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End-to-End Biometrics

Powering clinical trial analytics with automation

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Improvements in standardisation

We have already made some important inroads. Data standardisation is one of the key developments towards increasing efficiency implemented over the last two decades. CDISC (Clinical Data Interchange Standards Consortium) has, in collaboration with the pharmaceutical industry, pioneered the development of high-quality standards with a framework for effectively planning, collecting, organising, and analysing clinical and non-clinical research data.

The benefits of the CDISC initiative have been multifold. For one, the standards support faster, more efficient review of data packages by regulators. They are, in fact, now required by the US FDA and Japan's PMDA agencies for regulatory submissions. The standards facilitate transparency in the data analysis and research process by providing a clear linkage between one data element and its predecessor. Using standard data formats also promotes more seamless data exchange between sponsors and CROs. Beyond these operational benefits, the adoption of standards has enabled organisations to maximise the value of their clinical trial data by facilitating easier 'pooling' across individual datasets and studies to yield new insights.

Since the CDISC consortium established its first draft standards in 1999, we have seen them develop from simply standardising data collection to determining data analysis and planning protocols. Today, the framework is highly evolved, with specific standards reflecting individual therapy areas' data collection and analysis requirements.

It's fair to say that data standardisation has been one of the most impactful developments in clinical trial reporting over the last decade.

Yet, despite these advances in data standardisation, the way we work currently in clinical trial reporting is still limited by the capacity of our manual labour. Teams of statistical programmers painstakingly create individual programs and develop reports, outputs and TFLs (tables, figures, and listings)- often requiring months of work before we can share results with medical colleagues to inform their decisions.

Automation offers potential for a step-change

There is now potential for a step-change in productivity. Across the drug discovery and development value chains, we see an increasing drive to apply automated methods to yield greater efficiency, such as in laboratory research. Automated approaches will also define the next era of efficiency in clinical trial analytics.

By removing our reliance on manual programming tasks and embracing automated methods, we can pivot towards a more seamless data flow from protocol design to data submission – enabling faster results, higher quality, and improved consistency.

End-to-end automation is a 'computer aided design' paradigm-shift in which Clinical Trials will be designed, or modelled, collaboratively up-front using new software tools based on existing clinical data standards extended to include machine-readable biomedical concepts.

The digital model of a clinical trial is stored as metadata, which is used to automate the digital data capture, analysis and reporting systems that are today configured manually.

In a world of end-to-end automation, we wouldn't need to start from scratch every time we initiate a new trial. Instead, we could harness relevant aspects of previous trials to build out studies without trawling through legacy paper trails.

Yet, this new era won't come in a single leap. To achieve the ultimate vision of end-to-end data automation, we will need to progress through a stepwise, incremental approach. First, we need to enhance and develop our existing standards framework. While extremely valuable, our current CDISC standards have been developed for manual processes. To drive automated analytics and reporting, we will need to specify more detailed information within them in the form of metadata.

Then we need to eliminate duplication. In clinical trials, we typically work as a network of organisations and stakeholders- sponsors, CROs, data managers, statisticians, medical investigators, and writers, to name a few. The numerous manual steps involved in moving from protocol design to clinical study reports and data submissions involve significant duplication of effort across these different roles. Investigators design the trial protocol; the data management team translates that document into a data capture tool that repeats information such as the number of study visits. Then, statisticians produce the statistical analysis plan, reiterating much of the same information.

Moving to a genuinely electronic and interactive data source document would be a foundational step in eliminating redundancies, allowing all stakeholders to extract the information they need from a single point.

From here, we will be well placed to tackle automating clinical data analysis by reading in the protocol at the outset, extracting the data from the data collection tool, and transforming it into tables, listings, figures, and informative data visualisations without the need for time-consuming manual programming. Fully harnessing the power of automation could enable us to deliver actionable insights to medical stakeholders in real-time to inform in-stream decisions in days or hours, rather than in months.

The transition from manual to automated approaches brings unique challenges and considerations. To a great extent, pharmaceutical organisations are still grappling with the technology stack required to implement solutions, including enterprise tools to support central data repositories and data transformation steps.

Outside of the life science industry, data scientists use different tools, standards, and languages to automate data analytics, and we must put our heads above the parapet to consider what we might need to bring into our toolkit.

For example, the pharmaceutical industry is now diversifying its statistical programming capabilities beyond traditional SAS with open-source programming languages such as R. R's growing community of users provides a strong foundation for collaboration and innovation.

As well as having the right technology, we will undoubtedly need to consider different complementary skill sets – such as data science skills in data systems and machine learning to complement traditional clinical trial reporting skills in statistics and statistical programming.

Where might this all lead us in the longer term? If we could analyse more trials more quickly to a higher quality, this, in itself, would be an enormous leap forward- delivering substantial efficiency gains.

At a more aspirational level, harnessing automation tools and advanced analytics could help us de-risk the clinical development process by systematically leveraging clinical trial and real-world data insights to make better decision throughout the product lifecycle from drug discovery onwards.

Expediting with expertise not workforce efforts

Our experience during the pandemic- with the impressively expedited development of vaccines and treatments- has further fuelled industry appetite for accelerated development timelines and drug approvals. However, these pandemic achievements have primarily drawn on extensive combined workforce efforts and came with associated opportunity costs of deploying most resources towards COVID research. Automated clinical trial analytics presents a powerful opportunity for us to work smarter and allow technology and expertise to do the heavy lifting - boosting R&D productivity and delivering much-needed new medicines to patients faster.

Get in touch with us to learn more about our automation services.

GET IN TOUCH

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