DATATRAK® Enterprise Cloud

CTMS

Key Features of a Decentralized Platform Providing a Complete Solution

Many life sciences organizations are unaware that complete DCT solutions exist, or they do not realize how significant an issue data integration is within their organization.

By Tim Lyons, *Datatrak*

Solutions designed to help life sciences organizations recruit and engage patients in decentralized clinical trials (DCTs) are ubiquitous across the industry. However, many of these solutions are customized "point" products, designed to accomplish a niche activity, necessitating another layer of data integration on top of clinical data already collected by other means.

Such solutions were more prominent a decade ago and the industry has shifted toward system consolidation to eliminate redundancies as technology has evolved, as well as to centralize data storage to support analytic abilities and to manage programs and product development more efficiently. Many life sciences organizations have aligned technologies to reduce the number of disparate systems and potential functionality redundancy across platforms. The effort cost organizations a significant amount of time and money but now, in the wake of the COVID-19 pandemic, most organizations find themselves applying the same exercise to execution of DCTs.

A tidal wave of disparate systems has appeared in the past 18 months, a response to the need to capture patient data when clinical sites may be unavailable or in-home therapy has technology requirements. This flood of point solutions was not the industry's intended response and the landscape now mirrors that of traditional trials a decade ago: many organizations have turned to niche solutions that address limited needs, allowing their programs to move forward in some viable manner. But, again, a concerted effort is being made to regain a more consolidated state (i.e., in terms of systems and technology choices), leading to a more efficient balance in the tools we use and how we use them.

How Did This Happen?!

Most DCT products require technology providers to perform all design work and leave someone with the need to cobble together multiple systems to provide a complete solution, increasing service cost and implementation time. Largely, these providers specialize in collection of patient data, but the customized, standalone products they provide for this purpose are not standardized platforms allowing for convenient setup and configuration. That burden generally lands at the distribution layer, with a clinical research organization (CRO).

A sponsor might ask a CRO for help supporting study execution, saying, "This is the ePRO or patient-direct vendor we have selected. Figure out how to consolidate their data with everything we are doing." Prior to the pandemic, though, the industry was evolving, with sponsors taking greater control of the systems they used. The sponsors still worked with CROs but stipulated, "Use these systems because we are standardized across them."

Now, in executing DCTs, sponsors are back to asking CROs to solve the solution integration-and-consolidation problem, drifting away from the hard-earned autonomy they carved out in traditional trials. Thus, solutions that address the current issue at a reduced cost or with greater efficiency are in high demand.

The utopian approach would involve collaboration among vendors, with a shared goal of improving and saving more lives, more quickly, by working together. However, vendors need to carve out an area to exist and flourish and, right now, point DCT solutions enable many to do so. They may build customized software solutions, at high cost, for every customer, every trial, and every opportunity. Very little repeatability is built into their product models because their systems are not yet mature enough to leverage expected repeatability.

These vendors are attempting to standardize their proprietary product offering by building a platform that allows for standardization to add efficiency, reduce margins, and keep the business viable moving forward. It could be surmised that need (for consolidated DCT solutions) was accelerated between two and three years before the industry was ready to support it, leading to a number of immature products. Many vendors are building the plane as it flies, so to speak, trying to handle current business needs while constructing a platform that does not truncate future opportunities.

Must-Have Attributes: Complete DCT Solutions

As vendors' products mature and more refined DCT solutions hit the market, sponsors and CROs have a variety of options. When comparing vendors and their solutions, organizations should look for a combination of agility, diversity, quality insights, and control.

Agility — A truly all-in-one solution includes a flexible feature set that provides users the ability to design based on any specification. This may mean overhauling the way patient data is captured, cleaned, and/or managed.

Using a disparate point solution, sponsors and CROs can capture data, but they have to build a new data-cleaning model, creating redundancy with other systems. The sponsor or CRO may use an electronic data capture (EDC) system for investigational sites to store data collected from lab samples and clinical assessments — information not coming directly from the patient — but all that data must be consolidated and cleaned, too. This redundancy adds administrative burden and cost.

An agile platform allows users to extend their data-capture footprint and account for patient needs, eliminating the need for redundant supporting processes to ensure quality data. Monitors and data managers should not have to perform the same tasks in both the existing EDC system and a new system, or significantly change workflows the organization has used for years. The system should wrap around the company, not the other way around.

Diversity — A diverse solution empowers sponsors and CROs to achieve a larger sphere of influence in patient selection and data. In terms of patients, DCTs offer potential access to a wide spectrum of patients from culturally diverse backgrounds and geographically diverse areas. People who have been unable to participate in trials because they cannot physically travel to a location, either because of geographic proximity or their own health limitations, are now viable participants — but only if they have tools enabling them to take full advantage of the opportunity.

Breaking down those walls and expanding the pool of data that can be collected provides greater visibility into product development efforts, improving investigator understanding of different individuals' physiology based on gender, race, environmental impact, etc. This diversity is key to ensuring more robust healthcare-related product development, tailored to serve numerous different individuals.

In terms of data diversity, smart devices have created opportunities for trials to connect to automated, sensor-based technology to gather health data, as well as leverage preexisting data within proper context. Collecting this additional data, without additional patient burden, supports creating a full picture of that person's health and contributing factors that might impact product success. Five years ago, a patient's full data profile probably represented 2% or 3% of the data they have potential to produce. Now, technology enables the tracking of patients' general motions, heart health, blood pressure, etc.

This sensor driven data, in turn, not only provides significant amounts of potentially useful supplemental information that could support the current and future trials, it eases investigational efforts when things like adverse events occur. Previously, investigators had to rely heavily on questions asked of the patient, a strategy dependent on the patient's understanding of their own health, which in the majority of situations is limited. But, capturing data with tools designed specifically to look for irregularities completely changes the nature in which data can be used on a large scale to understand not just the patient's direct data contributions, but their indirect contributions simply via inclusion in the study.

Insights — Insight into trial progress requires rich reporting tools and analytic reports that properly contextualize and apply the data collected. Staggering amounts of data are collected daily in a clinical trial, but that data only becomes information when it is analyzed against expectations and other data. As life sciences organizations develop a product, they define what function that product will perform and how it will be investigated. So, they are turning some portion of this data into information by analyzing it and developing a hypothesis of how it might benefit the world. But, they also have to determine the state of their total data picture, as well as how they might develop it further.

Consider that every product development opportunity in the clinical trial industry creates a "starburst" opportunity. Data is applied to product No. 1 and offshoots of product No. 1 may be defined from events that occur within that trial, creating new product opportunities. For example, perhaps a product intended to combat body aches for a certain condition failed to do so, but it was discovered the product reduced the frequency of headaches caused by that condition or eliminated another symptom. Those data points cannot be ignored (i.e., because doing so undermines the possibility of a future product development effort).

In having the ability to collect such diverse and voluminous data, we also have a responsibility to do something with it, to develop new therapies or to be more efficient moving forward. Therefore, any complete DCT platform must offer sufficient analytic tools to enable efficient development not only of product No. 1, but also to be a catalyst for potential products spawning from product No. 1's development effort. Sponsors and CROs cannot afford to waste time chasing down a single data element and figuring out exactly what that means; they need to gather 20 million data points and apply a tool set and a platform that can help figure out what each data point means and where it can be applied, now or in the future.

Control — Control, for sponsors and CROs, simply means empowering the customer with the ability to design your own trials and apply changes. Ideally, from a tool and a platform perspective, "control" means the technology provider teaches the sponsor or CRO how to design their own trial, collecting target patient data and integrating it into the platform smoothly. This model is the epitome of the adage, "Give a man a fish, he'll eat for a day; teach a man to fish, and he'll eat for the rest of his life."

Datatrak embraces this model. We want to empower clients to make their own determinations regarding how to apply their time, personnel, and financial resources. We aim for clients, after a few days of ap-

plication design process training, to be able to create their initial trial (e.g., perhaps a demo trial or a training trial) and begin collecting data within a week.

Compare that model to a provider offering immature custom solutions: initial discussions with the vendor, laying out platform requirements, may take a few weeks. Coding that solution can take six to eight weeks. Then, after initial delivery, it can be expected several aspects of the solution will require adjustment, adding several more weeks to the process. At the end of that 10-14 weeks, the client receives a custom solution tailored to their needs.

But what happens when product No. 2 advances to clinical trials? The client must start again at square one, defining requirements and moving through subsequent steps over a matter of months. At this point, the sponsor is operating at the whims of that vendor, impacting timelines, resource allocation, and the status of product pipeline (i.e., it is sitting, waiting for product development to advance). Technically, the technology and the provider are doing their job, but they are not moving as expeditiously as the client would like, nor are they allowing users to operate in the way they want to operate.

Datatrak's Complete DTS Solution

From its inception, Datatrak's Enterprise Platform was designed with a unified code set. Data is collected centrally in one database, one system, and all parties benefit from the efficiency that creates. We created standardized tools as a basis for the platform, allowing customers to design and configure their own applications, rather than just us. Sure, if a customer requests an EDC or ePRO database for a study, we could build it. But we can also provide that client access to the tool set and they can oversee database design, since each element is standardized and every life sciences organization needs the same general functionality.

Our more vital task is ensuring a customer-centric independence model, wherein users can wrap the platform around how their business functions, from its available personnel and instrumentation resources to its internal workflow. Users are free to design their own (hybrid or fully virtual) patient-direct trials with mobile applications. They control their own total cost and timelines internally, as well as their implementation concepts and mechanisms. So, users can design trials — stem to stern — based on patient concerns from day one, eliminating the need for data integration from disparate systems.

For example, Datatrak recently has served several clients who started on a different path, procuring competitor platforms for patient data capture. However, these tools were not integrated into the clients' existing systems, stranding their data on an island, essentially inaccessible. We were able to help those clients access their data and, due to the Enterprise Platform's standardized features, none of those clients needed to use the entire platform. Like all our clients, they were able to pick and choose from among the platform's features, choosing only those applicable to controlling and accelerating the outcomes of their specific clinical trials.

In the above example, Datatrak served as the bridge between the client and the island where their data was stored. But our ideal scenario comprises eliminating the need for any bridge: getting a trial up-and-running in a short time while ceding control to the sponsor or CEO. One of the clients discussed above was working with a vendor whose solution to collect data from patients took more than six months to create and establish. Data integration, after Datatrak was hired, took a fair amount of time because it had not been considered by the previous vendor. The product didn't have a standardized structure on the back end — everything had to be created on their side of the bridge from the bottom up.

But Datatrak was hired to assist with a follow-up study for that same client and, using our solution, the client built out the study in a fraction of the time. By reducing the number of systems they used, the client also reduced their required setup initiatives, requirements to be defined, and amount of user acceptance testing.

In fact, the biggest problem most organizations have with a complete DCT solution is lack of awareness: they may not be aware such solutions are available, or they may not realize how significant a pain point data integration is for their organization. They may not realize the direct-to-patient solution they are using offers little agility or control to adjust as needed, simply tolerating (rather than designing and embracing) the workflow processes or profiles for how their studies will be conducted. Again, a DCT platform should accommodate how users function without forcing them to compromise, while consistently moving the project forward.

For more information, visit us at https://www.datatrak.com/.

Additional Reading

- https://www.datatrak.com/industry-insights/blog/posts/why-a-centralized-data-platform-is-the-key-to-opening-the-door-for-decentralized-and-hybrid-clinical-trials/
- https://www.datatrak.com/industry-insights/blog/posts/why-datatrak-direct-epro-a-combination-of-decentralized-trials-and-clear-data-insights/
- https://www.datatrak.com/industry-insights/blog/posts/why-datatrak-direct-epro-flexibility-to-go-virtual/
- https://www.datatrak.com/industry-insights/blog/posts/why-datatrak-direct-epro-powering-teams-to-take-control/

About The Author

Tim Lyons is Vice President of Product Development and Operations for Datatrak. In this role, Tim oversees the strategic direction of product development and organizational operations to deliver an exceptional user experience. Tim has held a variety of leadership positions at Datatrak, including roles in Software Development, Product Management, and Clinical Project Management services. Prior to joining Datatrak, Tim worked with Pharm-Olam, a global CRO, and IntraVantage Medical Devices. Tim earned a Bachelor of Arts degree from the University of Minnesota.

About Datatrak

Datatrak built its multi-component, cloud-based solution through a single, unified clinical research platform, leveraging a single-database architecture and expanded this concept to include services delivery from the company's service group. Datatrak delivers a complete portfolio of software products designed to accelerate the reporting of clinical research data — from sites to sponsors and, ultimately, regulatory authorities — more efficiently than loosely integrated technologies.