Getting broader, deeper insights faster to deliver more value from your clinical data

Much has changed in clinical development since the beginning of the pandemic. And from the outlook, we are on a path of continued growth requiring we continue to innovate and change. Since 2019, venture funding is up 105%, the trial pipeline increased 17%, planned trial starts is up 885 trials and the number of subjects is up 28%, and this is excluding COVID and Ebola trials!

With the pandemic, and even prior, clinical development innovators were delivering technology that enabled the implementation of decentralized clinical trials, from the use of connected devices and patient wearables to centralized or remote monitoring. New digital tools were available, such as eCOA and eConsent to streamline processes and data collection. New techniques for identifying sites and patients for trials, including the use of artificial intelligence (AI), machine learning (ML) and natural language processing (NLP) tied to advanced and predictive analytics has helped streamline some of our processes.

These innovative changes have been there, even pre-pandemic. Now, we're seeing more motivation and willingness to adopt newer technology innovations. The industry has adopted new remote study approaches and moved to digitize and automate data management, clinical operations, and safety workflows.

Traditionally, systems used to run clinical trials, such as CTMS, eTMF, EDC, and more, were siloed. When attempting to use this data, along with existing EMR, real-world, lab, patient and other data sources, the data was difficult to share at best. Now we're generating vast amounts of data, more than ever before with each trial.

To harness this 'big data' is challenging. And not just harness it, but capture the insights buried in the data.

A 2019 Harvard Business Review article spoke about how effort and spend are "upside down", with 80% of time and resources spent preparing and managing the data and only 20% spent utilizing and benefitting from the value of the data.

The volume and variety of data is simply so tremendous, we **risk getting LESS intelligence** from the data. There is more data, but it's harder to make the right decisions. For stakeholders, the implication is less intelligence, not more, in spite of the availability of more data because it's extremely difficult to turn so much raw data into meaningful information.

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– Harvard Business Review

It's not simply acquiring and having access to the data that will make the difference; it's knowing *WHAT* the information can be used for and **connecting it in the right ways**. It's understanding what problem you are trying to solve and **what data can be connected to drive real insights**.

Think about the patient and all the information about that patient to drive disease detection. Combining labs, claims, EMR data, and patient journeys gives you the potential to develop algorithms that identify patients at risk for developing or having an undiagnosed or under-reported disease using predictive analytics. This can help with site and patient identification and recruitment.

Consider Site identification – with the availability of historical clinical trial data along with real world claims and wholesale drug data, you can identify the types of facilities that have patients of interest. A good example of this is searching for Crohn's investigators who have patients who are biologic naïve.

All of these examples, all of this thinking, is about combining the right data in order to drive innovative and predictive insights. It's about truly helping the stakeholder turn raw data into actionable information.

Connecting data to generate intelligent insights requires a robust data engineering platform.

For this 'Connected Intelligence', we need **flexible, automated, near real-time data acquisition**, regardless of sources, type, format, structured or unstructured data. And we need to then harmonize the data into a common model that enables the aggregation of right data to answer the questions being asked or to drive the right actions.

We need to adopt machine-driven automation of data review, allowing for automated data quality checks that capture a high percentage of data discrepancies, and let the machine do as much work as possible on the sheer volume of data coming in to allow the data managers of the world to focus on high risk, more complex review of data that requires human intervention.

We need descriptive AND intelligent prescriptive data analytics capabilities that provide critical business intelligence and data transparency.

We want to start putting data science in the hands of the experts and provide data science toolkits that provide AI/ML driven innovation and data exploration.

And, ultimately, we want to harness all of the data pipeline and quality automation to then build AI solutions that make applications more intelligent!

To put intelligent apps into context, that is really the outcome of the 'Connected Intelligence' paradigm.

- First, harness clinical data from various sources – get the right data.
- Next, develop automated and machine augmented insight generation – the right insights.
- Then use those insights to drive downstream intelligence and next best action recommendations – *drive the right actions!*

We see intelligent applications driving the right actions in several ways today:

With **Risk Based Quality Management where statistical algorithms and machine-driven outlier detection** are used to surface risk quick action

Innovate solutions like **Intelligent eTMF using a series of AI algorithms** to enable document digitization, quality checks, and automated categorization of documents, culminating in a human-in-the-loop last step to confirm model accuracy and provide feedback, further enhancing the machine learning.

Data review and management is starting to benefit from **AI-driven models for discrepancy detection** and query recommendations, providing fast, efficient, and less duplicative queries to sites and greatly reducing the timeline to database lock.

So, how do we flip the metric previously mentioned and provide the ability to reduce the time harnessing data and increase the time gaining intelligence from the data? With Connected Intelligence, we are taking all of this information, applying this new technology and generating, in as real time as we can, **insights that help drive the next best action.**

With Connected Intelligence, we are shifting the focus to 20% harnessing and managing data and 80% gaining value!

To learn more about Connected Intelligence and other Intelligent Applications in our Clinical Data Analytics Suite, contact us for a demonstration at **OrchestratedYourTrials@iqvia.com**

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Wendy has 25+ years experience in the life sciences industry with a career spanning academic research, preclinical drug discovery, and clinical trials, culminating in a focus and passion for delivering technology solutions that help bring treatments to patients faster. Wendy is currently part of the product strategy leadership team for IQVIA Clinical Data Analytics Suite (CDAS), providing both SaaS solutions for the market as well as IQVIA's internal CRO needs. As part of the CDAS team, Wendy is responsible for strategy, product management leadership, and Go to Market activities.

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