

Fast, Efficient, and Automated Real-time Analytics for Clinical Trials

Anish Iyer, MMS Holdings Inc.; Bangalore, India
Aditya Gadiko, MMS Holdings Inc.; Raleigh, USA
Chris Hurley, MMS Holdings Inc.; Canton, USA

ABSTRACT

Opportunities are boundless for real-time visual analytics to provide rapid, actionable insights from essential clinical trial information. Dashboards based on standard CDISC data domains empower trial stakeholders to quickly react to the tens of thousands or even hundreds of thousands of data points collected throughout the lifecycle of a clinical trial. Operational data can be displayed in dashboards to significantly improve the efficiency of the clinical trials. Data visualization can be very helpful when looking for hidden trends in the data and assessing risks from any aspect of the trial.

Dashboards can be used to augment the establishment of efficacy, tolerability, and safety profiles of investigational therapies. Application Programming Interface (API) functionality with near-real-time visibility into the EDC domains provides frequent data updates when time is of the essence. Standardized data models like SDTM and ADaM provide an excellent source for more result-oriented dashboards where endpoint summarization and advanced analytics are in demand by the study team. This paper will present visual analytics within the context of a typical study. It will show the end-to-end process starting from automated recurring EDC data feed, transformation, carrying through to the end of the process of visualizing, summarizing, and gaining valuable insights into trial safety, efficiency, and more.

INTRODUCTION

Clinical trials require us to adhere to high ethical, scientific, and regulatory standards over the years. Continuous evolution over a period led us to our current advanced clinical trial standards but there is still room for improvement in adapting to emerging technologies. Many of the current clinical trial advancements leverage technologies to enable better decisions and ultimately better care for patients. A steady progression of scientific methods such as randomization, use of placebos, comparison of interventions, and blinding in trials demonstrates on a high-level technique that are responsible for the continuous advancement of clinical research.

Understanding the history of clinical research may help investigators appreciate the responsibility of conducting human subjects' research [1]. From the first recorded trial of legumes in biblical times to the first randomized controlled trial of streptomycin in 1946, the history of clinical trial covers a wide variety of challenges - scientific, ethical and regulatory. In parallel to ethical guidelines, clinical trials started to become embodied in regulation as government authorities began recognizing a need for controlling medical therapies in the early 20th century. [2]

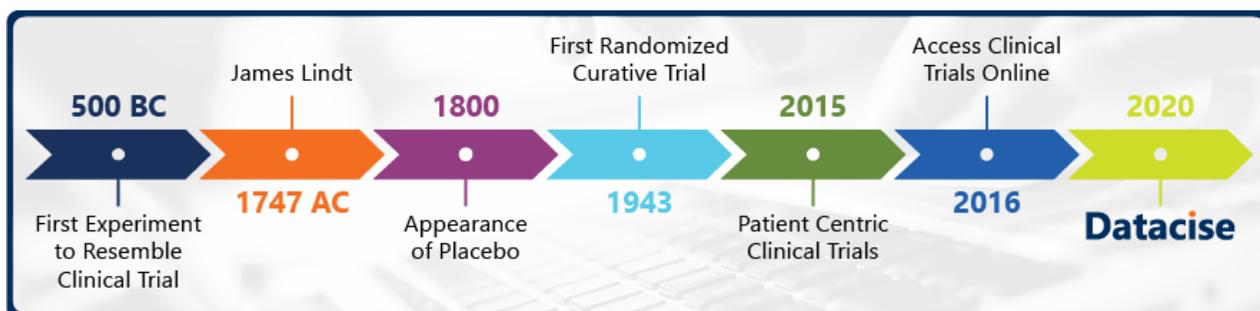


Figure 1. History of Clinical Trials

In this paper, we will focus on utilizing multiple tools and programming languages to develop a platform which can bring clinical data insights into hands of decision makers in a matter of minutes instead of months. Below are the items we will explore:

- Real-time data can be extracted, analyzed and visualized from IBM Clinical, Medidata Rave or other EDCs by utilizing automation on the Azure-based Datacise platform.
- Automation results in faster access to data and improved accuracy by removing the manual data steps. This may result in improved patient compliance and safer clinical trials.
- In the annals of history, automation of clinical trial analysis was simply not possible. Leveraging emerging technologies brings us to a new epoch of Clinical Trial research where real-time analytics bring instant insights from your data.

PROCESS

In Figure 2, view a high-level end-to-end automation process that was utilized to carry out the automated data extraction, visual analytics and risk-based notification:

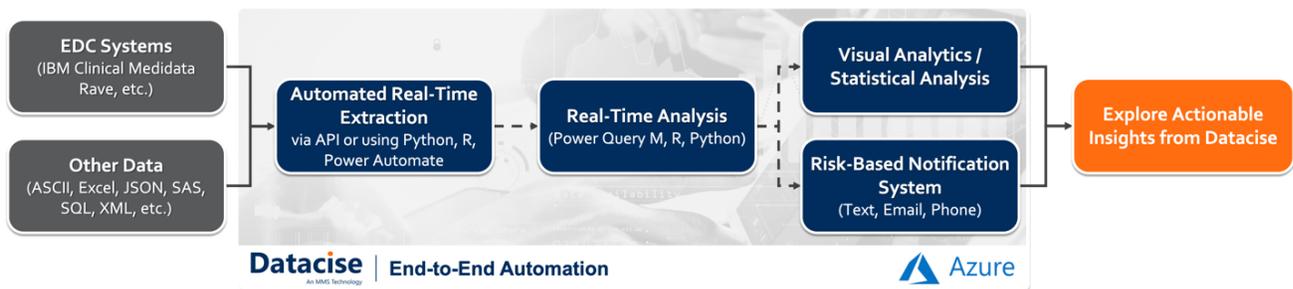


Figure 2. End-to-End Automated Real-Time Clinical Trial Analytics utilizing Datacise

STEP 1

Recurring automated data extraction via paths like Application Programming Interfaces (APIs) from wide variety of EDCs and automated file transfers of XPT, CSV, ASCII, Excel, XML, Oracle DB, Azure DBs and many other file types including rich files like images, audio and video. Datacise also has the capability to ingest streaming data from IoTs like watches, heart rate monitors, glucose monitors in addition to medical images like DICOM.

STEP 2

The extracted data is then ingested into cloud-based platform – Datacise. The entire platform is developed on Microsoft’s Azure cloud infrastructure so the security on this platform is Federal Risk and Authorization Management Program (FedRAMP) compliant and validates our standardized approach to security authorizations for cloud service offerings. Utilizing the power of programming languages like R, Python, Power Query M or DAX, we were able to perform both simple analyses and run advanced statistical models. In addition to interactive visuals and a risk-based notification system which informs the end user in real-time if it identifies a pre-defined risk.

STEP 3

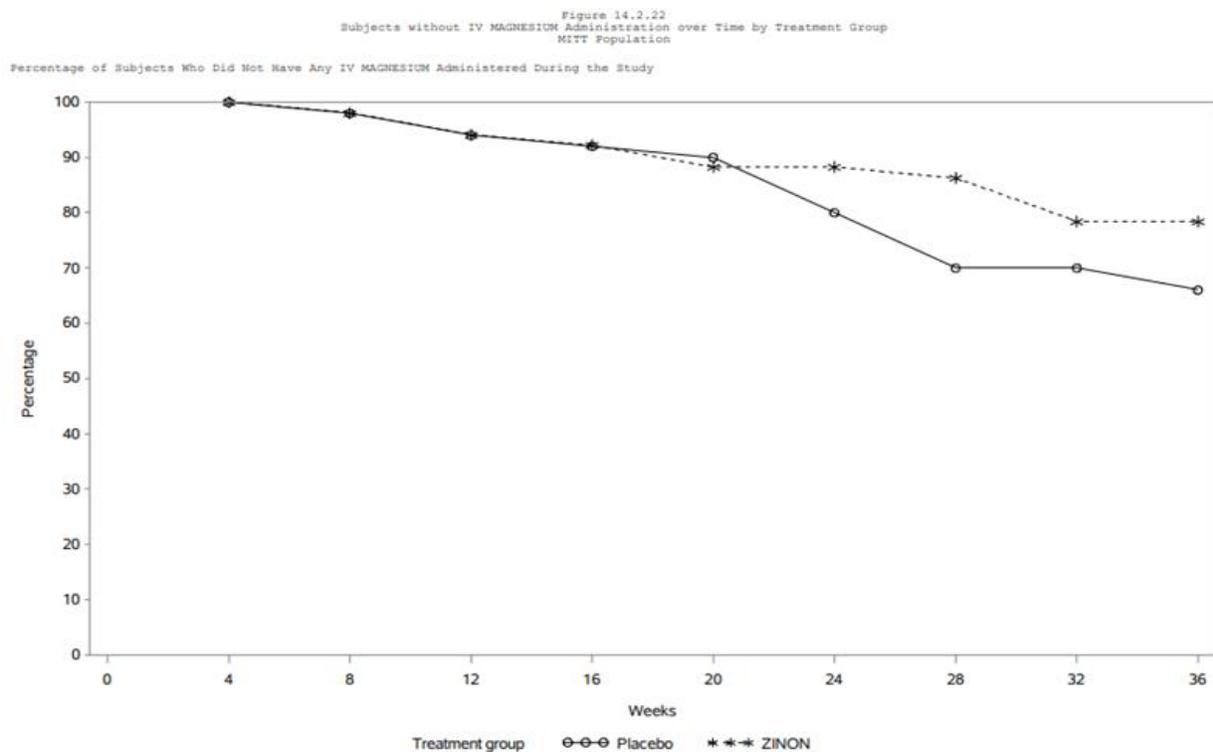
Utilizing real-time visual analytics and notification system, the end user can make an informed decision quickly based on actionable insights produced by Datacise. We were able to access data securely utilizing 2 factor authentication and also control the user access to the dashboards.

RESULTS

In the past, typically one static presentation was shared to show results. In addition to real-time data extraction, analysis, and visualization advancements, Datacise gave us the ability to:

- Dynamically link multiple domains
- Interact with visual with drill down functionality
- Mitigate risk by identifying them with real-time with notifications
- Natural Language querying of the entire database – we can ask Datacise questions like “*Patients with Low hemoglobin and who has medical history of anemia and currently on folic acid*”
- Ability compare data from multiple trials in single view
- Decrease dependency on programming for querying database
- Develop a story based on your data to present to regulatory authorities or other audiences

Using Datacise, we were able to give access to safety data to medical services team much faster and help them understand trends and risk in a more efficient manner.



Display 1. Static visualization of data with a very limited scope



Display 2. Interactive, real-time and dynamic visualization of data developed on Datacise

CONCLUSION

Datacise has been a game-changer in the way it has enabled our sponsors to interact with their data. Faster access to the data improved their actionable response to emerging project and patient level risks.

For instance, real-time alerts for monitoring critical conditions, such as a subject encountering serious or life-threatening events or assessing if any subjects fall under pre-determined stopping criteria, led to eventually decreasing the dosage or discontinuing the subject from the trial within the span of few hours. Regarding flexibility, custom dashboard designs empower the user to drill into the most precise features of the data without the need for programmer intervention. This has shown to not only save reviewer time but save programming time as well. The ease of determining the context of data in real-time increases the effectiveness of operational or clinical data review.

In summary, Datacise is an end-to-end automated FEDRamp compliant cloud-based platform which can have applications designed for zero manual intervention. By leveraging this platform, we were able to improve the efficiency and quality of our sponsors' data review. Our industry needs to start moving towards adopting emerging technologies to more efficiently bring safer drugs to the market and foster a positive change to patient lives.

REFERENCES

[1]Author name: Nelhouse, Emma. "Evolution of Clinical Trials throughout History" Marshall Journal of medicine. Accessed April 2nd 2021. Available at <https://mds.marshall.edu/mjm/vol3/iss1/9/>

[2]Author name: Bhatt, Arun. "Evolution of Clinical Research: A history before and beyond James Lind" Perspective in Clinical Research. Accessed April 3rd 2021. Available at <https://www.picronline.org/article.asp?issn=2229-3485;year=2010;volume=1;issue=1;spage=6;epage=10;auiast=Bhatt,type=3>

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Aditya Gadiko
MMS Holdings
+1-734-245-0310DataScience@mmsholdings.com
www.mmsholdings.com

Any brand and product names are trademarks of their respective companies.