LIFE SCIENCES

PK/PD MODELING AND SIMULATION SERVICES

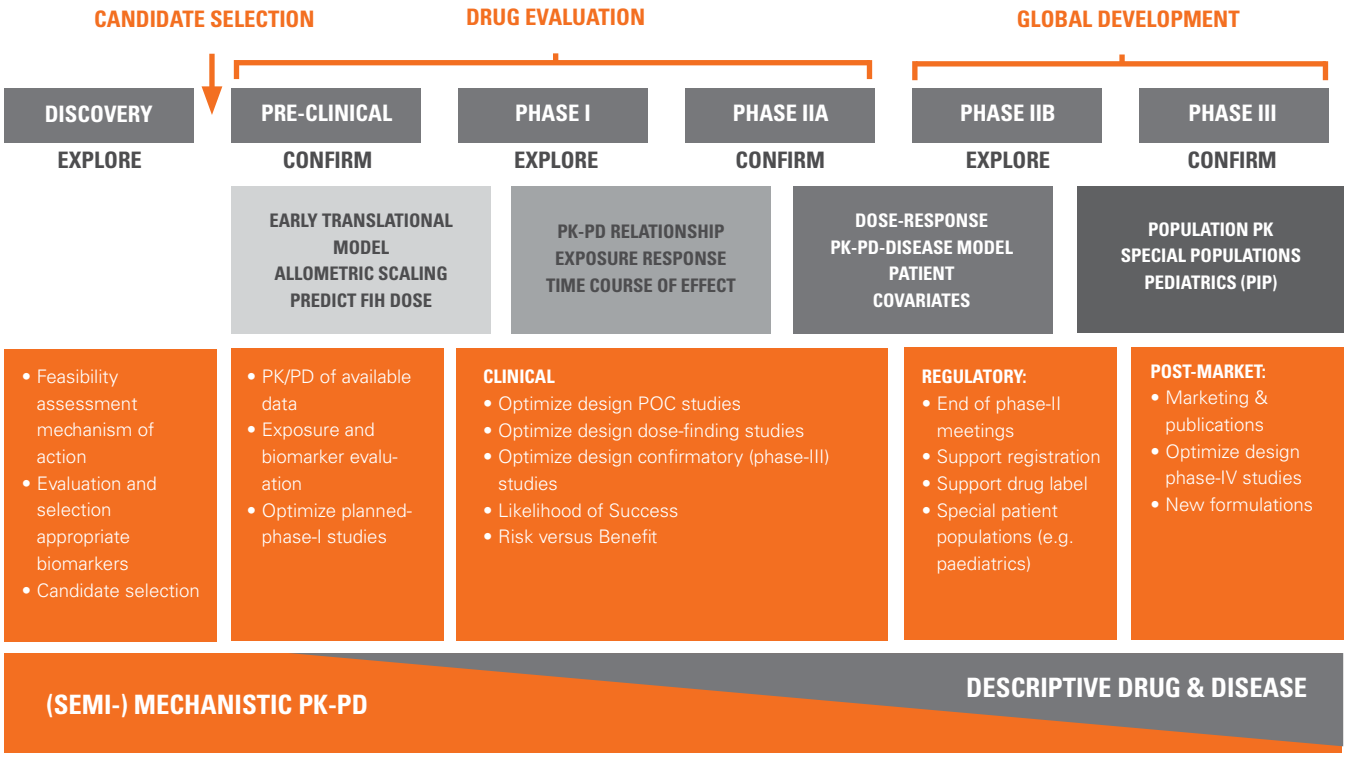
LIFE INSPIRED, QUALITY DRIVEN

SGS EXPRIMO

Pharmacokinetic/pharmacodynamic (PK/PD) drug-disease modeling helps pharmaceutical and biotech companies make fast and well-informed decisions about their drug development programs and clinical trial designs.

POPULATION PK/PD MODELING AND SIMULATIONS THROUGHOUT DRUG DEVELOPMENT

The implementation of model based approaches in drug development helps to bring new, safe, and effective medicines to patients more efficiently. At SGS Exprimo, we are focused on the application of quantitative, model-based approaches at all stages of pharmaceutical development.



BE A STEP AHEAD IN YOUR DEVELOPMENT PLAN

With many years experience, over 300 modeling and simulation projects performed, and the latest software, our >10 modeling and simulation experts provide input that can lead to more informative studies, fewer study failures, improved investment decisions and better justified label claims.

- **Predict efficacy and safety:** maximal drug response, onset and duration of response, disease-progression, inter-patient variability
- **Optimize clinical trial designs** with simulations: inclusion/exclusion criteria, doses and dosing intervals, sampling schedules, sample size, probability of success
- **Combine and compare** available in-house data and public domain knowledge on competitors
- **Explore** the mechanism of action
- **Manage expectations** through objective evaluations of data
- **Facilitate communication** between team members, management and regulatory agencies
- **Save time & budget** by providing quantitative support to decision making (e.g. Go/No-Go investment decisions and dose selection)

IN-DEPTH ANALYSIS AND CONSULTING SERVICES

As a standalone activity, or combined with the SGS general clinical trial services, we offer the following, including all reports to regulatory standards:

- Population pharmacokinetic modeling
  - Study design, analysis and interpretation
  - Covariate model building and exposure in demographic subgroups
  - Model evaluation
- PK/PD and disease-progression modeling (empirical or mechanistic models)
  - Study design, analysis and interpretation
  - Covariate model building and exposure-response in demographic subgroups
  - Linking dose, exposure and biomarkers to clinical outcome
  - Positioning of new drugs in the therapeutic area landscape
  - Model evaluation
- Clinical trial simulation and support for decision making
  - Visualization of results
  - Optimizing study design and choice of analysis method
  - Assessing likelihood of success for clinical trials
  - Dose selection and justification of dosing in subgroups of patients
- All therapeutic areas and endpoints with related services
  - Provide general strategic support to drug development programs
  - Scoping of projects to identify key questions and model-based solutions
  - Inter-species scaling
  - Extrapolation/bridging across populations (e.g. adult to pediatric, Japanese to Global)
  - Biologics and antibodies
  - Cardiac safety and QT analysis
- Regulatory consulting/advice with respect to all aspects of modeling during drug development
  - Writing summaries of M&S work for submissions and regulatory interactions
  - Reviewing documents prior to regulatory submission
  - Attend and present at regulatory meetings
- Customized training
  - Clinical trial simulation courses

CLINICAL TRIAL SIMULATION SOFTWARE

SGS Exprimo offers access to Simulo, a software for PK/PD and disease-progression model simulations with a user-friendly interface. Any type of classical or user-defined type of PK/PD drug-disease model (literature or in-house) can be implemented in Simulo, allowing for advanced clinical trial simulations to visualize results or for exploring optimal study designs. The platform provides easy comparison of complex dose adaption rules, study designs, sample sizes and power calculations. The resulting R-script may be applied outside of Simulo in any R environment, but is structured and harmonized across projects to simplify for regulators and peer reviewers.

ABOUT SGS LIFE SCIENCES

SGS is a leading life sciences CRO providing clinical research, bioanalytical, biologics characterization, biosafety, and quality control testing. Delivering solutions in Europe and in the US, SGS offers clinical trial (Phase I to IV) services encompassing clinical project management and monitoring, biometrics, PK/PD modeling and simulation, and regulatory and medical affairs consultancy. SGS has its own clinical unit in Belgium and two phase I patient units based in Belgium and Hungary. SGS has a wealth of expertise in first in human (FIH) studies, viral challenge testing, biosimilars and complex PK/PD studies with a focus on infectious diseases, vaccines, and respiratory therapeutics.

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WHEN YOU NEED TO BE SURE