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PPD partners with CISYS LifeSciences

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Pharmaceutical Product Development(PPD) and CISYS LifeSciences has announced PPD's implementation of Sequence WebEAS, a new Web-based event adjudication system, through a collaboration between the two companies.

Sequence WebEAS is a single, comprehensive system that automates and captures all activities, documents and data required for adjudication. It significantly reduces the administrative effort and cost needed by PPD and its biopharmaceutical clients to collect, manage and prepare dossiers for presentation to event adjudication committees (EAC). The system frees committee members to focus on their reviews by providing simple, easy-to-use dashboards and electronic classification forms.

"By implementing Sequence WebEAS, PPD will help clients reduce the effort and cost associated with managing adjudication activities," said Dr Cindy Elko-Simms, vice president of pharmacovigilance for PPD.

She added, "This new system will improve the overall quality of the adjudication process by providing a consistent automated approach to event identification and management. In addition, it will help reduce costs associated with overall project management and data reconciliation by having all adjudication activities and documents captured in one system. At the same time, the convenience and accessibility of Sequence WebEAS make it easy to use for adjudication committee members."

The use of EACs to adjudicate research endpoints is steadily growing, driven by expanding safety requirements, especially those aimed at more rigorous evaluation of cardiovascular risk. The Sequence WebEAS data import function automates the

event identification process to automatically pull in event/patient data from various electronic data capture (EDC) systems. Once into the system, the Sequence WebEAS adjudication workflow process automates document collection, dossier preparation, EAC committee selection and scheduling, and dossier distribution. This process enables the system to improve efficiency of activities and quality by maintaining consistency.

"Sequence WebEAS enables PPD to establish an efficient, structured and consistent adjudication process, compiling information from various sources to provide reliable and accurate data to adjudication coordinators and committee personnel," said Mr Jim Saunders, president of CISYS LifeSciences. He added, "The system features role configurable dashboards, intuitive adjudication coordinator and committee member workflow, a robust search engine, powerful edit checks and data validation. The system also has the ability to interface with a variety of EDC platforms and includes many other features that increase compliance and greatly improve process efficiency."

Sequence WebEAS enables EAC members to view all documents and data needed to adjudicate an event/patient through an easy-to-use, Web-based interface that captures all committee actions and retains the reviews of electronic forms. These proprietary interfaces for viewing event/patient data and generating electronic classification forms are highly configurable, allowing committee members to organize and present information to meet the specific needs of the indication. The system's built-in flexibility accommodates various EAC models and associated workflows.

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