

KOOP!

SUMMER '07



iTrials, the Clinical Research Platform

May 2007 Singapore – iTrials was recently put through a series of successful tests and deployments at the Centre for Molecular Medicine / National University Hospital. The purpose is to study 5000 to 10,000 Hepatitis B subjects over a period of 5 to 10 years.

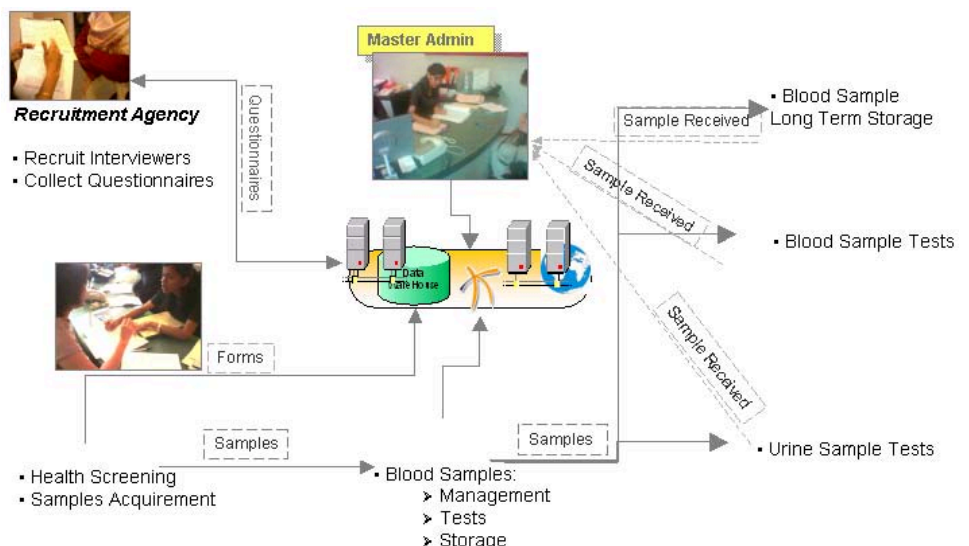
iTrials is positioned to satisfy growing needs of clinicians, CROs and pharmaceuticals for clinical trials, personalized medicine, drug studies, epidemiological studies, call center management, laboratory results collection, etc. As what Dr Aung Myat Oo, senior research officer ASTAR mentioned, the system is “a state of the art system which can handle patients' clinical data intelligently for clinical care as well as sample

management for research. As HOPE study database manager & professional advisor during the development, it is a dream come true.”

Various clinical processes are streamlined and automated to facilitate efficient management of subjects and samples, via the following modules:

Questionnaire Module - This allows setting of questions (English, Chinese and Malay). If required, an expert system can be attached to generate summary of findings.

Subject Recruitment & Appointment Module – This is to manage call centers to contact subjects and assign visit dates. The module also verifies the quota of subjects for a day and



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allows further web based filing of questionnaires.

Subject Registration Module – This includes Pre-screening assignment of subjects. Search functions are provided to verify particulars of subjects.

Subject Screening Module – This includes HL7 components to collect data from existing LIMS systems. It also includes software agents that can directly collect data from instruments so as to facilitate 'real time' analysis. This module facilitates Good Laboratory Practices.

Protocols Management Module – This is an intelligent system that can assign protocols for subjects, depending on the conditions of the subjects. The system allows customization of protocol parameters for reminder and alert purposes.

User Management – to control read, write access of different types of users.

Just like Rome, iTrials is not built in a day. The iTrials team leverages on expertise and components built up over the past 6 years of clinical focus to ensure successful delivery. The track record includes HL7 version 3.0 Message Exchange Prototyping with Ministry of Health (2001), Tissue Management System for Tan Tock Seng

Hospital (2004) and Clinical Decision Support System at National University Hospital (2005).

KOOPrime are now exploring opportunities with various CROs and hospitals. This is to extend the platform to many of the clinical trials and research labs that are rapidly setting that are coming up across Asia.

Validation in a Laboratory

Environment - the



way

Apr 2007 - Pfizer Asia Pacific Pte Ltd recently performed a major upgrade for its Laboratory Information Management System, SQL*LIMS, from version 4.0 to 5.0. As a key system that manages data across the laboratories, LIMS influences the safety and quality of the pharmaceutical products. Validation is thus required not only to verify that the system works as according to the specifications and regulatory requirements, but also to protect data from unauthorized access, changes and unintended losses. KOOPrime Consulting (KPC) (an active partner of Pfizer for GMP-compliance) hereby monitors and provides compliance consultancy services throughout the process of design, development, implementation and kick-off of the upgrade. To ensure product safety and record integrity, KPC based the validation approach on a couple of important guidelines:

a. FDA Good Laboratory Practice (GLP) which governs how lab studies are planned, per-

formed, monitored, recorded and archived, and

b. CFR Part 11 which provides guidance on the audibility and validation of electronic signatures for manufacturing and product quality procedures.

The validation effort can be viewed as a 'V-model' which shows how the procedures are executed in conjunction with the deliverables of a computer system validation framework.

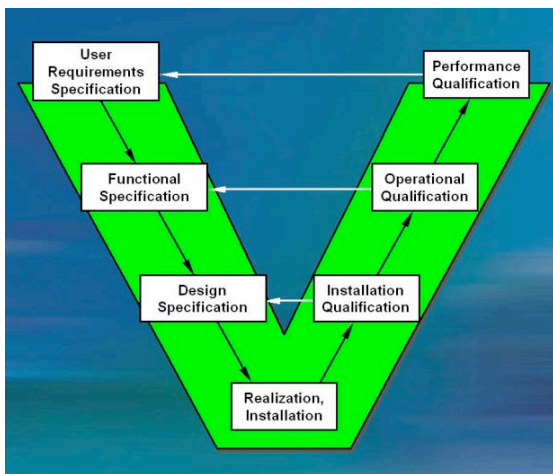
a. The left arm represents the specification stream where the system specification and validation documents are defined and designed.

b. The right arm represents the testing stream where the system is being verified against the corresponding specifications defined on the left arm.

Since 2003 when the LIMS validation started in Pfizer, KPC consultants have been producing the necessary validation documents in collaboration with users. Documents such as User Functional Requirement Specification (UFRS), Design Specification (DS), Installational Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) encompass the entire life cycle of validation.

Before the SQL*LIMS 5.0 was launched for production, the consultants ran through all the documentation to test the existing and new functions. This is in spite of the fact that SQL*LIMS 4.0 has already been previously validated and qualified. Such full validation is essential to obtain evidence of whether the system perform-

ance is able to meet preset criteria, thus allowing Pfizer QC/QA laboratories to determine its analytical capabilities objectively. Furthermore, it elevates the credibility of the analytical



data. This can prove useful if the release of a manufactured lot is questioned.

To enable Pfizer to build quality into its processes, KPC also advised Pfizer in the adopting of a thorough and risk-based methodology based on qualified regulatory risks and identification of key areas for increased efficiency. This cuts down unnecessary costs and shortens the time for the drug to reach the market.

With the newly implemented LIMS adequately validated and documented, Pfizer ensures that the manufacturing processes meet all the pre-determined specification. Pfizer is now assured that the system is able to perform effectively and reproducibly. Indeed, the production has been running smoothly since the launch.

Phenyx & Scaffold

May 31, 2007 - Geneva, Switzerland and Portland, Oregon, USA – Geneva Bioinformatics (GeneBio) SA announced that GeneBio's Phenyx software platform for MS data analysis has been successfully integrated into Proteome Software's Scaffold proteomics meta-analysis software. This is to give users access to an even greater abundance of and confidence in available results as well as the opportunity to go beyond a certain level of analysis, thanks to Phenyx's innovative features.

Developed in collaboration with the Swiss Institute of Bioinformatics (SIB), Phenyx is GeneBio's renowned software platform for the identification and characterization of proteins and peptides from mass spectrometry data. Phenyx is specifically designed to meet the concurrent demands of high-throughput MS data analysis and dynamic results assessment. It offers a flexible user experience and an adaptable architecture to help instill confidence in results assessment. (<http://phenyx.vital-it.ch/pwi>)

Proteome Software's Scaffold meta-analysis software statistically validates peptides and proteins from tandem mass spectrometry results data. One advantage is that it considers the results from multiple search engines amongst which are Phenyx, SEQUEST® or Mascot®, as well as optionally running X!Tandem on data files. This combination of results

from several applications yields numerous cross-validated protein identifications, after which Scaffold displays the results in multiple biologically relevant formats.

"We strive to listen to our users to find out what tools they need us to support, and an ever-increasing number are asking that we incorporate results from Phenyx," said Mark Pitman of Proteome Software. "This makes perfect sense, as it adds yet another high quality search engine to the Scaffold platform. We are always excited when we can deliver more value to our users, and we consider Phenyx to be of high value to our users and our overall platform."

"We are very pleased to have Phenyx join the list of results users can validate using Scaffold," said Nasri Nahas, CEO of GeneBio. "We are assured that our innovative approach to data analysis used in conjunction with the other leaders in the field will give Scaffold's users a level of results integrity hard to find elsewhere; everybody is a winner in this situation."

GeneBio will be present at ASMS 2007 in Indianapolis, from June 3rd to June 6th at booth #90.

Paperless Validation Management with ValGenesis

May 2007, USA - ValGenesis is a 21 CFR Part 11 compliant enterprise validation management and tracking Software solution. Easy and quick to implement, ValGenesis is the only software solution offering 100% paperless validation management to cut validation cycle time in half. ValGenesis is designed to automate, manage, and track the entire validation process – from generating validation document numbers to online execution of validation documents. The solution is designed to overcome the inherent flaws associated with paper-based validation processes and to deliver the benefits of an electronic system. The result is a streamlined validation lifecycle with improved efficiency and cost reduction.

The features of ValGenesis include:

- Track validation status in real time via the Dashboard feature
- Ensure data integrity and accountability, with complete audit trails capturing user ID, date, and time stamps
- Create consistent validation documents via templates
- Automatically generate unique, consistent validation document numbers
- - Systematically control and store documents securely for easy retrieval
- Allow users to develop validation test scripts in a collaborative manner, following Good

Document Practice (GDP) requirements for version control

- Notify users of impending tasks via routing through approval workflows
- Assign Severity Levels for Deviations
- Dynamically create audit trails for development, execution, and approval tasks for real-time retrieval during audits
- Manage complex revalidation schedules by alerting user groups to impending and delayed revalidation tasks
- Capture spelling mistakes or typos during the execution of validation document test scripts
- Can be customized to meet specific organizational needs, thus reducing Ready For Service (RFS) time, and achieve immediate Return on Investment (ROI).

The highlights of Valgenesis design include

- Modular Construction
- Web-based System (N-Tier Architecture)
- Fully Configurable Application
- User-friendly Graphical User Interface (GUI)
- Role-based Security
- Relational Database Design
- Compliance with 21 CFR Part 11

(To contact Justin@koopprime.com for more details)

About KOOPPrime

KOOPPrime was established in year 2000 with the endeavor to be the leading provider of IT products and solutions for the Biomedical industry. This is made feasible via its flagship product, the workflow-agent (KOOPPlatform) and web-services (KOOPortal) platforms that integrate components dealing with Data Collection, Data Warehousing, Data Mining and Data Visualization. Systems delivered are Cross-Platform, Cross-Language and Cross-Domain. KOOPPrime currently have operations throughout Asia, with focus in Singapore, Japan, Malaysia, Thailand, China and India. KOOPPrime has also established presence in Europe and USA. Find out more at www.koopprime.com.

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