



## Safety Profiler

### THE SAFETY PROFILER ADVANTAGE

Making it easier to accurately record adverse events

Safety Profiler is software that facilitates the clinical data assessment, grading, and reporting of adverse events during the clinical trial process. The application is a breakthrough solution that leverages wireless information technology, such as personal digital assistants (PDAs) and laptops. With Safety Profiler, clinical trial professionals are ensured the proper capture and coding of adverse events because they have immediate access to a patient's medical history through the use of mobile devices. In addition, the National Cancer Institute's Common Toxicity Criteria (CTC 2.0) and Common Terminology Criteria for Adverse Events (CTCAE v3.0) dictionaries are built right into the software for easy connectivity. Safety Profiler enhances workflow and collaboration among investigators, physicians, and clinical research staff. The application can function as a stand-alone tool. It also can be easily integrated into CTIS' other clinical trial research and management solutions or a client's existing back-end management system. Now, through the use of mobile devices, you can accurately capture safety data in real-time, reduce human error risks related to paper-based direct data entry, and thereby bring new treatments to market sooner to help solve simple human health problems.



### THIRD-PARTY CERTIFICATION

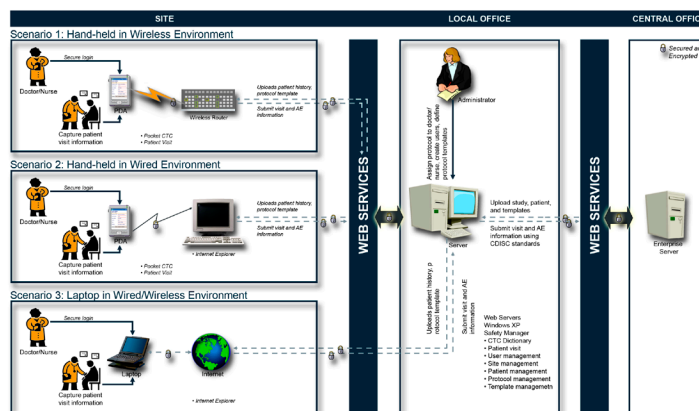
Technology you can trust



Standing behind Safety Profiler's proven technology is the clinical experience and expertise of CTIS. As a proud member of the Microsoft Gold Certified Partner Program, CTIS specializes in the design, deployment, and customization of small business solutions using Microsoft technology. Gold Certified Partners represent the highest level of competence and expertise with Microsoft technologies and have the closest working relationship with Microsoft.

## Workflow

The Safety Profiler application is certified to meet the Windows Mobile 5.0 and 6.0 Operating System requirements for use on Windows mobile-based Smartphones and Pocket PCs. To ensure end-user satisfaction, CTIS designed and built Safety Profiler to adhere to a set of best practice design guidelines specifically instituted by Microsoft. Safety Profiler is listed in the Microsoft Mobile2Market Application Catalog [www.microsoft.com/windowsmobile/catalog](http://www.microsoft.com/windowsmobile/catalog).

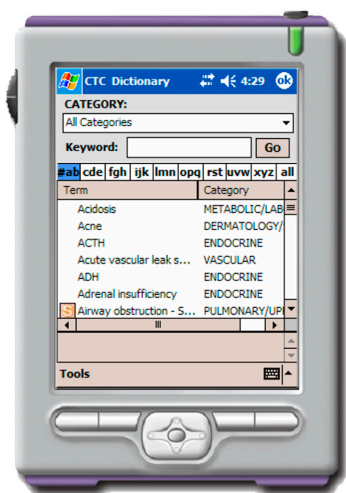


## OBJECTIVES

- Functions as a stand-alone tool or as a complement to other clinical research software
- Install, modify, and easy use; imposes no additional burden on end users
- Improve quality of source documentation
- Improve accuracy and efficiency of clinical trials staff
- Support a wide variety of commercially available devices
- Integrate easily with existing clinical software
- Offer secure access to sensitive patient care data
- Conform to relevant industry standards and government regulations

## REGULATORY COMPLIANCE

In the design of its products and services, CTIS adopts the rules and regulations of 21 CFR Part 11, as applicable, and the Health Insurance Portability & Accountability Act (HIPAA). CTIS solutions comply with the most up-to-date privacy and security standards including the Clinical Data Interchange Standards Consortium (CDISC).

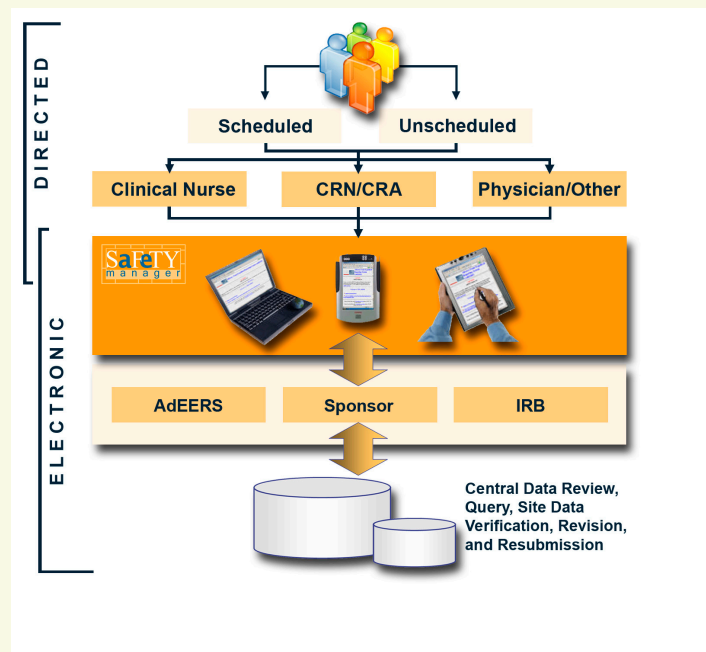


To learn more about Safety Profiler, other products, and services, e-mail us at [sales@ctisinc.com](mailto:sales@ctisinc.com). For additional information about CTIS, please visit us at [www.ctisinc.com](http://www.ctisinc.com).

## BENEFITS

- Provides convenient access to standardized coding
- Increases real-time access to clinical trial data
- Enhances communication and workflow productivity among clinical research staff
- Reduces human error related to paper-based direct data entry
- Decreases transcription errors
- Delivers accurate reporting to multiple parties
- Improves clinical research data quality and accuracy

## Solution Process



**ABOUT CTIS, INC.** CTIS has over 20 years of proven history in providing total informatics solutions to the health sector. CTIS provides innovative, appropriate, timely, and quality information technology solutions to health systems, health professionals, research organizations, and payors to support their goals in serving patients. To address this need, CTIS' informatics solutions converge health sciences, information technology, process reengineering, total quality management, and organizational effectiveness in order to optimize the capture, storage, and use of information in health and biomedical sciences.

CTIS is also building needed personal information solutions that serve patient directly in dealing with their healthcare providers. CTIS' leadership is at the forefront of national discussions that are defining the next generation of biomedical, clinical research, translational research, personalized medicine, comparative effectiveness research, performance driven healthcare, health disparities, elder care, and chronic disease management programs that will not only provide better patient care, but also meet the cost management goals of the health industry.