



The New Age of Decentralized Clinical Trials

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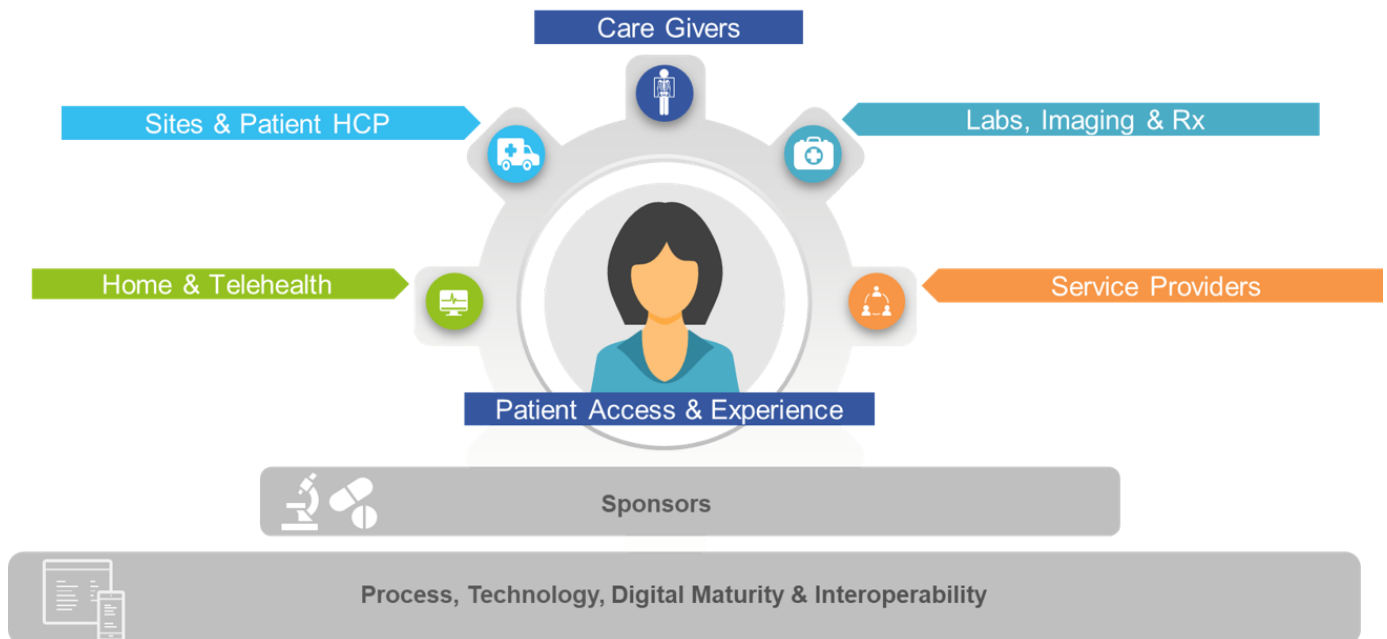
Introduction

We are hearing from our clients, as well as through our experience in the industry, that modernization of clinical trials and the role of decentralized clinical trials are becoming an important focus. As we know, life sciences organizations are facing a changing ecosystem. Patient access-diversity is driving the need for different types of interactions with the various stakeholders, as well as with the sponsors. It is also impacting how process, technology, interoperability, and digital maturity, are playing a role in providing patient-centric and patient-site enabled services.

In this white paper we explain:

- The Working Definition of DCT
- How Trends in DCT can be Understood
- What DCT is actually Enabling
- How DCT's Impact can be measured
- How to Achieve the Adoption of DCT

Decentralized Clinical Trials



The Working Definition of Decentralized Clinical Trials

FDA defines Decentralized Clinical Trials (DCT) as, “those executed through telemedicine and mobile/local healthcare providers, using processes and technologies that differ from the traditional clinical trial model.” 1 The working definition of DCT is more complex than the FDA definition would seem to describe.

There has been substantial attention paid to, and emphasis on, DCT lately. Despite the explosion in interest among sponsors, CROs, and tech providers, the reality is that there remains much more to explore and understand relative to the feasibility of new approaches, the technologies and capabilities needed to support DCT, and how DCT impacts trial design, trial management, data collection, and analysis.

Much of the focus is on the more common elements, such as those focused on electronic informed consent, eCOA, and telemedicine (See Figure 1- and the left side of the spectrum).

Decentralized Clinical Trials Defined

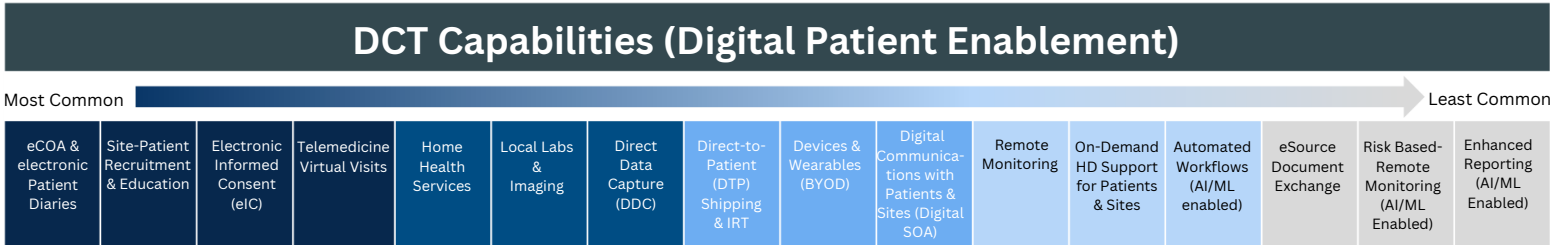


Figure 1

It is estimated that there are more than 200 DCT technology, device, and service vendors in the marketplace today. As the drive for technology increases and technology providers continues to proliferate, wading through their offerings can be a daunting prospect for sponsors.

However, it's important to consider how to advance across this DCT spectrum and contemplate the impact of other more advanced approaches; impacts on:

- both the patient and site experience
- the technology and data implications necessary to support capabilities for direct-to-patient (DTP) shipping,
- remote and risk-based monitoring, and
- automated workflows,

These are depicted in figure 1-Moving from the left to right across the spectrum.

Ultimately, the aim is to drive increases in adoption of “patient-centricity” or “digital patient enablement” in which the focus goes beyond just being able to implement these types of offerings as part of the clinical trial technology toolkit to enable DCT to lower the barriers to sites, sponsors, and patients.

Expanding Opportunities for Patient-Site Access

As we look ahead, the outcomes of DCT should:

- Accelerate clinical development,
- Enable patient-centricity, and
- Support the delivery of a stronger evidence package than traditional clinical trials.

To achieve these outcomes, we need to consider how to further expand DCT and to go beyond the most common capabilities into more advanced technology-enabled capabilities.

Expanding Opportunities for Patient-Site Access

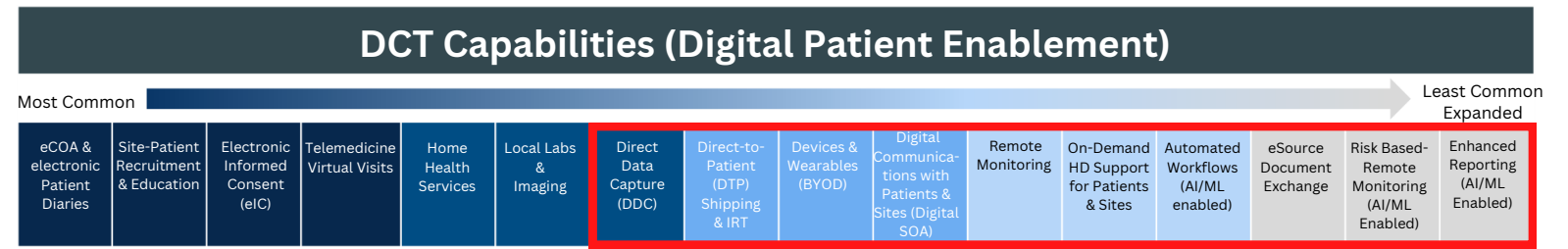


Figure 2

Moving across the spectrum (Figure 2), the clinical data landscape (e.g., types of data, data sources, data collection and ingestion mechanisms, etc.) expands in breadth and complexity. To support these increasingly complex data landscapes with new and additional sources of data, different approaches to capturing that data, as well as transferring and integrating it within a broader ecosystem is required. Enabling capabilities to harness evolving trial data within the overall trial technology ecosystem becomes even more vital as we progress across the spectrum.

Moreover, there is an opportunity for sponsors to accelerate beyond the pace that traditional study models will afford and at the same time look for ways to reduce both site and patient burdens as compared to more traditional trial models.

Trends in Decentralized Clinical Trials

What becomes important, as the use of DCT expands, is the level of digitalization and how well various parts are connected. Additionally, the level of patient centricity, which can be thought of as customer centricity, can be enhanced as we are interfacing not only with sites, but with the patients and some of the longer-term vision within HCPs or other care entities, towards ‘value-based care outcomes’

Figure 3 is an illustrative view (versus a quantitative analysis) that depicts the level of digitalization on the x-axis, versus the level of patient centricity on the y-axis.

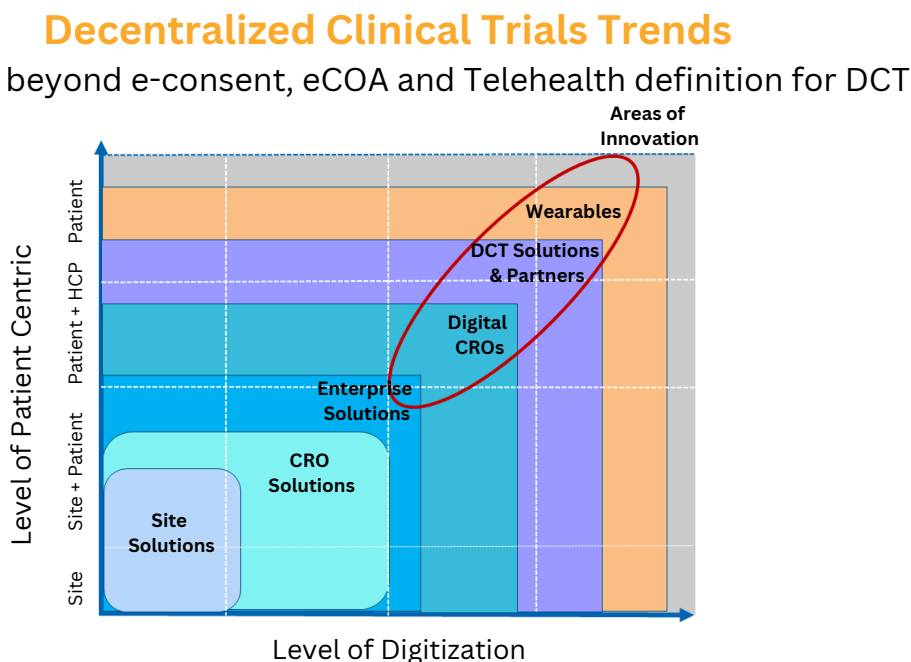


Figure 3

We are seeing the following trends in clinical trial modernization being facilitated by increasing DCT use:

- Limited growth in solutions with cross Patient-Site-Sponsor views and exchanges of information, with enabling workflows (e.g., Still Point Solutions)
- Increase in offerings and tools around:
 - Digital CRO and DCT vendor/partner solutions
 - Digital Diagnostics for DCT outcome measures
 - AI/ML enablement
- Continued challenges with:
 - Interoperability to share DCT as a ‘Service’ (vs adjunct technologies and service providers)
 - Sites want to use their own technology beyond e-content, eCOA, and the Telehealth definition of DCT. Innovation is happening in Digital CRO, DCT Solutions & Partners, and in Wearables and the medical home, along with ‘value-based care’ outcomes.
 - Need for sponsors to have measurable outcomes for site and patient adoption of DCT, i.e. what are the benefits to the customer vs sponsor value.

Decentralized Clinical Trials Enablement

Much of our work is being done for our clients looking to improve their process, technology, capability, and organizational culture. Figure 4 illustrates three quadrants: Foundational, Enabling, and Innovation representing areas of focus.

Decentralized Clinical Trials Enablement

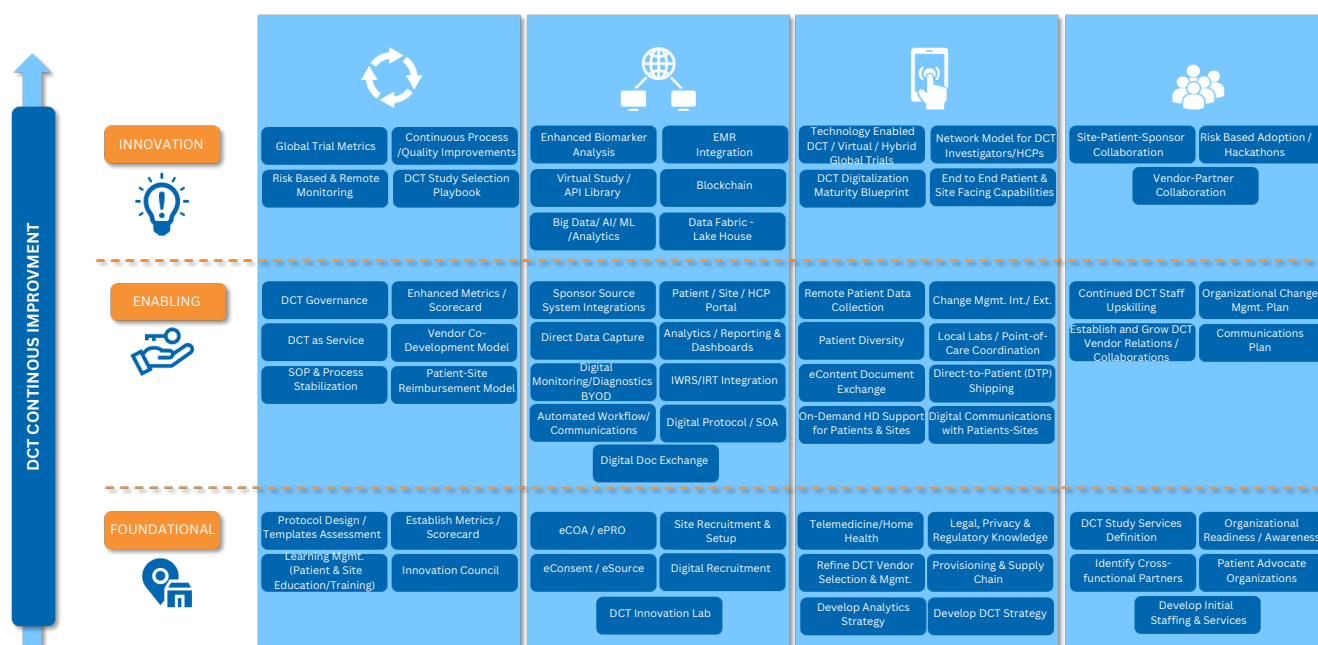


Figure 4

Most of our clients are split between the Foundational space and Enabling areas with some moving up into the Innovation region relative to clinical trial modernization enablement through DCT.

Our clients are focusing on some key DCT areas. While some are focused on capabilities associated with Telemedicine, Home Health, and the coordination of care, others are enabling technologies centered around digital protocol, and SOA to automate workflows and communications.

Some of our clients are considering the incorporation of:

- e-content document exchange,
- risk-based, and remote monitoring.

Any of these can influence the designs of the actual protocol, as well as changes to current process and ways of working. One theme among our engagements is assisting our clients to assess ways in which they can improve the overall clinical operating model through: simplifying the number of points and use of platforms and integrations, and reducing [the volume of] data capture, entry, and updates as they work to improve their overall clinical operating model.

In working with our clients, one main area they look to focus on is clearly understanding the availability of DCT capabilities, technologies, and the vendors providing them. This is typically one of the first areas we focus on with the client to understand capabilities and how they could be leveraged. Using this information, we can help shape the organization's requirements and construct a client-centric strategy for clinical trial modernization for both the current and future business needs.

Decentralized Clinical Trials and Measuring the Impact

The drive to establish capabilities cannot come at the expense of measuring meaningful impact. Establishing criteria for success will help guide sponsors in selecting the appropriate DCT elements for a given trial to best meet goals for patient recruitment, diversity, and retention, along with the site and sponsor benefits. As sponsors carefully consider different DCT elements and as the industry progresses through to the point of increasing adoption, it's important to measure both short and long-term value and to determine how to best interpret that value for future decision-making. DCT represents a way to provide value to both patients and sites as well.

Ultimately, sponsors should look to how best to create both value and differentiation in terms of understanding the impacts of DCT enablement. This, then, helps organizations to assess where and how to invest, and how to measure outcomes, and impacts of DCT for their trials. Sponsor organizations that succeed in understanding DCT impact will be better positioned to make strategic decisions to establish their DCT portfolio to succeed as leaders in digital patient engagement.

Decentralized Clinical Trials Considerations



Figure 5

Decentralized Clinical Trials Adoption

Leveraging these approaches requires a thorough digital transformation. It involves a change in the way the organization works to transform the business and the operating models. It requires a rethinking of how the value to the patient and site experiences are ultimately delivered.

DCT exists on a spectrum and the journey to enablement relies on continuous improvement. In the last few years, there have been significant changes in the area of clinical trial modernization. We see a rapid pace of change in many of the capabilities being offered. Whether it's related to patient recruitment, site enablement, or novel ways of capturing patient data, capabilities are continually progressing. As we work with our clients and look at the longer-term view and the road ahead to map out the vendors and suppliers, we're seeing many new innovations that are disrupting the market. We, therefore, need to work towards an agile transformation. Concepts like hackathons and innovation labs, along with establishing different ways of working, can hasten the enablement of effective digital transformation.

Delivering on the promise of digital transformation will, however, require thinking beyond the frameworks of technology and data. It requires a look at the structure of the business processes and roles, both internally and with partners, so they are oriented to fully capitalize on improvements in data access and decision-making, (i.e., modernization of the operating model). Taking a holistic view can provide the organization with the ability to pilot models for clinical trial modernization at a smaller scale to not only validate the technology but also enable, through evaluation and planning, adoption to scale.

It starts by looking at the concept of human centricity and how we can foster and empower the workforce to embrace a continuous Improvement mindset mindful of the customer experience.

Several Key Considerations Relative to an Organization's Adoption of DCT

Think People First

- Organizations change when people change
- Understand the organization change readiness & opportunities for adoption... quick wins

Align Across the Business-Customer

- Understand the impact of a new solution/services on people, process & governance and how value is defined and measured

Agile Transformation

- Many organizations are looking to change their ways of working to adopt "Human centricity" approaches
- This places humans at the centre of a business's purpose, strategy and everyday business, to enhance the human experience
- It aims to create organizations which are agile and optimized for continuous improvement of the customer experience, while empowering the workforce

Digital Transformation

- Digital transformation marks a rethinking of how an organization uses digital technologies with data, people, and processes to fundamentally change business performance and the customer experience

Change as way of working

- Change is as much a journey as it is a destination, grounded in qualifiable measures to manage the transformation

Summary

We're seeing the first iteration of DCT 1.0. This area continues to evolve with new technology and methods to improve both digital trial enablement and digital patient centricity.

It is critically important, when looking to incorporate clinical trial modernization via DCT into your business, that you ensure you have the right external organizations involved who can assist you. Formulating the appropriate strategy along with the proper processes, and technology is imperative. Astrix's team of professionals has worked with many of the top life science organizations to assist them with respect to their business needs in these areas. As a technology-agnostic partner, without a preconceived preference for a specific supplier or product, we work closely with your team to ensure solutions are reviewed and incorporated into your business so that you succeed in realizing your vision and achieving your organizational goals.

About Astrix

Astrix is the unrivaled market-leader in creating & delivering innovative strategies, solutions, and people to the life science community. Through world-class people, process, and technology, Astrix works with clients to fundamentally improve business & scientific 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 strategic, technical, and staffing services designed to deliver value to clients across their organizations.