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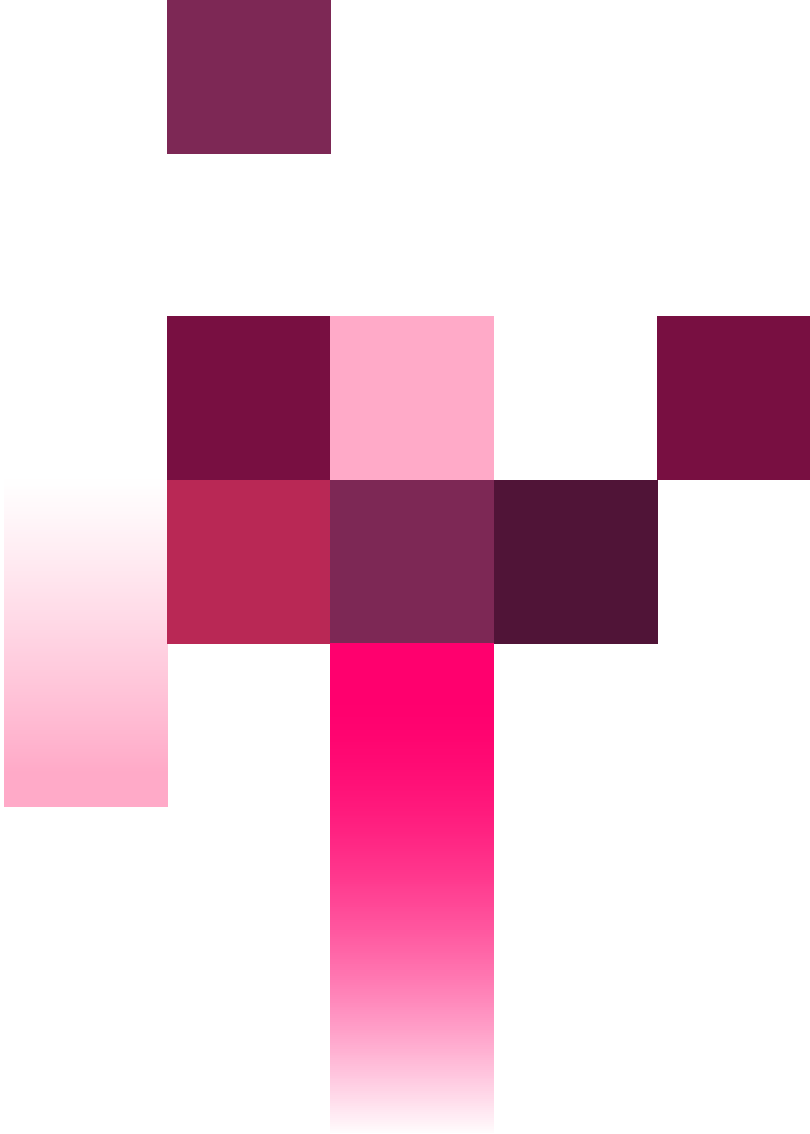

CRO governance and collaboration in clinical trials using CTMS

September 2020

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Executive summary

Increased outsourcing and globalization continue to expand the number of CROs and specialty outsourcing specialists participating in a single clinical trial. While outsourcing has brought expertise and cost reductions, the practice has changed team composition, adding more layers of complexity in managing data and clinical trials themselves. Sponsors recognize a need for management and governance tools supportive of collaboration to realize the strategic benefits of outsourcing.

Activities once performed internally, such as trial design, data management, monitoring, site management, payments and clinical review oversight, today are outsourced to CROs and external providers from a wide geographic region.

While outsourcing has brought expertise and cost reductions in a variety of areas, the practice has changed team composition, adding more layers of complexity in managing data and clinical trials themselves. Reporting, communications and data sharing and management present some of the greatest challenges. Inadequately addressed impacts may be felt in areas ranging from operations to regulatory compliance.

This white paper focuses on overcoming these challenges using CTMS to provide a solution for:

CRO governance and collaboration

A way to successfully monitor and govern providers and manage activities consistently across trials while strengthening collaborative ties to realize the strategic value in outsourcing.

Data management

Centralizing logistical and operational data from disparate sources to enable streamlined management and enhanced control.

Visibility and reporting

Consolidation of multiple reports/exports from a variety of formats and timelines into a central system for visibility and advanced reporting.

Compliance and traceability

A means of ensuring data and activities are auditable for accuracy and completeness and in compliance with regulatory requirements.

Situation overview

Clinical trial activities that traditionally took place in-house have shifted off site to CROs and other specialty providers from around the globe with the promise of speed, quality and cost advantages. However outsourcing can create more work to manage a network of providers and surrounding processes. This becomes especially apparent when working with data in multiple formats and on different timelines. Integration is key.

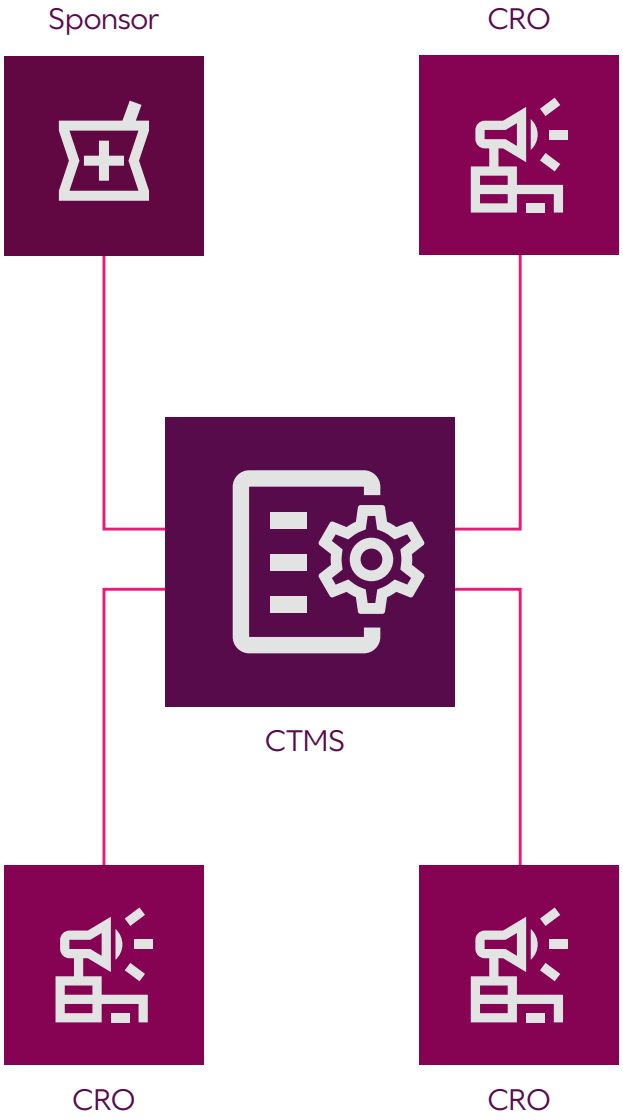
Sponsors must have the ability to import data from a variety of internal and external sources — to standardize, normalize and gain control over the data and, ultimately, their studies.

Real-life scenarios

The uptick in outsourcing has left many sponsors looking for a way to manage activities consistently across all of their providers and research programs. Below are real-life examples of sponsors who've sought a solution in CTMS

- Two scenarios, same CTMS solution: One sponsor is working with nearly a dozen CROs.
- Another engages specialty CROs, each operating in a different country to accomplish different functions on a single study.
- A large global pharma uses CTMS to help it manage and govern its many external sources.
- A virtual company with limited internal experts engages many external partners and operates in a large geographic footprint. CTMS supports this unique business model.
- Enterprise CTMS is used by this sponsor to manage multiple CROs in a global research environment. Visibility into the performance of specialty providers managing different regions is a necessity for this sponsor.

In all of these scenarios, CTMS provides many CROs access to the same data. The system automatically associates multiple CROs and other providers classified by their association with a study. Data is siloed so that CROs cannot see others' data.



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Many challenges, one solution

What was once a straight line of management has been disrupted by outsourcing, touching activities critical to clinical trial quality. Below are some of the most common challenges and ways CTMS can be used to overcome them.

Multiple partners, multiple data sources

Consolidating information from fragmented sources where sponsors can see operational study data in one place is essential. Among the key considerations are the ability to import data in batch, run reports and perform in-depth analysis. The advanced CTMS system enables sponsors to see time-sensitive items surrounding dates, such as days to site activation. A consolidated view enables sponsors to manage and act on data from all sources in an easier and more cost-effective way. No longer is data a one-way street. CTMS should enable easy data sharing among permissioned parties, especially useful where one CRO manages payments and another manages monitoring.

Consolidating disparate data

Sponsors must be certain all of their data feeds into a central location where the study can be seen as whole. It is advantageous to have one central data model that enables the sponsor to report on and make decisions. Today's leading CTMS products are designed to perform data consolidation activities in highly automated ways (e.g. migration, integration, batch import). Without automation, consolidation of diverse data to run analytics on a cross-study or single-study basis is a painful process.

Data exchange

Ease of getting data in and out of a CTMS is an important consideration. A Microsoft Office-Smart CTMS is a streamlined alternative to legacy systems where data exchange can be unnecessarily complicated. This model enables universal translation through SharePoint, making it simple to import thousands of fields quickly and expose the data in any Microsoft format.

Hub

One of the mission-critical functions of CTMS is a data repository for all of the operational trial data needed to manage a study, including dates and milestone status information.

Some sponsors continue to use the fallback method of obtaining CRO summary data, which is then consolidated for reporting purposes. A growing number of organizations however recognize the value of using CTMS as a data hub with the added benefit of advanced analytics and metrics as well as cross-study and country-level analytical reporting capabilities.

Monitoring sourcing models

Ideally, the CTMS will account for differences in monitoring sourcing models, whether the function is performed using internal or external resources, or if a mixed monitoring model is used.

MVR

The Monitor Visit Report (MVR) is an important piece of the monitoring puzzle. It too should be flexible to readily accommodate different monitoring sourcing scenarios.

This allows sponsors to view activity status and maintain control of the monitoring process. Easy translation, reporting and metrics are also critical.

Without a CTMS designed to accommodate complexities that come with using a mixed outsourcing model, it can be difficult to achieve success.

When different CROs use their own MVRs, the sponsor ends up with a patchwork of reports. This situation is readily solved by standardizing on one MVR format, now available in an integrated CTMS/MVR solution.

SAE/SUSAR tracking

It is becoming increasingly more common for one CRO to perform monitoring and another to manage serious adverse events (SAEs)/suspected unexpected serious adverse reactions (SUSARs). Regardless of who performs monitoring, accountability falls upon the shoulders of the sponsor. While CTMS is not a pharmacovigilance system, it should support SAE/SUSAR tracking and allow easy data import from other systems, providing the sponsor a continually updated status.

Standardized reporting

Standardized reporting — on demand when and how sponsors want it — is now available in leading CTMS products. This provides a superior alternative to extracting CRO data and rolling it up into sponsors' own reports. The old method presented limitations and failed to solve the root problem — the most significant being an inability to manage the data all in one place.

Communication

A central location is needed to communicate tasks with clinical research associates (CRAs) and other study personnel to keep workflows progressing. CTMS connects all of the moving parts of international trials and the various participants by removing communication barriers and facilitating collaboration. This is a better alternative to emails, which can be easily lost, and ad hoc communication that lacks workflow triggers and accountability.

Visibility into CRO performance and comparative tracking

Without visibility into provider performance, study quality is put at risk. Sponsors now have the ability to use CTMS to track CROs at the site, site group (region/country) and study levels. This allows comparison of CRO performance metrics. CTMS can further broaden visibility by adding information such as site initiation and enrollment projections.

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Master milestone tracking

The ability to track milestones rolled up at the study and program levels improves control and governance. CTMS can provide performance data across multiple CROs and study sites for big picture visibility into timelines and status. This enables sponsors to spot issues that are brewing and take proactive corrective action. Master milestone tracking makes it easier to manage multiple providers and allows sponsors to see CROs performance relative to one another. In the most advanced CTMS, information is bi-directional, keeping sponsors informed of delays and other issues. The ability to see across all outsourcing partners and track original, modified and actual milestone dates as well as status across studies, regions and sites brings tremendous value in terms of overall study management and governance.

Tailored views and privacy

CTMS must be designed to ensure that the correct data — and nothing more — is exposed to the intended party. Sponsors are now able to give outsourcing partners access to CTMS to complete their respective assignments. Data exchange, monitoring and payment processing are some of the most frequent activities accomplished this way.

Flexible and user-tailored data views controlled through permissioning allow individual users to only see what they need. Permissioning assigned by region for instance, is available in a Microsoft Office-Smart CTMS. Leveraging SharePoint enables many different users to access data for their specific needs.

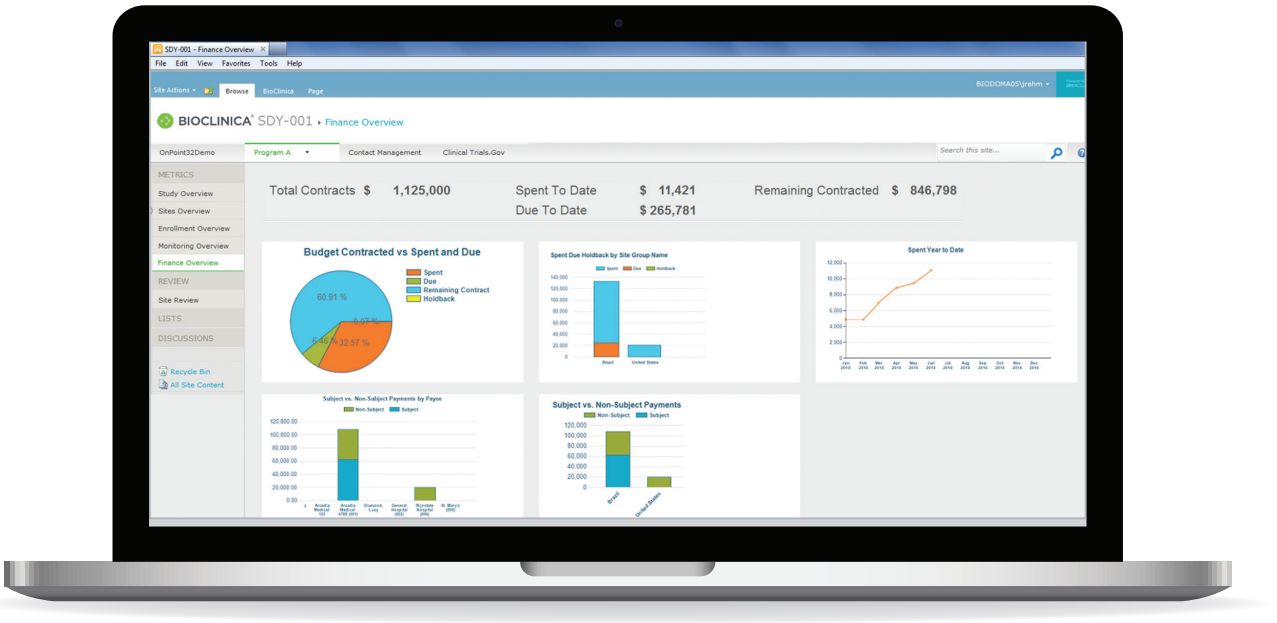
Payments and invoicing

Without easy data exchange across systems, from the electronic data capture (EDC) system to the payment management system for example, burdens may be introduced in managing the process. This can slow payments and create friction with sites, a common problem when systems are hosted by different organizations.

When it comes to activities such as payments and invoicing, data mapping from external systems should be seamless. A highly automated CTMS allows easy importing of data from multiple sources so that it can be normalized and easily pushed through the payment module. Having all information in a single repository expedites invoicing and payment processing, making for both happier outsourcing partners and sites.

The solution

CTMS advances bring a new level of oversight and proactive study management with tools supporting successful outsourcing.



CTMS checklist

When evaluating CTMS as a tool for CRO governance and collaboration, be sure to carefully examine system capabilities including:

- Ease of getting data into CTMS from CRO and other provider systems.
- Visibility into CROs and their performance (Are sponsors able to see who manages a region and/or sites? Can performance metrics be extracted?).
- Ability to get performance metrics showing how well CROs are doing in fulfilling their Service Level Agreements (SLAs).
- Flexibility to accommodate clinical trial operations specific to each trial.
- Strength as a hub to provide a consolidated view of the data within a single repository.
- Degree of automation to efficiently and quickly handle vast amounts of data.
- How different monitoring outsourcing scenarios are supported.
- Presence of an integrated MVR.
- Method of support for SAE tracking.
- The robustness of on-demand reporting.
- Provision of master milestone tracking.
- Handling of CTMS access and privacy.
- Method of permissioning.

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Key benefits of CTMS in outsourcing

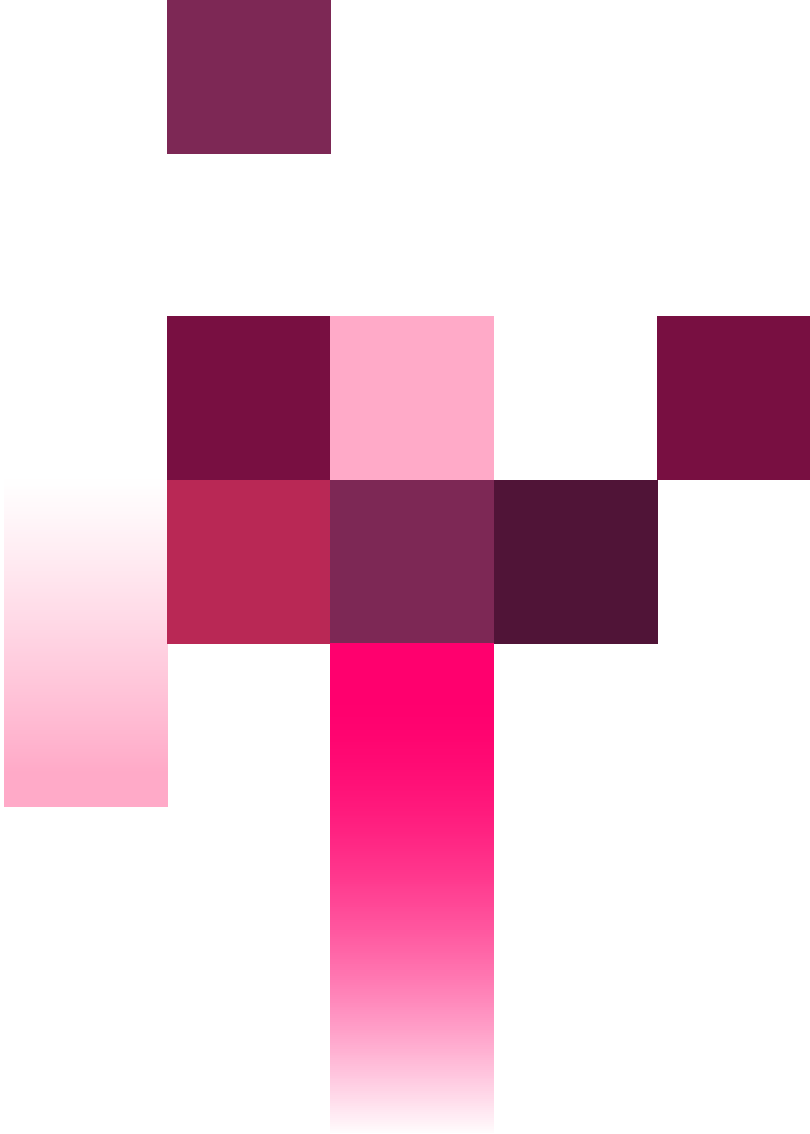
Some of the potential benefits of utilizing CTMS for CRO governance and collaboration are:

- Centralizes operational study data for enhanced control.
- Bridges the gap and strengthens relationships between sponsors and contract organizations.
- Provides insight, not merely oversight.
- Builds collaborative relationships for mutual benefit.
- Enhances communication across the trial lifecycle.
- Eases sharing of information and priorities.
- Provides master milestone tracking rolled up to the program and/or enterprise level, improving transparency.
- Provides actionable alerts to keep studies on track (e.g. enrollment metrics and analytics).
- Enables tracking and monitoring of CRO performance at site, region and study level.
- Streamlines and accelerates issue identification and remediation (e.g. cost per subject exceeded, milestones unmet, monitoring delays).
- Allows early trend spotting (e. g. slow or fast enrollment, putting clinical supplies at risk).
- Allows sponsors to see how well CROs are performing in relation to time and budget.
- Provides proactive tools to see items trending off course and what corrective actions must be taken, while providing a view into compliance.
- Facilitates a proactive and transparent approach to governance.
- Helps protect sponsor interests through automated tracking of activities, contracts and regulatory requirements.
- Drives overall excellence in clinical trials.

Conclusion

CTMS can provide a comprehensive outsourcing solution by helping to streamline and standardize governance processes across providers and geographies. Roles and responsibilities can be clearly defined and mapped to performance for transparency and accountability.

The underlying platform must support scalability and extend across the global trial network, bringing all suppliers into one common ecosystem. This integrated approach improves visibility into performance and other key data, enabling stakeholders to fully realize the strategic value of outsourcing.



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