SimulationsPlus

SCIENCE + SOFTWARE = SUCCESS

PKPlus™

"Plug n Play PK"

Powerful, Practical, Affordable

www.simulations-plus.com

+1-661-723-7723

What is PKPlus™?

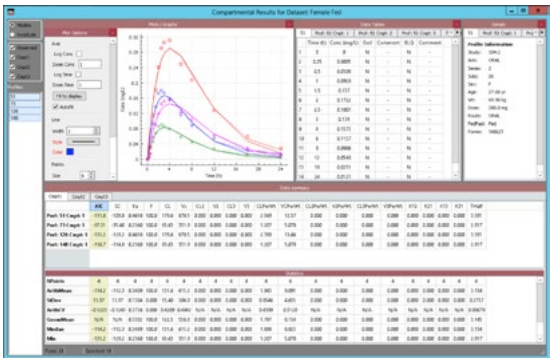
PKPlus™ 2.0 is a new program that combines sophistication and simplicity, providing the capabilities to meet the needs of scientists across departments at pharmaceutical companies, contract research organizations (CROs), and other non-pharma markets, all with the value pricing and flexible licensing policies to make it the best choice for cost-conscious organizations.

Features of PKPlus include:

- Point-and-click ease of use:
  - Eliminate/minimize typing errors
  - Maximize productivity
- Easy import of common data file formats (.csv, .xpt)
- Easy file mapping to internal display names
- Easy Data Preview/Exploratory Data Analysis (EDA)
- Easy setup of Analysis Datasets:
  - Filters, BLQs, and/or Exclusions
- Easy noncompartmental analysis (NCA)
- Easy compartmental analysis (CA)
- Assistance with 21 CFR Part 11 compliance:
  - Audit trail
  - Validation
- Easy report-quality output of Tables, Figures, and Lists
- Value-based licensing

New features of PKPlus™ 2.0 include:

- Addition of Non-Parametric Superposition (NPS)
- Compartmental multi-dose simulation
- Command line version for fast validation checks
- Save map/report settings for use in other projects
- Ability to edit and exclude data from files before import
- Create custom variables to store data
- Manual plot options that allow users to plot data by selecting the variable to use for each axis
- New Statistics plot
- Migrate users to Windows logins
- and more...



Every lead compound entering preclinical testing warrants some form of non-validated noncompartmental analysis (NCA). Promising candidates heading into clinical trials require 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 PKPlus™ 2.0 to help with these processes.

Spend less... time, money, and IT resources with PKPlus™ 2.0.

Affordable Licensing Models

Commercial Licensing - PKPlus™ 2.0 is the most affordable, commercially supported PK platform software in the marketplace with a new low cost, flexible floating license model. Small/mid-size Pharma and CROs will appreciate avoiding paying premiums to software vendors based on the number of user licenses required. Your license fees are the same regardless of whether you install PKPlus™ on a standalone computer or server.

Academic Licensing - PKPlus™ 2.0 is offered to academic institutions at "no-cost". Simulations Plus is dedicated to investing in the next generation of researchers who will be advancing the science of simulation and modeling.

What can it do?

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

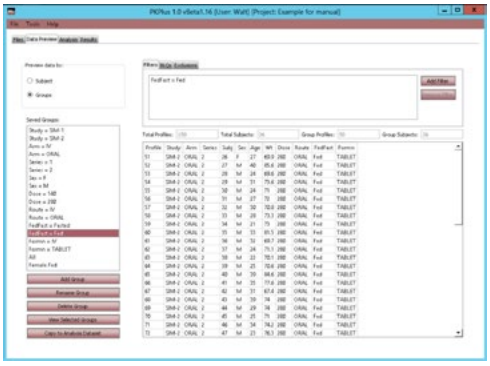
PKPlus™ 2.0, designed in collaboration with our clinical pharmacology/pharmacometric consulting experts at Cognigen Corporation, a Simulations Plus company, meets all requirements:

- A validation procedure to confirm PKPlus™ 2.0 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 award winning customer support at no additional charge.

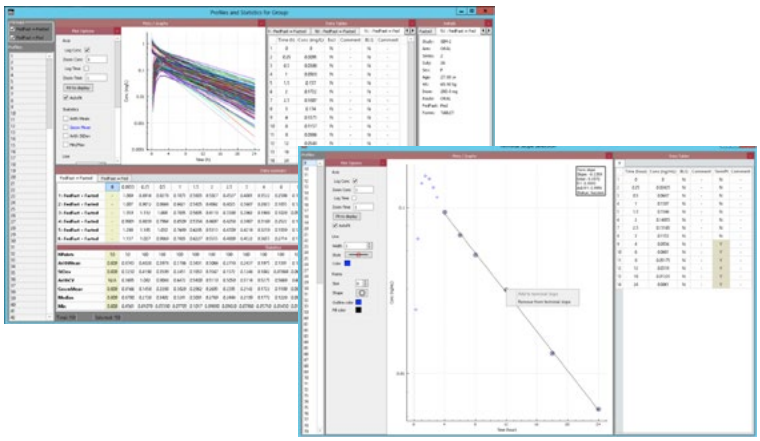
What are the key features?

- 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™ 2.0 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
- 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™ 2.0 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
- No-cost Academic Program



Who should be using it?

- DMPK/preclinical scientists needing to generate quick, accurate PK study reports from the high-throughput animal studies performed in early development.
- Clinical pharmacologists analyzing & handling large amounts of PK data, assembling groups, and creating custom plots, figures and tables
- Modelers needing to produce parameter estimates for inputs into GastroPlus™ PBPK or NONMEM® population PK/PD models
- Small/mid-sized Pharma and CROs



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™ 2.0. 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**

Ask about our 'No Cost' academic PKPlus™ program!

21 CFR Part II compliant features

Intuitive 'point-and-click' workflow

Exploratory data analysis (EDA)

Custom PhUSE standard reports

Common file formats

Value pricing

Floating licenses

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