Unified Trial Governance: Why CTMS is the Jewel in the Crown

In today's extremely regulated and progressively global life sciences marketplace, managing clinical trials can be exceptionally challenging. It requires an end-to-end system that offers oversight into trial costs and regulatory risks, while being flexible and compatible with other technologies. This is where clinical trial management systems (CTMSs) play a part. A CTMS is primarily about knowledge and integrating data from disparate sources to help people make proactive and informed decisions. Admittedly, in the past that has not always been the case. Yet historical challenges of poor usability, legacy applications, lengthy implementation cycles, slow innovation and costly maintenance can be overcome by CTMS systems grounded in modern agile engineering practices like continuous validation and continuous integration.

These days, innovative CTMS systems are engineered for change and offer extensive automation to deliver new features in a regulated industry, faster than current products. Intuitive systems that utilise flexible cloud architecture allow biopharmaceutical and medical device companies of all sizes to leverage affordable enterprise technology to fit their particular organisation model. This article will highlight that by using CTMS to its best ability, it is possible to extract value from a process-intensive and procedure-orientated industry, ensuring increased governance on trials. Which is ultimately what everyone is striving for. Technology is evolving at a rapid pace, and how users interact with it in their everyday lives is as well. It makes sense that clinical trial systems should evolve in that way too.

Introduction

The early to mid-1990s saw the introduction of clinical trial management systems (CTMSs), where they played a part in managing clinical trials in clinical research within the biotechnology and pharmaceutical industries. An often-misunderstood software system, numerous smaller organisations view CTMS as a discretionary tool, its value overlooked and not quite recognised. Yet it is a system that can do so much: store centralised contact information and subject data, manage enrolment, track milestones and statuses; and maintain and manage planning and monitoring activities, performance and reporting functions, along with payment tracking – essentially the crown jewels of a clinical trial. Surely it is time for organisations to find a way to harness the value of CTMS.

Indeed, market research suggests that CTMS is set to play a fundamental role in the clinical software ecosystem, especially as the number of clinical trials continues to grow and regulations continue to evolve.[1] Markets such as Asia Pacific continue to invest heavily in clinical research.[2] China CTMS industry revenue is forecast to produce more than USD 270 million by 2024.[1] Government initiatives to establish research centres along with high spending on research activities across pharmaceuticals, life sciences, and clinical research sectors will drive regional growth. Furthermore, there is anticipated growth of mobile optimisation in aspects of CTMS solutions, such as analytics, business intelligence and site monitoring.

In addition, continued changes in regulations affecting both biopharma and medical device companies will have an impact on the CTMS market. The new MDR legislation3 could increase the number of trials in the medical device market, potentially increasing CTMS adoption in this segment. Enhanced regulations are also impacting the CTMS industry, especially in terms of good clinical practice. For instance, the regulatory landscape has evolved with increased requirements for risk management plans, and risk evaluation and minimisation strategies. For example, with ICH GCP E6 R2 necessitating a "systematic, prioritised, risk-based approach to monitoring clinical trials" the need for an intuitive monitoring solution has never been greater.

Responding to Challenges

Over the years, CTMS has promised to ease the challenges of managing a clinical trial by providing increased visibility and data insights so that problems can be addressed, progress can be made, and new possibilities uncovered. However, many have failed to deliver as they are not supportive of users that are in the field. Historically, CTMSs have had their challenges, being complex, difficult to implement and set up, and deficient in integration. Classic systems can be heavy, clunky and slow, lack intuitiveness and focus too much on manual data entry and rekeying of data that exists in other systems. Other operational systems can be used instead of CTMS, including spreadsheets and in-house developed systems, however they can often be burdensome to manage and lack compatibility. Disparate systems, non-standardised processes, siloed information and organisational boundaries all obstruct clinical trial management.

Image 1: Design Sprint Process

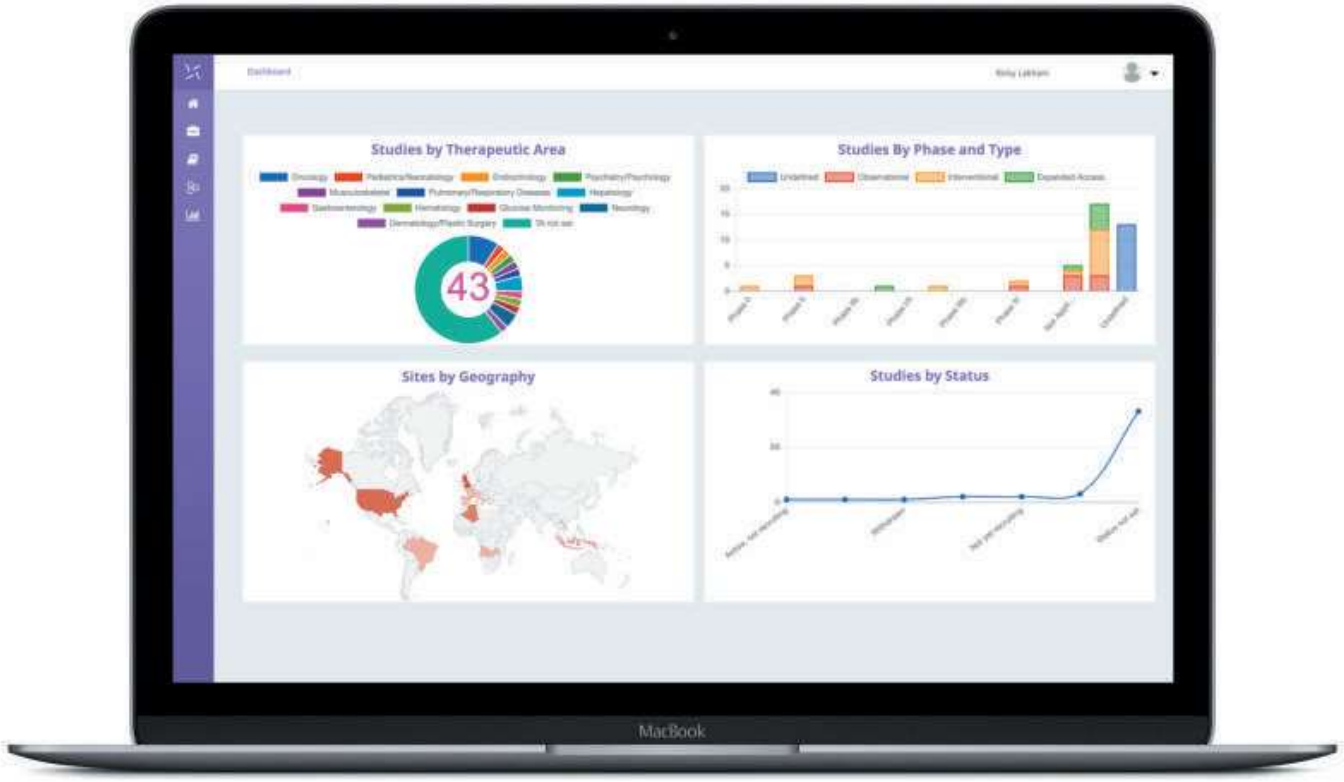

Image 2: Full Visibility of Clinical Trials

CTMS solutions will continue to form a fundamental part of an ecosystem of clinical and operational systems that a company will have. As such, the market is ripe for change, and inventive approaches using modern technologies are beginning to emerge. As the healthcare industry evolves, companies demand a smarter CTMS designed to simplify the management and control of clinical trials. The evolution of clinical trial management has come a long way, from paper, to spreadsheets, to on-premise systems (spreadsheets on a server), to hosted systems (the negative view being spreadsheets in a 'system' wrapper that someone will host for you) and now to a world of true SaaS solutions that are trying to change the way clinical trials are managed. Evolution is not just about doing the same thing and just hosting it differently.

CTMS systems have been rightly considered as expensive, monolithic systems that are costly to both implement and maintain. Through improvements in technology, this has begun to change with SaaS offerings. The continued growth and adoption of SaaS technology solutions especially for CTMS will be a key industry trend in the coming years. This is especially true for SME companies striving to reduce the cost and overhead of either home-grown or hosting their own solutions. Further, with the continued focus on data collection and analysis, companies are adopting CTMS solutions to eradicate the inefficiencies of spreadsheets and other manual tools. With regard to data collection, CTMS systems are increasingly positioning themselves in the middle of an ecosystem of inbound and outbound data, reducing the amount of manual data entry and increasing the transparency of data for reporting and informed decision-making.

CTMS Design Considerations

It is important that clinical operations executives at life sciences companies address clinical trial management issues proactively and thoroughly to enable successful product development. Yet many organisations face a dilemma when it comes to selecting a CTMS solution to manage clinical trials. To choose an existing approach/solution or explore alternative options? This is where CTMS design plays a crucial role. CTMS design needs to be considered from several perspectives; technically, functionally and identifying what the USPs are going to be right up front.

As with any other enterprise software, building a CTMS requires some up-front design to ensure that the foundations are scalable and maintainable as the product grows over time. Not putting in strong foundations will increase the costs of adding features and maintaining the software over time. Then there is interoperability – CTMS systems should be designed to be able to exchange data with a variety of other systems using mechanisms that can reduce the need for custom point-to-point integration. Functionally, usability needs to be at the core. Legacy systems have failed as their focus has been on capturing the data rather than the outcomes that the end user needs to achieve from utilising the technology. Other key factors are configurability, ease of adoption through data standards and pre-configurations to reduce the overhead to implement the system.

Agile flow-based engineering practices can also be applied to CTMS, benefiting the validation process. Software validation is an important consideration for biopharmaceutical organisations, CROs and medical device companies. The time and cost of validation can cause version lock, delay time to value, and reduce agility. While validation is required in a regulated industry, some approaches allow users to increase the pace of innovation in a controlled way. For instance, a CTMS that utilises 100% test automation would accelerate innovation and new features, giving clients greater trust, reliability and confidence that any issues will have already been identified. CTMS systems designed and developed utilising agile engineering practices with extensive automation could help ensure that validation assets can be generated with higher accuracy and quality utilising a continuous validation framework.

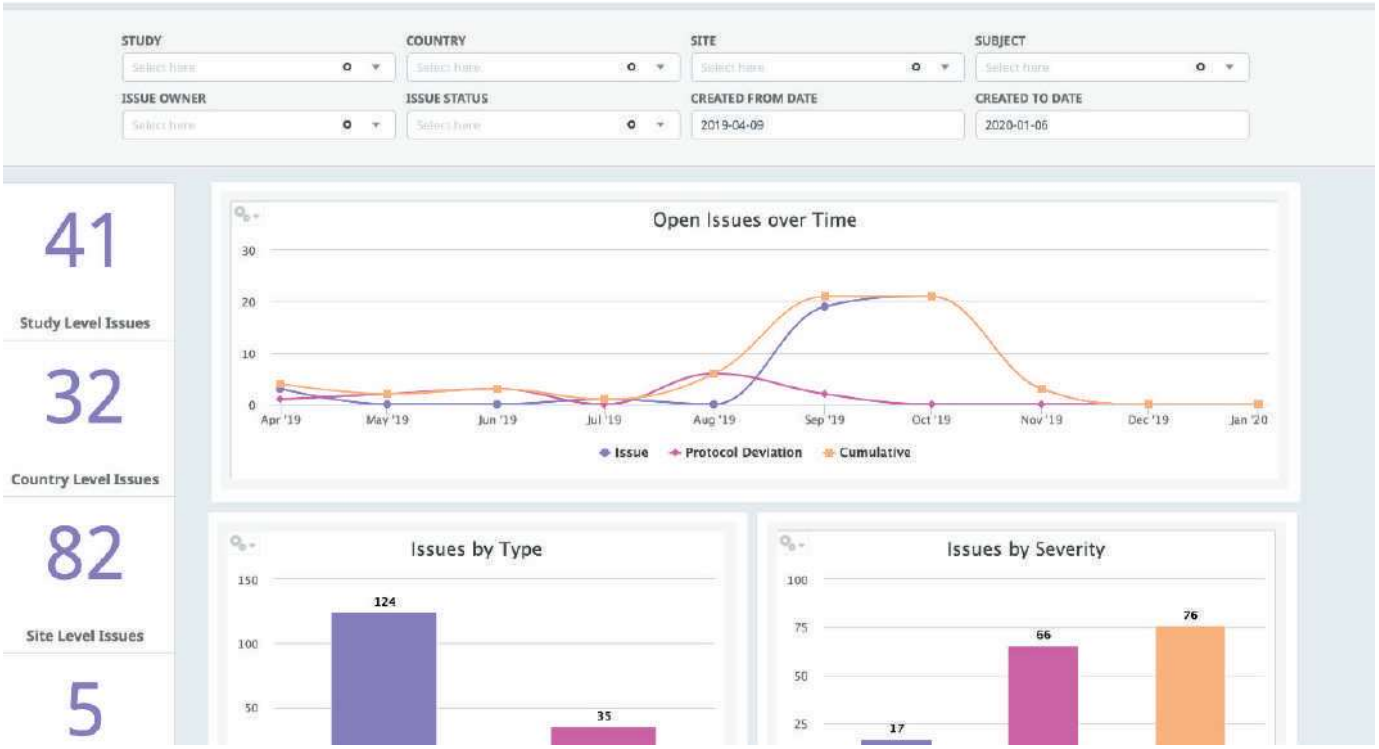

Image 3: Business Intelligence

Integration is Crucial

To properly manage clinical trials, it is vital to understand the role of information within different technologies across all clinical trials and this is where CTMS comes into its own, seamlessly integrating with eClinical applications. CTMS is one of many systems that can be integrated with other technologies, such as electronic data capture (EDC), electronic trial master files (eTMF) and interactive response technology (IRT) systems, enabling multiple technologies to be utilised within a clinical trial, streamlining workflows and improving productivity. Interoperability is a crucial factor of CTMS. The import/export capabilities must be flexible to accelerate set-up and allow users to perform additional data processing, and reduce manual data entry and reconciliation. This can all help improve clinical trial transparency to simplify registration with public registries such as ClinicalTrials.gov.

CTMS forms a cornerstone product across the lifecycle of a clinical trial, from initial budgeting and planning, to protocol development, compliance with government regulations, project management, financials, patient management and recruitment, investigator management and site monitoring and issue management. The objective is visibility into operational metrics and strategic management of clinical trials, with the goal of getting studies up and running quickly and smoothly and increasing the likelihood of success.

If the appropriate CTMS solution is chosen and implemented in the right way, then the impact of data access and collection should be hugely positive. A good CTMS solution should increase the capture of structured data and reduce the need for data duplication through both inbound and outbound integration capabilities. This streamlines processes and speeds up data collection. It also increases data access for a wide range of stakeholders wishing to have insights into various aspects of the clinical trial portfolio.

Knowledge is King

While having oversight of a specific clinical trial is crucial, the value does not start and end with each individual trial. The ability to deliver enterprise control across a portfolio of clinical trials is invaluable. CTMS can provide powerful business intelligence through features such as embedded dashboards and system reports across study management, site monitoring and issue management. The ability to track study progress including enrolment, milestones and essential documents, maintain organisations and associated contacts including global investigators and manage GCP oversight across flexible supply chains, provides the foundation for a corporate knowledge base. This master hub of information can be mined to track performance across clinical trials, and organisations can use the metrics to learn from and improve future studies. The ability to select and filter reports across study, country and site generates a searchable, user-friendly audit trail which supports regulatory compliance.

Extending the Benefits

A CTMS should be adaptable enough to adjust to specific circumstances. With a flexible CTMS, it is possible to improve internal and external communication and enhance supply chain management. Using a CTMS that is adaptive, both functionally and technically, can benefit a company in a multitude of ways. Adaptive CTMSs improve the ability to manage more complex trials and can substantially reduce the cost and time spent by eliminating duplicative or unnecessary tasks. Furthermore, they can improve interaction and increase collaboration across multiple stakeholder groups, providing greater insights into clinical trial data, thus reducing inefficiencies that have previously existed with siloed business processes.

CTMS can also help to mitigate costs. Adopting a SaaS CTMS system in replacement of an existing hosted solution or even just to replace home-grown solutions is the common way to mitigate some costs of trial management spend. But just replacing the system is not the only way to mitigate costs; adopting standards, increasing collaboration with a single system and streamlining processes which a CTMS implementation requires all can help reduce the cost pressures.

Conclusions

Today's enterprise technology needs to be much more affordable, much more accessible, easier to use, quicker to implement and deliver real value to those running clinical trials. Now, CTMS can no longer be viewed as a discretionary system, especially with regulators asking for increased governance of clinical trials and additional guidelines to follow such as ICH E6 R2. Organisations engaging in global clinical trials can benefit from the enhanced levels of real-time communication that come from using a collaborative CTMS that works seamlessly with other clinical solutions, helping researchers realise the benefits of their global trials.

There are still challenges to address. Designing and agreeing the future state business processes to help realise the ROI on a CTMS is a key challenge to overcome. CTMS supports multiple groups within a sponsor or CRO and different roles at varying levels within these companies. Each will have different requirements and goals, as well as different priorities. Other challenges include the lead time required for setup and configuration, and in some cases unfortunately customisation, which increase the cost and time of implementation. However, with a CTMS it is possible to demonstrate every touchpoint of a clinical trial (CRO, suppliers, provider, external organisations) all captured within the system to fully demonstrate regulatory compliance. The value of CTMS as a tool for unified trial governance is rising.

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