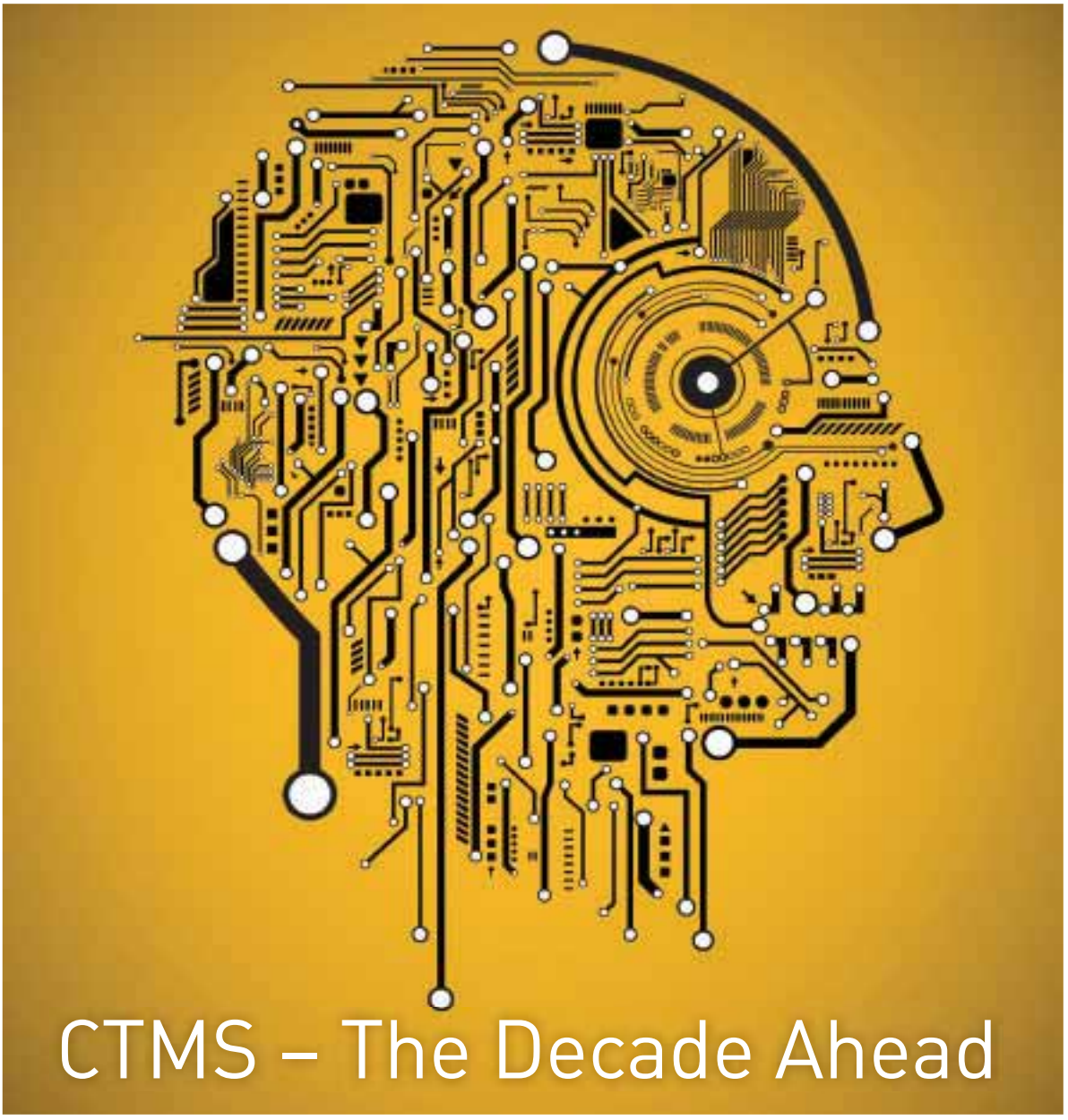

CTMS – The Decade Ahead

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A clinical trial management system is the hub of any eClinical environment but, to maintain its successful role, it is moving towards a modular structure – providing master data and bringing better functionality for study teams

Liz Love at PAREXEL

As the clinical research industry evolves, so too must the technology solutions that support it. An essential part of that eClinical environment is the clinical trials management system (CTMS), which provides a 'single source of the truth' for operational data related to the planning, management and reporting of trials.

Key Elements

Many of the leading CTMS solutions provide similar functionality, including the ability to plan studies, particularly around enrolment and milestones, as well as the tracking and management of study progress, budgets and investigator payments.

Support for data-driven monitoring and the conduct of site monitoring activities are further key elements of a CTMS solution, in concert with other applications, such as randomisation and trial supply management and electronic data capture – all combining to provide a full eClinical platform.

Due to the enterprise nature of a CTMS, it is also desirable to have the ability to configure and customise the solution

so that it can become a central part of the corporate environment, integrating with human resource, finance and enterprise resource planning systems.

The question the industry now needs to address is around the future direction of CTMS – as we move into a new era of clinical research activities, these systems need to evolve to meet the changes.

Core Values

While CTMS operational functionality and reporting are vital to the management of clinical trials, the value of these systems comes in another form too – master data and study definition. The 'single source of the truth' that is so important relates to the master data used by all studies, as much as to the study data itself. As a result, the core of a CTMS should provide that master data in a format that can be used by any other application.

Following an industry standard, such as the Biomedical Research Integrated Domain Group model, certainly helps in this. Master data includes the list of investigators who either have been or could be used on a study, along with information regarding their past performance, helping with site feasibility and site selection activities for future trials.

In addition to an investigator database, it is important to maintain a master list of the associated centres, as the combination of investigator, centre and study give the definition of a study site. As so many eClinical applications rely on that 'core' data, CTMS becomes much more than just another product in the set – it should be at the heart of any technology in use within an organisation.

Shaping the Study

While every study type has differing needs, the basic definition of the study is something that always needs to be tracked, so it makes sense to manage this information in a central manner. This 'spine' includes the details of the study hierarchy – drug/device, programme and study identifiers, plus details on the countries and sites where the study will take place.

The study design, including visit structure, needs to be here, along with the approval of the protocol and any amendments which have been applied to it. Clinical research is a very human endeavour – it involves the studying of people, by people; so the management of those who work on studies should also lie within that central location.

Moving to Modular

If we evolve towards a modular structure, with master data and the basic study definition at its core, then it is necessary to consider the 'modules' that will surround it.

We are all used to the idea of CTMS modules – site monitoring, site feasibility, cost tracking, document management, etc. Although these modules often have a logical barrier within the system – usually menu-based barriers – they are very much a part of the CTMS application itself, closely intertwined within the structure. Moving to a truly modular approach, these functions need to be supplemented with other modules that facilitate study operations, such as data-driven monitoring, study compliance, study planning and tracking, resource management and vendor management.

Providing all of these functions in a way that is truly modular reduces the burden of upgrades and validation as we edge towards a world where each module can be managed individually, allowing modifications to be implemented on a module-by-module basis. The advantage of this is that the validation overhead of a major upgrade is drastically cut, resulting in quicker adoption of new features and a reduction in the complexity which is often associated with CTMS implementations.

Tomorrow's Users

In evaluating the likely future of CTMS, we have to consider the end-users and their profiles. In five or ten years, who will be using the systems, and what will they expect from the software?

It is clear that mobile technology will play a big part in the future, as users become more comfortable with accessing data via mobile devices rather than a desktop PC or laptop. Tomorrow's users are today's teenagers, who expect to be able to access key features using a mobile app or similar method.

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While technology should be supported on the iPad and other tablet devices using the browser, key tasks need to be accessible via mobile apps. The clinical research associate (CRA) needs to know when and where their monitoring visits are planned, which activities need to be carried out, and what needs to be checked at the site. Although this information is available within a site monitoring solution, accessing it via a mobile app should be much more convenient for the CRA, and make their already busy lives a lot simpler.

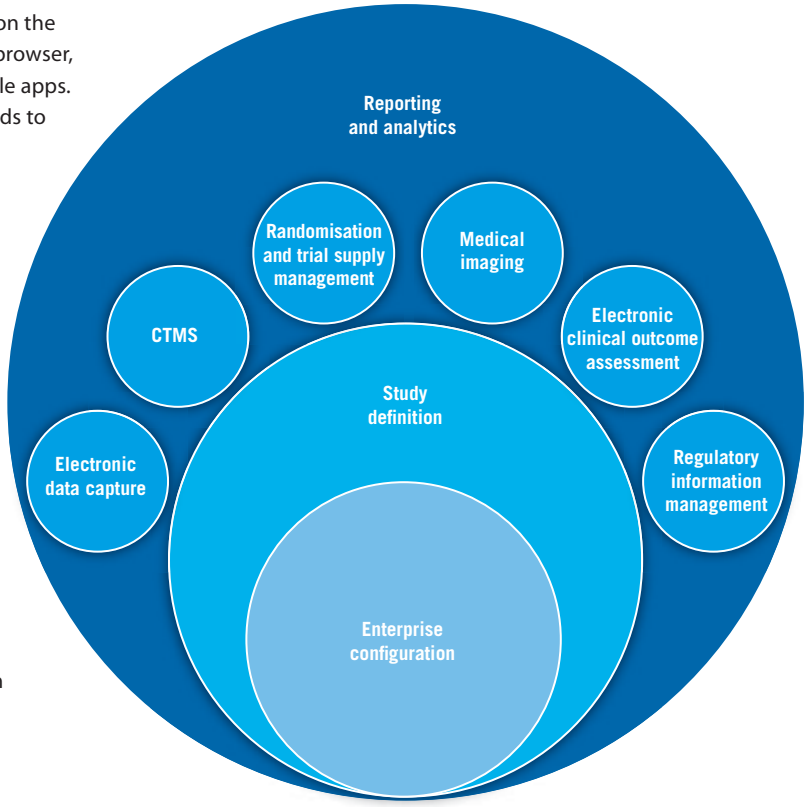

Figure 1: CTMS is evolving into a 'core' – enterprise configuration, study definition – plus study management functionality, working together with electronic data capture, randomisation and trial supply management, medical imaging, electronic clinical outcome assessment and regulatory information management

Mobile Functions

The in-built functions on mobile devices also give the opportunity to consider much richer content for monitoring visit reports. Why fill in a drug accountability report when a photograph of a partially empty blister pack can tell the same story? Why write out a lengthy visit 'narrative' when an audio recording of discussions can be listened to? The potential for change to reporting of monitoring visits is huge – and mobile technology could contribute much to the change that is currently being seen around monitoring activities.

Outside of the site monitoring arena, mobile devices could make life easier for the busy study manager or programme manager. At this level of the study team, access to real-time operational data via a mobile device removes the need for 'running reports', so questions on study progress can be answered quickly and with confidence.

Data-Driven Decisions

Taking a deeper dive into the needs of the study management team, it is impossible to talk about the future of CTMS without mentioning reporting and analytics. While it is necessary to maintain a database of operational data, the ways in which we access that database are changing. There is an increasing focus on data analytics, with the industry in general investing heavily in data-driven decision support and innovative methods to access and act on trial data.

There are a variety of ways in which data should be served up to the end-user:

- Actionable insight – the ability to quickly identify upcoming tasks and actions based on predefined criteria, enabling the user to navigate directly to the source system to take necessary action
- Operational reporting – providing users with the ability to understand the current state and/or trends, and a predefined path for determining why it happened and what may occur in the future
- Analytics – utilising surface-relevant data via an analytic tool to give trained or specialised users the ability to perform ad hoc queries and analysis to support unique/undefined scenarios

The CTMS is evolving to fit the changing needs of clinical trials, in line with industry trends. By providing master data for all eClinical applications, functionality to support clinical trial operations and unprecedented access to real-time operational data across all functional areas, CTMS is experiencing a shift away from the traditional single application. It is now moving into a series of connected but disparate modules working within a platform to provide the standards required for successful trials.

About the author

Liz Love is the Product Director for Clinical Trial Management Systems at PAREXEL, and has been working with clients in a variety of roles since 2001. After beginning her career in product support, Liz moved over to product management in 2007, working with the industry to understand user problems and help guide the future of CTMS. Her focus is on understanding the processes and challenges around study management and monitoring, ensuring that supporting technology is developed in a way that introduces efficiency and is beneficial to clients.

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