NEW!

PKPlus™ 1.0

PKPlus™

from the developers of GastroPlus™

the validation you require... the value you deserve

A next-generation software program for preclinical and clinical trial data analysis. Easily generate high-quality, custom analysis and reporting of pharmacokinetic data for internal reports or use in submissions to regulatory agencies.

SimulationsPlus

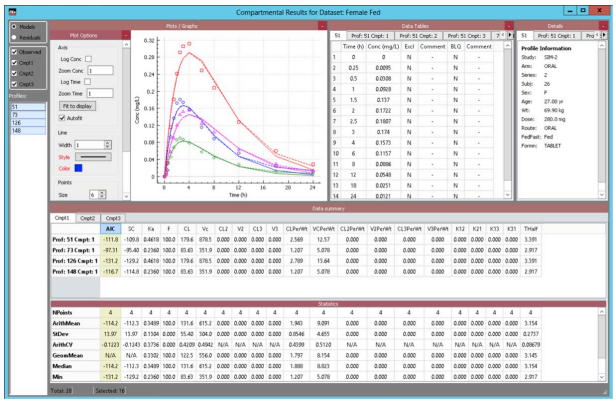
SCIENCE + SOFTWARE = SUCCESS

What is PKPlus™?

Every lead compound which enters preclinical testing warrants some form of non-validated noncompartmental analysis (NCA), with promising candidates heading into clinical trials requiring validated NCA as part of the new drug applications submitted to regulatory agencies. Compartmental PK analysis (CA) is also often used to support submissions as well as to understand how various factors affect the absorption, distribution, and elimination of drugs from the body. If you decide not to write your own source code or create validation data sets to confirm results, you may depend on commercial software to help with these processes.

When considering a commercial program, is it important to you to utilize a PK modeling platform which offers:

- Intuitive workflow?
- Validation?
- Audit trails?
- Automation?
- Value pricing and flexible licensing?



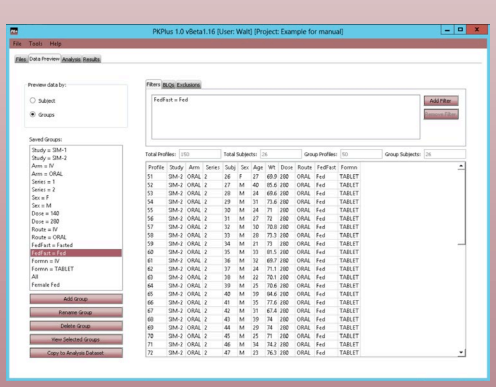
If you answered yes to any of the above questions, then we can help. Simulations Plus is pleased to introduce PKPlus™, a new program that provides high-quality, user-friendly pharmacokinetic data analysis and reporting for validated and non-validated purposes.

PKPlus combines sophistication and simplicity, providing the capabilities to meet the needs of scientists across departments at pharmaceutical companies, contract research organizations (CROs), and other non-pharma markets, all with the value pricing and flexible licensing policies to make it the best choice for cost-conscious organizations.

What can it do?

The underlying mathematics behind NCA or CA models is relatively straightforward. The key features that must be met when providing a commercial package are: validation, automation, and workflow.

PKPlus, designed in collaboration with our clinical pharmacology/pharmacometric consulting experts, meets all requirements:

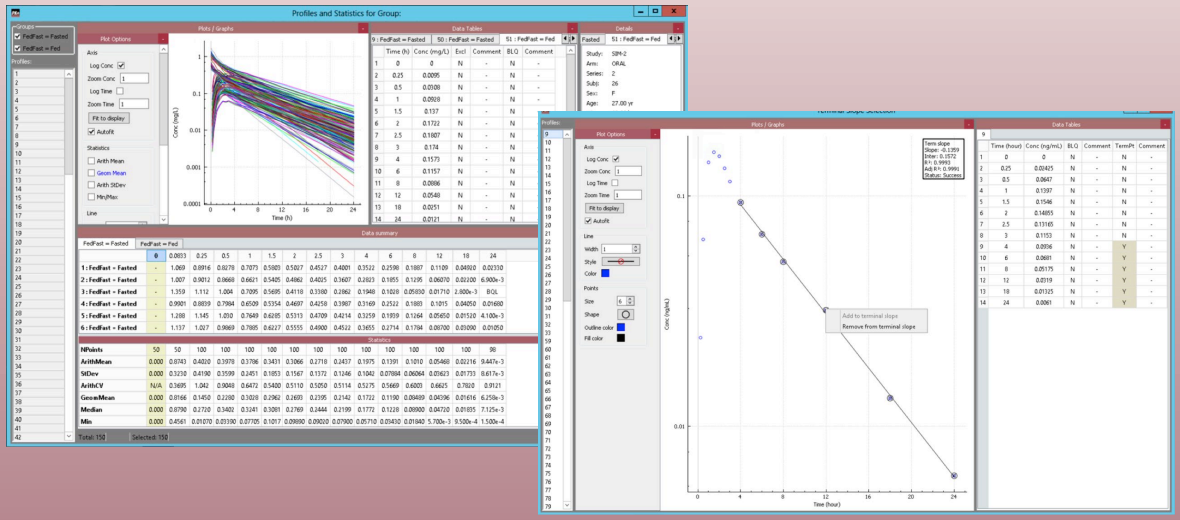


- A validation procedure to confirm PKPlus is giving you the correct results on your systems
- An automated process for fitting NCA and/or CA models, with subsets of data you select, without the need for writing any equations
- A simple 'point-and-click' streamlined workflow to minimize errors.

All of this is available through a flexible licensing model at a **fraction of the cost of competing tools**, with excellent customer support included.

What are the key features?

- Automatic and custom report generation is provided, along with full audit trail and validation, which are required to assist companies in complying with 21 CFR Part 11 for their submissions to the U.S. Food and Drug Administration
- Calculation of pharmacokinetic parameters using industry-standard NCA methods
- Calculation of pharmacokinetic parameters using compartmental analysis with 1-, 2-, or 3- compartments – you decide which models to solve in an automated fashion!
- Support for importing and exporting common data file types
- Fast and easy Exploratory Data Analysis (EDA) - data management functions to deal with organizing and examining data
- Knowledge-based' selection of groups – PKPlus learns from your data input fields and intelligently creates groups of data without any user interaction!
- Relational database infrastructure - highly flexible selection of records to analyze and compare desired subsets of a total data set
- Unique tracking of exclusions or outliers: define reasons for exclusions which can be included in reports
- Production of high-quality tables, figures, and listings for export to reporting programs – designed in accordance with PhUSE
- View PK profiles, statistics, and model parameters from a single screen – can easily select point(s) to exclude and recalculate the outputs
- Audit trail (saving all software settings) to ensure the ability to duplicate results from submitted analyses in the future
- Validation data sets to confirm PKPlus is giving the correct results on your system
- Flexible licensing options: you decide whether to install each license on a standalone machine or treat each one as a floating seat – no difference in license fees!
- Value pricing – all these features AND still less expensive than similar tools



Who should be using it?

- Clinical pharmacologists analyzing & handling large amounts of PK data, assembling groups, and creating custom plots, figures and tables (in accordance with PhUSE)
- Modelers needing to produce parameter estimates for inputs into GastroPlus™ PBPK or NONMEM® population PK/PD models
- CROs doing the work for sponsor companies and wanting to avoid paying premiums to software vendors based on the volume of studies performed or on the number of user licenses required*

***Remember, our license fees are the same regardless of how you use PKPlus.**

How can I move forward?

There is a choice when deciding on a PK modeling software package. If convenience, validation, workflow, automation, and value are important to you, then check out PKPlus. To request a product demonstration, evaluation, or pricing information, please visit us at:

www.simulations-plus.com Or call us directly: **+1-661-723-7723**

Intuitive 'point-and-click' workflow

Validation data sets

Audit trails

Exploratory data analysis (EDA)

Custom PhUSE standard reports

Common file formats

Value pricing

Floating licenses

SimulationsPlus SCIENCE + SOFTWARE = SUCCESS
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