VIEW POINT

CLINICAL TRIAL DATA MANAGEMENT

Identifying Gaps in the Product Market and Designing Solutions for Gap Fitment

Abstract

Clinical trial data management plays a pivotal role in modern healthcare, facilitating the advancement of medical treatments and disease management. Despite the availability of various Clinical Trial Management Systems (CTMSs) and Electronic Data Capture (EDC) platforms, gaps in functionalities persist, necessitating the development of tailored solutions. This paper addresses the critical need for developing tailored solutions to bridge existing gaps in CTMSs and EDC platforms. Through a systematic process of identifying prevalent service offerings and evaluating their impact, ten key gaps were identified, focusing on areas with limited prevalence and high user value. Subsequently, three priority service offerings - safety monitoring, blinding, and decentralized trial preparation - were identified which may be targeted for initial solution development, based on their potential for rapid implementation and significant user benefit. By prioritizing these solutions, the paper underscores the importance of leveraging technology to address specific challenges in clinical trial data management, ultimately enhancing the efficiency and effectiveness of healthcare research processes.

Infosys®
Navigate your next

Introduction

Clinical research forms the foundation of modern healthcare by constantly seeking to improve the way we prevent, diagnose, treat, and manage diseases, ultimately leading to a healthier society.

Clinical research relies on a variety of tools and technologies, yet even well-established ones may have their drawbacks. For instance, CTMSs are adept at streamlining data management but might lack the flexibility needed for complex trials or real-time patient data insights. Certain trials might require specialized treatment of data that a specific CTMS software might not be able to handle.

Similarly, EDC platforms simplify data entry but may overlook nuances in diseases or patient experiences, thus limiting the depth of gathered data. Clinical research teams typically solve these problems by creating small solutions that fit the gap that their existing CTMS products do not match. However, there is a scope for creating better robust products that use best-in-class technology that will allow people to have better flexibility and control over the particular area for which their existing CTMS product doesn't provide a solution. Figure 1 provides a generic view of the end-to-end clinical trials data management application and data landscape.

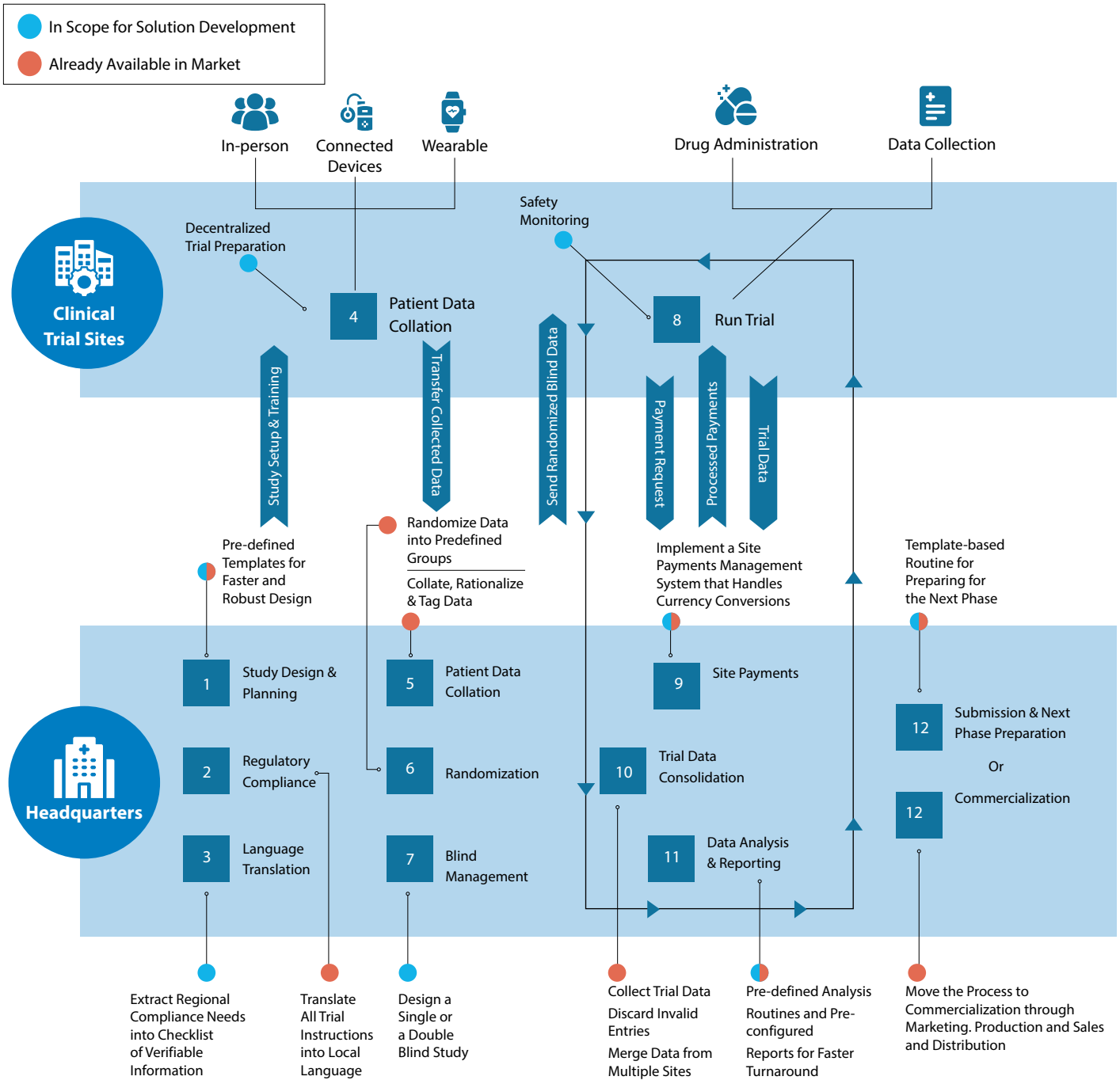

Figure 1: End-to-end Process Flow for Clinical Trial Data Management

The purpose of this thought paper is to explore the different CTMS products that are available in the market, identify areas of gap, explore them and prioritize certain areas for developing solutions that can be plugged-in to the products that are present in the existing CTMS landscape.

Identification of Gaps in the CTMS Landscape

To identify the gaps in the existing CTMS landscape we followed a process, where we first explored the list of products that provide any form of CTMS services and cataloged those services. Based on that data, we created a master list of all CTMS product offerings that are available in the market. This gave us a list of every unique service offering that is available to the consumer to choose from. It should be noted here that this list of service offerings is not something that is provided by any one individual CTMS product. The purpose of creating this master list of service offerings was to identify the gaps that the different CTMS products have with regards to a particular service offering.

We wanted to evaluate the available CTMS products for gaps against the master list of service offerings that is provided by the super set of all CTMS offerings. The reason for doing that was very simple. In the landscape of clinical research, very few research teams, if any, opt for using more than one CTMS product. Hence, if the chosen product has certain gaps that other CTMS products fill, the teams do not have the capability to incorporate the additional functionality that is provided by the second or third CTMS product. That is the gap for which one can try to provide a solution.

Adverse Event Data Management	Auditing	Blinding	Budgeting
Change Management	Coding	Complaint Management	Data Management
Decentralized Trial Preparation	Document Management	EDC	End of Study Data Generation
Financial Management	GTM Analysis	EHR / EMR Capture	Imaging Data
Integration	Intelligent Assistant	Patient Consent	Payments
Quality Monitoring	Randomization	Regulatory Compliance	Reporting and Analytics
Risk Management	Safety Monitoring	Site Management	Stakeholder Management
Training Management	Trial Management	Trial Supply Management	

Table 1: The Various Service Offerings That Are Available across the CTMS Product Landscape

To determine the prevalence of service offerings, 14 CTMS products available in the market today were evaluated. Based on the diverse service offerings that these products provided, a distinct list of 31 service offerings was identified (Table 1) that were provided by at least one of the 14 CTMS products. Then, for each service offering, we determined (in terms of percentage) the number of products that provided that offering.

Based on the prevalence of the service offerings we decided to target service offerings that have less than 40% prevalence across the various CTMS products. Along with that, we also looked at the service offerings that will add significant value to the customer and can also fall in the purview of our expertise in developing a robust and best-in-class solution.

Then, for each of these service offerings, we mapped them with respect to their prevalence across various CTMS products as shown in Figure 2.

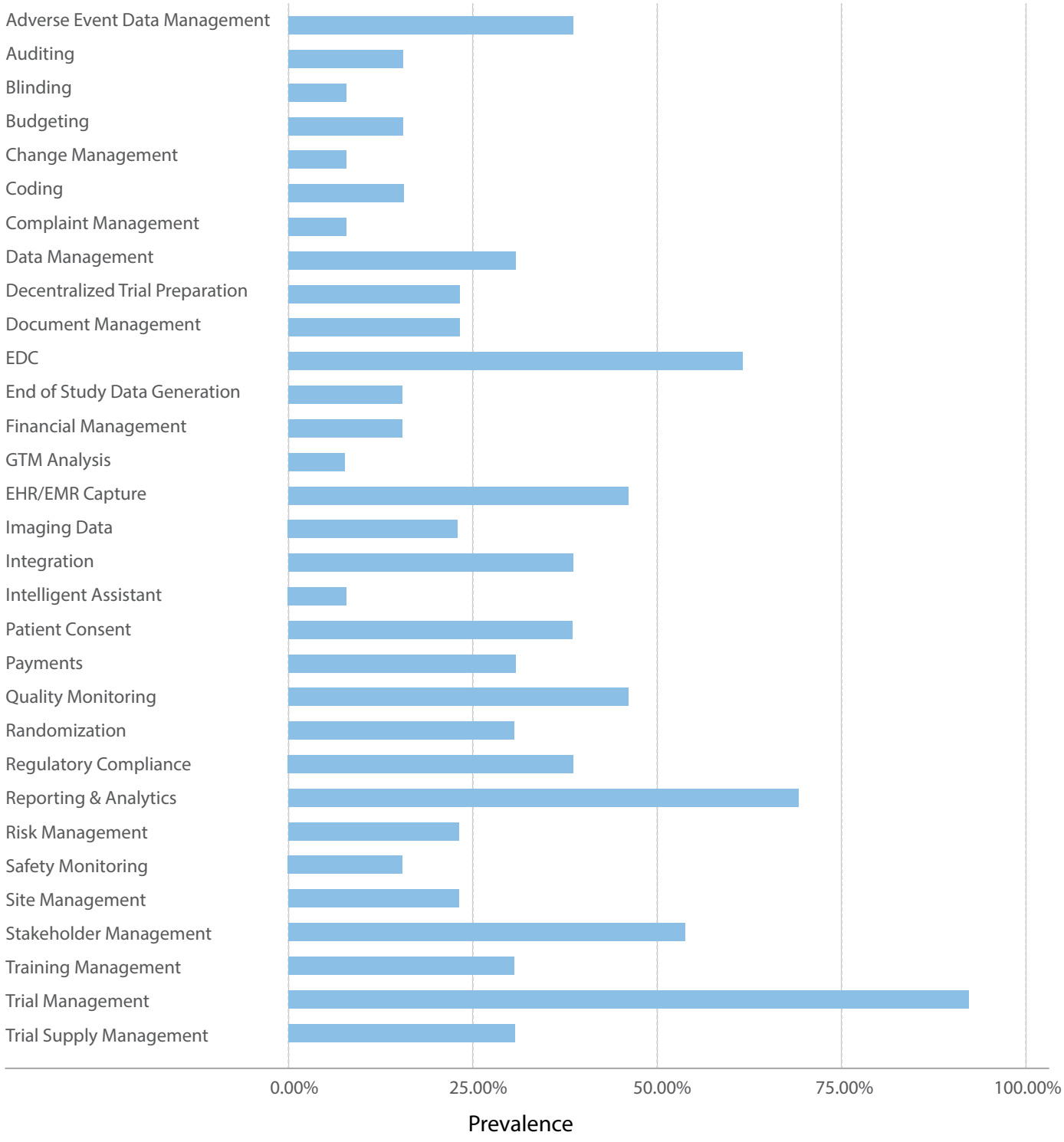

Figure 2: Prevalence of Service Offerings

The prevalence is determined by how frequently the service offering is available across the various CTMS products in today's market.

Potential Products for Addressing Gaps

We evaluated the different service offerings available with various CTMS products in the market and have arrived at 10 that have both a limited prevalence across the different CTMS products as well as have the potential for adding significant value for the end user of the CTMS product. These service offerings have been highlighted in green in Figure 3.

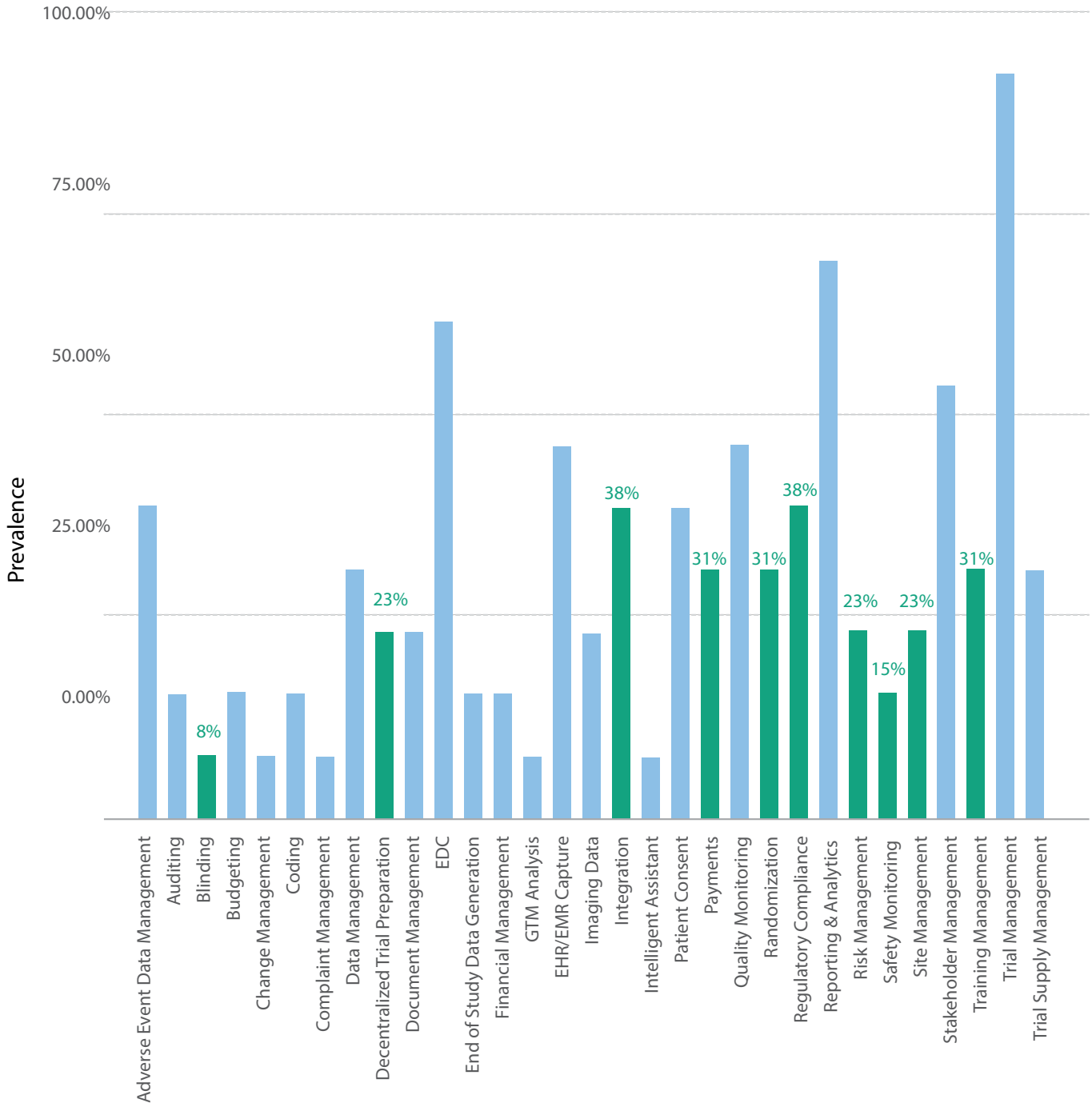

Figure 3: Service Offerings for Solution Development

The service offerings highlighted in green can be selected for solution development based on their prevalence and the impact they will have on the team using the developed product.

Upon further analysis of these 10 service offerings that warrants our focus, we have estimated the relative time and effort required for creating each solution/service offering and distributed them in a pie chart, Figure 4.

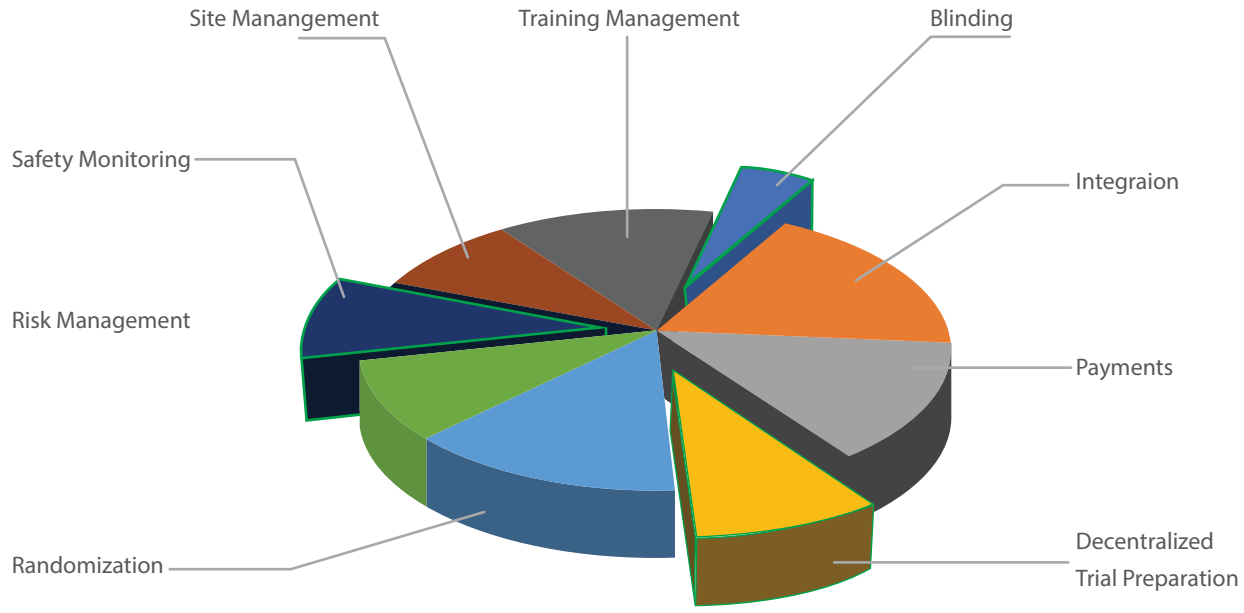

Figure 4: Relative Prevalence of Identified Service Offerings

The pie chart displays the relative effort and time-to-market of the identified service offerings as a part of the whole. Out of the 10, three have been selected which can be targeted for the initial phase of solution development

In Figure 4, the area of the individual pieces of the pie indicates the total estimated relative effort and time-to-market for that particular service offering.

As a starting point for developing the solutions, three service offerings, namely, safety monitoring, blinding, and decentralized trial preparation have been identified as the first three that can be focused on for further development of fit-gap solutions as they provide a relatively quick go-to-market along with a significantly positive impact for the end user.

Conclusion

The need for figuring out how to provide a more seamlessly integrated end-user experience in management of clinical trials shows how important it is to keep developing new healthcare technology solutions. Since good clinical research is the key to make progress in medicine, we need to acknowledge that the tools we have now, like CTMS and EDC, have limitations.

This exploration highlights the importance of understanding what exactly clinical research teams need and then creating solutions specifically to address those needs. By carefully looking at what services different CTMS products offer, we can focus on building strong and adaptable solutions that can easily work with the systems we already have while also offering new features. Also, prioritizing services based on how common they are and how valuable they could be is a smart way to use our resources and get the most out of them. By focusing on important areas like safety monitoring, blinding, and getting ready for decentralized trials, we have a clear roadmap for what to develop next.

The concept presented in this thought paper isn't just about making clinical trials run smoother and faster. It is also about using technology to improve healthcare overall. As these solutions are developed and they become part of how clinical research is done, they have the potential to completely change how data is managed, which could ultimately lead to better outcomes for companies, patients and lead to a healthier world.

Author

Tanushree Banerjee,
Senior Consultant, HLS-Transformation Enablement Practice

Tanushree holds a PhD is biochemistry with over 15 years of research experience in Life Sciences. She was the Principal Investigator of two Phase I clinical trial studies conducted in Maharashtra, India. She is currently engaged as a PMO for the Roche account, where she is managing the SAP S/4 HANA-based ERP project operations.

For more information, contact askus@infosys.com