CERTARA

Strategic Benefits of an Online Clinical Data Repository

Introduction

An accelerating pipeline of candidate drugs is emerging from discovery, waiting for efficient and fast evaluation of their pharmacokinetics (PK) before they can be pushed through to the next stages of drug development. The ever-increasing cost of clinical studies is forcing more elaborate and intensive evaluations of PK and pharmacodynamic (PD) characteristics at earlier and earlier stages of development. The Food and Drug Administration Critical Path Initiative has called for more use of PK/PD modeling. As a result, leading companies are turning to technology to improve productivity and leverage scarce scientific talent in PK/PD analysis and reporting. This document highlights the benefits of an online clinical pharmacology data repository to address the PK/PD data problem.

The Challenges of small and mid-sized pharmaceutical companies

Small and mid-size pharmaceutical and biotech companies have their unique challenges. They are very focused—often on just one therapeutic area and always on a very small number of compounds. They need to move fast and get results quickly by focusing their financial resources on the scientific work. Much of their work is outsourced or done in collaboration with partners.

However, the issues that PK/PD data managers face are big company problems:

- How to support optimized modeling and simulation workflows for PK/PD analysis and reporting
- How to efficiently provide high-quality, regulatory-compliant storage for PK/PD data
- How to speed secure data transfer and information exchange among various partners in a dynamic network of collaborators

Following analytical assay of biological matrix samples, individual drug concentration values are merged with sample collection times to generate time-concentration data that PK/PD scientists or modelers must prepare (often with help of a SAS® programmer) and analyze for the clinical PK information related to the drug.

Clinical study reports must be produced in a regulatory compliant fashion to support submissions. This means that for data that are created, stored, managed, and/or transmitted electronically, there must be audit trails, signatures, and other procedures to ensure that the analysis and reporting are performed using computer systems and processes that conform to 21 CFR Part 11 requirements.

Collaboration partners are often used in place of internal staff at many stages in the process including data management, protocol writing, study conduct, and lab analysis. As a result, a great

Powerful Solutions from Certara

PKS Online is the hosted version of the Phoenix Knowledgebase Server, our 21 CFR Part 11 compliant clinical data repository that is used by biopharmaceutical organizations around the globe

deal of time is spent by the few pharmacokineticists on staff preparing datasets for partners or trying to understand results provided by partners in slightly different ways across various studies, projects, and organizations.

For small to medium-sized drug development companies, managing the study data according to 21 CFR Part 11 distracts them from focusing on the science of their work.

PKS – The Certara repository

Typically, companies without PK/PD data repositories operate in a mixed environment, copying Microsoft® Excel® files into Phoenix WinNonlin and storing data and derived parameters on some file system. This makes later retrieval and integration difficult and cooperation with external partners inefficient because data cannot be shared easily. Creating compliant final reports requires extensive manual intervention.

Certara introduced the first PK/PD repository over 12 years ago. Many companies have now invested in the Phoenix Knowledgebase Server (PKS), a single, secure PK/PD data repository where all clinical pharmacology information is maintained in a consistent format. PKS is integrated with leading PK analysis software such as Phoenix WinNonlin and provides tools (data connectors for data import, automatic recording of changes, password control, and other features) that directly enable development of efficient, electronic workflows for producing regulatory-compliant PK/PD analyses and reports.

By deploying PKS as their PK/PD data repository and PK workflow system, companies achieve tactical and strategic benefits such as:

- Global data accessibility
- Data and workflow standardization
- Compliance with 21 CFR Part 11
- Higher productivity through integrated support of model-based drug development

PKS Online – The next logical step

Recognizing the specific situation of small and mid-size companies, Certara has developed PKS Online—a hosted version of the Phoenix Knowledgebase Server.

PKS Online is nothing less than PKS "ready to go"—customers sign a service agreement and get access to the PKS Online system that is managed by Certara experts and hosted by an industry leader in software-as-a-service.

PKS Online provides all the benefits of PKS as a data repository, and also enables a new level of collaboration between partners during the drug development process. By using PKS Online—based on secure access and data sharing limited to the relevant study data for the specific project—sponsors and service providers can efficiently work together and exchange information instantly. PKS Online as a collaboration tool benefits small and mid-size companies that can't perform all the required work in-house as well as large pharmaceutical companies that manage a dynamic network of drug development partners.

PKS Online requirements

Several business drivers motivate the implementation of a clinical pharmacology data repository. Adoption of a data repository—either online or "in-house"—requires evaluating the system's features and performance. PKS Online offers an evaluation environment that does not require internal resources for setup of servers or backend software. The rollout following an evaluation can start small—with only a few users—and can be expanded as the need (or the company) grows.

PKS Online requires minimal internal resources for rollout to an organization—no database implementation or management, no special hardware or software purchases. All it takes is an Internet connection. PKS Online is accessed through the Web browser or through tightly integrated analysis tools such as Phoenix WinNonlin and Phoenix Connect.

Building on success

Most companies start with a small rollout—as few as 1 to 5 users—and add more repository seats later. It is not unusual that initial customer interest in PKS Online is generated by collaboration with Certara's global scientific consulting team, in which PK/PD study analyses and regulatory reports are delivered utilizing Certara tools. In this case, access to PKS Online is limited to a 'read-only' account for accessing intermediate and final study results while project work is ongoing.

Validation

Because PKS Online is a ready-to-go deployed version of PKS, the validation effort can be dramatically reduced. Certara's Quality Assurance group has validated the PKS Online environment. All that's left is to validate online access through the Web browser and the analysis tools in the customer's environment. "Certainly each company must decide its own path for validation activities," says Debra Fontana, Certara Quality Assurance Manager. "The core functionality of PKS Online has been validated based on our long experience with customer's validation of 'in-house' PKS systems. PKS Online customers typically review our validation effort and perform a rather small, additional 'access validation' project." Certara supports this effort through streamlined validation services provided by its deployment team.

Summary

PKS Online meets the need for high-quality, regulatory-compliant production of standardized PK analyses and reports, specifically for small and mid-size companies. It supports modeling and simulation by making PK/PD data more readily available to multiple partners across organizations. The low cost structure, the flexibility, and the minimal need for internal IT resources make PKS Online a cost-effective and efficient solution to the PK/PD data management challenges faced by all pharmaceutical and biotech companies.

A PKS Online subscription creates a number of concrete benefits, including standardization of analysis rules, definitions, and formats. Standardization leads to automation, which can further increase productivity of drug metabolism and pharmacokinetics staff and facilitate seamless collaboration across partner organizations. Compliance is achieved by careful definition and management of workflows and an efficient validation process. The implementation of a PK/PD repository remains an exercise in organizational change, and as such requires careful project management and training of users. PKS Online reduces implementation, cost and IT resource barriers dramatically and enables strategic use of PK/PD data repositories.

References

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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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