

5.4 Veracity

We can associate veracity with the key attributes of data integrity and particularly ALCOA+ (Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring and Available). Veracity can also be associated with some of the attributes of data quality such as data credibility and reliability. In this context, CDM needs to establish pro-active measures to secure the authenticity and security of the data. This is becoming critical in the world of e-Source and RWD where data can rarely be corrected, and where anonymization is increasingly challenging and critical.

Additionally, with the adoption of risk-based approaches, not all data may be subject to the same level of scrutiny. Different quality targets may be acceptable across different data types and sources. CDM will need to not only manage data, but determine and enforce fit-for-purpose data quality standards.

We must, most importantly, focus on QbD. Preventing issues at the source while ensuring the integrity and security of data will require new processes, tools and governance models. As an example, solutions like blockchain will ultimately enable undisputed veracity by ensuring that data cannot be tampered with. The origin of the data will be 100% guaranteed, access controlled by its owner (i.e., the patient) and any change documented in an unalterable audit trail. Unfortunately, the use of blockchain is in its infancy within clinical research. In the meantime, we must implement process and technology strategies that ensure full traceability, security and transparency of the flow of data.

Eventually, we will also need to secure the veracity of data on systems that we do not directly control, such as EHR with their disparate and complex data structures, like genomic data, medical imaging, unstructured data and documents, metadata and sequenced data.