



SIMULO

CLINICAL TRIAL SIMULATOR

Simulation is an inherent part of pharmacometrics, where different PK/PD and disease-progression models are used for making inferences and for exploring the expected consequences of e.g. altered dosing, alternative study designs or various analysis methods. To adequately capture the impact of uncertainty and variability, simulating from these models often requires cumbersome scripting.

SGS Exprimo has developed Simulo, a simulation software with a user-friendly interface, to provide a clear but solid simulation framework. Simulo offers a platform on which mathematical/statistical drug-disease models easily can be implemented and efficiently run, based on pre-programmed modules.

SIMULO FACILITATES & EXPANDS YOUR RESEARCH SCOPE

- **Implement** any existing model (in-house or literature), allowing you to perform all empirical and advanced type of simulations
- **Reproduce** prior simulations already performed at SGS Exprimo and explore new scenarios based on your own assumptions
- **Visualize** the simulated data to facilitate accurate decision-making
- **Confidently** handle model-based simulations for regulatory submissions
- **Enhance** cross-disciplinary team collaboration by translating your data and model results into tangible knowledge well understood by your colleagues

SIMULO FEATURES

A wide variety of classical or user-defined population PK-PD and disease-progression models can be assembled through algebraic, ordinary differential, or delayed differential equations

- **Study attributes** such as population characteristics (e.g. covariates, inclusion and exclusion criteria), treatments (e.g. route and mode of administration, dose and dosing schedule), observations (e.g. type and schedule) and design (e.g. sequential, parallel or adaptive) can be defined
- **Variability and uncertainty** can be generated at between-subject, between-occasion and between-study replicate levels from non-correlated (e.g. constant, uniform,

normal, lognormal, logit, logistic, poisson, negative binomial) or correlated (e.g. normal) parametric distributions

- **Covariates** and model parameters can be bootstrapped (sequentially or at random, with or without replacement, independently or jointly) from existing databases
- **Adaptive designs** and conditional events with complex decision trees can be addressed
- **Analysis methods** and visualization of results can automatically be applied at the end of each replicate through customized R scripts
- **The resulting R-script** may be applied outside of Simulo in any R environment

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ACCESSING AND USING SIMULO

- A free version of Simulo is now offered to all pharmaceutical companies, academic institutions and regulatory agencies, once some basic training has been received.
- For SGS Exprimo active clients and academic collaborators, a full expert version of Simulo is available, supported by a dedicated scientific team
- Training sessions about Simulo and general clinical trial simulations are offered by SGS Exprimo on a regular as well as on a request basis



ABOUT SGS EXPRIMO

SGS Exprimo, part of SGS, is a European Life Science consultancy company with strong focus and expertise in the development and application of quantitative model as well as model-based simulations during all stages of bio/pharmaceutical development.

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

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