
b) Artificial Intelligence (AI) based applications

The use of “Artificially Intelligent” applications leveraging Natural Language Processing (NLP), Machine Learning (ML) and Robotics is fast growing outside our industry. These AI “*based technologies have the potential to transform healthcare by deriving new and important insights from the vast amount of data generated during the delivery of healthcare every day*”¹¹. Intelligent applications have long left the Silicon Valley computer labs and have entered many homes. Interactive systems like Alexa, Apple Siri and Google Home have gained adoption and trust. This evolution is primarily fueled by the accumulation of huge amounts of data associated with strong computing power. This is enabling the training and validation of complex ML algorithms.



It is technically possible today to automate repetitive and simple tasks as the cost and ease of implementation of AI technologies is becoming attractive.

Chatbots are intelligent “virtual assistants”. Leveraging text messaging, Chatbots can partially replace an actual support person. Based on ML and NLP, they offer a “human-like” interaction between people and machines. As an example, it is technologically conceivable to develop chatbots to provide updates on study activities (e.g. Ask a CDM Chatbot to “*provide the counts of sites with more than 5 pending queries on study A*”). You could also easily improve the user experience by adding voice recognition instead of typing text (e.g. using Siri for Apple devices, Cortana for Microsoft, etc.). Chatbots could radically change the study team dynamics and reduce the time many CDM professional spend in relaying information to their peers in the Clinical Trial Team.

Robotic Process Automation (RPA) is not new but is now becoming simpler to implement and a cost-effective solution. RPA enables automation through configurable software that simply mimics well defined human actions. Unlike using scripts on the backend to “automate” manual tasks, RPA is enabling virtual robots to do predictable and repetitive human activities. As an example, a Virtual Robot could be fed with the details of external data reconciliation errors. The Virtual Robot could then login in EDC with its own account (e.g. Login: CDM Robot) and post the corresponding queries. The advantage of such a method is that it does not require changes to EDC (e.g. no integration needed). It leverages EDC traceability (Login logs, Audit Trail, etc.). You could have as many virtual robots as you need working 24 hours a day and 7 days a week to manage the study workload. The same technology could apply to other simple CDM tasks. Virtual robots can become an unlimited virtual CDM workforce. However, RPA requires programming, full understanding of the domain being automated and may be somewhat limited in its scope of applicability. Last, as RPAs are sensitive to User Interfaces (UI) layouts (i.e. RPAs must be adjusted if the UI is changed), CDM need to consider the stability of the systems involved in task automation or anticipate updates to RPAs when systems are upgraded.