Accelerating Clinical Research as Study Complexity Grows

How Early Planning and a Unified Data Platform Can Cut Trial Timelines and Costs

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The Challenge: Growing Clinical Trial Complexity Slows Research

The exponential growth of new data required for developing modern therapies, coupled with longstanding patient recruitment challenges have overwhelmed traditional, often manual, clinical trial approaches. Since 2001, the complexity of clinical trials has grown dramatically. From 2011 to 2015, the number of procedures performed per patient in Phase III trials jumped 70 percent compared to the same five-year timespan starting in 2001. Over the same period, the number of planned study volunteer visits grew 25 percent and the cost per visit increased 34 percent for Phase II studies and even more for Phase I and II protocols.[1] Not surprisingly, more complex trials take longer to run. Higher complexity trials are more likely to require more amendments, and these, too, add to timelines.[2]

Cost of Delay

The cost of longer therapy development timelines can be very high for patients, especially those with potentially fatal conditions. One study estimates the patient economic benefit, alone, of approving a highly active antiretroviral therapy (HAART) one year sooner would have totaled $19 billion. That figure reflects only additional income and spending resulting from an average 14-year lifespan extension with no monetary value added for improved quality of life for a very large group of HIV/AIDS patients.

Similarly, introducing trastuzumab for breast cancer one year sooner would have produced $8 billion in additional patient benefit, and rituximab for non-Hodgkin's lymphoma, $310 million — again based solely on additional economic activity generated by a longer average lifespan. The same study estimated that the firms marketing these three compounds would have reaped, respectively, an additional $3.7 billion (14 percent), $730 million (8 percent) and $260 million (8 percent) in profits from a year-earlier approval[4].

> "Approval one year earlier of a breakthrough HIV/AIDS drug that extended lifespans 14 years would have added $19 billion in patient economic benefits and $3.7 billion in additional sponsor profits."
>
> **– Manhattan Institute, 2010**

While reducing total study timelines by one year or more is not always possible, shorter delays are common, with protocol amendments being a major cause. From 2010 to 2015, two-thirds of Phase III protocols were amended, with an average of 2.3 amendments per protocol and an average direct cost to implement at $535,000 each. More than three-quarters of Phase II trials were amended at an average direct cost of $141,000 per amendment. Moreover, studies with substantial amendments took about three months longer to complete than those that did not, contributing to an estimated direct and indirect cost of amendments at $20 billion annually industry wide.[5,6]

The overall consequences of trial delays are not lost on Wall Street. Recent announcements of clinical trial issues and related delays in FDA approval have resulted in one-day stock losses of 30 percent or more with even larger long-term losses.[9] Short term losses due to approval-related negative news are much larger than gains associated with positive approval news.[10]

> "Clinical approval delays can cost as much as $600,000 in lost sales per day for niche products and $8 million per day for blockbuster drugs."
>
> **– Cutting Edge Information, 2005**

More importantly, any delay in being the first to get a drug to market can have long-term financial consequences. On average, first-to-market drugs still enjoy a six percent advantage in market share 10 years after the first launch in class. Average market shares are even higher for first-to-market specialty drugs versus primary care drugs, as well as for drugs launched by large companies that have only one competitor or have added multiple indications over time.[8] These potential advantages can be wiped out through any type of delay.

Acceleration of Greater Clinical Study Complexity

The trend toward greater clinical study complexity, and associated delays and data errors, will accelerate, driven by factors, including:

- **Technology advances yield more and more data** – To develop targeted therapies that make up a growing proportion of the pharmaceutical market entails collecting, standardizing, integrating and analyzing data from a growing range of sources, including:
  - Genomic and proteomic information from patients and disease biopsies
  - Imaging and lab data
  - Data from previous trials and research
  - Real-world information from electronic health records (EHR)
  - Pharmacy orders and insurance claims
  - Patient reported outcomes from mobile apps
  - Near-continuous streams of vital signs and motion data from mobile sensors

Indeed, to this last point, the greater detail of therapy effects under real-world conditions provided by mobile sensor data may soon make its collection a standard practice for most clinical trials. Continuing advances in data gathering technology and the greater precision it fosters likely will continue to increase the volume and variety of data collected in clinical trials.[18]

- **Regulatory requirements** – As datasets grow, meeting existing data submission rules, in addition to complying with emerging regulatory guidance, will become increasingly challenging. The need to validate new types of endpoints and biomarkers, and to develop statistical models to ensure the integrity of flexible studies will further increase the complexity of trial planning, design, execution and analysis.
- **Outdated study practices** – Legacy study management and monitoring practices are already stressed by traditional study designs — such as 100 percent source document verification (SDV) that does not improve data quality. This stress will only be magnified by the volume of data being generated by complex studies. In addition, adhering to historical site-by-site manual data monitoring, prevents study monitors from identifying potential data quality problems or protocol deviations that may be suggested by data variations among sites. Over-reliance on traditional protocols and trial execution practices also may prevent applying risk assessment learnings from one study to the next, and from taking proactive steps to prevent avoidable data quality issues.

Clinical Trial Growing Pains

The stress of increased study complexity and related delays is reflected in the top concerns reported by industry executives. In a 2016 study, patient enrollment was most frequently named as the top clinical trial pain point by pharma sponsors of all sizes. Integration and validation of multiple technologies was named second most often by large firms, while post-study data clean-up was second for mid-size to smaller firms.[11]

In another survey, reducing trial timelines up to regulatory submission, and reducing the risk of approval failure or delay were the two top concerns of executives at the director level or higher from a wide range of pharmaceutical, biotech, and contract research organizations (CROs). Here, again, efficiently recruiting patients and retaining them throughout studies were seen as key to shortening timelines. Reducing regulatory risk revolved around eliminating data quality issues that might produce a request for more analysis or testing that could delay an approval, or an outright denial.[3]

> In an era of shrinking patient pools and masses of new data, developers can no longer afford the delays and costs of inefficient legacy clinical study practices.

Likewise, the avalanche of data from many new sources will increase the challenge of collecting, verifying, monitoring and reporting trial results. Current data-related issues, including tech integration and post-study data clean-up, will become even more complex and will need addressing to keep development programs on schedule and reduce the risk of regulatory delays.

In an environment of drugs coming off patent, growing margin pressure and emerging regulatory requirements; sponsors, CROs and other developers can no longer afford the delays and higher costs of inefficient legacy clinical research practices.

Elements of a Comprehensive Solution: Early Trial Planning Supported by a Unified Clinical and Business Data Platform

Sponsors and CROs have tried to solve the challenges of growing trial complexity and data flow by automating data collection and reporting, yet these solutions have had limited success. Because clinical research involves so many different clinical and scientific disciplines, diverse data sources must adhere to regulatory, business and cultural requirements that vary widely by location.

The Piecemeal Approach

The decision to automate a trial process typically is driven by specific needs that arise in unique study circumstances. For example, oftentimes IT solutions are developed internally — such as creating study-specific data source forms using word processing or spreadsheet software — even when EHRs are in use for non-study clinical practice.[12] Other packages may be bought from IT vendors to address specific trial functions, such as consenting patients, reporting adverse events and billing services. This piecemeal, non-integrated approach is inadequate for two reasons.

First, a non-integrated approach causes inefficiencies and burden on site staff. In-house custom source forms can take a day or more of staff time to design[12] and often require manual transcription of patient data captured into a study EDC, adding, on average, about 45 minutes per patient site visit, according to a 2016 survey by the Society for Clinical Research Sites (SCRS). Multiple third-party apps requiring myriad logins, sometimes called "swivel-chair interoperability," are also a leading complaint for site staff, with up to 10 different software packages supporting a single study, the SCRS survey found.[13]

> A fragmented approach to automating study operations delays trial data reporting making it harder to quickly identify and correct problems as they occur.

Second, a fragmented approach leads to delays in reporting and filing trial data and content, and a lack of transparency into ongoing operations. This makes it harder to quickly identify and respond to problems such as protocol deviations or even fraud as they crop up. Failure to correct data problems early can result in costly data loss, late protocol amendments and patient loss, as well as delays in regulatory submission, data submission errors, or even outright rejection of approval submissions.

From a systems and risk management perspective, fragmented study software solutions impede cross-functional team collaboration and hinder a centralized approach to data that would otherwise enable real-time data quality management and early error detection that can increase study efficiency. Fragmentation also does not support broad-based data analytics needed to identify trends for risk assessment, monitoring and detection, or predictive analytics to guide study decisions.

***Bottom line:* Fragmented study software solutions cannot support real-time data quality management and analysis needed to accelerate clinical research.**

The Generic Business Data Aggregation Approach

More recently, sponsors and CROs have turned to data aggregation and analytics firms that focus primarily on business financial and consumer data sources to integrate data from multiple disparate sources and support decision-making. These generic tech solutions, too, are problematic for several reasons.

Merely loading data from disparate sources into a common data warehouse is not sufficient to support meaningful reporting, analysis and predictive analytics. Data also must be standardized and consistently structured to ensure they are comparable across sources and uses. In the context of clinical research, this requires a level of clinical, operational and regulatory compliance expertise that general business data firms often lack.

Further complicating the challenge, clinical research is a rapidly moving target requiring ongoing expertise to harvest data from new and changing sources. These include third-party and internally developed apps, mobile sensors, EHRs, genomic studies and even environmental data such as weather and air quality. These data sources must be validated and structured in ways that are usable to support clinical study data collection and analysis, and regulatory filing needs. This is unfamiliar territory for many generic business data firms.

> “Loading data from disparate sources into a common data warehouse is not sufficient to support analysis. Data also must be standardized and consistently structured.”

Moreover, data from a single trial or a handful of trials provide a limited basis for benchmarking and assessing clinical and business performance in the clinical development realm. As data accumulates from multiple trials, development stages, sponsors and therapeutic areas over several years, it becomes more and more powerful. General business data firms, and even newcomers to the clinical trial field, lack access to very large sets of detailed, standardized clinical data needed to make comparisons meaningful.

Drawing useful scientific insights and developing predictive analytics that support clinical hypothesis confirmation and generation from even standardized data requires not only a high level of data management, analytics and machine learning expertise, but also expertise in addressing scientific, trial operations, regulatory and business challenges unique to clinical development – which, again, business data firms generally lack.

Even business support decisions in clinical trials, such as assessing the costs and performance of prospective study sites, are highly specialized. They rely on clinical, operational and financial data that are not typically available through general business databases.

***Bottom line:* General business-oriented data firms cannot provide the comprehensive clinical and specialized business data, industry expertise and pioneering analytics needed to address the unique clinical and business challenges of accelerating clinical research.**

The Flexible, Comprehensive Clinical and Business Platform Approach

So what does an ideal data platform for accelerating clinical trials look like? It includes the following capabilities and features supporting data management, clinical operations, site investigators and patients from the earliest clinical safety testing through post-market approval surveillance:

Massive, detailed clinical and business database – To support broad performance analysis and benchmarking from end-to-end, an ideal clinical research platform would include the largest possible, up-to-date, detailed clinical trial database, including:

- Anonymized patient-level clinical data from trials across major therapeutic areas and indications
- Trial data from Phases I-IV
- Trials across multiple sponsors
- Trials from around the world
- Information on historical and current standards of care for patients by indication
- Deep operational and financial data from all trial sources

Validated, standardized data – To enable meaningful comparisons across multiple data sources, an ideal clinical research platform should include master data management with automated and manual data validation and standardization within studies and across the industry with:

- All data curated and standardized regardless of source
- Industry standard data formats meeting regulatory requirements

Flexible, scalable unified interface – To accept data from the entire range of current and potential future inputs into a single unified user interface, an ideal clinical research platform should include a cloud-based interface that:

- Supports third-party and custom apps
- Supports adding new apps and data sources as needed
- Makes data from all trial and historical sources available for analysis in real time
- Is scalable and flexible enough to support any size or stage study

Powerful analytics – To analyze and extract correct, actionable insights in real time, an ideal clinical research platform should include advanced analytics and artificial intelligence techniques, including:

- Machine learning
- Natural language processing
- Predictive modeling
- Support from experienced data scientists with clinical trial and diverse industry experience to customize analytics as required

User friendly technology – To support trial staff and patients as well as sponsor, CRO and other study execution personnel, an ideal clinical research platform should include a unified, user-friendly interface with:

- One login for all trial functions
- All authorized functions accessible from any connected device through a single interface
- Tools for customizing and streamlining trial functions such as protocol development, study monitoring and safety reporting
- Patient-friendly tools such as eConsent, ePRO, sensor links, trial support apps and telemedicine capabilities to reduce site visits

With all the data and tools needed to design, optimize, manage and submit trial results in one place, sponsors and CROs could make better-informed decisions at every step, avoiding costly errors. Other potential benefits include:

- Data collection and management efficiency gains that significantly reduce manual work and administrative burden for sites and study monitors
- Freeing CRAs from manual reviews to focus on higher value tasks
- Easing patient burden of participating in a trial

***Bottom line:* Reducing trial timelines and costs helps get products approved faster, and ultimately, to patients sooner. This is only possible with a flexible, unified trial platform powered by an extremely large, standardized database of highly specific clinical, operational and financial data.**

How a Flexible, Unified Trial Platform Can Help Relieve Major Clinical Trial Pain Points

As noted above, patient enrollment is the number-one clinical trial process pain point for pharma sponsors of all sizes, with tech integration and validation second among larger firms, and post-study data clean-up second among smaller firms. Furthermore, site selection, patient retention, study design, and reporting and analytics were frequently mentioned as other pain points in a Medidata survey of executives from across the clinical research field.[11] While patient recruitment is more often top of mind, solving the tech integration and validation challenge is key to solving other problems at a time when the volume of data generated overwhelms manual and fragmented study processes.

A unified data platform can seamlessly integrate multiple data streams from every phase of current studies with performance benchmarking and risk management learnings from historical trials using advanced analytics. Adopting this type of platform enables data-driven solutions at every trial step that can:

- Optimize study design and streamline operations, minimizing site and patient burden
- Improve site selection and patient enrollment and retention with multivariate models based on prior site performance and current study needs
- Accelerate study conduct, data capture and standardization, and overall operations
- Increase chances of study approval

Creating an overall plan at the start of a clinical development program is also essential to coordinate the broad range of resources needed to design trials that deliver scientific results while meeting tight timelines and budgets. Here again, the integration of specialized clinical and business information with predictive analytics needed to create a realistic plan is made possible by a unified platform and historical trial database. As development programs progress, the same unified platform can help solve common trial pain points at every step as discussed below.

Pain Point: Patient Enrollment

Patient enrollment is a leading cause of study delays. On average, the actual time spent enrolling patients is nearly double planned timelines – which can add six months or more to a study.

Actual enrollment time nearly doubles planned timelines

Therapeutic area	Percent actual timeline exceeded plan
OVERALL	+94%
Oncology	+71%
Respiratory	+95%
Cardiovascular	+99%
Endocrine/Metabolic	+113%

Source: Tufts Center for the Study of Drug Development, 2012

Patient enrollment is a multifactorial challenge affected by several trial development steps that must be coordinated to succeed. It illustrates how complex and costly trial challenges can be addressed through an integrated feasibility process enabled by a unified data platform supporting the following steps:

- **Protocol design and optimization** – Successful trial protocols must balance several competing demands. Constructing a lean study design that achieves the essential clinical and statistical outcomes, with a focus on minimizing the site and patient burden, leads to a more positive patient experience.[13, 14] Protocol design and optimization is a good example of how integrating detailed clinical and business data from a wealth of previous trials adds value.

  Assessing protocols from previous studies in terms of how they affected achievement of endpoints helps reduce the frequency of superfluous procedures, which in turn reduces site and patient burden. The optimization process may also prevent future amendments by rigorously establishing the connections between protocol requirements and data elements required to prove scientific hypotheses. This can only be done with a huge database of very specific protocol, clinical and scientific outcomes and operational outcomes usually within a therapeutic area for the same or similar indications as the current study.[8]

- **Site- and patient-friendly services** – A key element of reducing site and patient burden is simplifying processes for enrolling in and participating in clinical trials. Services such as eConsent, which give patients clear visual information they can access via smartphones, tablets and other devices at any time, makes it easier to learn about trial details even before the first visit and remain engaged throughout the trial. Integration with other data platform elements reduces site paperwork at signup and subsequent visits, and provides secure communication for tracking and verifying patient identity.

Similarly, electronic clinical outcomes assessment (eCOA) and electronic patient reported outcomes (ePRO), can automatically capture subjective and objective assessment information including how patients function and feel from electronic survey instruments connected to EHRs and patient mobile apps and sensors, reducing paperwork and enabling virtual trials. A flexible and powerful integrated digital platform is required to connect to the various data sources and custom apps that may be required.

- **Study feasibility** – Determining which countries and which sites are likely to perform best in recruiting and retaining patients, executing the trial on schedule, and keeping costs down can help sponsors and CROs improve the proportion of high-performing sites.
- **Establish study budget** – Benchmarking data for fair market value for procedures by country helps build country strategies against budget scenarios, assess directional costs against protocol design, and plan site grants based on set appropriate payment rates that comply with local regulatory requirements and speed site negotiations. Accurate budgeting requires comprehensive specific data on procedure payments by country, as well as regulatory expertise, and the ability to import and integrate specialized third-party content not typically available in general financial and business records.

***Bottom line:* Careful data-driven planning and feasibility analysis reduces risk of future trial delays due to non-performing sites and protocol amendments. Along with user-friendly enrollment and data collection apps, they reduce patient and site burden, encouraging recruitment and retention, thus potentially accelerating clinical research.**

Pain Point: Site Recruitment and Retention

Another pain point is site selection and retention with a top site concern being quick, accurate payment for services rendered. A data platform integrating clinical and financial data flows can address this issue by automatically detecting and quickly paying reimbursable services.

Since competition for sites is fierce in many therapeutic areas, quick payment may help make a sponsor or CRO achieve preferred status. In fact, a recent SCRS study found that 71 percent of sites are under financial stress, requiring loans to cover expenses, and 51 percent prioritize trials paying monthly.[15] In addition, a survey by Greenphire found that 90 percent of sites prefer to work with partners that automate payment reconciliation.[13]

While current manual payment processes can take 90 days to one year to pay, adopting an integrated system that links payment to EDC for clinical services can reduce payment cycles to 30 days or less. After setting up the study system, completion of a service automatically triggers payment procedures, such as invoicing based on predetermined payment rates, including indirect tax, split payments or amendments, currency exchange rates, withholding local taxes, and payments.

Other advantages for sites include:

- Reduces administrative burden invoicing services and reconciling payments[15]
- Completes transparency of accrued charges, invoices and payments, both pending and paid
- Matches payment service dates, removing doubt
- Integrates with other trial data services in a single portal

Other advantages for sponsors and CROs include:

- Eliminates need to tie up cash in escrow accounts – funds can be drawn from sponsor bank account on demand if desired
- Reduces administrative costs up to 50 percent and minimizes hassles[16]
- Provides transparency of payments whenever needed, full audit capabilities on demand
- Ensures compliance with national regulations and tax laws
- Enables integration with any EDC system with flexible interface

Therefore, integration with a native unified data platform EDC can further reduce study set up time by 80 percent, reduce payment cycle time by 60 percent and improve data quality compared with linking to a third-party EDC.[17] Support from financial and operating experts backing a unified data platform helps ensure success.

***Bottom line:* Paying sites in less than 30 days with full transparency can increase site satisfaction significantly and potentially accelerate trials through partnering with the most effective and efficient study sites.**

Pain Point: Data Clean-Up

Data clean-up is the second most frequently mentioned clinical trial pain point for mid-size to smaller sponsors. The risk can be daunting, with regulatory applications often failing due to avoidable data quality issues.[26] An ideal integrated platform supports data clean up in a variety of ways, including:

- **Automated patient data collection** – As noted above, in addition to easing patient and site burden, eCOA and ePRO can improve data quality and accuracy by eliminating the need to manually enter or transcribe data to the study EDC. An integrated platform flexible and powerful enough to receive and standardize data from a wide range of sources is essential to enable automated data collection.
- **Anomaly detection and advanced analytics** – Data quality characterizes how much trust we have in the data. Inconsistent results undermine that trust. Near real-time access to complete study data including EDC, lab and PRO data, allows analysis of such data from all sites to detect data anomalies that may suggest quality issues such as adverse event patterns, potential protocol deviations, data entry errors or even fraudulent activity. It may also help spot overall protocol issues, such as overly restrictive inclusion/exclusion criteria that unnecessarily restrict patient enrollment. Data quality can also be measured by assessing metrics on a continuous basis throughout the study, focusing on areas expected to be problematic (known risks) and by scrutinizing the data for any unusual patterns that arise during the study (unknown risks). Ensuring data quality continuously helps ensure data points are ready for regulatory submission at the end of a trial, potentially shortening timeframes for preparing regulatory findings.

  An ideal integrated platform solution helps identify problems with sites and protocols early so they can be addressed, preserving data quality and avoiding delays associated with manual and fragmented automated processes. Furthermore, anomaly detection powered by machine learning adds valuable capability to centralized monitoring. Most systems can find known risks that they have been set up to look for, such as data trends suggesting lack of protocol compliance. Advanced machine learning analytics can go above and beyond, finding unknown risks such as misconduct, data inconsistencies not captured through standard edit checks, and adverse event reporting issues.
- **Expert regulatory analysis** – Specially designed anomaly detection algorithms can help flag data issues that may trigger a regulatory delay. Analysis by experts with detailed experience with FDA and other regulators can help transform these findings into actionable insights to proactively address potential FDA reviewer concerns before they become an issue.

Bottom line: **A comprehensive solution involving changes in trial processes and monitoring roles, powered by a flexible, integrated data platform automatically collecting and analyzing site data in near-real time, can help accelerate clinical research by increasing study efficiency, and finding and addressing data quality issues as they arise that may delay regulatory approval.**

Pain Point: Risk Assessment

Intertwined with data quality and monitoring issues is complying with new risk-based monitoring requirements under ICH GCP E6 (R2). These harmonized standards are required by regulators and will necessitate changes in risk documentation and monitoring methodologies (i.e., process, as well as trial planning and management systems, technology). These issues can be well addressed through an integrated platform-enabled risk assessment.

Risk-based monitoring in all but the smallest clinical trials generally entails centralized monitoring. Indeed, risk assessment drives the design of centralized monitoring by establishing data-based definitions of key risk indicators that should be automatically flagged. As noted above, machine learning analytics greatly extends the power of central monitoring to find unknown as well as known risks, helping avoid study problems that could delay regulatory approval.

Centralized monitoring can also help improve CRA efficiency. Combined with a comprehensive risk assessment, it allows study monitors and staff to identify and focus on data issues that present the highest risk to patient safety and/or data integrity. This eliminates the need for 100 percent source document verification, which is expensive and minimally effective in detecting and correcting data errors. Instead, cross-site data allows CRAs to find and focus their attention on higher risk problems.

Finally, risk assessment must be iterative, evolving and continuously re-evaluated. Choosing and training a team with clinical, data management and operational experience is an important step to developing a compliant risk-based assessment program.

Regulators generally agree Transcelerate's Risk Assessment Categorization Tool (RACT) works best. More advanced tools are available that combine the key functionality provided by RACT and extend it to tools that create metrics for risk indications and measure deviations against clinical results. By integrating RACT with centralized monitoring tools as well as site monitoring and issue management systems, the risk teams can configure workflows and notifications to ensure not only that deviations can be monitored almost at real-time against study data but also drive resources' action towards mitigation of known and unknown risks and corrective activities.

Bottom line: **A unified platform with proper expert support can help organizations unfamiliar with the approach develop and document compliant risk assessments.**

Pain Point: Maintaining Trial Master Files

Managing essential documentation, including the trial master file (TMF), is another compliance and efficiency challenge that can be effectively addressed with an integrated platform approach.

In today's clinical trial environment, huge volumes of regulated and unregulated information flow to and from many partners, including sponsors, sites, CROs and vendors, and across multiple trial phases. To track and manage the hundreds of thousands to millions of documents involved, systems can be proprietary legacy on-premise systems as well as off-the-shelf solutions such as DVDs and spread sheets that are typically dispersed across many locations. Such fragmented document management presents inspection readiness and operational risks including:

- Incomplete TMF or not readily accessible TMF and audit trail.

- Content quality risks such as incorrect, duplicate or not timely document filing.
- Lack of collaboration and trial oversight between CROs, sponsors, and sites due to difficulties accessing and filing essential documents.
- Internal reporting and analysis of critical trial data can be delayed, potentially missing key insights that might improve trial performance.
- Historical data from previous trials is not readily available for analysis with transformative new tools, potentially slowing advancement in clinical research and leading to wasteful duplication of efforts.

A cloud-based unified document management system can address these problems, reducing regulatory risk and accelerating clinical research. Such a system:

- Creates a "single source of truth" accessible by all trial partners and participants according to role-based access protocols.
- Links to all types of information sources, including trial EDC, statistical plans, centralized monitoring, enrollment, supply management and standard operating procedure (SOP) management documents.
- Keeps all changes current across all sites, preventing procedural errors based on out-of-date or incomplete information.
- Makes all trial information available for analysis during trials as well as after and across trials, accelerating research findings and fueling insights for further advancing clinical development.

In addition, an ideal unified TMF and document management system:

- Provides a single interface for all users.
- Includes configurable file and workflow structures.
- Can automatically populate a significant amount of the required TMF content, dramatically reducing effort required for maintaining an accessible TMF for regulatory review, reducing delay.

Bottom line: **A cloud-based unified document management system helps ensure regulatory compliance by providing timely access to all trial documentation needed to maintain trial compliance with good clinical practice and data quality and integrity standards, avoiding TMF inspection delays and reducing the risk of approval delays due to data quality issues.**

Conclusion: Achieving the Benefits of Tomorrow's Ideal Unified Clinical Trial Platform Today

Many key technologies for creating an ideal unified, integrated clinical trial platform are already in place or close to market. The capabilities such a platform offers work best when guided by a detailed plan and implemented early, even for smaller or early phase trials.

Solving the IT/platform integration problem goes a long way toward addressing other problems including:

- Ensuring compliance with regulatory requirements
- Identifying of data and performance issues early on that might delay trials
- Ensuring regulatory submission pass muster

Most importantly, by adopting a unified platform, companies can gain efficiency in trial execution and program development, while avoiding regulatory delays, thus accelerating the availability of life-saving therapies. Finding an experienced partner to provide, help customize, and implement a comprehensive solution may help you reap these substantial benefits today.

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