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WHITE PAPER

Digital technologies for clinical trials:

Toward faster time to market

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Introduction

Most life sciences organizations today are well on their way toward a new sophistication in their use of digital technologies. Mobile, cloud computing, real-time analytics, Artificial Intelligence, wearable devices—these are quickly becoming ubiquitous, ready to become a reality in the life sciences landscape. And in truth, the demands of globalization, market turbulence, competitive pressures and even user expectations are requiring organizations to capitalize on the enormous advantages inherent in digital transformation. When the organization sets digital transformation as a strategic objective, technology can deliver in tangible, quantifiable ways. For example, mobile and wearable devices can make a huge difference in the ability to recruit patients for a clinical trial by conveniently fitting touch points into their lifestyle, while significantly reducing the investigator workload.

In short, the industry is poised for a true breakthrough in the use of technology to support its mission and mitigate their costs, as well. Central to that mission is the efficacy of the clinical trial process, and by extension, to managing the documentation that supports it. Documentation, after all, is the critical common thread, and its completeness, quality, and timeliness are essential for efficiency, safety, and compliance.

Clinical operations departments are making great strides on initiatives to digitize content with electronic versus paper trial master file (TMF) documents. According to 2014 Drug Information Association (DIA) findings, they are cutting the use of paper for most or all TMF documents, typically from 41 percent to 28 percent.

Using information as a strategic asset

Yet an overdependence on paper-based TMF continues to impede true digital transformation. Most clinical operations departments are not yet taking full advantage of solutions that can enable them to use information as a strategic asset that supports real-time, actionable insights for decision-making. For example, they have limited capabilities for tracking trial progress, typically relying on spreadsheets that require constant manual updates. They should be able to take advantage of tools to generate reports that can help detect areas for improvement. Are particular sites consistently problematic, requiring additional oversight? Are there certain investigators frequently late in their submissions who might benefit from personal outreach? And executives should be able to check into trial progress at a higher level, using simple and intuitive tools to create on-the-fly reports that are meaningful to them.

Seamless linking of regulated content across domains

Accurate, up-to-date information, available when needed, is essential to timely reporting and analysis that can support sound decision-making. When information is gathered and shared across many constituents, however, achieving this objective can be a real challenge.

Despite a diverse range of tools to help analyze, interpret, and share information, clinical operations typically lack a coordinated means of linking and sharing documentation across domains, divisions, and external partners. As a consequence, they are not yet delivering on user expectations for timely access to content anytime, anywhere.

Meanwhile, many of their counterparts in the regulatory submissions area are advancing quickly toward an automated way of handling and communicating change throughout the drug lifecycle. The idea is to provide access to documents from various functional areas—regulatory, clinical, manufacturing—and a single source of truth across the extended enterprise.

They are accomplishing this via a unified enterprise-wide repository for managing regulated content that seamlessly links the approved, current version of the document in the clinical system, for example, directly to the regulatory solution. Having ready, shared access to current documentation can have real business impact, such as helping to accelerate regulatory approval and study startup.

Similar to regulatory, clinical operations have the same requirements for a shared source of content to communicate essential information—to efficiently plan, collect, and properly maintain clinical trial documentation. They need to control and synchronize study artifacts, track progress in clinical trial documentation, and ensure fast, secure access to documentation both during and after trials.

Supporting collaboration for complete, compliant documentation

Clinical trial processes, like regulatory submissions, involve countless internal and external stakeholders, operating across multiple regions around the world. These include contract research organizations (CROs), which play a vital role in clinical trials. The coordination necessary to collect and maintain vast numbers of trial documents, and to keep track of required documents in the context of the trial's progress, is a monumental task.

Yet there is no room for missteps: Incomplete documentation leads to trial delays and potentially, risk of an incomplete audit trail and associated compliance implications. Throughout the clinical trial, which can span many years, sponsors must be able to produce documentation on demand for inspectors. Ultimately, it is the sponsor who bears responsibility for the conduct of the trial and for compliance.

Ensuring ease of use and minimal training

It is also the sponsor who has the most to gain from efficient processes and timely approvals—a direct corollary to faster time to market. Efficiency depends on people; the faster they can work, the faster things get done. This leads to another essential driver for digital transformation. Users today are sophisticated and tech-savvy, and they expect mobile access and a modern, consumer-like experience in a professional environment that requires minimal training.

Let's take a look at how clinical operations can take advantage of advanced digital technologies in their domain, and what to consider when moving forward.

Before the trial: Accelerating startup

It's time to move past spreadsheets, faxes, and email for sharing and submitting critical documents: consent forms, indemnity contracts, investigator CVs, and everything else that comprises the TMF. This is a recipe for inefficiency, errors, and user frustration. Today's solutions take content digitization light-years further through a fully electronic TMF that enables searching, linking, sharing, collaborating, reporting, and managing the content across multiple sites and stakeholders. The best solutions have at their core a unified document repository that enables centralized control to ensure a single source of accurate documentation.

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Streamlining document creation and approval

The authoring process can be streamlined dramatically with the use of sophisticated tools.

By leveraging industry-standard dictionaries, taxonomies, and object models with a template-based authoring process, organizations can boost author productivity and collaboration. Authors can use a predefined inventory of industry-standard documents that are automatically linked to templates compliant with International Committee on Harmonization-Common Technical Documents (ICH-CTD), adding efficiency to submission-ready document creation.

These templates, combined with workflow-driven processes, can guide authors through the content development process and push documents to the right contributors and reviewers at just the right time. Multiple contributors can make edits, changes, and annotations to documents simultaneously for much faster document creation and review. Thanks to the unified content repository, they can easily share with regulatory for submission content such as a clinical study report.

The result: faster completion of regulatory submissions to the Institutional Review Board (IRB) for approval, and an earlier start date for the trial.

During the trial: Improving transparency

After the trial is approved, the trial setup begins with recruitment of sites, investigators, and patients. Often, trials are starting at different times in different countries and conducted concurrently; yet all activities and documents must be properly coordinated.

Today's eTMF solutions make it easy for sponsors to collect and provide access to relevant trial documentation from CROs and sites by integrating compliance and security models to enable controlled access. When the solution incorporates an investigator portal, investigators can directly view key documents, upload any that are missing, and participate in workflows, including signing documents with Part 11–compliant electronic signatures.

eTMF solutions purpose-built to support the clinical trial process can streamline and automate file planning at the product, trial, country, and site level. What is important here is that milestones are applied to registration forms and artifacts in the file plan. The milestones are tracked for the trial as well as for individual countries and sites—essentially providing real-time insight into the progress of trial document collection.

A best practice is a solution with pre-configured, granular placeholders that reflect what TMF document is required, what's missing and what's completed, based not only on the trial status, but also on the progress of the countries and sites. Color-coded icons identify the state of the placeholder, providing a quick visual indicator of document collection status. Essentially, the solution creates a visual status report to help manage timely completion. When a missing document is entered—for example, an investigator's CV—it can be synchronized with the placeholder, seamlessly ingested into the eTMF and shown "green" for complete. Automatic quality checks detect mismatches when the wrong document is entered, for instance, or an image is unclear, or a document is missing a sign-off.

Simplifying change notifications

Throughout the course of the trial, changes inevitably occur that must be captured in the TMF and communicated across domains and systems of record. An adverse event will trigger a safety notice, for example, linked to the pharmacovigilance system. Should a principal investigator leave the project or if an amendment to a protocol occurs, an eTMF simplifies the effort required to route the amendment and supporting documents for regulatory approval. And with an integrated content repository, all of these notifications are linked to key stakeholders of the documents.

Facilitating controlled access through the cloud

The availability of cloud solutions adds another dimension to the concept of digital transformation. With a public cloud model, a single-tenant application gives users easy, controlled access to content anytime, anywhere through the internet for secure exchange of information with both internal and external stakeholders. Another possibility is to choose a private or hybrid cloud model to suit the organization's individual needs. In any case, cloud deployment can enable organizations to get up and running in weeks, with no hardware to install and no demands for system administration and maintenance. That equates to reduced costs and a lightened workload for IT.

Boosting user adoption, productivity, and compliance

Solutions purpose-built for life sciences offer role-based user interfaces tailored for the job at hand, with a modern, consumer-like experience, essential to avoiding the costs and time involved in training CROs and investigators. Ease of use leads to fast adoption and ready conformance, and reduces compliance risk. People are much less inclined to bypass controls—reverting to email, for example—when their user interface helps them accomplish their tasks. Equally important, the solution should include built-in access controls to protect proprietary information. Access controls ensure that only authorized users can access and navigate documents such as consent forms, indemnity contracts and investigator CVs, or that inspectors can view only finalized documents relevant for auditing. CROs can see only the product trials on which they are working.

After the trial: Cost-effective, accessible archiving

After the trial, the TMF must be transferred from CRO to sponsor, which is much simpler when the file is in fully electronic format, and also ensures searchability and access required for compliance.

The eTMF must live on long after the trial is completed, given regulatory requirements that documents be retained and accessible for years after trial completion. Digital archiving solutions manage structured and unstructured information in a single application, accessible and functional without the need to refer to the application that generated the information. The result is preservation, maintenance, and control of long-term access to the archived eTMF, providing authorized users with a comprehensive view.

OpenText™ Documentum™ for Life Sciences

Documentum for Life Sciences breaks down information silos to transform how organizations access, manage, and share regulated content. Available on-premises or in the cloud, the solution is designed to offer you choice and flexibility with the ultimate goal of unifying and streamlining processes while reducing complexity.

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For clinical trials, OpenText™ Documentum™ for eTMF helps effectively plan, collect, track, and maintain essential GCP-compliant clinical trial documentation.

The fully integrated solution includes the following:

- OpenText™ Documentum™ for Research and Development: Manage the creation, review, and approval of regulatory submission documentation
- OpenText™ Documentum™ Submission Store and View: Store and manage published submissions in a controlled environment together with related correspondence, while improving security and compliance
- OpenText™ Documentum™ for Quality and Manufacturing: Control quality and manufacturing documents, automate workflows, and ensure GMP compliance

For more than 25 years, OpenText has helped life sciences organizations meet compliance requirements, increase productivity, and securely collaborate across the extended enterprise. For additional information about Documentum for Life Sciences solutions, please visit www.opentext.com.

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