Phoenix IVIVC Toolkit™

The Clear Choice in Drug Development and Formulations for Obtaining Biowaivers

In Vitro-In Vivo Correlation (IVIVC) is a predictive mathematical tool that describes the relationship between the *in vitro* property of a drug dosage form and an *in vivo* pharmacokinetic (PK) response. Developing IVIVCs for solid dosage forms, especially for extended release formulations, is encouraged by the US FDA[1], EMA, PMDA and other regulatory agencies. It is considered an important tool for supporting biowaivers and has become a surrogate for *in vivo* human bioequivalence (BE) studies.[2]

The Phoenix IVIVC Toolkit™ from Certara provides enhanced tools for *in vitro-in vivo* correlation studies used by formulation and pharmaceutical scientists to improve the success of BE studies. The IVIVC Toolkit approach requires less assumptions, as compared to other methods, and helps the user define the correlation observed from real *in vivo* profiles as compared to the dissolution profiles.

Streamline development time, standardize the process, and reduce costs of expensive bioavailability/bioequivalence (BA/BE) studies

In most cases, a large amount of available dissolution and PK data will be used to develop and test a robust and predictive IVIVC. By using the IVIVC Toolkit, scientists can accelerate the analysis and documentation of IVIVC to support regulatory filings.

- Decreases the number of costly BA/BE studies by quickly generating IVIVC results using workflows and high quality outputs
- Organizes and simplifies the process, saving time and reducing error every time an IVIVC is needed
- Shortens the typical IVIVC development effort from weeks to days, dramatically lowering cost and bringing the drug to market quicker
- Facilitates collaborations—entire projects can be stored in a single file that can be easily shared internally or with external partners

Phoenix IVIVC Toolkit

Modeling Capabilities

- Deconvolution
  - Wagner-Nelson
  - Loo-Riegelman
  - Numerical
- Convolution
- IVIVC Wizard

Workflow Management

- Visualize data flow and analysis pathways
- Store analysis steps and documentation in a single project
- Simplify QA

Reusable Workflow Templates

- Save up to 75% of time spent on routine analysis with templates
- Make changes without rebuilding the whole analysis project
- Create a corporate library of workflows and templates for standardization and training

High Quality Outputs

- Create report- and publication-quality tables, listings and figures
- Assess the time-scale of dissolution experiments with Levy Plots
- Reuse favorite plots with new datasets
- Utilize export and overlay features

Compliance and Validation

- Verification tab indicates status of object execution and errors
- Settings output indicates which options were selected
- History output shows when objects were executed
- Toolkit was built in accordance to software development lifecycle (SDLC)

The Phoenix IVIVC Toolkit is differentiated from other commercial software for *in vitro-in vivo* correlation studies

- **Affordability**—Low start-up expense and add-on costs make Phoenix IVIVC Toolkit an affordable choice
- **User Interface**—Dialog-guided tools and wizard provide unique time savings
- **Quick Learning Curve**—The easy-to-learn Phoenix interface includes examples to get users up to speed quickly
- **Navigation**—IVIVC wizard provides an easily navigable interface that walks users through the process of creating a Level A IVIVC; informative status indicators signal completion, missing information or out-of-date steps
- **Deconvolution Methods**—Numerical deconvolution is a documented method known for its stability and accuracy, and overall is less susceptible to study design variations
- **Fitting the Correlation**—IVIVC Toolkit provides Level A correlation; unlike other software packages, Level B and C can be done using WinNonlin
- **Custom Models**—Unlike other IVIVIC software, the Toolkit provides the flexibility to use built-in correlations or the ability to develop a custom correlation model
- **Dissolution Modeling**—Built-in models better interpolate dissolution data, resulting in accurate interpolation that can make the difference between failure and success
- **Proven Phoenix Workbench**—Trusted powerful workbench can easily handle the large amount of data that an IVIVC can generate