For Scientists involved in pharmacokinetic studies who wish to rapidly turn around high-quality analyses and reports, Kinetica is a high-throughput, template-driven pharmacokinetic analytical solution that allows rapid analysis of data and ensures consistencies between analyses and analysts. Kinetica has a unique template format that users can reuse and share.

Thermo Scientific Kinetica

Pharmacokinetic/Pharmacodynamic (PK/PD) data analysis, simulation and reporting system.
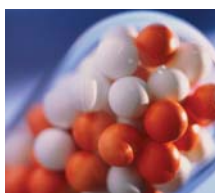
Thermo Scientific Kinetica - the analytical data solution that simplifies data analysis and safely enables multiple analysts to share study templates.

The Goal of PK/PD Analysis

One of the critical aspects of drug development is the determination of ultimate dosage for a new drug substance. Analysis via PK/PD processes determines the dose-response behavior of a drug, i.e., how much of a drug is good and how much is toxic or potentially lethal. PK/PD analyses also play an important role in drug labeling, providing indicators for populations at risk or potentially intolerant of the drug (pediatrics or geriatrics) or populations that have conditions that should prohibit use of the drug (kidney malfunction, heart disease or compromised immune systems). PK/PD analysis will determine the optimized dosage of a particular drug, before the drug is considered for costly Phase III trials.

How does Kinetica help the PK/PD process?

Kinetica has been designed with multiple standardized settings so that each PK analyst has a set of pre-defined templates. With this standardization, Kinetica eliminates the need to hire additional QA personnel to review all the PK data in a study report. Additionally, this standardization saves time for laboratory and study managers who would have to double-check all subordinates' findings. The results are more consistent and reviewing those results is less time consuming.

Thermo SCIENTIFIC

Benefits of Kinetica Standardization of PK Studies

- Reduction in manual transcription error from transferring data
- Seamless transition of data from Thermo Scientific Watson LIMS™ saving analysts significant time in data transfer
- Non-compartment, standard compartment and population PK/PD bioequivalence, graphs and reports in a single application
- Templates provide consistencies and standardization, customizable to specific corporate SOP
- Pre-set options and settings provide consistency of analysis and reporting across multiple analysts

- Template format allows analysts to apply the same analysis to multiple datasets
- Single file for graphics, tables, raw data and analysis results means time saved in searching for applicable formats and compiling computation specifications
- Unit Management feature provides complete set of mass, volume, and time combinations, plus molarity and pharmacokinetic parameter outputs

The Kinetica Solution

For scientists involved in pharmacokinetic studies, a primary challenge is to be able to process bioanalytical data into meaningful parameters for dose optimization and decision-making processes. The Kinetica solution is an easy-to-use application that allows user to seamlessly import data from Watson LIMS, as well as other data sources, perform computations, and graph and create tables in a single application.

The Kinetica Solution

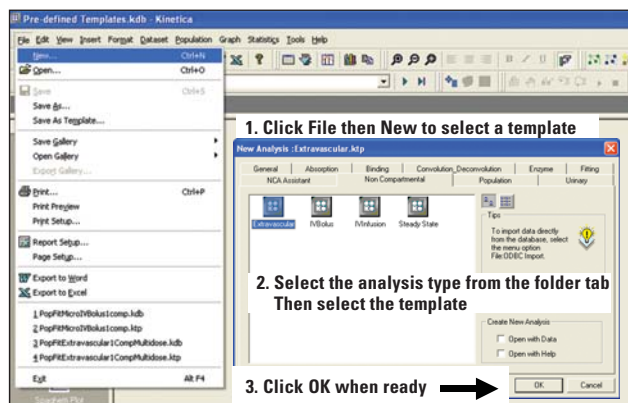| Challenge	Solution	Product Description
Process bioanalytical data into meaningful parameters for dose optimization and decision-making processes	Easy-to-use purpose-built application that allows users to import data from Watson LIMS and other sources, compute, graph and create tables in a single application	Automated calculation of pharmacokinetics with predifined templates and methods Supports Excel, ASCII, Watson LIMS, Oracle, P-Pharm data import
Able to perform all types of analyses in a single package	Ability to perform from non-compartmental through to population analysis, bioequivalence, graphs, table script More than one analysis method can be performed at a time	Includes more than 60 different validated templates to support wide range of pharmacokinetics/ toxicokinetics calculations • Noncompartmental & compartmental analyses • Population PK analysis • Bioequivalence • Predefined Table scripts • Enzyme kinetics • Protein binding

Kinetica in Action

Kinetica comes with predefined templates for any type of pharmacokinetic analyses from non-compartment through to population pharmacokinetics. To access these predefined templates, (1) click File then New from the menu. A dialog box will appear showing various folders for these templates. The folders are separated according to the type of analysis these templates perform. For example, the non compartmental folder will contain pre-defined templates for the three main routes of administration and an additional template for steady state profile. (2) The second step is to select the folder for the type of analysis and then select the template itself. Notice that on the lower right hand corner there is a box that allows you to open with data. If you are not familiar with what the template is doing, open it with data. It will show you what the methods do and where the results go. (3) Click OK when ready.

Kinetica's Population Pharmacokinetic Module

Kinetica's robust population analysis module gives you fast and accurate results. The system includes a powerful multi-dimensional search option to identify relationships between the model parameters and available co-variables. Kinetica is equipped with a user-friendly Parameter Initialization tool, which not only allows you to enter initial parameter estimates, but also provides graphical control to set these values accurately. Population analysis results and graphs are generated and stored in a single file.
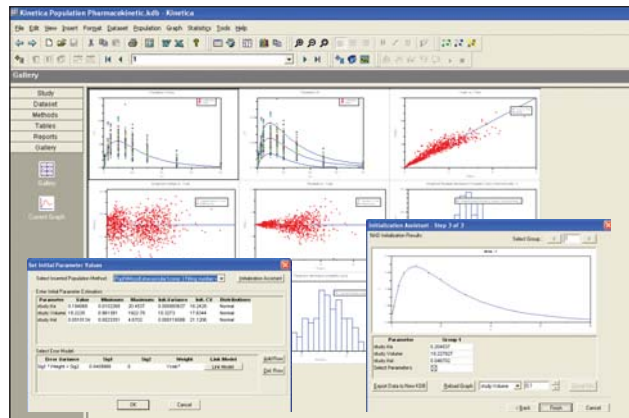
Standardization by Pre-defined Templates

As companies are driven by the pressure to increase efficiency and productivity, pharmaceutical scientists need to maximize throughput with faster and better quality of analysis and reporting. There is also a need to establish a single standard across laboratories and sites, thus minimizing variability between analyses and between analysts. Designed as a template-driven system, Kinetica allows you to create predefined templates and settings. The template format allows high-throughput solutions and customized automation of business workflow based on company's SOP and guidelines. The same format can be applied to any other studies thereby offering standardization across your organization. The advantages for your company are high consistency in the process, as well as time savings in not having to put effort in validating each user's analysis and version control.

The Kinetica Solution

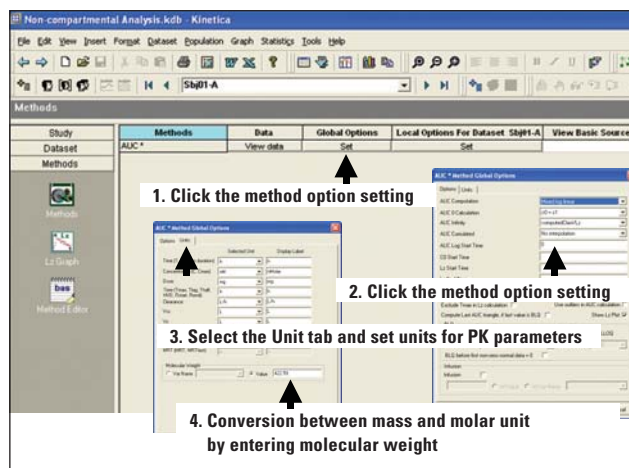| Challenge	Solution	Product Description
Maximize throughput analysis for faster and better quality of study analysis and reporting	Template format allows high-throughput analysis Fully scalable to multi-site, enterprise-wide use to promote standardization	Shareable, re-usable templates to define analysis procedures; no programming required Seamless interface with Thermo Scientific Watson LIMS
Establish standards across labs or sites	Customized automation to standardize analyses based on company SOP and guidelines Template format can be applied to any other studies Built-in Basic scripting language allows user to build customized methods and macros to automate their workflow	Allows standardization of experimental designs, settings and calculations among laboratory staff and between different labs of sites Option setting can be preset in the templates Powerful unit conversion for management of unit for derived PK parameters plus molar conversion

Non-compartmental Analysis Module

Using the non-compartmental method as an example, click the method global option setting. The AUC* method global option dialog box appears. The first tab shown on the right hand side allows you to set the computational procedures. Once the computational options are set, select the Unit Tab to set the input and output units for your time series data and your output parameters. The powerful unit management tools let you specify the output pharmacokinetic parameter units as well as input time and concentration units from an extensive list. This list includes both mass and molar units. By simply entering the molecular weight of your drug, Kinetica will automatically convert mass to molarity.

1. Click the method option setting
2. Click the method option setting
3. Select the Unit tab and set units for PK parameters
4. Conversion between mass and molar unit by entering molecular weight

Thermo Scientific Kinetica

Single File Format Simplifies Data System for Drug Submission

As data and analyses from years of research and drug development will eventually be used for drug submission and filing, users need a simple way of storing and retrieving data. Kinetica provides the convenience of storing your raw data, analysis information, method and options, table scripts and graphical output in a single file. So that every time you run an analysis, you can have confidence when the time for filing comes, that you only need to retrieve one single file.

Scripting Language to Automate Workflow

Kinetica comes with a visual basic scripting language for user to create macros and methods. The basic scripting language offers customization to automate workflow, import and export. Kinetica customers have utilized this tool to create their own templates equipped with the ability to send data to SAS. First, go to the Macro Editor or Method Editor and start creating your macro. Save the macro you have created by selecting Tools, then Macro, then Save Macro in Kinetica File. If you select Macro, instead of Save Macro in Kinetica File, a dialog box appears to let you run, edit or rename a specific macro. As you can see, even the macro is saved along with the file.

The Kinetica Solution

Challenge	Solution	Product Description
As data and analysis from years of research will eventually be used for drug submission and filing, a need for simplicity of storing and retrieving data	All data and analysis information are stored in a single file, including method information, algorithms, graphs and report setting Can also be saved as template for user to import data from other studies and use the same option settings	All information from the analysis stored as a single .kdb file

2. Select Tools from the menu and Macro to save or run macro

1. Select the Macro Editor and start creating your macro

3. Macro dialog box allows user to select and run specific Macro

KIN608

Thermo
SCIENTIFIC