CTIS | A HEALTH INFORMATICS COMPANY

SAFETY PROFILER

CHALLENGE/SITUATION

During the clinical trial process, the system of monitoring and reporting of Adverse Events (AEs) is hindered by a lack of summary and display methods, variations in reporting methods, data collection practices, and multiple grading systems. Additionally, the paper-based, manual data entry method resulted in greater human errors. The ability to access and code reliable Common Terminology Criteria (CTC) grading criteria at the point of care had also become increasingly difficult. The practice of reporting AEs faster and more accurately needed to be realized in software that would capture such data consistently and efficiently.

APPROACH

In order to improve the situation, we needed to develop a cost-effective, comprehensive, and globally deployable mobile/wireless solution that would improve reliability, completeness, and uniform collection and distribution of safety data, as well as improve the workflow and collaboration between investigators/physicians and clinical research staff. The solution needed to function as a stand-alone tool or as a complement to other clinical research applications. It needed to be easy to install, modify, use, and impose no additional burden on end users. The solution needed to overcome the wireless restrictions; improve the quality of source documentation, the 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 AE data, and conform to relevant industry standards and government regulations.

SOLUTION

Safety Profiler facilitates the clinical data assessment, grading, and reporting of AEs during the clinical trial process. It features quick access to the Common Terminology Criteria for Adverse Events (CTCAE); point-of-care AE capture; AE wizards that guide the user through AE capture and coding. It streamlines data transfer and contains reporting tools that record patient history and staff activities; signature capture; and Safety Console administrative system.

It leverages wireless information technology and ensures the proper capture and coding of AEs for clinical trial professionals. The application also provides workflow management from patient recruitment to visit and AE assignment of attribution; allows electronic access and user guidance to the CTC Dictionary; and provides protocol-specific AE templates and a customizable assessment tool.

BENEFITS

Safety Profiler provides convenient access to standardized coding; increases real-time access to clinical trial data; enhances communication and workflow productivity among clinical research stakeholders; allows data capturing in both online and offline modes; reduces human error related to paper-based manual data entry; decreases transcription errors; delivers accurate reporting to multiple parties; and improves clinical research data quality and accuracy.

- Compatible with a range of relevant data standards, including the Common Data Element model, Health Insurance Portability and Accountability Act (HIPAA), 21 Code of Federal Regulations (CFR) Part 11, and International Conference on Harmonisation (ICH) Clinical Data Interchange Standards Consortium (CDISC) standards
- Deployed at 4 beta sites: Johns Hopkins University, Summa Health System, Moffitt Cancer Center, and the University of Miami
- Meets Windows Mobile 5.0 and 6.0 OS requirements for use on Windows mobile-based Smartphones and Pocket PCs
- Improves data integrity, reduces fragmentation, improves connectivity, and supports mobilization and intervention during the management of AEs