
c) Blockchain

Blockchain is a promising emerging technology yet to be used meaningfully in Clinical Research. As its name suggests, a blockchain is a chain of interconnected blocks (i.e. data). Each block contains a time stamped and non-modifiable version of data. Blocks can store different data types including files, images and time sequenced data from sensors. Each block has its own encryption key and a link to its previous version of the data. Users can therefore retrieve the full version history of the data whenever it is needed. However, Blockchain offers more than the functionalities of a bullet proof audit trail.

By nature, a blockchain is distributed in a peer to peer network where each peer joining the network has a full contemporaneous version of the blockchain (i.e. data sharing). If a member of the network is changing the data, a new block is created and sent to all peers in the network so that all members have the same synchronized data with its full history. There is no more original vs. copy of the data. Blockchain allows for a systems agnostic data management approach. All systems can read or modify the same data and all systems are constantly aligned. We could theoretically trace data from its inception in an EMR system to its review by a regulatory agency in a submission package.

In addition, each block could be linked to a digital contract. The contract would enforce what can or cannot be done to the data. One could consider attaching the Informed Consent to the data and limit the access and use of that data to only people authorized by the Informed Consent (e.g. patients, sites, Contract Research Organizations, Central Laboratories). Any member of the contract could be given access to all the data or just a subset of it. No one could modify the data without a contract or without other data subscribers being unaware of it.

Pharmaceutical companies are just starting to understand the potential of blockchain in Clinical Research. In addition, its implementation would require significant changes to the technology infrastructure that most systems use today. Nonetheless, Blockchain and AI are believed to be two of the most impactful upcoming technologies which could radically transform how we do Clinical Data Management.