

San Francisco
Boston
Copenhagen

January 22, 2010
March 4, 2010
April 22, 2010

Combining PK/PD Data Analysis with an On- Demand Data Repository

An emerging trend for many sponsors in clinical development is the use of global teams to run clinical studies, collect patient data and perform biostatistical and PK/PD analysis. However, one challenge resulting from this network of multiple partners is the management and oversight of complex PK/PD studies that lack standardization. Technologies now exist that can securely store data 'in the cloud' and act as the central hub to tie global team members together and offer a real time portal into data and reports. Such repositories can require significant capital investment and time to implement, but with the advent of PKS Online™ sponsors can gain all of the benefits with little of the upfront cost.

Join this workshop to learn how:

- NCA analysis using Phoenix™ and PKS Online™ can reduce your timeline to final report or regulatory submission.
- Multiple PK studies can be pooled and stored to simplify data management for multi-study analyses.
- All PK studies and analysis can be stored in a secure in a robust 'transaction ready' state for due-diligence, out-licensing and M&A activity.
- A web based portal can be used for easy viewing of data analyses, and reports.
- Studies can be exported in CDISC format.

10:00am	Introduction and Welcome
10:15am	Introducing Pharsight's Reporting and Analysis Services <ul style="list-style-type: none">• Performing regulatory compliant analysis from pre-clinical to Phase IV• Leveraging Pharsight's software tools to optimize quality and efficiency• Supporting end of Phase 2A FDA or EMEA meetings
11:30am	Introducing Phoenix™, the next generation environment for PK/PD and population PK/PD modeling. <ul style="list-style-type: none">• Greatly enhanced usability which minimizes training time• Generate and re-use graphical workflows that combine algorithms from third party tools such as NONMEM, SAS, S+, R• Superior graphics out-of-the-box• Powerful tools for data import and exploration
12:30pm	Lunch and demonstration of PKS Online™
13:30pm	Leveraging pre-clinical data to guide Phase 1 trial design <ul style="list-style-type: none">• Using pre-clinical data to guide dose selection• Leveraging publicly available meta-data
14:30pm	Wrap Up and Conclusion of Workshop

For more details and to register, contact Louise Murphy (lmurphy@pharsight.com).