RESULTWORKS
Transforming Strategy. Delivering Success.

Transformations

RESULTWORKS NEWSLETTER VOLUME 16 ISSUE 1

OF SPECIAL INTEREST:

- ***Delays introduced by paper-based data collection cascade to downstream study activities***
- ***eSource is the next wave of electronic data capture***
- ***Understanding end-to-end processes is the start to address bottlenecks & constraints***
- ***At some point innovation requires a strategy and a commitment to execute***

INSIDE THIS ISSUE:

FOLLOW THE DATA TO UNCOVER CLINICAL STUDY BOTTLENECKS & OPPORTUNITIES

Introduction

Technology has progressed a long way throughout the early part of the 21st century. It is hard to think about life without smart phones, tablets, WiFi and cloud computing. Despite our advancing technological society, significant volumes of clinical study data are processed manually. Clinical investigative sites are still recording study information on paper, which creates delays and errors that have downstream effects on study management, efficiency and timelines. As studies progress, lab results pass through many gates and require multiple integration steps along the way to the study team, limiting their ability to monitor study progress and make timely study decisions. By understanding and mapping the data flow throughout the clinical study lifecycle, it becomes easier to see the challenges and gaps which can be addressed through better information management approaches.

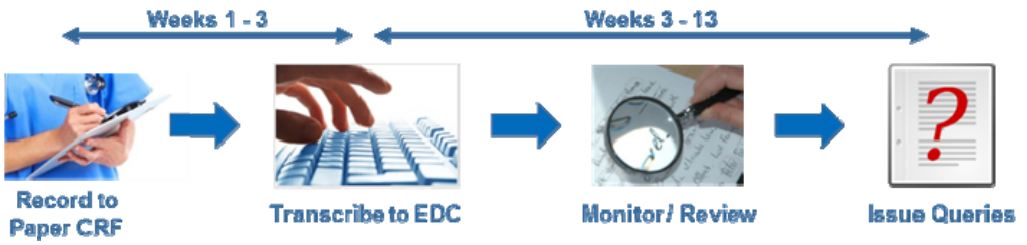
Paper Lingers as Frontline Data Capture

Electronic Data Capture (eDC) systems for clinical studies have been evolving for decades. Serving initially as a way to move data entry of Case Report Forms (CRF) from data management centers to sites, these systems provided significant benefit. They eliminated the copying and transport of paper CRFs to central data centers to be entered into clinical study databases. Unfortunately, these systems have lacked the portability and intuitive user interface needed for site personnel to enter data directly during subject visits. Hence, many site personnel continue to enter data onto paper CRFs and then transcribe the data into the eDC system days or weeks later. After data is entered, site monitors verify that the transcribed data matches the original handwritten source data and issue queries to investigate any observed discrepancies. As shown in Figure 1, this practice is very resource-intensive and introduces significant delays in the flow of information from subject to study team.

Clinical studies are one of the last bastions of paper-based work activity

This said, sites, sponsors and data managers all have strong desires to move ahead with paperless solutions. However, the complexity of providing tailored, up-to-date user interfaces in these areas is also increasing, with more emphasis being placed on clearly understandable consent forms in the subject's preferred language and the need to facilitate different study types and designs. Still, the business benefits of going paperless are compelling, enabling site monitors to focus on subject participation and study compliance while significantly reducing

Figure 1: Current Typical Subject Data Timing



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CLINICAL STUDY DATA FLOW (CONT. FROM PAGE 1)

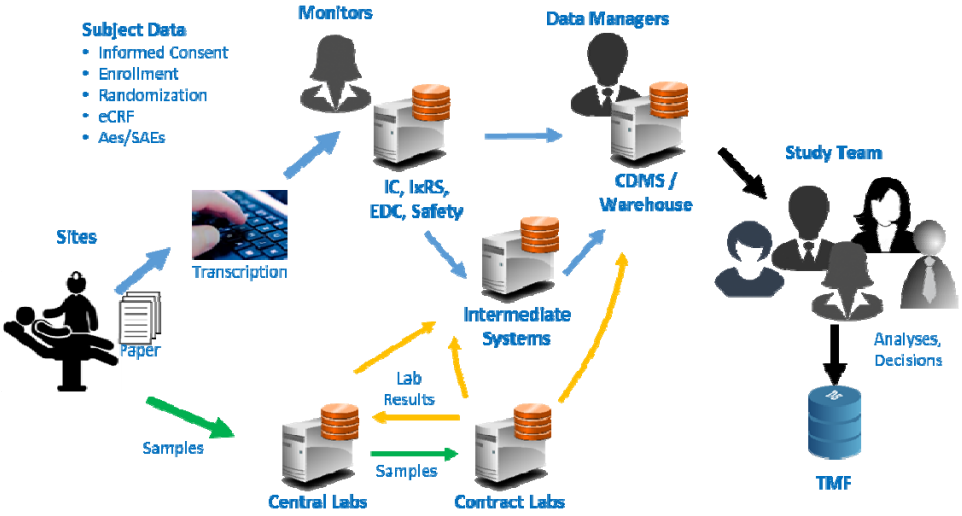

Figure 2: Current Clinical Study Data Flow

the effort required for data review and data queries, plus the ability to achieve real-time availability of subject visit information.

Delays introduced by paper-based data collection have cascading effects on downstream study activities

Bigger Picture for Clinical Data Flow

Delays introduced by the use of paper have cascading effects on downstream study activities. Samples taken during a study visit are often issued to central laboratories for recording, internal analysis and distribution to contracted specialty labs. Without visibility into the study records, the central labs must rely on limited information received with the samples for managing and processing the samples.

On top of the delays introduced by paper CRFs are the further data flow delays and complexity introduced by a myriad of data collection and aggregation systems often utilized by sites, partners, and sponsors. Site investigators may be required to use separate systems for informed consent, subject enrollment, randomization, CRFs/eDC and adverse event reporting for a given study and this difficulty is multiplied by the number of sponsors and data management partners across all studies. Downstream, the subject data must eventually be integrated into a clinical data management system (CDMS) or clinical data warehouse (CDW), but in many cases, the data travels via multiple paths, each with its own data ingestion and integration steps. This is especially true where sponsors have outsourced the study management or data management to a CRO partner where some data may be captured in sponsor-owned systems, while other data is captured into CRO systems. Data managers monitor data availability, determine which data have been verified and facilitate integration into data sets that are consumable by study team members.

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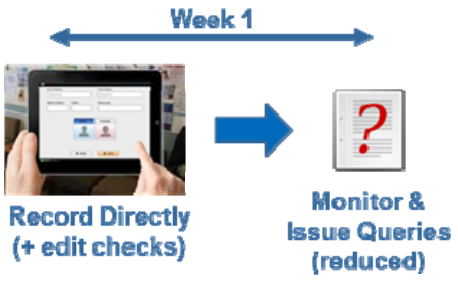
With the current distributed nature of data collection, data managers are often relegated to focusing on integration and issue resolution well after the data has been generated in order to deliver data snapshots for planned interim and final study analyses. Any unplanned request by the study team for delivery of study data may require significant effort, introduce unexpected delays and be costly to the study.

Real-time eCRF Data Capture

eDC systems are evolving, providing user interfaces to guide site personnel through subject data collection steps, including tailored navigation paths that are specific to study cohorts, subjects, and previously collected data. These systems also embed data verification rules (a.k.a. edit checks) to catch data entry errors at the point of collection, reducing costly queries and site investigations.

Going beyond the capture of eCRFs via eDC systems, the eSource movement has emerged to help streamline electronic capture of all study data electronically at the source. That data includes: bedside data capture (BDC); real-time direct data capture from on-site instruments; and data from electronic health record systems (EHR), wearable devices and electronic patient reported outcomes devices (ePRO). These capabilities are essential to enable efficient subject data collection as well as to support advanced monitoring devices.

Figure 3: Data Capture Improvements



While advancing toward paperless data entry, the growing complexity of these site data collection systems threatens to increase the duration and effort for initial study design and setup as well as study changes. To combat this complexity, study designs should be modular with reusable components, leveraging pre-built data collection templates within the eDC/eSource systems.

Assessing the Clinical Data Flow and Building a Strategic Roadmap

While these emerging technologies are clearly beneficial, the path forward to leveraging these new capabilities will be different for each sponsor and CRO

CLINICAL STUDY DATA FLOW (CONTINUED FROM PAGE 2)

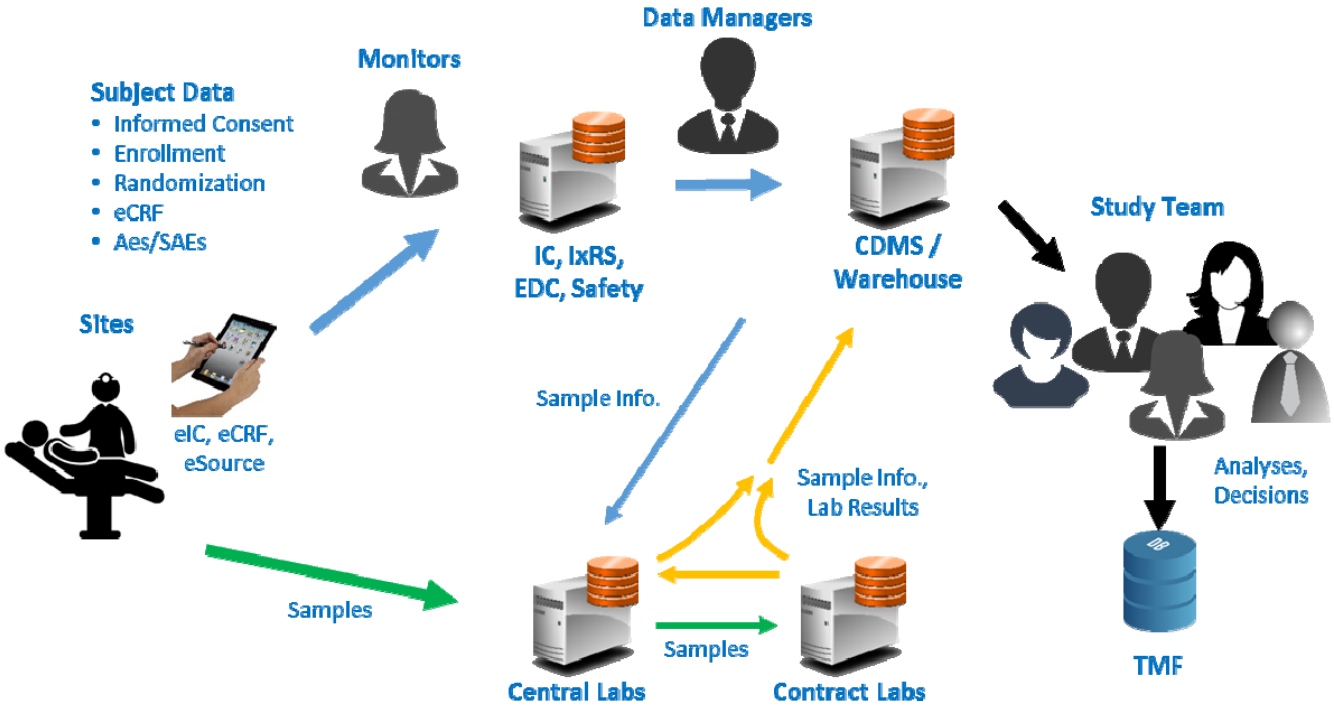


Figure 4: Optimized Future Study Data Flow

partner. By assessing the current workflows and data flows from study design through clinical study report, leaders can understand their current end-to-end processes, and begin to address bottlenecks and constraints.

By understanding current end-to-end processes, leaders can begin to address bottlenecks and constraints

However, simply addressing current weaknesses is a reactive measure offering limited gains over the long run. To drive significant change, a three to five year strategic vision is needed with buy-in from key stakeholders across the study functional areas. Once the vision is in place, gaps between the current state and future state can be identified. Projects can be defined to address specific needs and can be sequenced into a strategic roadmap accounting for business priorities and project interdependencies. When done correctly, the roadmap provides a structured path toward the strategic vision with incremental value being delivered along the way.

Vision with Streamlined, On-Demand Data Flow to Study Teams

Eliminating paper at the front-end of the process is important but further steps are needed to realize the full potential of streamlined studies. Data flow through back-end systems could also be improved, utilizing appropriate master data, standards, and controlled vocabularies to smooth data transfers, ingestion and integration. Subject data from enrollment, case report forms, adverse events and lab results need to flow readily into secure, accessible systems.

Study data could be available on-demand to study teams including sites, sponsors and partners to manage study progress, to perform risk-based monitoring, to better process and track samples , and to accelerate analysis and mid-course study decisions.

Conclusions

While many study teams remain trapped in the paper-age, new capabilities can provide substantial advancements that significantly improve access to study data and study timing. Understanding and streamlining clinical study data flow as described here provides the following key benefits:

- Timely awareness of site, subject and sample data through real-time data capture
- Significant reduction in queries and investigations by performing automated edit checks at point of entry
- Optimized sample processing based on availability of subject data
- Improved study management based on timely study progression information
- Increased awareness of safety events for proactive management
- Accelerated study decision making due to earlier data availability and visibility

The key first step for clinical development is to understand and map the data flow throughout the clinical study lifecycle. This quickly uncovers the bottlenecks and makes it easier to see the challenges and gaps which can be addressed through better clinical data management processes and information management solutions.

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HARMONIZING DRUG SAFETY STUDIES AND INFORMATION

After multiple mergers and acquisitions, a global pharmaceutical company was experiencing suboptimal workflow across Drug Safety without cohesive processes, systems or data models. In today's life sciences R&D environments, companies are interested in leveraging studies and having access to information across portfolios. At the same time, this environment is becoming more challenging with the use of specialized partners and the mandate to adhere to standards (e.g., SEND). Issues stemming from acquisitions coupled with inconsistent technical strategies across Drug Safety were hindering their ability to effectively conduct studies. ResultWorks was engaged to map business and information flows for a definitive view of common processes, information, standards, and ultimately solutions that could be embraced across drug safety functions.

Mapping drug safety functional business processes was the first step in understanding common information management needs

Read the full ResultStory describing the challenges in *Harmonizing Drug Safety Study Information Management*.

IMPROVE TIMELINESS & ACCURACY OF CLINICAL STUDY DATA

With the large volume of studies managed today and the amount of data processed, it takes a great deal of human capital to conduct studies in traditional ways. One global pharmaceutical company facing these business challenges was looking for a transformation of their study data flow that would bring about more timely and accurate access to clinical data. This required an assessment of what data was needed, who needed the data, how the data flowed, and where the data resided as a precursor to determining how to streamline the data flow, the workflow, and the information systems to optimize clinical study efficiency.

Assess what , where, when, and by whom study data is needed for decision-making

The project resulted in a common understanding of the clinical study processes, a shared data flow vision, and a three year strategy roadmap to realize the vision.

Review the complete ResultStory on the *Clinical Study Data Flow project*.

SPARKING INFORMATION MANAGEMENT INNOVATION

There is a lot written about the need for innovation in the Pharmaceutical Industry. Some think innovation has been lost. Others think innovation has never been better.

In a Harvard Business Review article, "What is Disruptive Innovation?" authors Christensen, Raynor and McDonald challenge the notions of innovation-driven growth.

While many areas of science in the Pharmaceutical industry might be considered innovative, what about the adoption and application of information management tools and technology. Industry standards like CDISC have existed for years and the adoption is still slow to happen. Tools like eDC have been around for decades and yet study data collection is still heavily paper-based. Now eSource is the next wave of study information processing. At some point, leaders have to stop just talking about innovation; develop a strategy and make a commitment to adapt and execute.

RESULTWORKS NEWS

Upcoming Events & Activities:

- Lab Informatics Summit - January 25-27
- Scope Summit - February 23-25
- Bio-IT World - April 5-7
- eSource Data Conference - May 2-3

Current / Recent Client Initiatives:

- Compound Mgt. Strategy, Requirements, Solution
- Biospecimen Mgt. (Process Opt. & Solution Selection)
- Managing Clinical Content for Regulatory & Publication
- Laboratory Results Data Management
- Centralized Data Curation to Support Adaptive Trials
- Information Mgt. Strategy Bridging Pharm Dev & Mfg.
- Clinical Trial Registry Data Quality (Regulatory Activity Reporting across Pharma, Devices, and OTC)

ABOUT RESULTWORKS

ResultWorks is a professional services company offering strategy innovation, integrated business analysis, information transformation, and knowledge management consulting services for the life sciences industry. Results are achieved through skilled facilitation and exceptional management leadership. The focus of our client engagements is optimizing life sciences effectiveness across research, development, clinical, regulatory, and manufacturing.

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