



MonolixSuite™

A fast, easy-to-use, and powerful suite of applications for pharmacometrics analysis, modeling and simulation



Consultancy

Model building, programming and validation, translation of your model description into Mlxtran, statistical analysis, etc.



Training

Lixoft frequently offers public training events on Lixoft products. Lixoft can also provide on-site trainings worldwide, for Universities and pharmaceutical companies.



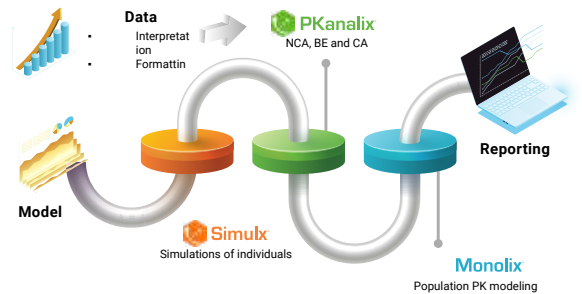
Expert support

Behind Monolix's suite is a dedicated developer and expert team you can contact for technical questions. Extensive and tailored support is available on request.



Model libraries

To help model development, Lixoft provides a fully documented, open source library with PK, PD, PKPD, TMDD, and TTE models.



Fully interoperable applications give you a complete modeling and simulation workflow from data visualization and non-compartmental analysis to population modeling and simulations. Intuitive, effective, and offering the most advanced calculation capabilities.

The Monolix Suite was developed in view of the increasing importance of pharmacometric experts in drug development. This key role requires integrated software tools with the most rigorous statistical methodologies to deliver high quality modeling results in time.

Experience the right tools for model-based drug development. All integrated for modeling in one go – without rewriting any data set, models or parameters:



PKanalix - Interactive non-compartmental and compartmental analysis.



Monolix - Robust parameter estimation with the SAEM algorithm and built-in diagnostic plots.



Simulx - High performance simulation of new scenarios, including clinical trials.



Monolix®

Easy to use and powerful solution

Monolix is the most advanced and simple solution for non-linear mixed effects modeling (NLME) for pharmacometrics. It is based on the SAEM algorithm and provides robust, global convergence even for complex PK/PD models. **Monolix** is used for preclinical and clinical population PK/PD modeling and for Systems Pharmacology. **Monolix** enjoys a large user community. **Monolix** is widely used by academia, the pharmaceutical industry as well as the US regulatory agencies.



Key features

Support of all relevant data types and statistical features
Monolix covers a wide range of data types and statistical features for population PK/PD modeling. For all cases the right statistical methodology has been developed and published for reference. Monolix covers:

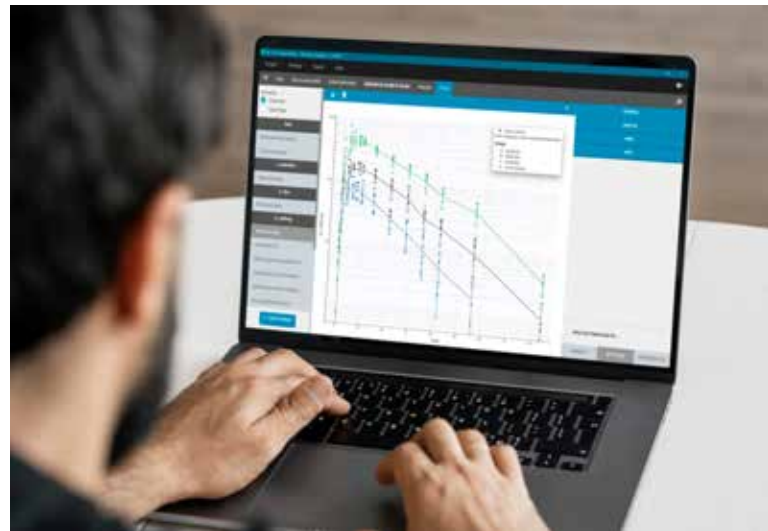
Continuous, categorical, count and repeated time to event data. Mixture models and mixtures of models. Inter-occasion variability with any number of levels. Proper handling of BLQ data. Normal, lognormal, logit, probit and user defined distributions for the individual parameters.

Mlxtran is used for custom-built models; a simple, yet powerful model language that is suitable for simple as well as complex Systems Pharmacology models. Monolix provides a fully documented, open source library with more than thousands of PK and PD models.

Comprehensive documentation and examples








Great care has been taken to provide the user with a comprehensive documentation that includes methodology, software manuals, tutorials, etc...

A wide collection of examples that include models and data can be used as templates to start your own project. A lot of online material (feature of the weeks, webinars, etc...) on our Lixoft University page.



A fast, easy-to-use, and powerful suite of applications for pharmacometrics analysis, modeling and simulation

Why Monolix?

- 
Advanced Statistical Methodologies
 Reliable convergence for all type of data is a centerpiece in population PKPD modeling, which is why Lixoft pioneered in collaboration with Inria the SAEM algorithm.
- 
Automated generation of diagnostic tests
 Monolix automatically generates a full set of diagnostic plots even for complex PK/PD models. For example, you can instantaneously create the Visual Predictive Check, split by any patient subgroup you would want to investigate.
- 
Increased productivity and quality
 Efficient C++ solver package, standardized model language with Mlxtran, PK/PD model library and integrated software all contribute to better productivity and quality.
- 
Very easy to use with its GUI
 Our solutions are designed for ease of use. Monolix can be used via a graphical interface or command lines for powerful scripting. This means less programming for you and more focus on exploring models and pharmacology to deliver in time to your customers.
- 
Easy of use & powerful computation
 Monolix can be used via a graphical interface or command lines for powerful scripting. This means less programming for you and more focus on exploring models and pharmacology to deliver in time to your customers.
- 
Model construction using Mlxtran
 Mlxtran is used for custom-built models; a simple, yet powerful model language that is suitable for simple PK as well as complex Systems Pharmacology models.
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Data Set
 The data set is a key element for the parameter estimation and is a key element to summarize the experimental data in a file.



PKanalix®

Intuitive, efficient and integrated in MIDD workflow

Reproducibility, correct installation and calculations are guaranteed by settings saved in the project and the integrated validation suite. Together with a direct link towards population modeling using Monolix assure the most informative workflow.

Key features

Non Compartmental analysis

The first main feature of PKanalix is the calculation of the parameters in the Non Compartmental Analysis framework.

This task consists in defining rules for the calculation of the λ_z (slope of the terminal elimination phase) to be able to compute the NCA parameters. This definition can be done either globally via rules (e.g adjusted R2 or time window) or on each individual where the user can choose or remove any point for the calculation.

Compartmental Analysis

The second main feature of PKanalix is the calculation of the parameters in the Compartmental Analysis framework. It consists in finding parameters of a PK model representing the kinetics in compartments for each individual. Automatic initialization is performed for a better convergence of each parameter for each individual.

Outputs and plots

All NCA, CA and Bioequivalence outputs are displayed in sortable tables and exported in the result folder in a R-compatible format. Interactive plots are also proposed for straightforward interpretation of the results.

R API to automate your process

All steps performed in PKanalix can be run from R with the LixoftConnectors package. What you have done once intuitively in the interface on a specific dataset can be generalized to a script automating the process for any other dataset.



PKanalix is a user friendly and fast application for compartmental and non-compartmental analysis (NCA)

Why PKanalix?

- ✓ **Very intuitive interface & automatization via scripting**
Intuitive settings panels, clear definitions of methods, visual tools to check the calculations and personalized display of results – all contribute to a better productivity.
- ✓ **Straightforward NCA & Bioequivalence Studies**
Integrated calculation of NCA parameters with industry-standard methods and bioequivalence study as recommended by regulatory agencies – is done in a few clicks.
- ✓ **Reliable and clear results**
Intuitive tables, sortable summaries and interactive plots provide a powerful environment for analysis of results All settings are saved in the project for reproducible results, and the integrated validation suite ensures correct installation and calculation..

Compartmental analysis & integration towards population modeling

Built-in library of PK models and automatic features help to describe PK dynamics within the Compartmental Analysis framework. Calculation of the parameters in the Compartmental Analysis framework is also proposed with a large library of PK models. In addition, it includes a direct link toward population modeling using Monolix.



Documentation

Great care has been taken to provide the user with a comprehensive PKanalix documentation that includes methodology, software manuals and tutorials. A wide collection of examples that include models and data can be used as templates to start your own project.



Simulx[®]

Why Simulx?

- ✓ **To gain new insights**
From interactive exploration of effects of dosing regimens and model parameters with real-time predictions
- ✓ **To anticipate clinical trials**
Results via fast simulations of populations of individuals
- ✓ **To save time**
By working in a simple and efficient environment interconnected with Monolix and PKanalix
- ✓ **To focus**
On modeling and simulation instead of implementation details thanks to easy and flexible simulation setup and integrated post-processing tools.
- ✓ **Fast and easy to use with intuitive GUI**
Simulx can be used via a graphical interface. This means less programming for you and more focus on exploring different treatments and effects of model parameters on a typical individual and/or simulating a clinical trial using a population of individuals in one or several groups with specific treatment or features.
- ✓ **Advanced Statistical Methods**
Outcomes and endpoints can be defined in the dedicated section. It provides a simple and efficient comparison between groups in the good statistical framework. PKanalix



Simulx is an easy, efficient and flexible application for clinical trial simulations

User-friendly and fast application

Simulx is an advanced clinical trial simulation software to build and simulate user-designed scenarios. It combines a user-friendly interface with the highest computational capabilities to quickly answer your questions and find optimal solutions.



Key features

Optimal environment to build and analyze simulation scenarios

Definition – create easily new exploration and simulation elements (parameters, treatments, outputs, covariates, etc.) of different types using built-in methods or external tables

Exploration – analyze in real time different treatments and effects of model parameters by simulating a typical individual; create several exploration groups, overlay experimental data and send a scenario in a single click to a clinical trial simulation

Simulation – simulate clinical trials using a population of individuals in one or several groups with specific treatment, individual characteristics or measurement times; use flexible post-processing tools, and get immediate feedback in intuitive exportable tables and interactive plots.

Outputs and plots

All simulation outputs are displayed in sortable and formatted tables easy to copy in any document and are exported in the result folder in an R-compatible format. Interactive plots are also automatically generated for straightforward interpretation of the results.