MANAGING AND INTEGRATING CLINICAL TRIAL DATA: A Challenge for Pharma and their CRO Partners
Within the Pharmaceutical Industry, nothing is more fundamental to business success than bringing drugs and medical devices to market rapidly and efficiently. Without well organized, easily accessible, thoroughly documented data, the value of a drug or device may not be fully realized.

THE CHALLENGE OF MANAGING AND INTEGRATING CLINICAL TRIAL DATA FROM CRO PARTNERS

For pharmaceutical companies, nothing is more fundamental to business success than bringing drugs and medical devices to market rapidly and efficiently. Clinical trials are critical to that success; clinical trial data provides the basis for submission, approval, labeling and marketing of a compound or device. Without well-organized, easily accessible, thoroughly documented data from well-designed trials, the value of a drug or device may not be fully realized.

Even as pharmaceutical companies continue to increasingly transfer any or all of their trial-related duties to contract research organization’s (CROs), the quality and integrity of trial data continues to reside with the pharmaceutical company. But for CROs to remain competitive in the marketplace, they are realizing the importance of implementing quality assurance and quality controls over data to support their sponsor’s trial requirements.

CROs are quickly beginning to understand that pharmaceutical sponsors are not in the business, nor wish to be in the business, of running clinical trials. Their sponsor’s business of manufacturing new medications provides CROs the opportunity to grow and expand their presence in the CRO market-space. But to remain competitive, CROs are also assuming the additional expense of maintaining personnel, ensuring staff expertise, and acquiring the IT infrastructure costs required to handle an influx of data from new clinical trial contracts.

But as trials are increasingly outsourced to contract research organizations (CROs), the ability to integrate and exchange data seamlessly has proven to be challenging for both sponsor companies and their CRO partners. Here’s a look at those challenges, as well as a unique solution that uses innovative cloud-based technology.

DISPARATE DATA SOURCES

While current data management techniques have made progress, they face significant challenges when it comes to true integration and collaboration. These challenges will become even more apparent as trends and innovations within the industry continue to shape the way pharmaceutical companies and their partners do business.

For example, traditional point-to-point and ad hoc integration can lead to problems with data integrity and require manual steps to share data. Applications often involved
include Electronic Data Capture (EDC), Clinical Data Management Systems (CDMS), Clinical Trial Management Systems (CTMS), Clinical Data Repositories (CDR) and Statistical Analysis System (SAS) Analytics.

While many large pharmaceutical firms (sponsors) use a standardized EDC system and can transform data in the right format before sending it to their partner CROs, many smaller firms don’t have that capability. In turn, CROs may or may not have systems in place that can effectively accept and translate that data in a way that the sponsors need during the trial or when it’s time to submit data to the FDA.

Both sponsors and CROs need a method of integrating and exchanging clinical trial data in a way that gives sponsors a holistic, actionable view of the data at any point in the trial. The inability to accomplish this delays time to market and increases costs. In fact, one study has shown that the pharmaceutical industry spends $156 million annually just to support data transfer between systems or organizations. Both sides need a comprehensive electronic data interchange (EDI) solution that works across all areas of research and development and recognizes each partner’s different needs.

ADAPTIVE CLINICAL TRIAL PROCESSES

New, more flexible approaches to conducting clinical trials are emerging. The adaptive trial methodology is replacing the long-standing approach where no data is moved until all the data collection is completed. Instead, pharmaceutical companies are using an adaptive approach of flowing the data in the early stages of collection. By analyzing interim data, companies can spot issues with a trial early and respond. Then, they can modify the trial to make it more effective, like changing a dosage. Or they can stop the trial if a major problem occurs.

DATA COLLECTION FORMATS MUST ALIGN WITH SUBMISSION REQUIREMENTS

The CDISC®’s (Clinical Data Interchange Standards Consortium) Clinical Data Acquisition Standards Harmonization (CDASH) developed 18 recommended data collection fields that align with the data submissions fields that pharmaceutical companies must use in the drug-approval process. Companies that use CDASH...
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can save considerable amount of time and money by avoiding the need to reformat data just prior to the submission phase. Clinical trial data feeds from multiple CROs must be able to be quickly aggregated and integrated into a single standardized format, such as STDM (Standard Data Tabulation Model).

THE CLOUD SOLUTION

The challenge with every new partnership or outsourcing opportunity lies in how quickly and efficiently a pharmaceutical company can analyze the data coming from different sources to make key business decisions. Meeting the challenge requires data management platforms that can connect, integrate, aggregate, harmonize and monetize information.

Cloud-based technology is well-suited to these requirements because it offers leverage, scalability and flexibility that cannot be obtained through traditional software models. It is important to recognize that cloud-based solutions support more than basic infrastructure needs; services offered through the cloud can be used to solve the business problems both pharmaceutical companies and their CRO partners face.

Cloud-based integration can turn vast amounts of data from clinical trials into information that supports business decisions quickly and accurately. Outsourcing through the cloud means that scalability, streamlined data mapping, improved data quality and fast, flexible data management all can be obtained through one solution. In addition, when implemented correctly by an experienced IT partner, set-up and management should be a simple, seamless experience that requires limited investment in infrastructure.

Integration as a Service, for instance, is an integration specialty focused on performing complex data integration in the cloud. It operates on top of a company’s existing IT systems and allows large amounts of data to be transported and analyzed quickly, easily and intelligently. With fewer dedicated internal resources than traditional methods, outsourced Integration as a Service provides the ability to:

- **Connect**: to successfully outsource clinical trials, there must be sophisticated solutions in place that can easily make the clinical trial data available to any target system. It is important that those responsible for data migration have extensive experience in working with SDTM standards and have provided efficient data transformation and data migration for clinical trials data involving typical entities such as ClinicalTrials.gov, FDA, NIH, global registries, DEA, etc. This capability joins disparate information technologies so they can send and receive information.
It involves linking the physical IT “plumbing.” There are a wide variety of methods for doing this—including FTP, HTTP, SSH and others—but common protocols enable connectivity.

• **Integrate:** Instead of linking the physical IT “plumbing,” integration links the data itself to make sure different interfaces, information and formats work together seamlessly. For CROs to be effective and pharmaceutical organizations to realize the value from outsourcing, an IT infrastructure that is able to handle the complexity of CRO Integration must be in place. Applications that traditionally provide basic data integration efforts using traditional software build models are not able to accomplish the requirements. Instead, it is imperative that the IT infrastructure required for clinical trial data integrations, must provide the ability to scale and configure the application functions to best handle complex data integration requirements.

• **Aggregate:** Aggregation is the process of assembling data from a multitude of sources. It is how pharmaceutical companies begin to support large volumes of information, often in real time. A sophisticated EDC solution provides the functionality to aggregate data, applying business rules to validate data prior to staging, as well as the ability to interact with the data in order to handle errors. An EDC solution provides a “data stewardship” role for user interaction with the process, an in-line data inspection capability. These capabilities are essential to a process that requires true data integration, not just data movement. When data management is not closely coupled with data integration, enterprises are dependent upon applications and/or application integrators to fill this gap. These tools and providers have proven to be poorly optimized to the businesses needs, very expensive, time consuming, and of poor or limited quality.

• **Harmonize:** This is the most important step in creating actionable data. It involves: 1) transforming data into a common, usable format, 2) “normalizing” it to minimize redundancy and dependency, and 3) “translating” it to equate semantic definitions. Through this process, for instance, you would know that a data field tagged as “last name” and another tagged as “surname” both contain information that mean the same thing. True harmonization reconciles the similarities and differences in data sets so that even with large amounts of diverse data, actionable clinical trial information is revealed through customized data analysis tools and functionality.

• **Monetize:** Monetizing data is the process of using actionable, intelligent data to drive business activity. Translating complex data and transforming it to obtain significant insight allows pharmaceutical and bio-tech companies to get drugs and devices to market faster. Cloud-based integration can turn vast amounts of data from clinical trials into information that supports business decisions quickly and accurately.
Benefits of a Cloud-based Solution

- **Reduce time, increase flexibility**
  - Reduce the number of days required to flow clinical trial data used for analysis
  - Accelerated data flow processes provide greater ability to make changes, as well as resolve errors
  - Increased capacity to handle simultaneous clinical trials

- **Achieve scalability**
  - Address growing volumes of data and connections when increasing the number of clinical trials

- **Streamline data mapping processes**
  - Map key clinical trial data to standard formats

- **Enhance data quality**
  - Improve data integrity, reliability and completeness of information in the clinical data repository
  - Multiple Integration Methods/Protocols
  - Multiple Data Formats: Any-to-Any Transformation and Translation

- **Reduce costs**
  - Avoid further customization of CTMS system
  - Avoid further build out of legacy IT infrastructures

- **Greater capacity to handle multiple trials simultaneously**

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**Technology Specifications**

- Source-agnostic
- Parses dumped file
- Normalizes data, checks data for initial errors
- Validates formats and data elements
- Matching / Merging / Mapping
- Initiates appropriate calls to your systems
- Enables sponsors to auto-extract and populate operational data into XML file or other formats
- Metrics and detailed jobs reporting
- Robust support process across sponsors and CROs
LIAISON HEALTHCARE’S GLOBAL CRO INTEGRATION HUB

Liaison Healthcare’s Global CRO Integration Hub provides real-time access to clinical trial information for both pharmaceutical companies and contract research organizations (CROs). This platform simplifies the integration and harmonization of clinical patient and operational data across the clinical trial process. With pharmaceutical companies outsourcing clinical trials to a variety of CROs, the information must constantly flow between both entities throughout the execution of the clinical trial process. Given the number of electronic data capture solutions and trial designs, standardizing data is quite daunting. Adding to this complexity, the U.S. Food and Drug Administration (FDA) prefers all clinical trial information be electronically submitted in the CDISC Study Data Tabulation Module (SDTM) format, which is typically not the way information is stored natively and can vary from firm to firm.

Liaison Healthcare Informatics has developed a scalable, easy-to-use solution that automates and streamlines data exchange; accurately transforming clinical trials data into a compatible format for pharmaceutical companies, CROs, Government registries and the FDA. The Global CRO Integration Hub provides cloud-based connectivity and translation support to enable interoperability throughout the clinical trial process. By implementing the Global CRO Integration Hub solution, pharmaceutical companies and CROs are able to:

- Exchange information from multiple CROs for multiple clinical trials;
- Translate clinical data from partnering organizations into compatible formats;
- Scale and access information from multiple trials undertaken by a single pharmaceutical company;
- Quickly and efficiently move specific datasets into various location(s) where they will be compiled, stored and analyzed;
- Create a standard global library that can be reused in and across multiple clinical trials.

ABOUT LIAISON

Liaison Technologies is a global integration, data harmonization and data management company, serving more than 1,100 customers in the healthcare industry. With customized solutions offered via a cloud-based platform, Liaison helps health systems, HIEs, pharmaceutical, and bio-tech companies quickly secure meaningful use from a wide variety of health information. For more information, visit www.liaisonhealthcare.com.