Organization: SGS Life Science Services

Presenter: Wim Verreth

Stream: Software Demonstration

Abstract Title: Introducing Clinic Automation in a Phase I unit with end-to-end eSource data processing

Learning objectives:

- Understanding clinic automation and eSource concepts, while referring to associated regulations (FDA, EMA and CDISC)
- Discuss the benefits of clinical automation and working with an eSource system
- Managing the challenges of implementing an eSource system
- eSource and centralized monitoring
- How to process eSource data within Data Management
- Share implementation experiences while replacing paper source at our Clinical Phase 1 Unit through embedding eSource in all operational processes

Abstract Text:

In a recent guidance (Sep 2013) the FDA promotes capturing source data in electronic form, ensuring the reliability, quality, integrity, and traceability of data from electronic source all the way through to electronic regulatory submission. eSource provides the opportunity to engineer accurate data with boundary and edit checks for missing and/or out of range data devoid of contradicting information often represented by subjective reporting in an unstructured format. The source data should be attributable, legible, contemporaneous, original, and accurate (ALCOA) and must meet the regulatory requirements for recordkeeping.

The Clinical Pharmacology Unit Antwerp (Belgium) is equipped with an automated solution to support the running of Phase I trials by a trial design framework that drives key operations. The automated solution efficiently collects all data types (trial execution, safety lab, and medical device data) directly into electronic format (eSource).

The use of eSource is key to achieving the full efficiency benefits of automation at the clinical unit. Checks, time-alerts, and tube barcode verification improve quality during collection. Transcription is eliminated and data are available for review in real-time. Using the eSource as eCRF rewards the sponsor with important additional efficiencies by eliminating source document verification from the process flow, thus allowing a Centralized Risk-Based Monitoring approach, as well as retaining the classic benefits of Electronic Data Capture tools. These benefits include an earlier database lock and online availability of clean data in real-time allowing dose-escalation decisions.

In this presentation we will share implementation experiences and lessons learned while replacing paper source at the clinical unit through embedding eSource in all operational processes, from set-up of the eSource to delivery of SDTM compliant datasets. An intensive collaboration between the sponsor and CRO lead to the successful implementation of the eSource tool in a Phase 1 setting.