DATA MANAGEMENT BEYOND CLINICAL TRIALS

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Electronic Health Records (EHRs) exist to aid in the delivery of care and the administration of health systems. EHRs were not designed to collect data for use in clinical trial research. However, we are seeing an ever growing appetite for sponsors and institutions wishing to accelerate the uses of EHR data. In the future, it is envisaged that the number of classic clinical trials will contract and the use of EHR or Real World Evidence (RWE) data will expand. EHRs contain longitudinal data representing the health of patients over an extended period of their lifetime which can provide valuable insights into how medicinal products are working in the real world. So it makes perfect sense to tap into the largest databases to gather this data.


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However, how can sponsors and regulators be sure that the data collected using EHRs meets the high standards currently used in clinical research? The FDA has responded to this question with their draft guidance, Use of Electronic Health Record in Clinical Investigations, May 2016. However, FDA's acceptance of data from clinical investigations for decision-making purposes depends on FDA's ability to verify the quality and the integrity of data during FDA on-site inspections and audits. Sponsors are responsible for assessing the validity, reliability, and integrity of any data used to support a marketing application for a medical product.

Even if the data is not being used to support an application for a medicinal product, when collecting data for which you wish to publish your results, it is important that the validity, reliability and integrity of the data are not questionable.

To ensure that the validity, reliability and integrity of data generated in clinical trials is of high quality, we use Clinical Data Management (CDM) practices. The CDM process begins with the end in mind. Clinical trials are designed to answer specific questions and the CDM process is designed to deliver valid and reliable data for statistical analysis. The acronym ALCOA is used in clinical trials and other regulated industries to ensure data integrity. ALCOA relates to data, whether paper or electronic, and is defined as attributable (who generated/changed the data), legible (readable), contemporaneous (time stamped), original (source data) and accurate (free from errors). The FDA considers ALCOA a fundamental part of the data collection life cycle when using data from EHRs, but herein lays the challenges. Thinking about this, unless the EHR is certified by the Office of National Co-ordinator (ONC) program, it seems unlikely that EHR data