



Chiltern Launches **GLOBAL EDC SOLUTIONS**



We want to make investigators feel that they are being fully trained and supported so that there are no barriers to the use of EDC, thereby improving sponsor support to investigators, says Karen Roy, Global Head of EDC Solutions at Chiltern.

Chiltern International is answering the global demand for information, training, and guidance on electronic data capture with the launch of a new service, EDC Solutions.

The company, which has offices in the United States, Europe, and Asia, has created a global electronic support team to provide support to all stakeholders in EDC projects.

According to current estimates, between 10% and 20% of clinical trials worldwide incorporate the use of an EDC system, and this figure is expected to rise to 50% of trials in the near future.

Even so, there remain problems in the uptake of this technology because of differing perceptions of sponsors and investigators. Many pharmaceutical companies believe EDC offers faster time to database lock, reduced paper records, and more accurate data.

But adoption of proprietary systems is being held back by worries about the cost, the range of features and applications the systems currently exhibit, the lack of a clear leader among EDC suppliers, questionable scalability of any given solution, regulatory concerns, and the fear that there may not be sufficient return on investment.

"By providing professional support for the EDC process, Chiltern will be able to reduce the focus of the research effort from the day-to-day detail to the study itself," says Karen Roy, global head of EDC Solutions, who heads up the new EDC solutions initiative.

Teranode Releases **LIFE-SCIENCES R&D PLATFORM, PATHWAY ANALYTICS SOLUTION**

Teranode Corp has released Teranode Design Suite 2.5 (TDS 2.5), an enhanced, closed-loop R&D platform used to integrate modeling into existing informatics infrastructures. The platform improves research productivity by giving scientists simplified, on-demand access to a comprehensive library of analytic models. New features, such as pathway database access, simulation export, and performance, and user-interface improvements extend analytic design automation for scientists with limited programming abilities.

TDS 2.5 enables users to predict and analyze experimental data using the comprehensive databases of pathway models from KEGG and simulations using MATLAB routines. Lab professionals can now easily reuse KEGG models and MATLAB simulations as part of their analytic workflows or for boosting productivity and streamlining experimentation. In addition, users can leverage TDS 2.5's visual collaborative environment to simplify exchange and analysis across scientists and labs in complex research.

TDS 2.5 puts experimental data and systems biology information to work enabling prediction, experimental design, analytic workflow, and reporting providing closed-loop R&D. In direct contrast to general purpose spreadsheets and databases, design automation software is purpose-built to capture and reuse experimental data and system biology information in a domain-specific language called VLX. VLX enables Teranode Design Suite to intelligently provide a comprehensive automation throughout the life cycle of experimentation to benefit the scientist.

"Scientists want more access to systems biology information and analytic libraries, but they don't have the inclination or time to learn the programming and data extraction that some systems entail," says Joseph Duncan, CEO of Teranode. "Teranode Design Suite 2.5 opens the door to this critical information for everyone with a collaborative, visual environment for reusing vast stores of information and analytics."



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ClinPro Launches **IVRS CAPABILITY**

ClinPro Inc. has launched its new interactive voice response system (IVR) service. Enabled by Envox 6 software from Envox Worldwide, the phone-based data-collection system expands ClinPro's global capabilities, including subject randomization, interactive surveys, and diary data collection.

The open, standards-based software allows user access 24/7. The system has multiple levels of security and keeps an audit trail tracking all activities. It also can be programmed to "speak" the user's language, including many local dialects. The IVR system is equipped with a user-friendly management tool, making it possible to make changes seamlessly during the trial as needed. It is fully validated and is 21 CFR Part 11 compliant.

"Our new IVR capability helps ClinPro in its drive toward globalization by offering an efficient global central subject randomization, survey, or diary data collection system," says Rich Purcell, president of ClinPro. "Being telephone-based, the IVR system does not require sophisticated technology on the user's side, thus enabling our clients to conduct their trials anywhere in the world. All it takes is a phone call."

Investigators working on a ClinPro study simply use a domestic or an international toll-free number that grants access to a menu-driven interactive dialogue in the user's local language. Callers are first identified by phone number and identification code; then the IVR system prompts the investigator in his or her native language.

The automated tool provides a myriad of important functionalities, including screening subjects according to a list of inclusion/exclusion criteria, stratification, and random treatment assignments. Investigators also can review subject information or register receipt of medication.

Follow up

CLINPRO INC., Bound Brook, N.J., is an independent, full-service clinical research organization with expertise in a variety of therapeutic areas. For more information, visit clinpro.com.

CHILTERN INTERNATIONAL INC., Berkshire, United Kingdom, has extensive experience running trials from Phase I to Phase IV across a broad therapeutic range. For more information, visit chiltern.com.

TERANODE CORP., Seattle, is an innovator of design automation software to accelerate decision-making, collaboration, and compliance in the life-sciences industry. For more information, visit teranode.com.