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Delivering Safer Clinical Trials; Using Electronic Healthcare Records (EHR) to Monitor, Detect and Report Adverse Events in Clinical Trials

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Abstract : Randomised controlled Trials (RCTs) of efficacy are still perceived as the gold standard for the generation of evidence, and whilst advances in data collection methods are well developed, this progress has not been matched for the reporting of adverse events (AEs). Assessment and reporting of AEs in clinical trials are fraught with human error and inefficiency and are extremely time and resource intensive. Recent research conducted into the quality of reporting of AEs during clinical trials concluded it is substandard and reporting is inconsistent. Investigators commonly send reports to sponsors who are incorrectly categorised and lacking in critical information, which can complicate the detection of valid safety signals. In our presentation, we will describe an electronic data capture system, which has been designed to support clinical trial processes by reducing the resource burden on investigators, improving overall trial efficiencies, and making trials safer for patients. This proprietary technology was developed using expertise proven in the delivery of the world's first prospective, phase 3b real-world trial, 'The Salford Lung Study, ' which enabled robust safety monitoring and reporting processes to be accomplished by the remote monitoring of patients' EHRs. This technology enables safety alerts that are pre-defined by the protocol to be detected from the data extracted directly from the patients EHR. Based on study-specific criteria, which are created from the standard definition of a serious adverse event (SAE) and the safety profile of the medicinal product, the system alerts the investigator or study team to the safety alert. Each safety alert will require a clinical review by the investigator or delegate; examples of the types of alerts include hospital admission, death, hepatotoxicity, neutropenia, and acute renal failure. This is achieved in near real-time; safety alerts can be reviewed along with any additional information available to determine whether they meet the protocol-defined criteria for reporting or withdrawal. This active surveillance technology helps reduce the resource burden of the more traditional methods of AE detection for the investigators and study teams and can help eliminate reporting bias. Integration of multiple healthcare data sources enables much more complete and accurate safety data to be collected as part of a trial and can also provide an opportunity to evaluate a drug's safety profile long-term, in post-trial follow-up. By utilising this robust and proven method for safety monitoring and reporting, a much higher risk of patient cohorts can be enrolled into trials, thus promoting inclusivity and diversity. Broadening eligibility criteria and adopting more inclusive recruitment practices in the later stages of drug development will increase the ability to understand the medicinal products risk-benefit profile across the patient population that is likely to use the product in clinical practice. Furthermore, this ground-breaking approach to AE detection not only provides sponsors with better-quality safety data for their products, but it reduces the resource burden on the investigator and study teams. With the data taken directly from the source, trial costs are reduced, with minimal data validation required and near real-time reporting enables safety concerns and signals to be detected more quickly than in a traditional RCT.

Keywords : more comprehensive and accurate safety data, near real-time safety alerts, reduced resource burden, safer trials
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