

Top 10 CRO Licenses PKS Online™ to Support Collaboration with Key Sponsor

Global CRO adopts Pharsight's Software as a Service solution to support key sponsor partnership in clinical PK services

ST. LOUIS, MO – May 17, 2011 – Pharsight[®], a market-leading provider of software and scientific consulting services to improve productivity and decision-making in PK/PD modeling and simulation, announced today that a global CRO has licensed PKS Online™ to support and enhance its clinical pharmacokinetics analysis and reporting service offering.

PKS™ (Pharsight Knowledgebase Server™) is the industry leading data management system for PK/PD, used by 30 of the top 50 global pharmaceutical and biotechnology companies. PKS greatly improves efficiency in the PK/PD analysis process by organizing all relevant data and providing a compliant environment for analysis and reporting with full version control. In concert with Pharsight's Phoenix[®] WinNonlin[®] PK/PD analysis software, PKS provides the technical controls that are required to implement 21 CFR Part 11 compliance by providing a complete audit trail, change history, electronic signature and time/date stamp.

PKS Online was launched by Pharsight as a hosted version of PKS. Benefits of this Software as a Service (SaaS) approach include:

- Full PKS functionality without the need for significant IT infrastructure and maintenance.
- Scalable data exchange platform between collaborators, e.g. sponsors and CROs working on the same project.
- Required technical controls to implement 21 CFR Part 11 compliance.
- Reduced validation effort focused on connectivity from the user's site to PKS Online, and on the audit of validated core functionality of PKS Online implementation.

"More and more pharmaceutical and biotech companies are turning to collaboration platforms to improve efficiency, increase security of data transfer and reduce information loss. PKS Online provides these benefits to organizations that are collaborating on FDA-required clinical studies by serving as a central hub to share all relevant PK/PD data, models and outputs," said James Hayden, Senior Vice President of Sales and Marketing for Pharsight. "Pharsight is pleased to be a trusted partner and enabler for these collaborative efforts and expects to see this trend gain momentum in the coming years."

About PKS Online™

[PKS Online](#) is an Internet-accessible implementation of Pharsight Knowledgebase Server (PKS), the company's clinical trial data repository for secure storage and tracking of PK/PD data and analyses. Using a standard desktop computer and a standard network connection, PK scientists, data managers, review staff and a sponsor's external development partners can access PKS Online through a secure channel from virtually anywhere and at anytime. PKS Online is fully integrated with Phoenix® WinNonlin®, Phoenix® Connect™ and earlier versions of WinNonlin®, as well as Pharsight's software tools for PK analysis automation and reporting. [PKS Online](#) is offered on a subscription basis, with flexible licensing and validation support services.

About Pharsight

Pharsight, A Certara™ Company, is a market-leading provider of software products and scientific consulting services to help pharmaceutical and biotechnology companies improve their drug development process, regulatory compliance and strategic decision-making. Established in 1995, Pharsight helps customers reduce the time, cost and risk of drug development, as well as optimize the post-approval marketing and use of pharmaceutical products. Pharsight leverages expertise in its software tools and in the disciplines of pharmacology, drug and disease modeling, human genetics, biostatistics, strategic decision-making, and regulatory strategy.

About Certara

Certara unites Tripos (www.tripos.com) and Pharsight Corporation (www.pharsight.com), and is dedicated to improving human health through a broad spectrum of software products and services, from molecular discovery through clinical research. Tripos provides innovative scientific software solutions and services enabling life science researchers to improve the efficiency of molecular discovery. Pharsight provides software and scientific services to improve productivity and decision-making in clinical drug development.

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