

Press Release

## **SciAn's SAE<sup>pro</sup> software assists biotechs to comply with safety reporting under the new IND Safety Reporting requirements.**

### **FOR IMMEDIATE RELEASE**

**TORONTO, ON – January 28<sup>th</sup>, 2011** – SciAn Services Inc., a Contract Research Organization (CRO) providing clinical research services and electronic data capture (EDC) software to biotech companies relaunched its serious adverse event (SAE) reporting software known as "SAE<sup>pro</sup>" that enables biotech companies to comply with the safety reporting requirements of 21 CFR Parts 312 & 320 set forth by the FDA.

As of March 28<sup>th</sup>, 2011, the FDA's amendments to 21 CFR parts 312 and 320 places the onus on the IND phase drug developers to collect organized data from all sources and notify the FDA and all participating investigators in an IND safety report of potentially serious risks from clinical trials or any other source. The final IND safety reporting rule introduced new requirements that were designed to improve the usability and quality of safety reporting and to strengthen the agency's ability to review critical safety information and to improve safety monitoring of human drug and biological products as well as harmonize safety reporting with the recommendations made by ICH, CIOMS and EU.

"Organization will be a key to success under the new rule," said Mark Donaghy, General Manager of SciAn. "The FDA has placed new responsibilities on sponsors to know what adverse effect information has been documented, and to be able to quickly summarize in the sponsor's reports cumulative information from multiple sources as it becomes available. With 15 calendar days to report after the sponsor's initial receipt of the information, or 7 calendar days in the case of unexpected, fatal or life-threatening suspected adverse reactions, effective management of information becomes critical."

SciAn's SAE<sup>pro</sup> Drug Safety Workbench for IND Phase I, Phase II and Phase III has been used by clients for six years to help organize their information by collating all of the AEs and SAE data across multiple studies into one system for analysis and reporting. SAE<sup>pro</sup> helps to increase the speed of delivering information and remove the ambiguity from recording SAEs with simple and effective functions that provides all of the references and tools needed to quickly summarize issues, analyze between reported events and complete submissions. SAE<sup>pro</sup> is customizable to meet individual client business processes and SOPs for the SAE review and approval process, notification and distribution workflow. Status and analysis reports are available in standard format or customizable to meet individual company needs. The beauty of SAE<sup>pro</sup> is that it can be configured to interface to other systems as required.

SciAn offers a full-service SAE program but also has three different SAE service levels that are scalable to meet specific support requirements. For further information about SciAn's SAE<sup>pro</sup> software please visit our website at [www.SAE-pro.com](http://www.SAE-pro.com) or to book a free SAE<sup>pro</sup> demonstration please call 1-800-915-9315 or email: [info@scian.com](mailto:info@scian.com).

### **About SciAn**

Established in 1986, SciAn Services, Inc., is a Contract Research Organization (CRO) and has been providing clinical trial services for 25 years and drug safety services of investigational new drugs for 15 years. SciAn is also a software developer and has two products on the market: EDC<sup>pro</sup> for clinical trial services and SAE<sup>pro</sup> for drug safety reporting services. SciAn has written

numerous knowledge-based articles on clinical trials and drug safety related topics. To date, the company has completed over 605 studies in a wide range of therapeutic areas

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