECULE TO CLINICAL FORMULATION

An integrated, iterative approach to de-risk development.



01

CHARACTERIZE

API
Formulation
Dissolution



02

MODEL

Mechanistic
PBBM/PBPK
absorption



03

SIMULATE

Release
Solubility
Particle size
Food effect



04

BUILD

Targeted
prototypes &
clinical formulation



05

DECIDE

Evidence-based
formulation
selection



From *in vitro*
insight to
in vivo impact.

LESS TRIAL-AND-ERROR. MORE INFORMED DEVELOPMENT.



FEWER ITERATIONS

Focus experiments
on formulations
most likely to work.



EARLIER HUMAN-PERFORMANCE INSIGHT

Link dissolution
and formulation behavior
to predicted exposure.



BETTER RISK RANKING

Identify the API and
product attributes
that matter most.



FOOD-EFFECT FORESIGHT

Explore fed/fasted
sensitivity earlier
in development.

Formulation science + predictive biopharmaceutics =
a clearer path to the right dosage form.

WHERE MODEL-INFORMED FORMULATION CAN ADD VALUE

Particularly valuable for development-stage oral small-molecule programs.



POORLY SOLUBLE MOLECULES

ASD • Particle size
Precipitation
Solubilization



MODIFIED / CONTROLLED RELEASE

Release-rate design
anchored to
target exposure.



FOOD-EFFECT RISK

Fed/fasted sensitivity
and dissolution
robustness.



FORMULATION BRIDGING

Predict the impact
of formulation or
process changes.



BIOAVAILABILITY UNCERTAINTY

Prioritize what needs
to be optimized
before the clinic.

FROM BATCH TO BIOLOGY

A mechanistic link between formulation performance and predicted human exposure.



API PROPERTIES

Solubility • Permeability • Particle size • Stability



FORMULATION DESIGN

Excipients • Process • Dosage form • Release mechanism



DISSOLUTION BEHAVIOR

Biorelevant media • Release rate • Precipitation risk



GI ABSORPTION

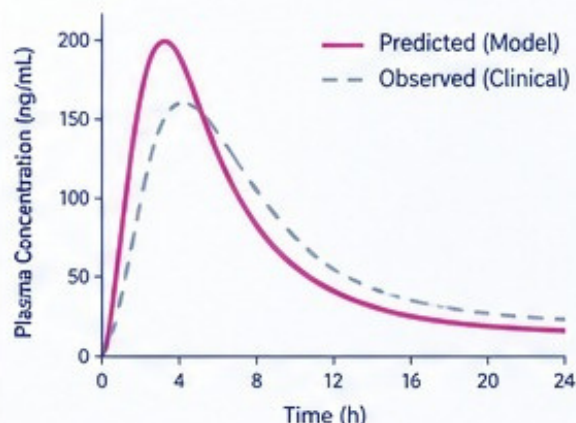
Absorption site • Transit • Food effect • Variability



PREDICTED EXPOSURE

C_{max} • T_{max} • AUC • Target profile

From formulation performance to predicted human exposure.



Inform formulation decisions earlier. Advance with confidence.

TWO AREAS OF EXPERTISE. ONE DEVELOPMENT STRATEGY.

COREALIS
Pharma

Formulation Science + Experimental Development

- Pre-formulation
- Oral solid dose formulation development
- Analytical development
- Dissolution testing
- GMP clinical manufacturing & supply



PhinC

Predictive Biopharmaceutics

- PBBM / PBPK modeling
- Mechanistic absorption modeling
- Formulation scenario simulation
- Exposure prediction
- Model-informed development strategy

IDEAL PROGRAM PROFILE

Development-stage oral small-molecule programs where formulation decisions could materially influence clinical exposure.

**DEVELOP SMARTER.
PREDICT EARLIER.
REDUCE RISK.**

Talk to our scientists about your molecule.

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SCIENCE
PARTNERSHIP
POSSIBILITY