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Beyond Compliance:

Regulated Content Management and the Digital Revolution

Introduction

Globalization of clinical trials, tightening regulatory requirements, a more competitive and collaborative commercial environment, and an increasingly mobile workforce requires life-sciences companies to standardize and improve regulated content management processes to ensure information is shared with the right people at the right time.

Digitization, enabled by cloud computing, opens the way for life sciences companies to streamline the way they work and the way they gather, store, and share content. Simplicity, efficiency, and harmonization are keys to sustainable and successful content management. However, the complex nature of the clinical trial process means that sponsor companies and CROs have multiple technology solutions in play to handle activities such as working with sites, recruiting patients, monitoring trial data, managing consent forms, and interfacing with the regulators.

A single platform that integrates all those activities, and more, while enabling functions to be adopted as needed can eliminate many of the complexities. The platform needs to combine a regulated content management solution with tools that are familiar, easy to use, and intuitive to users who access the system every day. And the platform must be easy and quick to implement. These are priorities for busy CIOs, who must ensure their user community is confident that compliance is maintained, therefore demonstrating value to the organization.

Unfortunately, many CIOs feel there is still a long way to go to achieve their goals. A Gartner report found that nearly 40% of CIOs are on a bimodal journey — building platforms that enable better digital performance while still working with their old systems — meaning more than 60% either have no digital initiatives, are considering one, or are just starting to design one.[1]

This paper explores issues that impact the way regulated content is managed and used and what CIOs can do to meet the needs of their companies.

Big-Picture Approach

Leveraging eTMF solutions beyond compliance

- Improve clinical trial operational efficiency and quality
- Improve audit and inspection readiness
- Leverage data for insights with centralized monitoring
- Automate global tracking and reporting functions
- Accelerate faster study start-up as well as overall timelines
- Remove some of the costs from clinical trials

Source: Electronic Trial Master File Strategy Alignment, Gartner

State of the Industry

The life-sciences industry is being pushed in all directions by change and heightened demands, increasing the need for companies to strategically manage content.

Pressures are coming from both regulatory and business demands, pushing decision makers to find solutions that address the increasing complexity their organizations face while remaining compliant with different global regulations.

Under good clinical practice (GCP) guidelines, companies must adhere to international standards for "designing, conducting, recording and reporting trials that involve the participation of human subjects.[2]" With this in mind, companies, organizations, and regulatory authorities have been moving toward an electronic trial master file (eTMF). This has been supported by the DIA Trial Master File Reference Model (version 3.0), which provides standardized taxonomy and metadata and outlines a reference definition of TMF content using standard nomenclature. Gartner has stated that eTMF solutions should enable companies to improve their clinical trial efficiency and quality, fully prepare them for audits, allow them to leverage data for insights through centralized monitoring, automate global tracking and reporting, speed up study start-up and timelines, and reduce costs.[3]

There are also significant commercial needs that are spurring CIOs to assess a more digitized, centralized approach to regulaed content management (RCM). They must seek ways to address content consolidation around product portfolios; manage affiliate and cross-functional collaboration and data sharing; monitor external collaborations and CRO co-sponsoring models (such as multiple sponsors running the trial); address pressures on margins; and navigate other mega trends in healthcare. In addition to addressing issues around compliance, CIOs must engage other functional stakeholders, and select vendors whose platforms and skills align with the company's objectives.

Managing Regulated Content

Until more recently, life sciences companies faced difficult choices when adopting a RCM solution. Most systems were either resource-intensive, off-the-shelf solutions; costly and complex in-house solutions; or paper-based solutions that might include tracking of content via Excel spreadsheets and other non-specific tools.

Users view off-the-shelf solutions as painful necessities rather than invaluable tools because the underlying technology is dated and not adapted to familiar operating systems.

And many homegrown solutions carry compliance risks, either because they are not designed to manage regulated content or because they are so complicated that users aren't deploying them. Homegrown solutions also depend on all users doing the right thing at the right time, all the time, or risk unfavorable audit findings from the regulatory authorities.

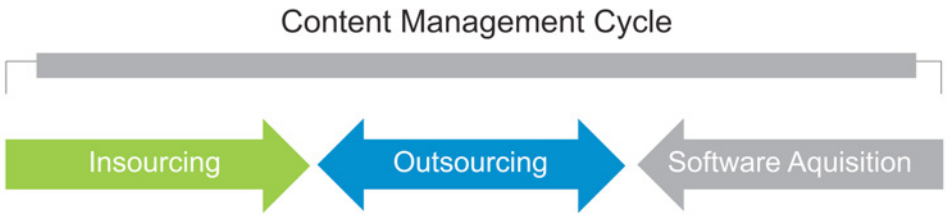
Paper-based solutions are cumbersome and expensive and no longer relate to the ongoing digitization of clinical trials.

To overcome these challenges, increasingly, CIOs have added non-regulated solutions to systems to enable cross-functional and external collaboration, creating additional risks associated with version control and audit trails. A further challenge is that many of these solutions are inflexible and can't be easily updated in response to changing regulatory and business environments.

Because managing regulatory content is often so complicated, companies are engaging dedicated document productivity departments to manage the paperwork associated with clinical trials.

Balancing Options

In response to the challenges with content management, technology decision makers, like those in many other industries, have gone through the insource-to-outsource-to-software cycle.



Many sponsors outsource parts of the regulated content management, such as eTMF, to clinical research organizations (CROs). While this can reduce costs and resources associated with managing eTMF, it can also result in loss of control and visibility into the content.

Furthermore, because the sponsor company must retain oversight of artifacts within the eTMF, they need a process and structure to manage this oversight. For example, the statistical analysis plan (SAP), which is one of the artifacts to be maintained in the eTMF, is typically handled by biostatisticians, but management of eTMF is typically the responsibility of clinical operations and much of the documentation comes from the data management function. Bringing in a CRO means four different parties are involved. And every time there is an adaptive trial design change, for example, the SAP changes, it must be updated in the eTMF. It's imperative that all those parties collaborate and that their processes are in sync, which is resource intensive and potentially risky in terms of compliance.

Using a CRO's eTMF solution creates additional complexities because documents are managed in multiple systems. This can be an issue during an inspection because regulators require the eTMF documents to be readily available.

Gartner warns that outsourcing eTMF to CROs or service providers also limits the sponsor's ability to access useful information for innovation purposes.[4]

As outsourcing will continue to play an integral role in clinical research, it's imperative that sponsors are clear about the processes and responsibilities of each party — CROs, investigators, and the functional areas within the company.

The software adoption cycle is another common business process. Most large life sciences companies have tended to use legacy enterprise content management (ECM) solutions, either by tailoring the ECM to their needs or acquiring commercial off-the-shelf (COTS) solutions to manage their regulated content. But product ratings conducted among pharmaceutical CIOs have found that legacy ECM solutions have very low user satisfaction ratings. And because these solutions are difficult to use, CIOs are forced to find creative solutions, such as deploying different platforms for their regulated and unregulated content. The problem is this requires users to switch from one system to another for different trials.

Some companies are considering cloud-based solutions as they seek to leverage next-generation technologies, improve scalability, and derive cost efficiencies. In fact, several sponsors have implemented a cloud-based collaboration platform (such as SharePoint or Google Drive) to work together on eTMF and share SOPs. But the more generic enterprise solutions often don't comply with 21 CFR Part 11 requirements around audit trails and electronic signatures, which makes it impossible to enforce proper controls.

These challenges demonstrate the pressing need for a validated, regulated environment to manage regulated documents (such as eTMF and SOPs) combined with technology simplicity so users can work in the same system for regulated and non-regulated documents.

Adapting to the Digital Era

The digital era creates opportunities for CIOs to improve business processes. But first, they must step back and understand why and how users access a regulated content management solution.

A regulated content management solution lets users: 1) initiate, participate in, or complete a task; 2) find content; and 3) follow up on an activity or find out what is happening with a workflow. Clinical or regulatory operations personnel typically aren't doing these activities all the time, meaning most RCM users access the systems intermittently.

Today, users expect the same ease of use in enterprise software as they have with consumer software. In fact, if users can't quickly work out how to use a solution or if mobility isn't easily integrated into cloud capabilities, there's a high risk they won't use the solution, which can lead to compliance issues. For example, managers unable to access a document from a mobile device might assign someone in the office to access or do the work for them, which is a violation.

Therefore, RCM solutions need to be user-friendly while ensuring compliance. The emphasis on ease-of-use is important for CIOs, with 29% of respondents to the ISR survey stressing they would like to see improvements to the ease-of-use for eTMF solutions.

Mobility is another important business consideration. Executives increasingly work remotely using their mobile devices. They need to be able to access and sign off on documents through those devices easily and securely. They need to be able to search for documents from their mobile devices and know where an activity is in the workflow.

Collaboration is yet an additional business driver. A single platform that allows for collaboration, while embracing technology and compliance makes it possible to consolidate separate platforms within different parts of the organization. As important as integration is with other solutions, including with competitor products, users also need to be able to achieve single sign-on based on open standards.

Barriers to bringing in more efficient technologies include the fact that many companies have legacy systems currently in place and CIOs haven't been able to justify the cost to implement a change to senior management. There are, however, powerful business arguments to be made for RCM efficiency: an automated eTMF has the potential to be transformative to the bottom line because it streamlines processes, speeds the clinical trial process, and leads to more timely new product applications.

The Way Forward

In this new digital environment, CIOs and life sciences records management professionals must focus on current and future needs when considering content management solutions. They must ensure the business can quickly adapt to changing requirements, is audit-ready, and can go beyond compliance to support broader business needs — from reducing implementation costs to addressing user satisfaction and systems use.

An out-of-the-box solution with pre-configured functionality and workflows is a cost-effective option that allows companies to move forward without the complexities that go with having to configure a customized solution. Pre-configured solutions are also faster to implement, ensuring user support and reducing the risk of solution obsolescence.

Analysts stress the value of cloud-based solutions to enable synergies with other systems across clinical, regulatory, and R&D functions, and allow various stakeholders to adapt processes to the solution. Such a solution needs to deliver the compliance and security required by life sciences companies; it must carefully manage how content is accessed, including clear segregation of roles and responsibilities in accordance with GCP ICH E6; it must give key stakeholders visibility into any updates; and it must be built with the user experience in mind.

Given the dynamic digital environment in which the industry now operates, a solution additionally must be geared to adapt to the latest developments, such as the Internet of Things and machine learning.

Medidata recognized that many of these key requirements were missing with existing solutions, and in response developed the Medidata Regulated Content Management™ (RCM) platform with solutions that include Medidata eTMF, Medidata RCM Archive, and Medidata SOP Management.

The cloud-based Medidata RCM tool is comprehensively geared for the digital regulatory environment with a mobile interface that enables seamless collaboration. Unified within the Medidata Clinical Cloud, users can create, store, view, search, edit, approve, and jointly work on an entire eTMF life cycle (or on other regulated content such as SOPs) in a single application with cutting-edge user-experience capabilities. Because the platform has been integrated with Box, the leader in cloud content management, users can search both regulated and non-regulated content in one platform. Electronic signatures and audit trails eliminate the compliance risks posed by homegrown solutions. And ease-of-use ensures stakeholders adhere to processes at all times, thereby driving compliance. Medidata RCM allows users to create digital versions of documents, ensuring version control, centralizing content, and making it easy to search for and find regulated and non-regulated documents.

Medidata RCM can be implemented easily, which reduces cost and requires fewer internal resources, allowing day-to-day activities to proceed without interruption. This is an important business differentiator for CIOs, who must demonstrate business and cost-efficiency.

Automation is also crucial for business efficiency and simplifies how crucial trial master file requirements are managed. For example, the DIA V3 Reference Model includes 197 artifacts that are "core," and managing these artifacts is time-consuming. The Medidata RCM platform — which combines systems that can hold a "single source of truth" like Medidata CTMS® and the Strategic Monitoring Suite, Medidata Balance®, iMedidata®, Medidata RaveX®, SOP Management, Enroll, ePRO, and Medidata Study Design Optimization Service® — has the potential to automatically manage as many as 80 of those artifacts, which reduces the cycle time and associated costs.

Another example of how Medidata RCM can improve efficiency is that it allows an investigator to upload his or her CV to the sponsors' EDC system as part of the user creation process. This information can be automatically shared across all the study sites where the investigator is working. This level of automation helps to accelerate study start-ups, removes inefficiencies, cuts costs, and ultimately, speeds the development process.

Medidata's RCM solution also integrates with other solutions, including Box, Google Drive, Okta — for single sign-on, and many others. Compatibility with multiple systems removes the need to integrate multiple solutions from different vendors, eliminating the need for multiple commercial and service level agreements, reducing the risk of complexities arising.

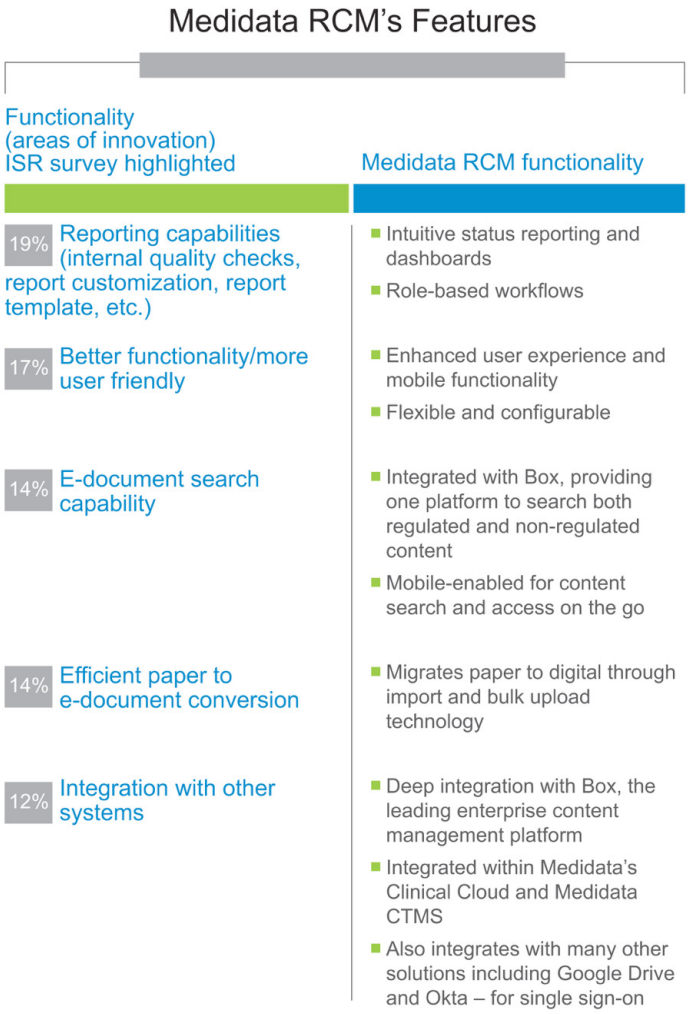
At the same time, companies must build in the appropriate processes and governance models to ensure users have the training and skills needed. These processes are based on best practices, and since best practices constantly evolve as the industry evolves, technology solutions must also adapt.

Beyond ensuring compliance, Medidata RCM helps companies derive intelligence into what is happening within the business — another crucial differentiator — and makes it easy for users to gain important insights and collaborate across the enterprise and with partners.

CIOs can take advantage of the many business benefits being driven by digital transformation. Processes are being streamlined across the entire clinical ecosystem by the adoption of new flexible and digital tools, which will lead to faster cycle times, including quicker study start-ups.

Digital processes eliminate time-consuming manual and inconsistent processes and let companies adopt a task-based approach to managing documents. For example, dashboards let users see how many documents are complete and alerts prompt users to update documents.

Another priority for CIOs is cost. Many heavyweight, validated solutions are extremely expensive, costing in the region of $200 to $580 per user, per month. On the other side of the spectrum, non-validated content management solutions cost as little as $10 per user. There is clearly a need for a cost-efficient solution that is also validated and compliant.



Case Study: Medidata RCM Delivers Compliance Assurance and Beyond to a Quality & Regulatory Team

Zosano Pharma, an emerging pharmaceutical company focused on the central nervous system, faced a challenge many life sciences companies experience: it needed a unified system and process to enable users to access regulated and non-regulated content.

The company had been using a file server system with folders containing PDF documents that needed to be tracked and traced manually. Zosano turned to Medidata to help it deal with its resource-intensive processes.

Medidata RCM, which was deployed in just six weeks, provides Zosano Pharma with a unified solution for standard operating procedure (SOP) management, for both regulated and non-regulated content, that is cost-effective and quickly deployable. The solution provides Zosano with tools for workflow management that help create, edit, and approve content with read and acknowledge capabilities, including reviewing documents via mobile platforms. Zosano introduced iPads equipped with Medidata RCM to their manufacturing area to facilitate training and familiarization with and access to SOPs.

Since Medidata RCM is fully integrated with Box, the leading enterprise content management platform, users can search both platforms for regulated and non-regulated content in one pass. An intuitive interface meant there was no need for additional training. Users can now search for all regulated and non-regulated content from one place, and review and approve content from anywhere, anytime with mobile accessibility.

The adoption of Medidata RCM has led to increased compliance and familiarity with documentation, and fewer regulatory risks. In addition, because users no longer waste time tracking down and indexing documents, productivity has increased allowing regulatory teams to focus on innovation and accelerated time to commercialization.

Conclusion

Compliance in the clinical world is obligatory, and companies need to know that their solution provider has fundamental experience and knowledge of the highly regulated clinical environment. At the same time, digitization has changed the way people expect to work and has opened the door to greater efficiencies and enhanced collaboration. The future lies in a next-generation approach to regulated content management, one that embraces the user experience, that facilitates collaboration, that leverages compliant cloud capabilities for greater efficiency and cost effectiveness, and that has the agility to change and innovate in keeping with a fast-moving digital environment.

Integral to future innovation will be machine learning and artificial intelligence, including creating user-specific search functions that learn and adapt to each user. Several surveys have found that workers spend anywhere from a day per week to 30% of their day searching for information.[5] By incorporating AI-enabled capabilities that learn users' preferences, progressive solutions such as Medidata RCM will speed up the clinical process from study start-up to data sharing, and ultimately, bringing products to market and to patients in need.

About Medidata

Medidata is reinventing global drug and medical device development by creating the industry's leading cloud-based solutions for clinical research. Through our advanced applications and intelligent data analytics, Medidata helps advance the scientific goals of life sciences customers worldwide, including more than 850 global pharmaceutical companies, innovative biotech, diagnostic and device firms, leading academic medical centers, and contract research organizations.

The Medidata Clinical Cloud® brings a new level of quality and efficiency to clinical trials that empower our customers to make more informed decisions earlier and faster. Our unparalleled clinical trial data assets provide deep insights that pave the way for future growth. The Medidata Clinical Cloud is the primary technology solution powering clinical trials for 18 of the world's top 25 global pharmaceutical companies and is used by 18 of the top 25 medical device developers—from study design and planning through execution, management and reporting.

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Endnotes

1. Building the Digital Platform: Insights From the 2016 Gartner CIO Agenda Report, Gartner, 2016

2. E6(R2) Good Clinical Practice, FDA, June 2015

3. Electronic Trial Master File Strategy Alignment, Michael Shanler, April 2016, Gartner

4. Electronic Trial Master File Strategy Alignment

5. Various Survey Statistics: Workers Spend Too Much Time Searching for Information, Cottrill Research