

Safety Profiler

Until recently, it has been difficult for research personnel to access and code reliable NCI CTCAE grading criteria at point of care. The Safety Profiler is an Adverse Event management software solution that uses mobile and wireless technologies to meet the unique needs of Clinical Trials professionals in the real world. The Safety Profiler is a joint venture of CTIS, Inc. (CTIS) and the Moffitt Cancer Center of the University of South Florida. The technology is being developed on behalf of the National Cancer Institute's Cancer Therapy Evaluation Program (CTEP) through a Small Business Innovation Research (SBIR) grant.

Beta Site Selection in Progress

The Safety Profiler team is actively soliciting comments from the Clinical Trials community. We are currently in the process of conducting beta testing at five identified sites. If your organization would like to be considered or if you have any other questions, please contact us:

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About CTIS

CTIS is a wholly owned subsidiary of Capital Surini Group International, Inc. (CSGI). Call us at (301) 948-3033 or e-mail us at info@ctisinc.com.

For more information about CTIS, Clinical Trials Research and Management (CTRM), Application Service Provider (ASP) hosting, and other healthcare solutions, visit the CTIS healthcare industry home page on our World Wide Web site located at <http://www.ctisinc.com/>.

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Pocket Adverse Event Recorder

Safety Profiler Features

- Quick access to the included Common Terminology Criteria for Adverse Events (CTCAE)
- Point-of-care Adverse Event capture
- Adverse Event wizards that guide staff through Adverse Event capture and coding
- Streamlined data transfer, presenting staff with only the patients and studies that they are authorized to administer
- Reporting tools that record patient history and staff activities
- Signature capture
- 'Safety Console' administrative system that manages user privileges and other supporting data

In addition to these features, CTIS is developing a design for the Safety Profiler that is compatible with a range of relevant data standards. The final product will be a fully integrated component of the company's TrialBridge™ software framework, and also a stand-alone application that is independent of any larger system.

Safety Profiler Objectives

The system will:

- Improve quality of source documentation
- Impose no additional burden on end users
- Improve the accuracy and efficiency of Clinical Trials staff
- Be easy to use, install, and modify
- Support a wide variety of commercially available devices
- Easily integrate with existing clinical software
- Offer secure access to sensitive patient care data
- Conform to relevant industry standards and government regulations

CTIS plans to integrate Safety Profiler with the NCI's Cancer Trials Support Unit (CTSU) clinical database system.



Common Terminology Criteria for Adverse Events (CTCAE)

