Pharmaceutical Services: Spotlight on Tech-Enabled Clinical Development

The shift of development dollars to biologics and medicines for smaller, targeted populations is creating opportunities for outsourcing partners with the expertise as well as flexibility to work with midsize and emerging biopharmaceutical companies.

INTRODUCTION

The pharmaceutical market has evolved from a traditional "one-size-fits-all" blockbuster medicines model to a market that includes a significant number of specialty and precision medicines. In 2018, the FDA approved a record 59 novel drugs. Of such approvals, 16 of the drugs (27%) were for specialty medicines and 25 of the drugs (42%) were for precision medicines. Meanwhile, only 31% were for traditional medicines.

This evolution has broad implications for both the pharma services market and the clinical development providers who partner with pharma services stakeholders. Provident has analyzed the following ramifications:

• Speed has become increasingly important to pharma sponsors due to the limited Total Addressable Market (TAM) for targeted patient sets in select cell, gene and immunotherapy markets. The market does not always justify competitive therapies for rare diseases

• The need to reduce cost and time between development phases and increased preference for data centric approaches by sponsors driving the eClinical market

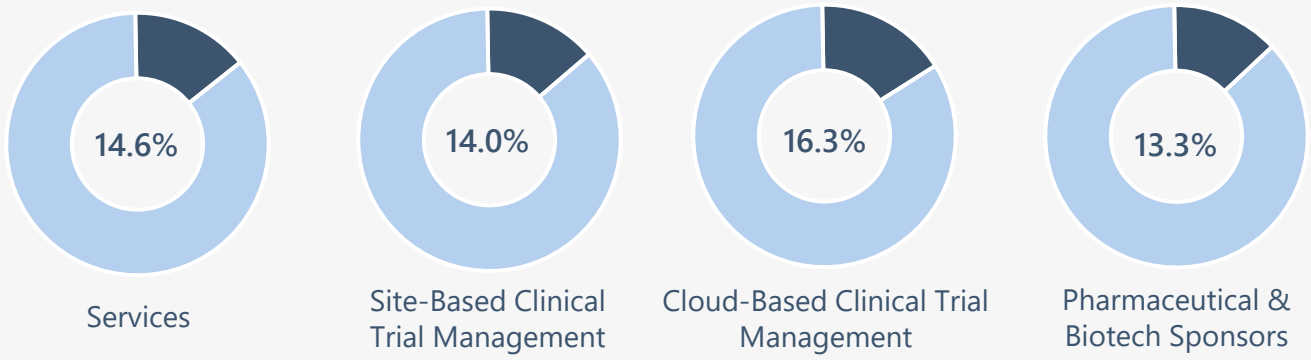
• As payers transition to value-based care, particularly for costly specialty and precision therapeutic approaches, there is an increased need to track outcomes and harvest post-approval data

• Increased need for data from the FDA due to the Technology Modernization Action Plan (TMAP) and post approval regulatory requirements with the analysis of real-world evidence (RWE)

• Outside of traditional eClinical consolidators, traditional CROs can often have a strong interest in acquiring technologies that supplement existing service offerings

As a consequence of these trends, companies with differentiated patient-centric solutions designed to mitigate major pain points during clinical development will garner the strongest interest for M&A.

Clinical Trial Management System (CTMS) Market
Projected CAGR By Segment (2019 – 2025P)



Source: Global Market Insights

KEY TRENDS & OBSERVATIONS

Limited TAM for Novel Drugs Increases the Importance of Speed to Market

As mentioned prior, sponsors of novel therapies are emphasizing speed to market as one of the most crucial variables to drug success. Evidence over the past 27 years collected by McKinsey & Company has confirmed that first to market drugs have secured greater market share and economic returns for pharmaceutical companies across all therapy types; from high-volume generics to targeted gene and cell therapies.

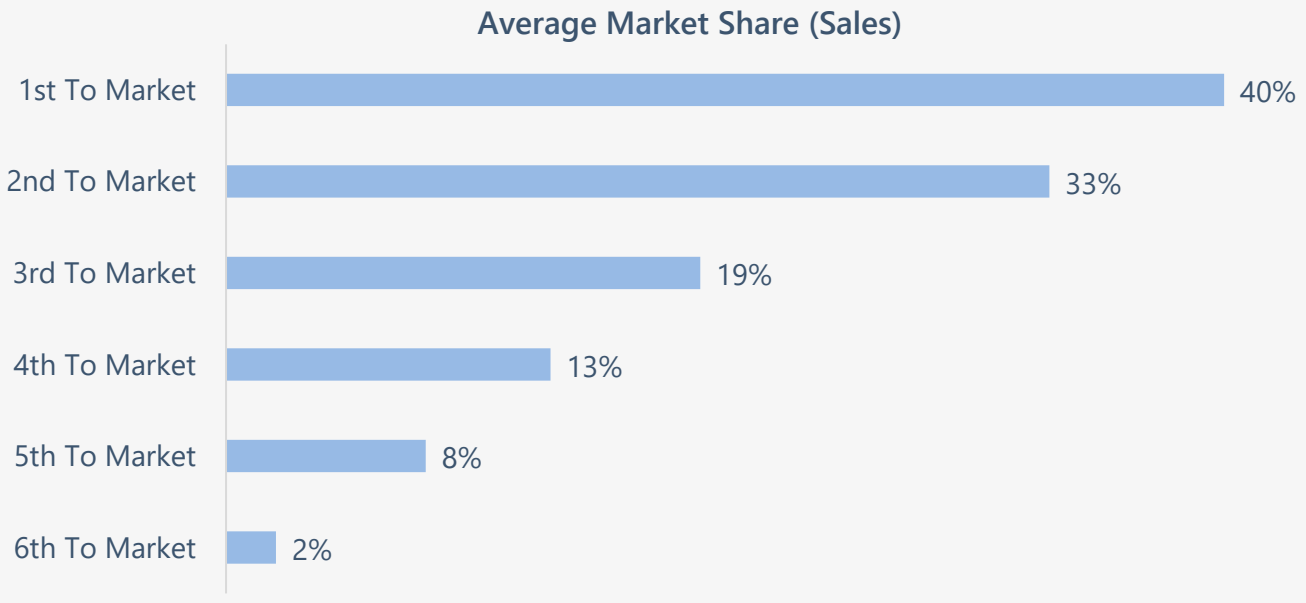
Emphasis on speed to market becomes most crucial in small rare disease patient populations that do not offer a sizeable enough total addressable market (TAM) to justify the entry of competitive therapies. This in turn directly affects clinical trial managers and their CTMS partners, who must innovate to keep up with the demands of their sponsor clients.

Technologies that allow for easier patient enrollment, quickly and cheaply amend study designs, and aggregate relevant data from comparable studies can alleviate many of these barriers to market that slow down or diminish the returns on new therapies.

Novel Drug Development Demands Greater Technological Ability Across Multiple Areas of Clinical Development

It is important to highlight that the sponsor community driving novel drug development is predominantly made up of small and mid-size pharmaceutical companies. Without the balance sheets and cash flow that Big Pharma possesses, these companies must utilize eClinical solutions more heavily to commercialize as quickly as possible. Many sponsors are adopting the "virtual sponsor" model, which relies on outsourced clinical trial services at even the earliest stage,

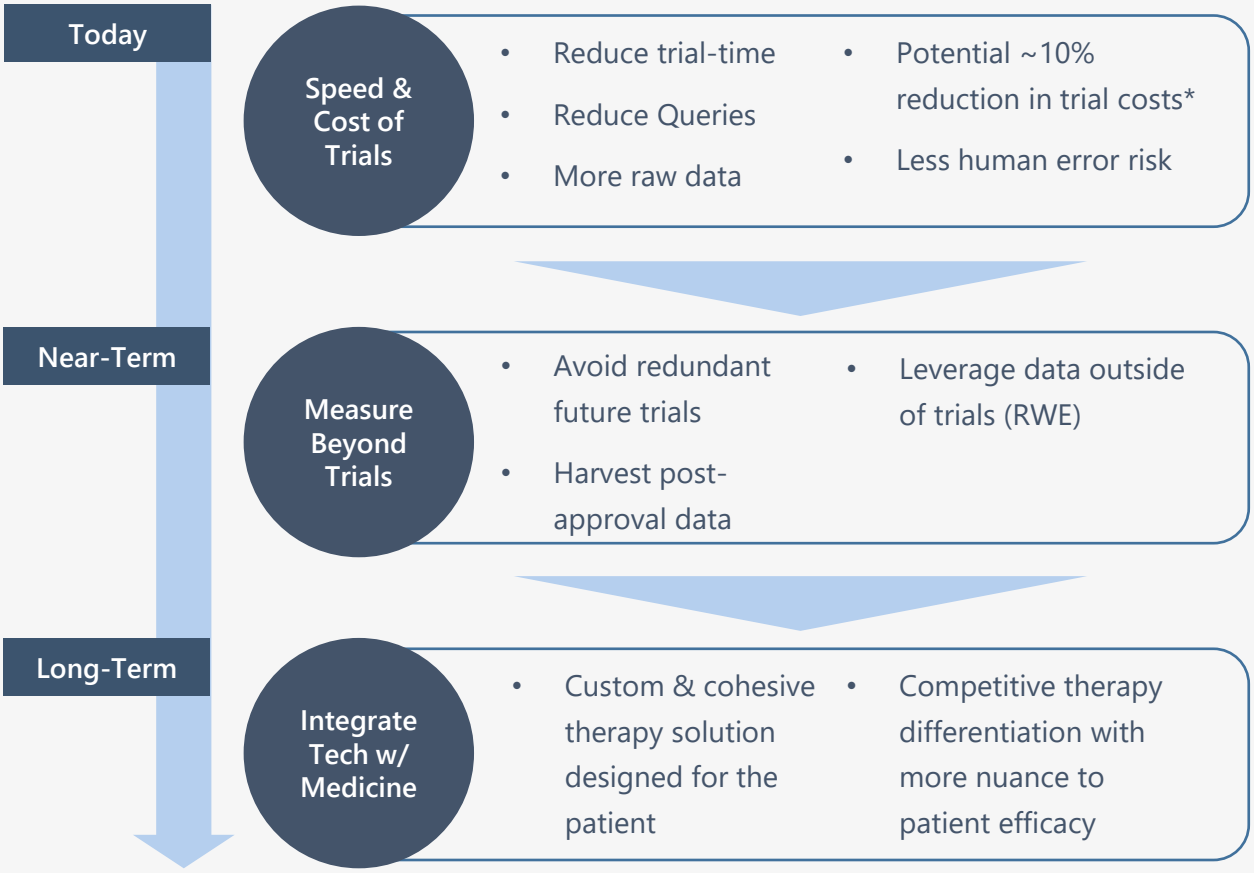
Order of Entry: First to market drug therapies have historically captured the greatest market share. This concentration is expected to increase as more specialty and precision drugs are launched



Source: McKinsey & Co.

KEY TRENDS & OBSERVATIONS

Progression of eClinical Value-Add as the Industry Increases in Sophistication



rather than the legacy model of managing early stage trials in-house.

The trend toward development of high dollar and precision therapies has also increased the demand for innovation in trial management. Without the broad patient populations that clinical trial managers had access to in the blockbuster drug era, site managers and CTMS providers must adapt to accommodate smaller patient populations. This translates to more targeted selection of patients, greater cost up front on biomarkers, and stronger patient monitoring/compliance.

The lack of innovation and flexibility provided by the traditional strategic players in pharma services has created a market for niche providers to the virtual and novel drug sponsor community. Despite the demand, many niche clinical trial and eClinical providers who have developed technologies to serve these sponsors are also struggling to expand and integrate suites of solutions together without the help of external capital.

There is demand for clinical trial management systems with both the innovation to serve data-driven drug sponsors and the scale to capture significant market share. One of the resources available to companies who wish to scale in this environment has been in the form of capital, both venture and private equity.

Source: Otsuka Pharmaceutical

KEY TRENDS & OBSERVATIONS

Much like how private equity was a catalyst for consolidation in relevant sectors such as the CRO space, capital partnerships will be a key component of future success in tech-enabled clinical development.

Payers Requiring Post-Approval Data for New Specialty and Precision Therapies

Through the 21st Century Cures Act enacted in 2016, the FDA opened the doors for increased communication between commercial payers and the life sciences community. This law established a feedback channel for drug sponsors to now engage with payers prior to FDA approval.

One of the goals of this initiative was to give the sponsor community more guidance on the economics and potential market opportunity of new therapies as they come to market in a value-based care system that continues to shift the goal posts in the eyes of the pharma and pharma services communities.

In turn, the payers are utilizing their own population health expertise to enhance their data-driven approach to reimbursement. Since many of these precision and specialty therapies targeting rare diseases are high dollar relative to their patient populations, some novel therapies will not be accepted by the payers.

The post-approval stage offers the most opportunity for improvement in this realm for both the drug sponsor community and the payers. By leveraging tech-enabled CTMS, both the payers and sponsors will have greater insight into long term safety, outcomes, and patient adherence.

For the payers, this insight will guide reimbursement and determine the opportunity and economics of competitive therapies for a given patient population.

Stages in the FDA Lifecycle: Increased Emphasis on Measuring Real World Evidence Post-Approval for High Dollar Specialty Therapies with Limited Clinical Trial Populations

Pre-Approval

- Proposal of clinical development plan
- Epidemiology/potential treatment population
- Market dynamics, including potential role amongst existing therapies

Approval Stage

- Pricing and transaction information
- Business & marketing strategies
- Care management considerations

Post-Approval

- LT safety & effectiveness
- LT clinical outcomes
- Patient adherence
- Outcomes for specific sub-populations
- Competitive landscape analysis

KEY TRENDS & OBSERVATIONS

FDA's Implementation of TMAP Increases Demand for Data Competency Throughout the Drug Life Cycle

The Technology Modernization Action Plan (TMAP) proposed by the FDA in 2019, outlines the regulators strategy to revamp its measurement and evaluation capabilities to better serve the current pharmaceutical pipeline. The three goals of the plan are as follows:

1. Modernization of FDA's technical infra-structure
2. Enhancing FDA's capabilities to develop technology products to support its regulatory mission
3. Communication and collaboration with stakeholders to drive technological progress that is interoperable across the system

While scientific development has accelerated in the past decade, drug commercialization has lagged in comparison, partially due to the FDA and the clinical trial community's inability to effectively assess the efficacy of novel drugs. The key to evaluating and regulating precision biologics and cell/gene therapies for the FDA lies in data. This shift in the regulatory environment places new pressures on clinical trial managers and their service providers to invest in appropriate CTMS solutions that can meet this demand.

In parallel with the FDA's framework to use real world evidence (RWE) to monitor efficacy post-approval, TMAP could re-align the clinical trial landscape as eClinical services become increasingly essential to a clinical trials success. Companies with competencies in data capturing will be positioned to capitalize on this opportunity.

CROs Are Showing a Strong Interest in Acquiring eClinical Providers

Despite a greater share of clinical and pre-clinical drug spend is being driven towards precision and specialty therapies, large CROs with strong market share have not fully adapted their strategies away from more traditional small molecule drug development. As this space continues to develop and the eClinical market becomes more crowded, Provident expects CROs to leverage their market position and brand equity to acquire more eClinical technologies.

One of the barriers to this evolving trend has been the relative scalability of many eClinical solutions on the market. Companies that can exemplify a track record of scaling their technology effectively over the next few years will continue to be identified as strong acquisition candidates by the CRO community. Provident expects the increasing CRO interest in the market to propel deal valuations through competition.

CONSEQUENCES FOR M&A ACTIVITY

Private Equity Investment

Much like how the entrance of growth-oriented private equity drove consolidation within the CRO sector in the past decade and is accelerating the consolidation curve of the CDMO sector currently, Provident expects the clinical trial management and eClinical sectors to undergo the same transformation. While private equity is not an entirely new entrant to the eClinical space, the current trends highlighted previously contribute to an environment that is rich for more investment. Much of this opportunity lies in small and mid-sized eClinical and CTMS providers who have exhibited impressive growth, but lack the internal resources to capitalize and appropriately execute their pipelines.

Barriers to growth that a financial partner can help in solving are providing the operational and capital resources to hire new product development and sales staff, scale back-end systems and support, acquire competitors and technology, and integrate complementary products into cohesive suites.

Stakeholders that attract a capital partner to help scale in this growing space will be best suited to take advantage of these current trends. As this sector matures, Provident expects those who succeed via private equity partnership to play a pivotal role in determining the future leaders in cell, gene, and immunotherapy development.

Strategic Mergers & Acquisitions

While growth-oriented private equity is re-allocating and consolidating many small and mid-sized CTMS and eClinical assets, strategic M&A has been most active at the top of the market.

Pure-play CTMS providers such as Medidata (acquired by Dassault in 2019) are being merged with broader life sciences and software companies who do not have the expertise to succeed in this space organically. By acquiring Medidata, Dassault plans to integrate their expertise in 3D simulation with Medidata's CTMS capabilities. This initiative is focused on innovating the patient experience in clinical trials to best suit evolving sponsor needs. Furthermore, unlike the CRO and CDMO sectors, non-healthcare specific players have succeeded in the eClinical space by leveraging their broad software and technology expertise.

As is demonstrated in other industries, many PE-backed mid-sized platforms will ultimately exit to the current market leaders. However, the relevant buyer community will not just be obvious strategic buyers; but also the broader life sciences and software strategics who wish to enter this space.

CONCLUDING THOUGHTS

As precision and specialty medicines become a larger portion of clinical trial spend, stakeholders have and will continue to undergo significant adaptations. Regulators, payers, sponsors, and outsourced partners are all re-evaluating their current value propositions and capabilities, which will result in change across the entire pharmaceutical landscape.

Tech-enabled clinical trial development is positioned to become a driving force in this transformation, creating the opportunity for companies to grow and consolidate in an increasingly competitive environment.

While strategic mergers and acquisitions re-shape the top end of the market, small and mid-sized players will have the opportunity to leverage third-party capital to create the next wave of CTMS and eClinical leaders.

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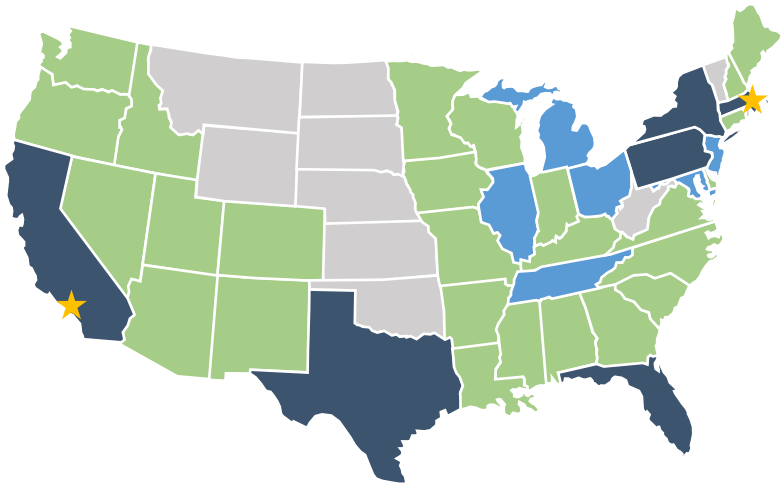
National Presence



1-3 Transactions
4-6 Transactions
7+ Transactions
Provident Office

21+	Years of Healthcare Investment Banking
130+	Healthcare Deals Closed
12-15	Landmark Deals Per Year
23	Banking Professionals

Note: The above map represents states where Provident clients were headquartered. Provident has successfully closed transactions with clients operating in 45 states and Puerto Rico.

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