

Bringing Clinical Development to a Successful Digital Transformation



Introduction

Accelerated drug development is being driven by increased market competition, downward price pressures, and growing complexity of regulatory reporting requirements. These, and other market factors, are causing industry leaders to embrace technologies and digital processes that were previously not widely applied. The industry is adjusting to a new normal which includes:

1. Maturing data management systems,
2. An expanding number of data sources, and
3. Unprecedented data volume growth.

Additionally, the problems posed by the COVID-19 global health crisis have accelerated the need for digital transformation.

Given the current forces impacting clinical development, it is imperative to have a solid business and technology strategy to ensure a successful digital transformation. Understanding the current environment along with the technology landscape is part of the process.

Developing a winning strategy requires both the business and technology stakeholders to align. Moving forward without a strategy and roadmap is a recipe for failure. Organizations engaged in clinical development need to bring together the right people, processes, and technology to ensure success.

In this eBook, we discuss the trends impacting clinical development and examine the technology, the data flows, and how a Platform and Data Centric model can contribute to success. Lastly, we review the key strategy steps, from both a business and technology perspective, to transform clinical development from its current reality to a successful digital future.

Topics

- 3 Important Clinical Development Trends
- Business Value to Clinical Development of a Platform Based, Data Centric Approach
- Clinical Development Transformation – The 6 Key Strategy Steps

3 Important Clinical Development Trends



There are three primary trends that are impacting clinical development. These trends are causing Life Science organizations to re-assess their current operations to find areas of improvement that can be made with respect to people, processes, and technology.

1. Changing Nature of Work

One significant change we are noticing is in the work environment. COVID has certainly expedited some of that shift. There are new trial paradigms that need to be addressed. There is an accelerating requirement for

decentralized trials, telemedicine, and other areas that are extremely critical as we transform the approach to clinical trials.

That includes allowing direct patient access to both the trials and the resulting information. Additionally, stemming from this patient access is the need to use real-world data and simulations in the analysis and ensuring that the data is presented in contextual user-friendly ways that can be understood by both patients as well as scientists and clinicians.

2. Increased Complexity

We are witnessing increased complexity in the clinical development environment. The ecosystem has been in place for a while allowing legacy silos of information to persist. An increase in the volume and the diversity of the data being collected has also added complexity. This is creating some gaps. Moreover, not all vendors and partners who are working together in the network on clinical programs are following the same data standards.

It is also complicated to share and reuse clinical data across studies because data standards are not aligned. However, we need standardized data to apply trial analytics across studies to inform clinical programs, trial design, etc. This lack of consistency and uniform data platforms leads to an onerous inability to access and use our data in innovative ways.

3. Emerging Technology Capabilities

We're also seeing major changes happening with technology as it relates to clinical development. For example, digital patient engagement and the use of wearable sensors along with other technologies and devices are becoming more prevalent and making an impact on how we design and conduct studies. Also, the increased capacity and capabilities of automation, artificial intelligence, and machine learning, as well as the ability to use knowledge graphs and semantic layers, natural language processing, and natural language generation are all emerging capabilities that we want to be able to take advantage of across the clinical development space.

The vendor landscape is changing as well, although some commercial solutions are still on older technologies. Most vendors are moving to a newer technology infrastructure, and this requires clinical development departments to be positioned to incorporate these scenarios into their strategy. At the same time they need to ensure cyber security, data privacy, and compliance with evolving data standards such as IDMP.



Business Value to Clinical Development of a Platform Based, Data Centric Approach



According to a GlobalData survey last year, over 70% of pharma industry respondents stated they expect that drug development will be the area most impacted by the implementation of smart technologies. With that being the case, it is imperative that Life Science organizations understand the technologies and concepts that are emerging and how they can enhance the Clinical Development area. Having an understanding of the technology trends, and then developing a strategy to take advantage of those trends, is critical to success.

Why a Platform Architecture is Required in Clinical Development

Many Clinical Development organizations currently have non-integrated solutions and redundancies with multiple systems performing the same function. This introduces compliance risks as well as business inefficiencies. A more thoughtful approach is to move from this situation to a more rationalized Platform environment focused on business value.

Platform Architecture

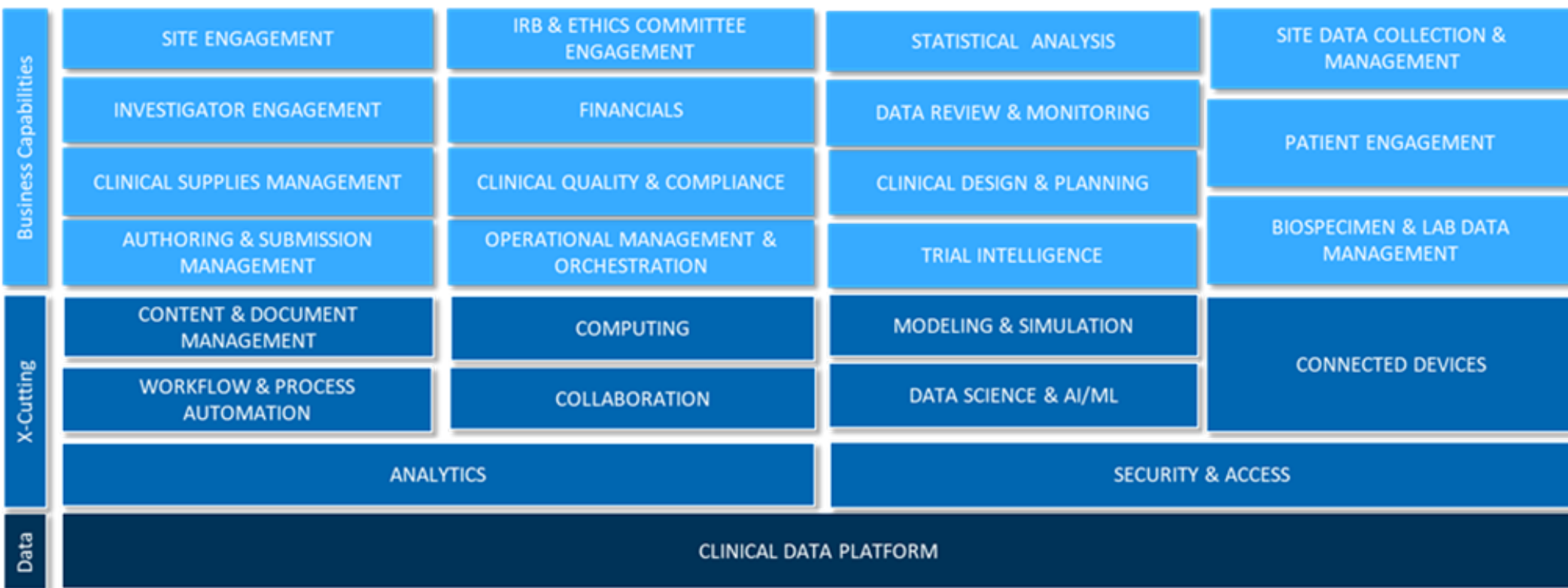


Diagram 1

A platform approach requires thinking differently. It involves incorporating a suite of modules, applications, components, and services, that are used together to deliver multiple complex business processes (Diagram 1). These are not typically from a single vendor, but rather an assembling of the best rationalized set of tools to deliver business capabilities that can be managed in a coordinated and cohesive way. For example, if we look at content and document management capabilities, there are typically many different flavors across

an organization. These various applications may be meeting slightly different needs, however, those could be managed as a platform service. We can rationalize these tools to offer standard services and reusable components.

Data Centricity and Why it Matters

Another area that needs to be addressed is data centricity and how a platform approach fits with this concept.

Data Centricity

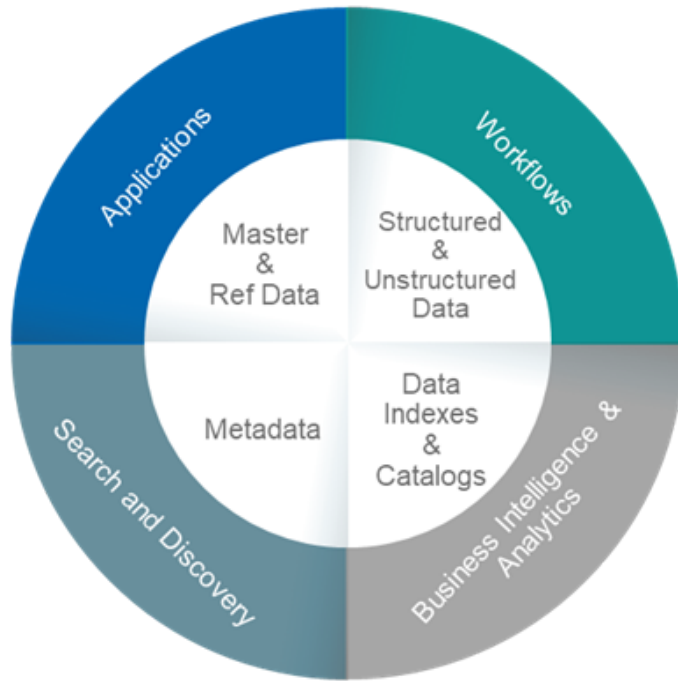


Diagram 2

With a data centric model we leverage an architecture where data is the primary and permanent asset, and applications come and go (Diagram 2). In the data centric architecture, the data model precedes the implementation of any given application and will be valid long after the application is gone.

The benefit of this model include:

- Data are not 'locked' in disparate and complex commercial applications (data outlives applications)
- Data are readily findable, accessible, interoperable and reusable (FAIR)
- Reduces the complexity of application integration, much of which currently stems from lack of data interoperability
- Facilitates the ease and flexibility of rapid application development, workflows, and analytics exploration
 - Easier to change applications
 - Eliminates data migrations when changing applications
- Independence of data from applications and the evergreening of the data.

However, the reality is that it's not that easy to realize this type of data environment in practice. Typically, the organization has many commercial applications, and they have their own data models, metadata, and controlled vocabulary with application code tied to those models. This complicates matters in that commercial applications are not designed to work with a common data model, and that paradigm isn't changing.

The logical data hub is centered around a common semantic data model which is extensible and facilitates business content search and navigation. The platform approach and the logical data hub architecture get us closer to our goal of data centricity.

Clinical Development Transformation – The 6 Key Strategy Steps



To successfully perform a transformation of Clinical Development to improve efficiency and effectiveness, there needs to be both a business and technology strategy that enables the process. There are six important steps that Astrix follows in order to ensure our client's success in this area.

1. Guiding Elements

First, we look at defining guiding elements to inform the strategic direction. Guiding elements incorporate the leadership vision, key business imperatives, as well as the critical issues that are being faced by the organization to ensure that they are addressed through the strategy setting.

Defining all of these elements upfront, including the guiding principles, which might include how we define and view the architecture, the data or information, and how the organization wants to deliver the user's experience, is the first step. These guiding elements clarify and drive the decisions regarding the strategy.

2. Capabilities Definition

Reviewing the business and technical capabilities in the clinical development space is the next step in the process. In this phase the core business processes and all the cross-cutting capabilities are evaluated through our framework (Diagram 3).

Defining Business & Technical Capabilities

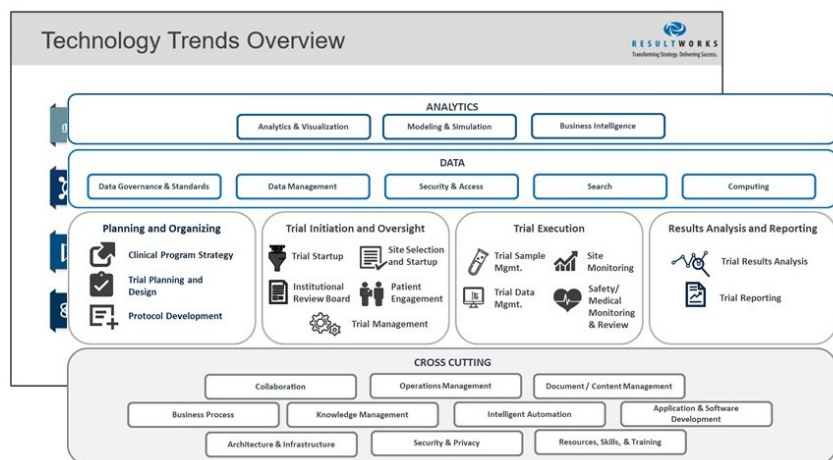


Diagram 3

This is done operationally as well as from a data and an analytics perspective. The clinical development trends and emerging technologies that can be impactful are all brought together. Leveraging the framework, the key capabilities for the organization are identified. These capabilities are viewed through the lens of different processes and the needs of different functional areas. Capabilities are also assessed from both the perspective of the capabilities and processes that are foundational to clinical development, along with the aspirational capabilities that we want for the future.

3. Conceptual Architecture

Using the capabilities as a basis, the conceptual technical architecture is developed. This is typically constructed from a platform perspective (Diagram 1).

Through this process, the capabilities to support both foundational and aspirational requirements are defined. Cross-cutting requirements are also designed (i.e., above the data layer). The cross-cutting requirements are those that span multiple areas of the business. For example, analytics capabilities are a cross-cutting platform that could be used by the biostats area, the clinical data management (CDM), as well as clinical operations. In this scenario all those groups are able to access and use the common analytics platform rather than buying or building their own. The more transactional business platforms provide more specific business capabilities at the top of the conceptual technical architecture.

4. Business Prioritization

Once the desired capabilities and platforms have been defined, the business needs to prioritize the implementation and timing of those capabilities. Not everything can be constructed on day one and all organizations will have gated investment decisions to make.

Capabilities can be built in an extensible way where you start small and build out according to an agreed plan. For some areas, there may be sufficient capabilities for the short term allowing us to focus on other areas that may be more urgent and impactful where there is no solution currently in place. This prioritization process addresses both the business priorities and the urgency from a technology perspective.

5. Strategic Technology Assessment

As in the case with most organizations, there are existing solutions in place. Therefore, in parallel to performing the capabilities determination, an assessment of the organization's current clinical development systems is performed. This involves understanding the current architecture. At this step, it is determined how the existing architecture will fit with the conceptual architecture designed for the future. This requires a rationalization that feeds later into the roadmap definition. A determination needs to be made whether the organization will continue with certain technologies and invest in them further or if they will just be maintained with no further investment. This determination will be based on whether there is another solution available that is coming in the near future which will replace it, or if this capability will no longer be required in the future. After this is completed, the organization's business priorities and urgency are both reviewed once again.

The final aspect regarding technology assessment is understanding the vendor solution landscape. Vendor solutions need to be measured against the agreed and prioritized business and technical capabilities. Those solutions need to be viewed based on vendor functionality as it exists today with some allowance for product plans that map to the time horizon of the strategy.

6. Strategic Roadmap

All of these steps culminate in the development of a high level strategic roadmap. Typically, the roadmap is broken down into three primary areas. One is a high level summary

overview which is usually workstream driven. These workstreams can tie to a variety of different mechanisms that can be either organizational, based on product lines if the organization has product line set up, or based on business outcomes the organization wants to achieve. The outcomes developed in the high level roadmap drill down into deeper and deeper levels of detail. For example, detailed work descriptions that serve as a preliminary charter for the project and for implementations that can help spin up workstreams within the right timeframe without losing strategic intent.

The roadmaps are built to be living documents that evolve overtime as technology continues to change. By using a platform-based data-centric model as the basis of the strategy and the future technology ecosystem, it facilitates versatility to incorporate new technologies while enabling the organization to deliver expanded business capabilities.

Transformation Requires Alignment

In order to ensure a successful project, the organization needs to have the key constituents involved throughout the project. It's important to get alignment along the way. The leadership of the organization sets the tone, drives through the business imperatives, and ensures they are well understood. Also critical is communicating decisions and intent along the way. Additionally, continuing to prioritize in terms of capabilities, technology, and urgency so that all those areas get factored into the alignment process.

The organization must ensure that stakeholder's voices are heard and accounted for throughout the journey. It is also important to be transparent in decision making, prioritization, and the development of the strategic roadmap. To be successful everyone needs to be part of the process and aligned to support the strategy. This alignment needs to continue throughout the implementation and as the strategy evolves.

Summary

Today's clinical development environment has complex, very siloed, and usually aging technology in use. Moving into the future requires a transformation of the business to a nimble integrated data and platform centric environment. This reduces the technical debt. This also creates a capability to have shared platforms that are used across the organization, particularly if we apply fair data principles.

Many Clinical Development organizations currently have non-integrated solutions and redundant systems that serve the same purpose. This creates many issues, including a lack of compliance and inefficiency related to how data is captured, managed and accessed. Moving from this circumstance to a more rationalized platform environment focused on business value is a more modern, effective approach.

Technology can be better leveraged to improve the outcomes of clinical development by employing a platform based architecture along with a data centric model. This makes organizations less dependent on commercial

applications while prioritizing the key asset of clinical development – the data.

About Astrix

Astrix is the unrivaled market leader in creating & delivering innovative strategies, technology solutions, and people to the life science community. Through world-class people, process, and technology, Astrix works with clients to fundamentally improve business, scientific, and medical outcomes and the quality of life everywhere. Founded by scientists to solve the unique challenges of the life science community, Astrix offers a growing array of fully integrated services designed to deliver value to clients across their organizations. To learn the latest about how Astrix is transforming the way science-based businesses succeed today, visit www.astrixinc.com.