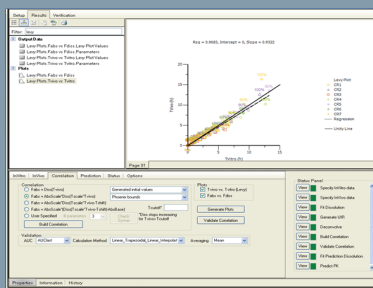




IVIVC Toolkit for Phoenix® WinNonlin®

Powerful IVIVC Exploration and Development

Easy to Use Wizard
Automates Key Processes



With the IVIVC Toolkit for Phoenix WinNonlin, you can visualize in vivo - in vitro relationships with new plotting features, improve collaboration between Clinical Development and Formulation, and easily apply correlations to predict PK from new in vitro data.

The IVIVC Toolkit for Phoenix WinNonlin is an optional add-on to Phoenix WinNonlin that enables the use of Phoenix WinNonlin for in vivo - in vitro correlations. As part of the Phoenix platform, there is a seamless integration with other Phoenix tools whereby the inputs and outputs from IVIVC can be easily be linked to other analysis tools within Phoenix. The IVIVC Toolkit for Phoenix WinNonlin brings enhanced deconvolution methods, numerical convolution, new plotting capability, and the "IVIVC Wizard" to pharmacokineticists and formulators.

DECONVOLUTION

Deconvolution is the process whereby, with defined pharmacokinetics, one can impute the necessary drug input rate that gives an observed plasma profile. The enhancements to the Deconvolution tool in the latest version of Phoenix WinNonlin uses numerical deconvolution and enables the user to deconvolve individual subjects using their unique pharmacokinetic profiles. The IVIVC toolkit for Phoenix WinNonlin expands the methods available for deconvolution to include: Wagner-Nelson, and Loo-Riegleman, and numerical deconvolution.

CONVOLUTION

Convolution is the reverse process of deconvolution. Given a known response to a "unit" input (e.g. bolus injection) and a known input profile (e.g. absorption), convolution finds the response to the input. The convolution tool is only available with in the IVIVC Toolkit for Phoenix WinNonlin and will compute output profiles from a collection of "Unit Impulse Response" (UIR) functions convolved with one or more inputs.

LEVY PLOT

A Levy Plot is an analysis chart that maps the in vitro dissolution and in vivo absorption times by fraction dissolved. That is, this plot compares the time taken

Highlights

- Extends and integrates with Phoenix WinNonlin functionality
- Additional deconvolution tools
- Powerful convolution tool
- Quality plotting capability with Levy Plot
- IVIVC Wizard automates analyses workflows and data management
- New options for deconvolution and convolution increase flexibility in analysis
- New plot outputs summarize important deconvolution and correlation results

to reach a certain fraction dissolved/absorbed between the in vivo and in vitro experiments. A Levy Plot allows one to assess the time scale difference between in vitro dissolution and in vivo absorption, and quickly determine if a correlation will be achievable.

IVIVC WIZARD

The IVIVC Wizard manages the multitude of data in a two-stage IVIVC workflow and helps the user efficiently track and move through the process. After mapping the dissolution and study data, the IVIVC Wizard automates the process of: fitting unit impulse responses; smoothing in vitro data; deconvolving absorption profiles; fitting a correlation model; convolving predicted absorption with subjects' unit impulse responses; and evaluating results. In addition, the IVIVC Wizard helps the user track the process through each stage and navigate and store the multitude of data that is involved. Users will appreciate the many options that the IVIVC Wizard provides for fitting unit impulse responses, smoothing dissolution profiles, and building custom IVIVC models.

USABILITY

Whether you are an experienced WinNonlin user looking to expand the program's capabilities, or a new WinNonlin user interested primarily in IVIVC, you will find Phoenix WinNonlin and the IVIVC Toolkit for Phoenix WinNonlin very easy to use. The interface theme of analytical tools operating on a worksheet is familiar to most spreadsheet users. In addition, the dialog-guided tools and wizards in Phoenix WinNonlin and the IVIVC Toolkit for Phoenix WinNonlin help simplify complicated processes and keep the user from getting lost in the details.