CERTARA

Pre-clinical Group Automates 90% of Their PK Analyses and Report Generation

Learn how the pre-clinical group at Gilead saved time and money by using Certara's Phoenix WinNonlin and Phoenix Connect

Background

Gilead Sciences, Inc., a global pharmaceutical company, has developed drugs to treat a range of diseases including HIV/AIDS, hepatitis, and cancer. The pre-clinical group at Gilead characterized the pharmacokinetic (PK) profiles of early stage compounds in animal models. The majority of their pre-clinical PK studies involved acute administration of the compound to an animal followed by serial blood sampling. Next, bioanalytical methods were used to measure plasma drug concentrations. Finally, the bioanalytical data were analyzed to characterize the PK profile of the drug. Their routine analysis included generation of a non-compartmental analysis (NCA) model to determine PK parameters such as area under the curve (AUC), clearance, maximum concentration (Cmax), and half-life.

They had previously used Microsoft® Excel® to perform PK analyses. However, this was not an ideal solution for several reasons. First, Excel macros often generated different results depending on which analyst conducted the study. Second, user errors often occurred when using Excel. For example, Excel macros could not be customized to import only the crucial PK raw data from the bioanalytical instruments, which could potentially result in incorrect calculations of PK parameters. Finally, when generating reports, analysts had to manually cut and paste tables, listings, and figures (TLFs) into their Microsoft® Word® reports—an inefficient, time-consuming, and potentially error-prone process! Since this group of scientists often conducted dozens of pre-clinical PK studies every month, they were interested in a more streamlined solution for PK analysis and report-generation.

Challenge

The pre-clinical group at Gilead was responsible for analyzing the PK profiles of large numbers of compounds rapidly. The findings from these pre-clinical PK reports determined which compounds were selected to enter Phase I "first-in-man" clinical studies. Therefore, efficiency, accuracy and uniformity of PK analyses and reporting for all 12 analysts in the Gilead pre-clinical group were paramount.

Challenge

The pre-clinical group at Gilead was responsible for analyzing the PK profiles of large numbers of compounds rapidly and efficiently; accuracy and uniformity of PK analyses was of paramount importance.

Solution

The Gilead pre-clinical group adopted Phoenix WinNonlin to perform their PK analysis and Phoenix Connect to automate exporting of TLFs.

Benefit

The Certara solution decreased the time it took to conduct pre-clinical PK analyses by 50%.

Solution

The Gilead pre-clinical group adopted Phoenix WinNonlin to perform their PK analysis, and worked with Certara's deployment team to generate Phoenix WinNonlin templates that were tailored to their experiments' workflow. For example, business rules for determining how to treat Lower Limit of Quantification (LLOQ) and Below Limit of Quantification (BLQ) values were customized for each study design. The Phoenix WinNonlin templates also facilitated preparation of data for NCA analysis by including data mapping, custom calculations, filtering to include/exclude parts of the data set, and modification of units.

Unlike Excel, Phoenix WinNonlin helped Gilead's pre-clinical scientists avoid errors by highlighting when changes were made to the data, thus signaling that an analysis needed to be re-run. The custom templates in Phoenix WinNonlin automated the generation of all the output needed for PK characterization of a compound—tables of PK parameters as well as graphs that illustrated the time-drug concentration relationships. Also, customized templates ensured the same results no matter which scientist conducted the analysis. According to Rachael Lansdown, Senior Research Associate at Gilead, customized templates allowed her team to achieve greater efficiency because "templates let you put in what you want [from the raw data] and get out what you want."

Finally, the pre-clinical group adopted Phoenix Connect to automate exporting of TLFs generated by Phoenix WinNonlin into Word study reports. Previously, they had to type appropriate captions for each and every TLF in the entire report. By contrast, the Phoenix Connect Reporter Object automatically generated context-sensitive captions for all TLFs. Ms. Lansdown credited Phoenix Connect with "taking the user error out of the equation."

> " Phoenix Connect has automated 90% of the preclinical group's report generation and the overall Phoenix Solution has decreased the time it takes to conduct pre-clinical PK analyses by half. "
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> – Rachael Lansdown, Gilead Senior Research Associate

Benefit

The drug development process is notoriously long and expensive. Technologies that increase the efficiency of scientists save money by decreasing the time needed to develop a drug. The combination of Phoenix WinNonlin, customized Phoenix templates, and Phoenix Connect has been a "big time-saver" according to Gilead's Lansdown. Indeed, she estimated that Phoenix Connect has automated 90% of the pre-clinical group's report generation. In sum, she credited the overall Phoenix solution provided by Certara with decreasing the time that it takes her team to conduct pre-clinical PK analyses by half.

About Certara

Certara is a leading provider of decision support technology and consulting services for optimizing drug development and improving health outcomes. Certara's solutions, which span the drug development and patient care lifecycle, help increase the probability of regulatory and commercial success by using the most scientifically advanced modeling and simulation technologies and regulatory strategies. Its clients include hundreds of global biopharmaceutical companies, leading academic institutions and key regulatory agencies.

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