WHITE PAPER

The Clinical Transformation Journey

NNIT

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Executive Summary

Twenty-first-century clinical trials demand clinical transformation. As life science teams grapple with new technologies, new trial designs, new compliance requirements, and process innovations, clinical transformation has become imperative.

Merriam Website defines transformation as "a change in form, appearance, or use." [1]

This seemingly simple definition belies the complex undertaking of transforming clinical capabilities. There are many factors regarding people, processes, technologies, and standards that must be addressed within a clinical transformation effort. Transformation is not possible if the organization does not take a holistic approach.

This paper shares the NNIT perspective on clinical transformation – the challenges, motivations, and benefits. We also touch briefly on where to start the journey. As with any trip, it is essential to know where you are and where you want to go. This may sound rudimentary, but any clinical professional will appreciate the nuances of this discussion.

The tightly woven web of systems, compliance requirements, integrated processes, cross-functional connectors, standards, and skillsets are required to manage the data lifecycle successfully. The problem underlying transformation is that the magnitude of complexity often interferes with the integrated weave that connects each component.

The Clinical Transformation Journey promises improved safety, compliance, and efficiency. Its focus on speeding up clinical trial conduct promises much-needed cost and effort reductions. It is a necessary journey to tackle the growing variety, volume, and velocity of clinical data, a key component to achieving the promised benefits.

1 www.merriam-webster.com/thesaurus/transformation

The Challenge of Clinical Transformation

Transforming clinical trial conduct within a life sciences organization is a complex effort that must address the people, process, and technology aspects of the business.

Historically, Clinical has seen many changes in operating models, tools, and practices. The function has evolved to meet the requirements of a regulated industry while still focusing on patient safety and operational efficiency. Many Clinical teams want to transform their business and improve performance using technology. A key challenge with clinical trials is that each study team operates within its scope of knowledge and expertise. Inability to use or reuse historical data and documents in decision-making hinders the ability to transform clinical operations.

Every organization is different, which means their transformational journey is different. Breaking down siloes, standardizing and consolidating data and content, and optimizing end-to-end processes require a thoughtful approach. The biggest challenge lies in developing a roadmap for transformation that comprehensively addresses the various facets of the business while aligning with company goals and ensuring long-term success. Clinical operations usually have limited resources to take on transformation projects. Trusted clinical advisors with a deep understanding of clinical trial processes, procedures, and stakeholder needs can play a crucial role in driving the change required for transformation.

Key Drivers for Change

A combination of factors is motivating transformational change across the life sciences industry. Combined, they provide a strong impetus for teams to take advantage of new technologies and reap the benefits of innovation and IT optimization.

Numerous business drivers are motivating clinical transformation. Scientific advances in R&D have opened up for personalized medicines. They transform treatment opportunities with advancements in gene therapies and editing (CRISPR), bio- and chemo-informatics, and immunotherapy. They challenge the traditional clinical trial design, especially concerning the patient's role throughout the trial conduct.

As these innovations move forward, there is an increasing regulatory focus on the (re)use of patient data, patient privacy, and security of both data and content across data sources and stakeholders. There is also a greater need for connectivity and interoperability across systems and partners. Quality and oversight continue to be strong influences as research teams increase engagement with key stakeholders. All of this occurs as teams look to emerging technologies such as AI, Big Data, BI, etc., to optimize clinical trial processes.

The path to clinical transformation is different for each organization. It requires an honest assessment of current skills, systems, standards, and practices. Digital transformation can be challenging because it requires a depth and breadth of business and technology understanding that is difficult to find.

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A Changing Clinical Landscape

As clinical teams seek transformational change, they must operate in a constantly evolving environment. Therefore, transformation projects must consider the ongoing trends that will influence the success or failure of the effort.

Clinical Trial Technology Consolidation
Modern clinical trials require a host of systems with varying levels of automation. Traditionally, clinical applications such as Electronic Document Management System (EDMS), Electronic TMF (eTMF), Clinical Trial Management Systems (CTMS), Interactive Response Technology (IRT), Statistical Computing Environments (SCE) etc. have been managed as fragmented and siloed stand-alone applications, separating data and content, and creating a barrier to optimization. It also detracts from the benefits of an end-to-end process by creating obstacles that inhibit visibility and access, impeding efficient collaboration and oversight.

Significant workarounds, manual data entry, and duplication between systems are inevitable side effects of siloed capabilities. For example, consider a protocol amendment authored and reviewed in an EDMS, referenced in the eTMF, distributed to CROs and sites, and included in a regulatory submission. Is the content of this document copied for distribution to stakeholders or simply referenced? If the author changes the document, is the update replicated throughout all the various systems and processes promptly? Do all of the users have access to the right content at the right time? Many organizations are moving toward unified platforms that enable seamless management of content and data. This trend supports standardized data models and use cases that result in greater compliance and operational efficiencies.

Fail Faster and Succeed Sooner
Traditional silos minimize the opportunities to use and reuse information across the organization. Many companies on their journey toward clinical transformation are taking a broader, more holistic approach by increasing access to relevant data for various internal stakeholders and purposes. Enabling greater access to information, they find new ways to use technology to support the "fail faster and succeed sooner" mantra. They learn to rely on the data to make decisions and act quickly. Access to data that results in better, more informed choices helps teams foresee potential issues and causes for failure and can provide early indicators for success. Examples include using data from external and internal sources such as wearables, patient records, trial governing sites, legacy protocols, and data sets for improved trial designs and site feasibility.

Compliance and Security Data integrity, privacy, and security are paramount to successful clinical research. With increasing patient engagement and the use of personalized data, sponsors and global regulatory entities prioritize patient privacy, data security, and compliance as foundational components of a successful clinical transformation. In addition, daily operations in onboarding and offboarding partners and vendors promptly while access to the right level of information for each individual and role must be managed.

Ethics and Use of Emerging Technologies
While the use of data is key to the transformational program, so are emerging technologies. For example, artificial intelligence shows great promise in the realization of both short and long term transformational goals. However, these technologies can also add a level of complexity to the discussion. Teams must consider the regulatory, reputational, and legal risks as well as potential ethical considerations that can derail a transformation project.

Starting the Journey

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The first step in clinical transformation is to define the digital strategy. This important foundational step requires the organization to articulate a vision. In doing so, they can begin to build a shared understanding and agreement on priorities, timelines, and scope. This foundational step also requires a full view of current capabilities, systems, and data standards. It often surfaces harsh realizations about the status of the organization. The availability of necessary expertise across business and IT to support such programs, the adaptability of existing systems and infrastructures, or an organization's willingness to transform may emerge as critical considerations.

The appropriate strategy to overcome such potential barriers to transformation will evolve throughout the transformation project. But the anticipation of these themes and their potential impact on the transformational project can be circumvented by the project team by focusing on the organizational change management required on such an important project. In this scenario, the input of an objective and experienced advisor is quite valuable. As the organization transforms, new challenges may arise. Cross-functional dynamics change. Roles and responsibilities evolve – still, the underlying requirements to maintain trial continuity, keep patients safe and maintain compliance never sway. An advisor who understands the business, challenges, enabling technologies, and their strengths and weaknesses can help life sciences teams navigate this complexity.

Developing a Vision for Clinical Transformation

Clinical transformation requires significant effort and time. More extensive transformation programs are often open-ended and require a phased approach. This method allows the organization to realize the benefits of each stage, which are then used as a foundation to springboard into the next phase. A guiding vision that spans the entire project is critical to success. The vision motivates teams toward their stated goals and drives people, processes, and technology decisions. Frequent communication and adherence to the vision influence and aid in the development of a culture of innovation. This culture embraces transformation and seeks out new and better ways of doing business.

NNIT understands the clinical data lifecycle as well as its stakeholders, processes, and technologies. With more than 20 years of experience working within clinical operations and data management, NNIT has supported customers wherever they are on their transformational journey.

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The NNIT Approach to Clinical Transformation

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Connecting Technology to Business Goals
NNIT continues to bridge the gap between R&D business teams and their enabling technologies. Our holistic approach ensures that any technology implementation aligns with the business requirements and goals.

We partner with our clients to build and maintain a long-term Clinical Transformation Journey as efficiently as possible. NNIT service offerings include advisory and implementation, validation, migration, and application services. We help life sciences teams navigate the complexities of clinical transformation.

We recognize the importance of experience and combine Clinical subject matter expertise with industry best practices to provide a pragmatic and efficient approach to transforming Clinical Operations.

If you want to learn how NNIT can support you on your way to clinical transformation, please contact us on **nnitcontact@nnit.com**

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Together we make a mark in business and society; bringing digital transformation to life

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We are a leading global RA advisory and consultancy unit committed to digitally transform Regulatory Affairs into an influential strategic and data driven business unit. We leverage thought leadership knowledge and the newest technology, with implementation excellence and successive maintenance service.

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