

In today's pharmaceutical climate, data is plentiful, which is both a challenge and—as long as it is properly managed—an opportunity. And that's where a vast number of data management systems and their developers come into the picture. For example, the Pristima data management system from **Xybion Corporation** (Cedar Knolls, N.J.) has been on the market for only a few months ... under that name. It is better known by its former name—PATH/TOX SYSTEM—under which it has been established in the pharmaceutical industry for nearly 30 years. The system's main use in preclinical studies is to capture animal model data such as pre-study weights and general veterinary history. During the preclinical study, the system is capable of capturing *in vivo* data as well as clinical pathology, necropsy, and pathology data, in addition to performing data analysis using internal statistical tools.

# Keeping Pace, Keeping Track

*Pharmaceutical companies continue to use an array of data management systems to keep pace and keep track of their preclinical study data.*

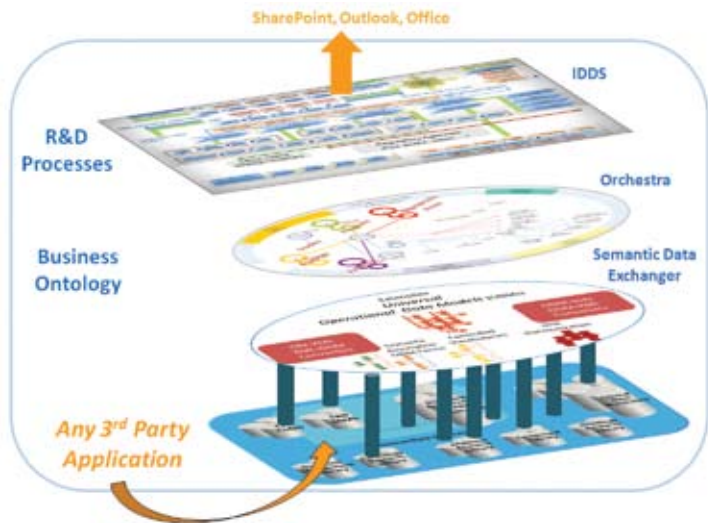
■ **James Netterwald,**  
**PhD, MT (ASCP)**  
Contributing Editor

“Our pharmaceutical clients want to do more work with fewer employees and even less experienced employees,” says Carlos Frade, vice president of business development for Xybion. “And they want our system to prevent errors, so that they do not need very highly-specialized workers to operate the system.”

**Core Informatics** (Branford, Conn.), was founded in 2006 by former formulary scientists Anthony Uzzo, president of laboratory information management systems (LIMS) and business partner Jim Gregory. The company provides data solutions as a single enterprise-wide data informatics platform to small- and medium-size pharmaceutical companies.

“Our system has LIMS, ELN, [and] SDMS capabilities, which, in traditional licensed software companies are offered as separate products, but in our system we provide them in a single integrated platform,” says Uzzo. “This feature benefits our customers by saving them significant licensing costs as well as the unnecessary need of having to integrate these products.” The technology covers data management needs from synthesis to investigational new drug (IND) application, which includes seeking registration of the chemical entity, signing a corporate identifier to it, tracking each synthetic launch or batch of that entity through all of the assays (e.g. tox screening or animal testing) needed to bring a drug candidate into clinical testing.

PointCross's Orchestra ontology engine and IDDS solutions contextually unify relevant R&D information and provide scientists with a semantically relevant environment for search, orienteering, and disciplined collaboration. (Source: PointCross)



## More Integrated Solutions

Another integrated data management system is DiscoverTrac, a data management and workflow enforcement solution from **BioPoint Solutions** (Gloucester, Mass.) With this one package, the user can address the critical infrastructure needs of validation management, perform integrated data acquisition, change a control/audit trail, develop a laboratory workflow, perform colony management, and generate reports conducted in preclinical studies, within the regulatory framework established by the U.S. Food and Drug Administration (FDA).

DiscoverTrac provides a secure environment in which data is maintained with strict controls embedded in the system to prevent data tampering and ensure security in either a closed or open system. “Authorized users have access to all information inside the database and are also connected to additional drug discovery sources enabling trouble-free, comprehensive access to information,” says Elery Leblanc, PhD, chief executive officer of BioPoint Solutions.

Data storage features include a central Oracle database as well as a raw data archiving feature that allows the user to create individual backup files for regulatory submissions; the system also assists with CFR Part 11 compliance by providing a full audit trail from raw data acquisition through analysis and reporting.

Trends in the Pharma industry that have led to a need for more powerful data management systems. "The advent of genomics, proteomics, miniaturization, and high-throughput biology technologies has generated the daunting task of managing an enormous explosion of data," says Leblanc. "Also, the ever-increasing sophistication of transgenic animal models for discovery and preclinical studies warrants the integration of colony management with complex behavioral and drug-response study data. Thirdly, higher levels of regulatory control have increased the critical demand for integrated systems with complete audit trails, efficient data access and robust reporting capabilities."



Pharsight's Reporting and Analysis Services (RAS) group offers core analytic competencies. (Source: Pharsight Corporation)

### Analyzing PK/PD

Pharmaceutical companies need software to store and analyze pharmacokinetic and pharmacodynamic (PK/PD) data produced during

preclinical studies. One software package that performs these general functions and many more is Phoenix WinNonlin from Pharsight Corporation, a Certara Company (St. Louis, Mo.). On the data storage side, Pharsight produces the Pharsight Knowledgebase Server (PKS)—"an enterprise-level repository that stores and manages preclinical and clinical PK/PD data in a secure, regulatory-compliant environment," says Mark L.J. Reimer, PhD, senior director of operations and preclinical development at Pharsight. "PKS links directly to Phoenix WinNonlin as well as other third-party software (for example, LIMS) through dedicated connectors."

"Turning data into knowledge requires ready accessibility of the data in a cost-effective, secure, regulatory-compliant, and searchable environment," says Jean-Francois Marier, PhD, FCP, vice president and lead scientist at Pharsight. The company has responded to this need by recently launching "a hosted on-demand version of PKS (PKS Online) that maintains and supports a

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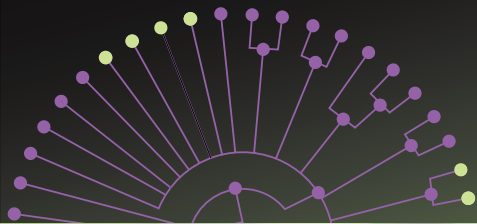
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Web-based PKS/IT infrastructure, allowing Pharsight's clients and their development partners secure 24/7 access to their data in a compliant repository and enabling them to make informed decisions on the development potential of their [new molecular entities]."

### Regulatory Standards

Pharmaceutical companies have to consider regulatory standards at every step of a drug's life cycle. "The pressure to reach surer, earlier decisions through quantitative pharmacology is growing, as is the need for rapid, efficient production of regulatory-compliant reports," says Marier. "Our WinNonlin AutoPilot software automates the creation of final, format-ready tables and figures from study data for regulatory reports, internal documents and presentations, which, for example, increased efficiency by ~70% in a preclinical toxicology study." Reimer adds that "the absence of uniform data standards ahead of a regulatory submission can significantly delay an IND application." In response, "FDA, together with the Biopharma industry, are working together to develop standards for submitting animal and human study datasets in electronic format based on SAS XPORT transport files and other formats."

Pharmaceutical companies have difficulty in performing comparative analyses across their entire knowledge base because preclinical data is often sitting in disperse systems and in disperse formats. "We offer a number of search and orienteering solutions, and business process automation, all built on top of our Orchestra platform," says Suresh Madhavan, PhD, founder and chief executive officer of PointCross, Foster City, Calif. For example, two systems built upon Orchestra are semantic data exchanger (SDE) and safety data integration (SDI). "SDI solution puts all available preclinical studies into a common universal operational data model with normalization, and with unit and taxonomy harmonization," says Madhavan, who adds that they also use a number of statistical techniques to extract layers of metadata from the raw data and pre-index them for rapid search. Following extraction, SDI then "allows researchers and study team members to navigate, search, and compare metadata across studies to discover patterns and correlations within the datasets." Ultimately, these

technologies perform such analyses to support early safety screening.

According to Shree Nath, PhD, vice president of pharmaceuticals at PointCross, there is also an increasing need by their pharma clients to "deal with new kinds of assays, studies, and cross-organization workflows their current systems do not support easily." In addition, he says that their clients also have a "growing interest in using other parts of the Orchestra platform to rapidly deliver data collection, business process automation, metadata extraction and analysis facilities across a network of organizations; this interest is driven by the need to pare down costs and inefficiencies."

Nath discusses the industry's move toward adopting non-clinical data standards driven by Clinical Data Interchange Standards Consortium (CDISC) and the FDA, as well as Pointcross' involvement in this initiative. "The area we are spearheading along with several sponsors [pharmaceutical companies] and contract research organizations is called SEND (Standard for the Exchange of Non-clinical Data). We again use SDE as the foundation for our data standards offerings, along with ToxVision, our data visualization and analysis tool that is built on the Orchestra platform," says Nath. "The major goal of this initiative is to improve and accelerate the review of non-clinical studies by the FDA," he says. "In the long term, this initiative will also enable the agency to build a semantic information base for non-clinical data."

"We anticipate that regulatory agencies will also want to analyze patterns across an entire database of preclinical studies from various companies to look for comparative trends that might raise red flags about the safety of a proposed investigational drug," says Nath. "We see a natural progression towards correlating sentinel and pharmacovigilance indicators from a broad clinical information base with signals from non-clinical systems as part of a continuum of capabilities that regulators need to ensure accelerated delivery of safe drugs to market and to monitor safety throughout the lifecycle of a drug." ■

*James Netterwald is president and CEO of BioPharmaComm LLC, a provider of writing, editing, and consulting services to the life science, pharma-biotech, and public relations industries.*