Been There Done That:

Learn From Your Peers Before You Formulate a Clinical Trial Data Integration Strategy

T he healthcare, pharma and biotech industries are in a period of rapid, significant and accelerating change where technology is revolutionizing the industry. Drug and biotech companies constantly strive to bring differentiated and high-quality medicines, vaccines and consumer healthcare products to as many people as possible. To bring a successful drug to market, companies spend over $1.2 billion dollars and many years of R&D and clinical trials. However, most studies suffer significant delays and well over 85% of them fail. Such a low success rate makes delays costly, and yet it is rare to find a study which hasn't encountered significant delays. Aside from patient recruitment and engagement, the next biggest cause of delay is the time it takes to generate insights from clinical data. This can affect governance, risk management, monitoring and submission. This problem is further aggravated by the explosion of point solutions that often operate in silos with no awareness of other tools. It is estimated that over 36 different software packages touch clinical data prior to its submission. And this is only during the clinical testing phase of drug development!

So it is no wonder that IT and operations groups within healthcare, pharma and biotech organizations are increasingly tasked with developing and implementing a data integration strategy before any further clinical informatics investments are made.

If you are one of those charged with this vexing task, it's wise to get advice from your peers who have been there and done that – informatics specialists who live and breathe data integration and interoperability every day. Here are their thoughts:

Interoperability: What it Means Today

It's simple. It means that data generated by one system can be easily understood and accepted by another. It also means having the ability to integrate proprietary and commercial off-the-shelf (COTS) tools, and to let you leverage your existing in-house investments, giving you the freedom to choose the best tools for your study. Is true interoperability possible? Yes, and it is a requisite in moving forward given the upswing in new devices (IoMT).

Understand the Importance of Interoperability for the Future

Internet of Medical Things (IoMT) brings together medical devices and applications and technology that procure data in real time and from diverse sources. Chronic diseases, which require frequent monitoring, can be tracked effectively using a phone's built-in sensors or wearables, so those patients receive timely and proper attention. Wearable devices like Apple Watch, Fitbit and Samsung S Health help users achieve their fitness and health targets but they also serve as excellent passive monitoring devices for clinical trials. They, therefore, could well be the future of eCOA type self-monitoring in clinical trials and healthcare as pharma and medical device companies look to innovate and keep up with technology to help patients and physicians operate more efficiently and accurately.

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According to a report by Allied Market Research, the IoMT market will reach $136 billion worldwide by 2021. These projections are based on the fact that IoMT has the potential to transform the healthcare industry in terms of delivery, affordability, and reliability. Pharma and tech companies are now taking things a step further and collaborating to make devices that can track chronic and lifestyle associated diseases like diabetes.

The challenge here is that these devises produce reams of data at an accelerated rate that need to be collected, filtered, aggregated and processed – something that is beyond the traditional Extract, Transform, Load (ETL) approach. Hence, intelligent, rule-based Interoperability will play an essential role in extracting clinical value from the data generated by these devices.

Interoperability: A Must for Artificial Intelligence and Machine Learning

Another factor in considering interoperability for your clinical data strategy is artificial intelligence (AI), the simulation of human intelligence processes by computer systems. Drug and biotech companies are analyzing huge amounts of data by applying artificial intelligence and machine learning as they strive to shorten the development cycle. These technologies are helping them identify patterns in ways that humans cannot. Artificial intelligence driven solutions are also enabling pharma and biotech companies to identify appropriate patient populations, reduce or eliminate the need for some studies, and in some cases even predict outcomes in a virtual patient. However, a prerequisite for proper functioning of all such AI tools is access to "good and clean" data" which is another reason why your data strategy must take into consideration future use of AI tools and how to aggregate data from all sources in a coherent and effective manner through interoperability.

Know What You Want to Integrate

There are many data sources when it comes to clinical trials. Data silos that direct safety, operational systems, R&D systems, maintenance, Real World Evidence data, Claims systems – you need to know what needs integration and then someone who knows how to make these systems effectively "talk" to each other. This goes well beyond simple API integration of all systems.

Don't Underestimate the DIY Effort

Just as it takes time for a new drug to go through the various stages of testing, it takes time before you can make integration work. Before integrating your applications, you need to allow time for careful planning, system development and deployment. While evaluating your integration needs, consider study timing, high-priority needs and the complexity of your IT landscape. Furthermore, take the time to estimate the ongoing cost of maintaining the integrated ecosystem. Building a true interoperable platform to connect all your data can take up to two years if not longer, and there are many examples of such DIY interoperability projects fail. It's important to find the right partner with proven expertise and from the pharma/ healthcare industry that can help you accelerate the process and

assure success. Since these projects are fairly new in nature, and the technology landscape is ever changing, this is a classic example of "Buy" instead of "Build."

Know the Playing Field

What are your options? There are a few decisions you will need to make. Perhaps you're considering making it easy on yourself and explore a single vendor with a comprehensive suite of eClinical tools. These vendors offer robust solutions and you'll need to learn how to use them. But keep in mind that for the price you pay – a large ticket price – not every tool they offer will be optimal for your study. Integration and data transformation are rarely their core competency.

Relying on a Single Vendor Strategy

If you build your data integration strategy with one vendor, be prepared to compromise on other aspects of your requirements.

According to Rajat Shukla of CitiusTech," you may settle on a very good solution, but end up tweaking it so much it becomes a rigid integration. Once you are locked in, it's just not possible to either upgrade the system OR to move to a new solution." He described a situation where a large pharmaceutical company spent several million dollars to create custom integrations and further customize their safety system. "The system worked well, but couldn't be upgraded to meet changed regulatory requirements. They had to wait for nearly a decade to upgrade to the next version – you must maintain flexibility."

Beware of the Allure of Simple Point-to-Point

Another option is to build your own point-to-point system. Depending on your unique needs, it could be the right solution but in many cases we see that it's too hard to build and deploy. The resource-intensive nature of building your own system is often cost *and* time prohibitive. If this is the case, you risk "shelving" the project – and then what? It's hard to back-peddle emotionally, financially and operationally. Or conversely, suppose you build it and it works, for now. What about tomorrow? Will it scale to handle the ever increasing complexity of your systems or comply with new regulatory requirements?

Heterogeneous Interoperability as a Business-Critical Strategy

Another option is to mix it up – pick best-in-breed vendors and maintain your freedom to choose the best solution – but you need to use a bus for your data connectivity. This option is really a best practice because you can take advantage of new technology and best in breed solutions and not be "locked in" or limited in flexibility and technological advancement. "When we think about integration, we think simple data mapping. The true benefit of integration, or better phrased "interoperability," is the ability to move data in a controlled way bi-directionally," said Sina Adibi of Adaptive Clinical Systems. "When you couple that with an intelligent middleware that can

transform the data in a way that the destination system can understand without much effort, you are able to leverage full features of all the tools that you've already invested in," Adibi added.

As the interoperability platforms become a key ingredient of any integration strategy, it is just as important to select the interoperability partner vendors carefully.

Find the Right Partner

As the healthcare space changes at an accelerating pace with these emerging technologies, mounting concerns around privacy, data protection and governance need be an integral part of any interoperability strategy. And while some of these areas are out of our control, we *can* control data integrity, compliance, and connectivity. It's best to do your due diligence in vetting best-in-breed vendors who understand the impact and importance of interoperability. Ask these vendors as to their ability to smoothly share data with third-party tools and how easy would it be to implement your interoperability strategy. For an example list of must-have eClinical tools that such integration vendors need to be compatible with click here.

A Final Thought

Sharing data and integrating systems is nothing new. It has been done in the Financial or ERP industries for years. However, you should never assume that someone who knows about those regulations also knows our industry's regulatory environment. Furthermore, the state of the art is now to achieve interoperability as described above; even those industries that were ahead of us in integration are now struggling with advancing to true interoperability. Whether you are new to interoperability or currently considering partners for your integration strategy, these points will guide your journey.

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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.

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