What to watch in 2019

With the help of Forbes, Frost & Sullivan and a few other healthcare sources, we're looking ahead to 2019 and sharing some top trends for healthcare. Looking back to 2018, it was an exciting year in the clinical trials industry. We have seen many changes in patient connectivity and information exchange as well as digital health and AI implementation. The well-established fields of quality, risk management, and vendor oversight are moving cautiously into analytics.

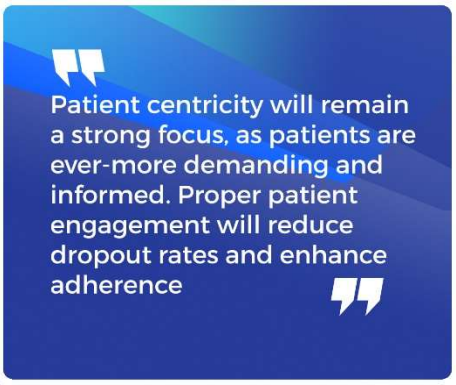
As we enter 2019, we discuss new trends that will continue to not only impact our businesses but will continue to shape the industry. Let's get started.

The Evolution of Patient Information Exchange and Connectivity

Health information exchange [HIE] will continue to be critical, enabling interoperability and meaningful use of health information and technology. Interoperability describes the extent to which systems and devices can exchange and interpret that shared data. For two systems to be interoperable, they must be able to exchange and subsequently present that data such that a user can understand it in order to extract value. To ensure interoperability, there must be standards to enable data to be shared across disparate healthcare settings regardless of the application or vendor.

Advances in HIE and interoperability means enabling data to be transformed into information to tend to patients' needs before, during, and after clinical trial participation – including incorporating the patient in study design, raising awareness about clinical trials with patients in their communities, providing supplemental materials during clinical trials, and giving data back to patients after clinical trial completion. Additionally, information exchange envelops study site feedback to improve the patient experience. Some companies are focused on establishing relationships through patient community outreach, and supporting study sites with tools, information, and resources to assist patients through the clinical trial journey. This includes social media.

Sina Adibi, CEO of Adaptive-Clinical Systems shared "Patient centricity will remain a strong focus, as patients are ever-more demanding and informed. Proper patient engagement will reduce dropout rates and enhance adherence"



Other companies are taking the approach of leveraging digital technology to maintain patient engagement with studies by educating them and engaging them whether they are qualified for the study or not. It is likely that we will see initiatives that give data back to patients in the future.

Artificial Intelligence to Gain Speed in Medicine

Drug discovery will continue to test the benefits of technologies such as Artificial Intelligence (AI), the Internet of Things (IoT) and Machine Learning (ML) can bring to the development process. For example, benefits could be seen from deploying informatics and data analytics platforms to inform clinical operations teams of trends seen in trial audit reports and simplifying adverse event reporting for pharmacovigilance practitioners.

AI across clinical and non-clinical use cases will begin to show hard results. Frost & Sullivan expects AI for the Healthcare IT application market to cross $1.7 billion in revenue by the end of 2019. They further anticipate that operationalizing AI platforms across select healthcare workflows would result in 10-15% productivity gains over the next 2-3 years[1]. These gains will have a direct impact on Clinical trials through enhanced recruitment techniques, better habit tracking, and even design and conduct of virtual trials.

While the pace of innovation in this area has been rapid with a number of startups and established vendors introducing solutions, the challenge for any AI system is two-fold:

- Access to clean data from ALL sources
- Pre-existing and credible existing conclusions along with the associated data to use as a learning corpus

This means that even if the algorithms are good and the research behind them is solid, there is a risk that if the data that is used for training or subsequently fed into the system is bad, the results will be suboptimal or even completely wrong.

Adibi states that "60% of effort on such projects is currently spent in harmonization and cleaning of data from various sources. Some side step this by limiting their input systems to just a few like Electronic Data Capture (EDC) only. This is contrary to the theory of AI where we look to the machine to process large volumes of data from every source that a human is not capable of processing."

So we look to the future for a single standard to emerge that enables the industry to generate uniform data. Post capture cleansing of data is exponentially harder than applying data transformation as the data is captured. Deploying technology solutions to inspect and unify data from disparate sources at the source will reduce the data cleaning effort.

Another challenge is that pricing for AI solutions remains critical as end-users are not convinced they should dedicate an additional budget item. A cost effective approach with clear evidence for potential ROI for both parties can help sustain the market growth.

Throughout 2019, AI and ML will further ion will take place and at an accelerating pace. AI will begin to see fruition, particularly in diagnostic imaging, drug discovery, and risk analytics applications.

More ROI Evidence on Clinical Trial Supply Simulation Software

According to Pharma IQ's recent research the clinical trial supply industry has seen enhanced integration between enrolment data and inventory levels from the use of IRT software in clinical supply chains. This integration has positively impacted overage and wastage levels.

Many clinical trial supply teams indicated reliance on spreadsheets for planning and forecasting. But according to Adibi, using spreadsheets should be a last resort and not the primary means of analyzing data for the purposes of forecasting. "Excel is vulnerable to unintended user introduced or system capacity errors. Supply chain forecasting systems have emerged that will replace these spreadsheets but their reliance on up to the minute real-time data is essential. While many do a good job on analyzing the data once it is loaded, their results are often outdated due to the inherent delays in data reporting and loading."

Effective use of online simulation tools that we move from the traditional Extract, Transform and Load (ETL) approach to one of Real-time interoperability. After all, to manage "just-in-time" supply change approaches one cannot reply on data that is on average 8 – 10 days old (Frost & Sullivan Survey October 2018)

To trigger widespread industry buy-in, simulation software providers will need to boost their product's accessibility, user friendliness and ability to demonstrate a clear ROI.

Mitch Collins, Chief Revenue Officer of Adaptive Clinical adds “Demands for ROI justification will be ongoing, especially as clinical trials focus on rare diseases requiring very expensive to manufacture experimental compounds. Managing and forecasting use of this expensive commodity will be a key success factor in all such trials.”

Analytics Shifts from Big data to Meaningful Small Data

As the healthcare industry gets comfortable with data management workflows, we foresee a high number of specialty-specific analytics solutions will gain prominence among providers striving to investigate drug utilization, treatment variability, clinical trial eligibility, billing discrepancy, and self-care program attribution specific to major chronic conditions.

Frost & Sullivan predicts that by end of 2019, “50% of all healthcare companies will have resources dedicated to accessing, sharing, and analyzing real-world evidence for use across their organizations.”[2] will this trend continue into life sciences?

Tech giants may start to enter the pharma and biotech field

There is a strong possibility that tech giants, like Amazon and Google, will begin to enter the pharma and biotech field. There is an expectation from various industry stakeholders that we will see large tech companies starting biotech initiatives because the industry is considered an attractive investment and ripe for disruption.

Amazon has made a major announcement and Google has been applying AI/ Machine learning technologies for digitization projects in Healthcare and Clinical Trials. We predict that this trend will continue and accelerate through acquisitions by the tech giants. Expectation is that this will evolve to an entity within AlphaBet to keep distance between the heavily regulated activities in this field and the corporate parent and other entities.

We recently learned of the Germany-based pharmaceutical multinational’s Canadian arm of Boehringer Ingelheim is set to trial IBM blockchain in Canada in a bid to raise the quality of clinical trials. According to the firm, they partnered with IBM “to improve trust, transparency, patient safety and patient empowerment in clinical trials” using the tech giant’s blockchain platform.

The firm said the trial aims to address quality issues with clinical trial processes and records, which are currently “often erroneous or incomplete” and could potentially put patient safety at risk.

The project will test how blockchain can help provide a decentralized framework that preserves the integrity of data, provides “provenance and transparency,” and enables the automation of processes, ultimately boosting patient safety and reducing costs.

2019 will be an exciting year for healthcare, with major transformations and new entrants in the market!

About Adaptive-Clinical Systems

Adaptive Clinical Systems offers a unique, simple, secure, validated, compliant, and cost-effective innovative solution for clinical data integration and interoperability. The cloud-based innovative Adaptive eClinical Bus® solution integrates clinical study data from multiple systems and platforms - EDC, eCOA, CTMS, Medical Imaging, IRT, analytical/data visualization systems and others - to ensure accurate and efficient transfer of clinical data for any study of any complexity while going well beyond simple and difficult to scale integration to full, real-time interoperability.

The award-winning Adaptive eClinical Bus software includes “connectors” for many leading clinical trial software tools from well-known vendors such as Omnicomm, Medidata, BioClinica, and Clinical Conductor to open source clinical trial tools such as OpenClinica and Clinovo. Connectors can also leverage internally-developed and proprietary systems and help customers retain their competitive edge. Adaptive Clinical’s eClinical Bus® can easily integrate technology into an interoperable, efficient, and accurate clinical trials system that streamlines processes and improves data reliability and offers the freedom to choose the best eClinical tools of any third-party or proprietary systems while enjoying all the benefits of a fully integrated system. For more information, go to adaptive-clinical.com, email info@adaptive-clinical.com or call 856-452-0864.

[1,2]Frost & Sullivan Survey October 2018