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Clinical Trial Technologies

Market Research Report

January 22, 2025

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Note: Includes transactions completed at prior firms

Five Key Take-Aways on the Clinical Trial Software Space

We see an ongoing steady trend towards greater consolidation among software/tech-enabled service solutions in the clinical trial space in the coming years. Based on our conversations with executives at leading software vendors and private equity firms, we think that there is a broad understanding that integrated software/technology platforms can lead to accelerated clinical trial timelines, enhanced data quality, greater scale efficiencies, and improved collaboration.

1 **The global biopharma industry remains a large and attractive end market for software vendors to sell into.** Advances in molecular biology are creating new opportunities for drug development, and the pharma industry is under significant pressure to develop new revenue streams to offset more than $180 billion of revenue that is "at risk" from patent expiries through 2030.

2 **Clinical trial complexity continues to increase** due to more nuanced science, novel therapeutic modalities, and the greater use of precision medicine -- as well as pressure on pharma companies to differentiate their products based on "quality of life" measures. There are now 3.6 million data points in an average Phase III trial -- *a sevenfold increase since 2005*. This, in turn, is pressuring sponsors, contract research organizations (CROs), and sites to adopt unified software/tech strategies to improve data quality.

3 **Updates to the ICH E6 guidelines will bring greater focus on "quality-by-design" and "risk-based quality monitoring"** concepts in clinical trials. Over time, this should have the effect of encouraging sponsors and CROs to bring in software/tech vendors earlier in the clinical trial design process -- rather than "forcing" vendors to fit to a protocol after it is developed. In our view, this elevates the role of software/tech vendors into becoming true "partners" in the drug development process.

4 **We see a positive regulatory environment for the biopharma industry under a second President Trump administration.** We think that software vendors selling into the clinical trial space will likely benefit from a less regulated environment for artificial intelligence development with the naming of pro-innovation venture capitalist David Sacks as the White House "A.I. Czar." Also, Trump will likely be significantly less antagonistic to healthcare mergers and acquisitions than the outgoing Biden administration.

5 **Platform vendors continue to generally outperform and command higher valuations** among investors. Simply stated, integrated software/tech platforms allow sponsors and CROs to work off of a single dataset in real-time, mitigating the risk of lost and erroneous data that can occur as a result of double-data entry and the interfacing of disparate software applications. This, in turn, reduces administrative costs, improves decision-making, and accelerates "time-to-market."

Macro Considerations for Clinical Trial Software Vendors

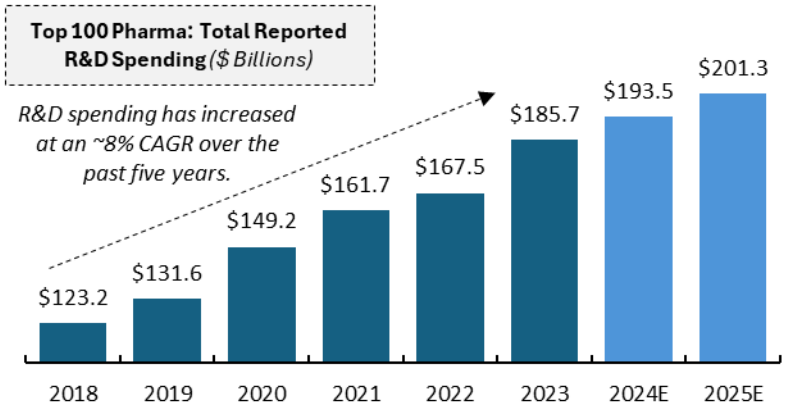
A Large, Attractive, and Growing End Market to Sell Into

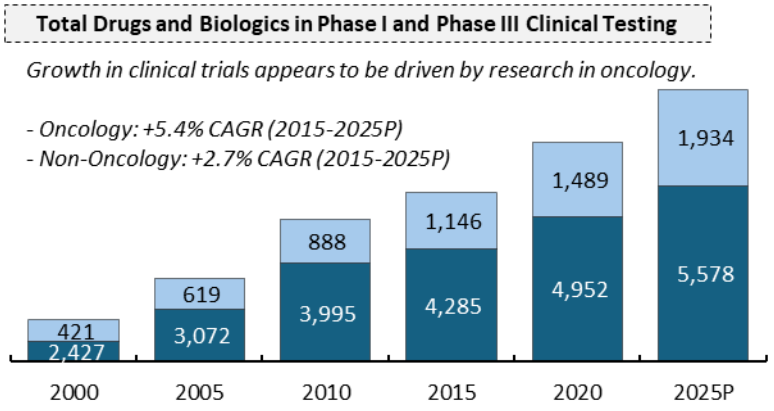
The global biopharma industry remains a large, attractive, and growing end market for software/tech companies to sell into. Over the past five years, we calculate that R&D spending by the top 100 global pharma companies has increased by over 45%. Worldwide R&D spending is on pace to $270+ billion by 2026, including $80+ billion spent on clinical trials.

Total global healthcare spending exceeds $10 trillion annually. Of this, spending on pharmaceutical products totals over $1.7 trillion, and this is projected to increase by 5%-8% annually through 2028 (to $2.3 trillion), according to the IQVIA Institute. In our view, much of this spending growth is being driven by demographics -- i.e., an aging population that requires significantly more medications. Also, there is a greater demand for targeted therapies with higher price points designed for rare diseases and genetic conditions. To meet this demand, we anticipate pharma companies and biotech firms will be investing more and more into R&D.

Adding to this, **advances in molecular biology have led to a greater understanding of the mechanisms of action and the biology of diseases.** This, in turn, is creating new pathways to address previously undruggable diseases and conditions.

At the same time, **pharma companies are facing a so-called "patent cliff"** with more than $180 billion of revenue "at risk" from the loss of exclusivity on branded drugs over the next five years (including a number of popular GLP-1 drugs). The industry is looking to fill this looming revenue gap with business development initiatives and mergers and acquisitions.





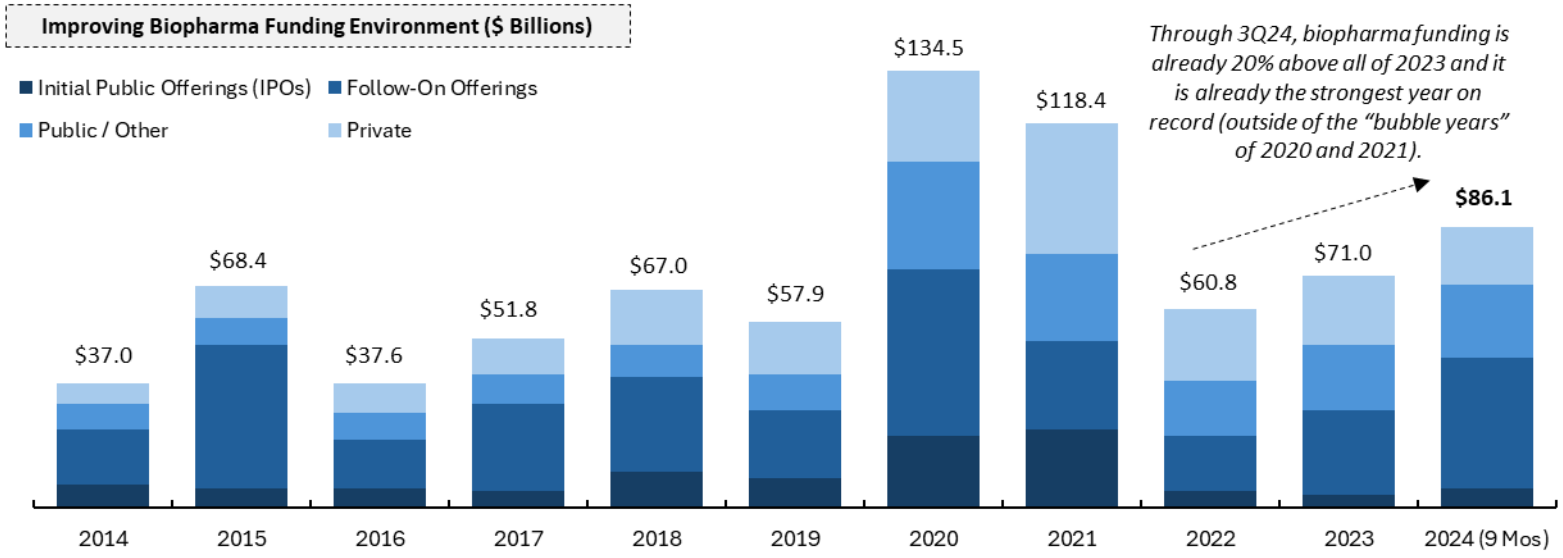
Source: The IQVIA Institute, L.E.K. Consulting, the U.S. Food and Drug Administration (FDA), Tufts Center for the Study of Drug Development, and Bourne Partners

Improving Biopharma Funding Environment Bodes Well

We view the improving biopharma funding environment as a good leading indicator for demand for software and outsourced services. In our view, there tends to be a 12-to-24-month lag between a funding event and the launch of a new clinical trial (and the associated software purchasing decisions). Accordingly, we think that the improvement in biopharma funding in 2023 and 2024 bodes well for increasing demand for software vendors in 2025 and 2026.

Year-to-date biopharma funding has totaled $86.1 billion through September 2024, according to BioWorld. This is up 67% year-over-year from the same period last year -- *and 20% above all of 2023*. In fact, we believe that 2024 is comfortably on track to be the strongest year for biopharma funding on record -- outside of the "bubble years" of 2020 and 2021.

The top four disease areas (oncology, immunology, metabolic/endocrinology, and neurology) accounted for 79% of clinical trial starts over the past year. Much of the new funding is geared towards oncology and rare diseases -- as well as new unmet disease areas in Alzheimer's Disease, central nervous system (CNS) disorders, and metabolics (GLP-1 drugs).



Source: Bioworld Report, IQVIA Investor Day (December 2024), and Bourne Partners

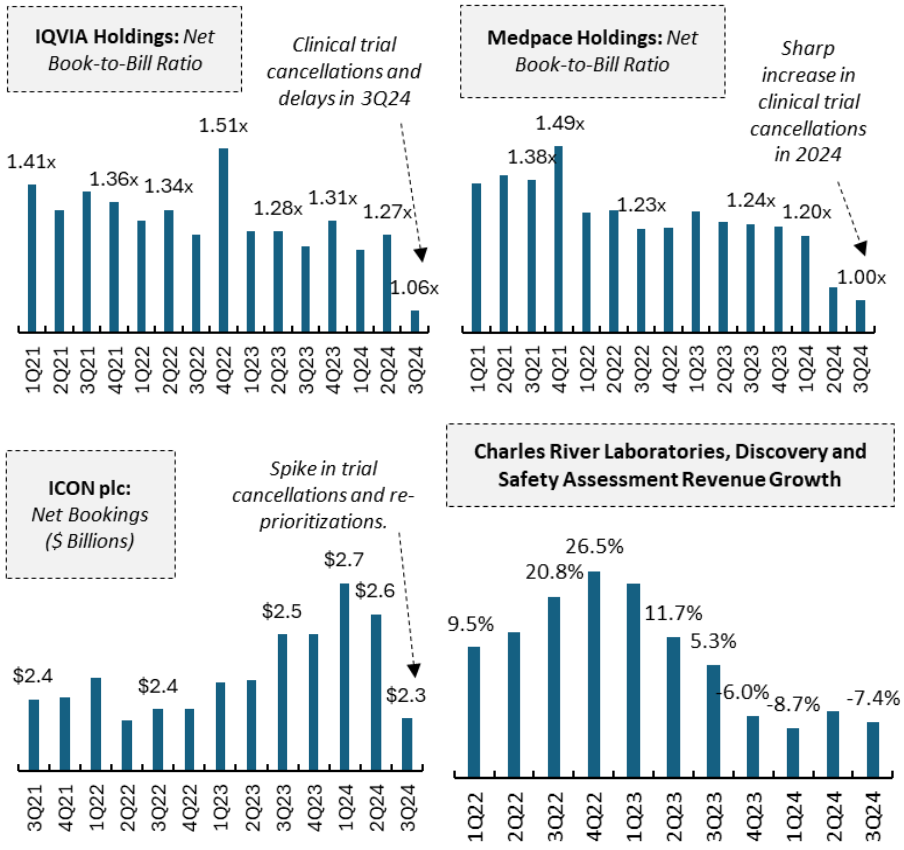
Near-Term Weakness Belies Long-Term Strength

Altogether, **mid/long term fundamentals on pharma and biotech R&D are attractive.** Still, R&D budgets can ebb and flow from time-to-time based on various economic and legislative factors. In our view, higher interest rates and the passage of the *Inflation Reduction Act* (IRA) have both contributed to a temporary reprioritization of R&D spending.

Over the past year, **we have observed an elevated volume of clinical trial delays and cancellations across all therapeutic areas.** Our sense is that much of this disruption is coming from small/mid-sized biopharma sponsors who were initially funded during the "bubble years" of 2021 and 2022 and have since struggled in a higher interest rate environment to cost effectively re-access capital markets to sustain their businesses. This pressure may continue into 2025, but we think that this is ultimately temporary in nature.

We are also hearing anecdotes of larger pharma sponsors re-prioritizing their product development strategies in response to the prescription drug price cuts associated with the ongoing rollout of the IRA. This pressure may continue into 2025 until the industry fully adjusts to the new legislative environment.

Finally, adding to all of this, **the "sugar high" in demand from the COVID-19 pandemic has winded down.** Many pharma and biotech companies who became comfortable relying on 'easy' vaccine work are now scrambling to find new revenue opportunities.



Source: Company reports and Bourne Partners

An Opportunity for Greater Deregulation Under Trump

We see reasons for optimism and concern on the impact of a second President administration on the marketplace for clinical trials software/technology. One area for optimism that comes up in many of our conversations is the hope for a much less restrictive regulatory environment for mergers and acquisitions and the development of artificial intelligence.

In our view, **the primary positive of a second Trump administration will (likely) be less regulatory resistance to mergers and acquisitions (M&A).** In December, Trump named Andrew Ferguson as his new Federal Trade Commission (FTC) chair. Ferguson has explicitly stated that he would be more receptive to M&A (vs his predecessor, Lina Khan), and he would look to roll-back burdensome regulations, such as the recently expanded Hart-Scott-Rodino Act premerger notification requirements. M&A is a critical exit strategy for many emerging tech vendors so a more liquid M&A marketplace may help bring more private equity interest in the space.

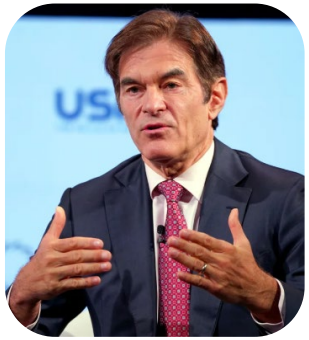
Another positive of a second Trump administration for software vendors will be a likely less regulated environment for artificial intelligence (AI) -- as evidenced by the naming of venture capitalist David Sacks as the "White House A.I. and Crypto Czar." In October 2023, President Biden signed an executive order to create a new regulatory infrastructure to assess new AI applications before they go to market and to monitor their performance/quality once in use. On his first day in office, Trump repealed this executive order and dismissed much of the early regulatory efforts initiated by the Biden administration that were deemed to be hindering innovation. Over time, this should free-up development of new AI applications to accelerate clinical trials.

President-Elect Donald Trump

Nominee for Sec of HHS Robert F. Kennedy

Nominee for FDA Director Marty Makary

Nominee for Director of CMS Mehmet Oz



Nominee for Director of CDC David Welton

Source: Bourne Partners

Keeping an Eye on Political/Regulatory Concerns

In our view, **the concern around a second Trump administration is his mixed commentary on drug price controls and his focus on preventative healthcare.** Any uncertainty around pharma pricing and economics could have a significant impact on overall clinical trial activity and, in turn, demand for software/tech companies selling into the space.

1) The Future of the Inflation Reduction Act (IRA) of 2022

It is not clear to us how Trump might address prescription drug pricing and the IRA, which was passed with zero Republican support. The first round of Medicare price cuts associated with the IRA occurred in August 2024, and we believe that this announcement is already having a material impact on how pharma companies are considering their product development strategies (and their associated software/tech budgets). The good news for the pharma industry is that Trump will not likely attempt to expand price controls into the commercial space. However, Trump does have a history of advocating for direct Medicare drug price negotiations (in the past through a "Most Favored Nation" approach). Also, Trump has a history of using market-based solutions to put downward pressure on drug prices, such as his prior efforts around price transparency regulations.

2) Focus on Preventative Care and Vaccines

We think that there will be a general preference by the Trump healthcare team to look to policy solutions that focus on preventative care and health and wellness -- rather than pharmaceutical solutions. This could have a downstream impact on clinical trial activity. For instance, at the National Institutes for Health, Robert F. Kennedy (RFK) has commented that he would like to "devote half of research budgets … toward preventative, alternative and holistic approaches to health." Also, in one of his last political actions, President Biden expanded coverage of expensive GLP-1 drugs (e.g., Ozempic) for Medicare and Medicaid beneficiaries for weight management. This is an area where RFK might be more interested in policies that instead address eating patterns and diet.

Finally, **many of Trump's healthcare nominees have voiced significant concerns on current vaccine policy.** RFK has explicitly stated that he does not plan to ban vaccines. However, he does want to "restore the transparency" around vaccine safety data, arguing that there is not sufficient recent scientific research on the short and long-term safety of vaccines. Increasing the volume of research on this topic would be an "immediate priority" of his leadership at the Department of Health and Human Services.

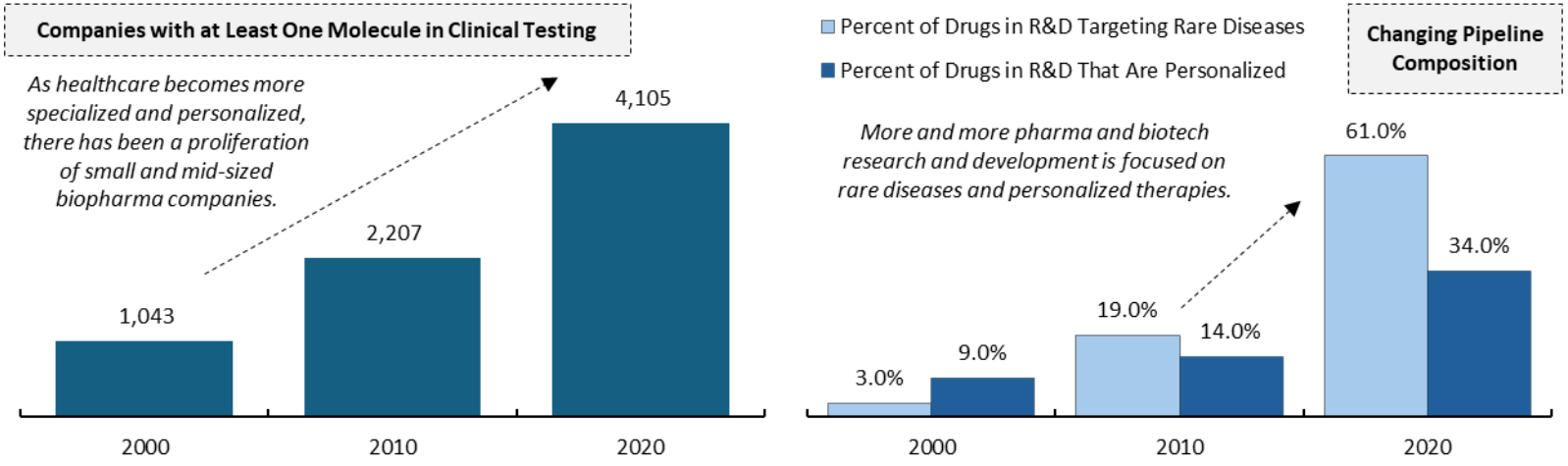
Source: Bourne Partners

Clinical Trial Complexity Drives Software Demand

We expect clinical trials to continue to become more complex over time requiring the need to collect, normalize, and analyze greater and greater volumes of clinical and non-clinical data. This, in turn, is pressuring sponsors, contract research organizations (CROs), and sites to adopt unified information technology platforms to improve data quality.

Advances in molecular biology have resulted in more complex clinical trial protocols that involve, among other features, biomarkers for patient stratification, more safety and efficacy endpoints, adaptive study designs, multiple treatment arms, and variable visit schedules. Also, there is increasing pressure on pharma companies to show distinction between products via "quality of life" measures and non-traditional data collected from wearables and remote monitoring. Altogether, this has led to a more than a sevenfold increase in the data collected in an average pivotal Phase III clinical trial over the past 20 years (since 2005).

To manage this increasing data intensity, **we think there is a need for sponsors, CROs, and sites to adopt integrated information technology platforms.** An integrated technology platform allows data analytics on a dataset in real-time from a single source, avoiding the risk of lost and erroneous data that can occur as a result of double-data entry and the interfacing of disparate software applications. This, in turn, reduces administrative costs, improves decision-making, and accelerates "time-to-market."



Source: The U.S. Food and Drug Administration (FDA), Tufts Center for the Study of Drug Development, Pharma Projects, Evaluate Pharma, and Bourne Partners

Dimensions of Clinical Trial Complexity

We consider increasing clinical trial complexity in two dimensions -- 1) protocol design complexity and 2) operational complexity. In both cases, complexity leads to a greater volume of data collection, normalization, and analysis (e.g., procedures and endpoints) -- as well as a greater need for information technology adoption.

Protocol design complexity arises from the design of the study itself, e.g., the clinical administration of the therapy, multiple treatment arms, dynamic visit schedules and cycle expansion, variable dosing, and multiple disease types. These methodologies are typically used in traditionally complex studies, such as oncology and rare diseases, to help tease out efficacy in niche patient populations. However, we are seeing them increasingly being used in other therapeutic areas as well.

Operational complexity arises with the use of multiple geographies and decentralized clinical trial methodologies. When clinical trials involve multiple countries/political jurisdictions, sponsors, contract research organizations, and sites must juggle various local considerations, including languages/dialects, cultural preferences, technology regulations, and supply chain management. Also, clinical trials across multiple geographies can be more exposed to geopolitical risk such as military conflicts, trade wars, and natural disasters. Finally, the use of decentralized clinical trials (DCTs) requires the implementation and integration of new technologies and services, such as home visits, direct-to-patient drug deliveries/collection, and the delivery/collection of devices.

Examples of Protocol Design Complexity

- Multiple treatment arms
- Dynamic visit schedules and cycle expansion
- Variable dosing schedules
- Undefined or variable dose strength, escalation, reduction
- Single or double-blind design, especially with multiple therapy administration methods
- Adaptive randomization or re-randomization requirements
- Multiple disease types (basket trial design)

Examples of Operational Complexity

- Decentralized clinical trials
- Variable supply chain strategies
- Cold chains
- Direct-to-patient shipping
- Global geographies, especially if patients have options to visit multiple sites
- Long trial duration
- Personalized medicine

Source: Bourne Partners

Quantifying Clinical Trial Complexity Over Time

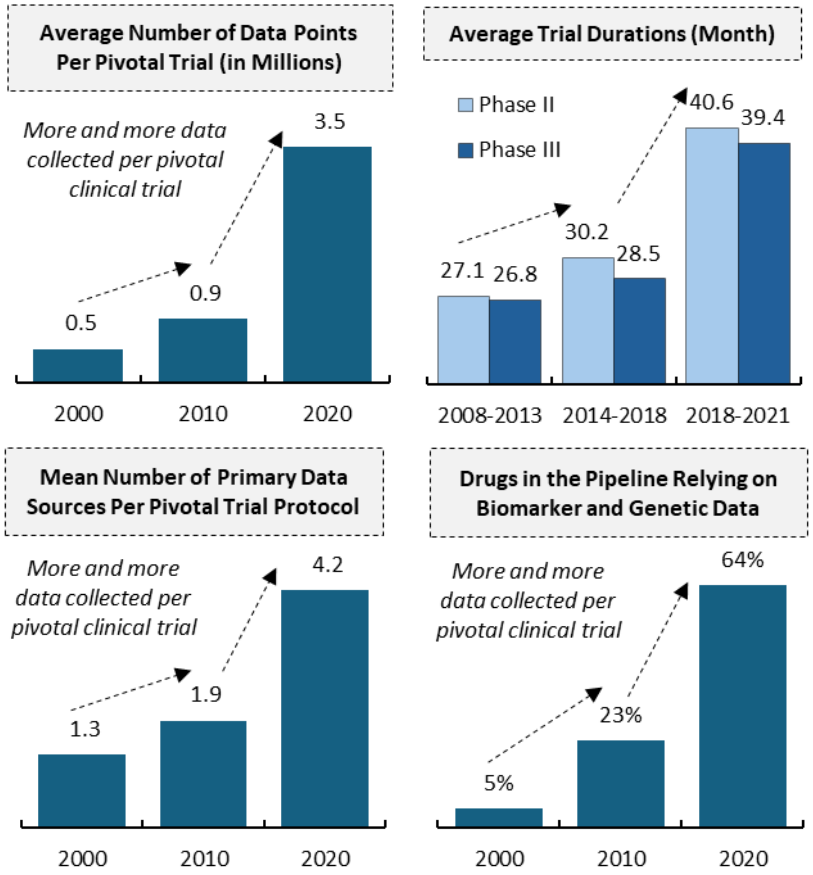
Recent empirical analysis in *Nature* showed that clinical trial complexity has increased significantly over the past ten years by 15%+ for *Phase II* and *Phase III* studies -- across every major therapeutic area. The increase in study complexity of *Phase I* clinical trials was even more pronounced, up 40% over the past decade.

In our view, **the increasing complexity of clinical trials is best objectively highlighted by a recent study in *Nature* (February 2024)**, which developed a "Trial Complexity Score" to objectively track complexity over time -- as measured by the number of endpoints, inclusion/exclusion criteria, study treatment arms, sites, and geographies, among other data points. The Trial Complexity Score has risen over time across different clinical phases and therapeutic areas.

Not surprisingly, **clinical trials involving oncology showed the most complexity**, across all major indications such as prostate, colorectal, breast, and lung cancer. From 2014 to 2020, the average complexity of oncology trials increased steadily, but it levelled off post-2020 perhaps due to COVID-19 trial planning.

Immunology and neurology trials were calculated to have average complexity, with Crohn's Disease, multiple sclerosis and strokes contributing to more complexity and other complexity driven by specific sponsors and modalities.

Complexity in cardiovascular and endocrinology trials have steadily grown driven by a surge in data collection from digital and wearable devices becoming more widely adopted.



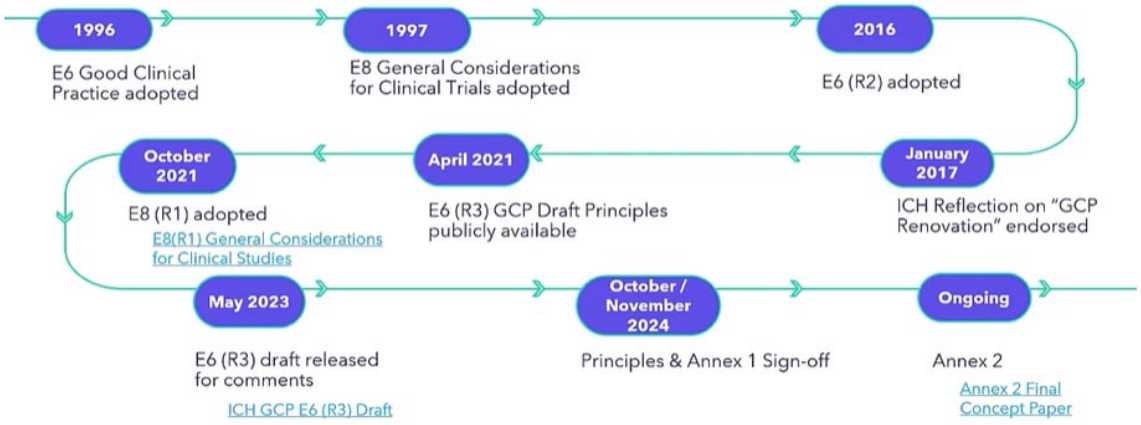
Source: Markey, N., Howitt, B., El-Mansouri, I. et al. Clinical trials are becoming more complex: a machine learning analysis of data from over 16,000 trials. Sci Rep 14, 3514 (2024), Tufts Center for the Study of Drug Development and Bourne Partners

Updated ICH Guidelines Emphasize Software/Tech

In the face of an increasingly complex clinical trial environment, **the ICH has released new guidelines addressing how clinical trials should be designed and conducted**, particularly with respect to the use of software and information technology. In our view, this will help put software/tech vendors at the vanguard of pharma research and development.

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (the "ICH") is an international consortium of regulatory agencies and pharma companies. The ICH was formed in 1990 by the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the Japanese Pharmaceutical Manufacturers Association (JPMA) to develop a global consensus on best practices for drug development and manufacturing. Since then, most regulatory agencies have joined. The ICH guidelines are not legally binding, but they represent an agreed-upon framework for Good Clinical Practices (GCPs) for the life sciences industry, and they establish the basic principles for pharmaceutical regulation worldwide.

The ICH released the original version of its E6 guidelines in 1996, addressing Good Clinical Practices (GCPs) related to the design and conduct of clinical trials that involve the participation of human subjects. For nearly 20 years, E6 provided the consensus view on how clinical trials should be conducted until the release of ICH E6 (R2) in 2016. Then, in May 2023, the ICH released a draft third version of its E6 guidelines, ICH E6 (R3). The final version of ICH E6 (R3) was released on January 14, 2025.

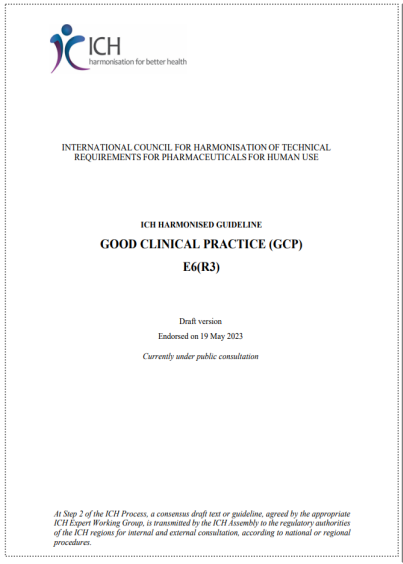


Source: WCG Clinical (Anticipating ICH E6 (R3): Awareness, Impact & Preparedness; November 2024) and Bourne Partners

Getting Up to Speed with the New ICH Guidelines

Feedback from clinical trial sponsors and sites who are knowledgeable about the ICH E6 (R3) guidance expect the new E6 guidelines to have a "significant impact" on how studies are conducted. Survey data suggests that sponsors are much more aware of pending guideline changes, while sites seem to have a steeper learning curve ahead of them.

Survey respondents -- who are most familiar with the ICH E6 (R3) draft guidance -- see the new E6 guidelines as being "significantly impactful" to clinical trials in several ways: 1) the adoption and integration of new digital tools and information technology, 2) a shift in mindset towards the use of risk-based/statistical approaches, and 3) a clarification of the responsibilities of the sponsor and the site investigator.



ICH
harmonisation for better health

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

GOOD CLINICAL PRACTICE (GCP)

E6(R3)

Draft version

Endorsed on 19 May 2023

Currently under public consultation

At Step 2 of the ICH Process, a consensus draft text or guideline, agreed by the appropriate ICH Expert Working Group, is transmitted by the ICH Assembly to the regulatory authorities of the ICH regions for internal and external consultation, according to national or regional procedures.

Federal Register / Vol. 88, No. 109 / Wednesday, June 7, 2023 / Notices 37257

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Sincerely,

/s/

Patricia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Dated: June 1, 2023.
Lauren K. Roth,
Associate Commissioner for Policy.
[FR Doc. 2023–12100 Filed 6–6–23; 8:45 am]
BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–1955]

E6(R3) Guideline for Good Clinical Practice; International Council for Harmonisation; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "E6(R3) Guideline for Good Clinical Practice." The draft guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The draft guidance outlines modernized Good Clinical Practice considerations to guide thoughtful design and responsible conduct of clinical trials in a manner that ensures participant safety and the reliability of trial results. This draft guidance encourages innovation, focuses on quality, and establishes proportionate and risk-based approaches for conducting clinical trials, while minimizing unnecessary complexities. The draft guidance is intended to provide flexible, modern, and clear Good Clinical Practice for conducting clinical trials.

DATES: Submit either electronic or written comments on the draft guidance by September 5, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

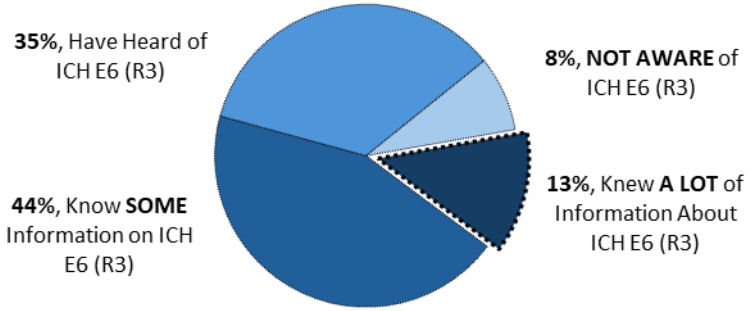
- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2023–D–1955 for "E6(R3) Guideline for Good Clinical Practice." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

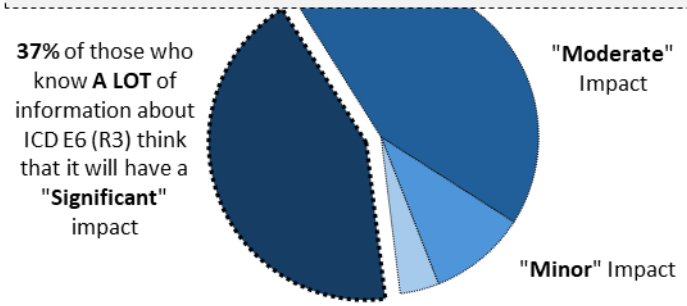
- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

Survey Question: How familar are you with the ICH E6 (R3) Draft Guidance? (341 Respondents)



Survey Question: How much impact will ICH E6 (R3) have on how you design/conduct clinical trials? *Respondents Who Know A LOT of Information About ICH E6 (R3)*



Source: WCG Clinical (The 2024 Avoca State of the Industry Report, June 2024) and Bourne Partners

Key Take-Aways from ICH E6 (R3) for Software/Tech

In our view, **the ICH E6 (R3) guidance emphasizes the importance of digital health and software/technology integration** in clinical trials. This should be a very positive validation of the role of software/tech in drug development, and it should serve to encourage more systematic software/tech adoption in the coming years.

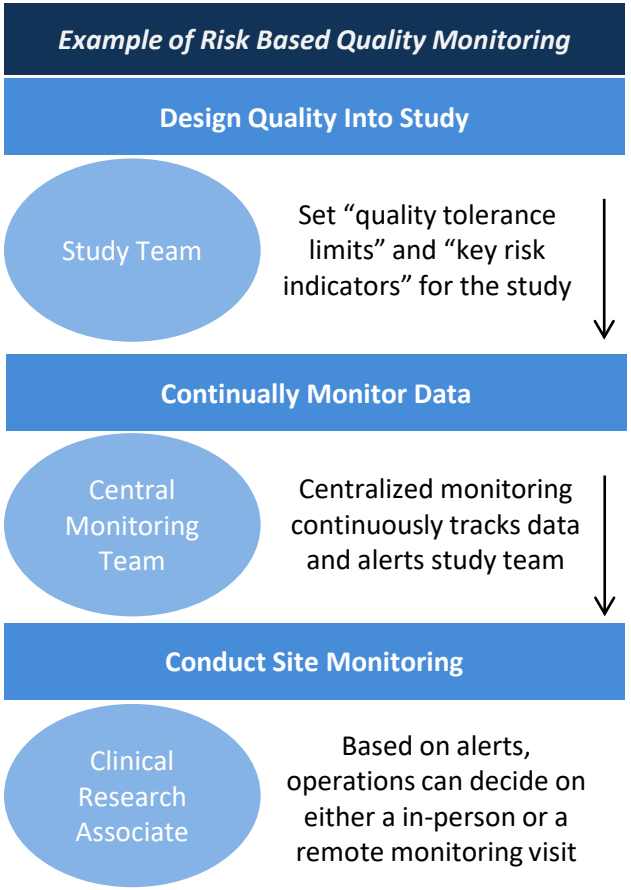
There were four concepts in the ICH E6 (R3) guidelines that caught our attention with respect to the use of software technology.

1) Quality by Design (QbD). R3 emphasizes the importance of proactively designing quality into the protocol at the early/planning phases. We interpret this as a recognition of the need to bring in software/tech vendors earlier in the clinical trial design process (rather than "forcing" the vendor to fit to a protocol after it is developed). This would seem to encourage the industry to view software/tech companies as true "partners" in drug development.

2) Patient Centricity. R3 acknowledges the major advances in information technology over the past decade with respect to wearables, virtual care, and digital health. Also, the draft guidance provides more detailed guidance on obtaining and documenting informed consent. We interpret this as a validation of the importance of software to improve patient engagement in clinical trials.

3) Risk-Based Quality Monitoring (RBQM). R3 stresses the importance of establishing a systematic approach to managing risk throughout a trial. This would seem to validate the use of centralized/remote monitoring technologies that track sites and participants, reducing the need for in-person CRA site visits.

4) Data Governance. R3 includes significant discussion around data integrity, audit traceability, and confidentiality. This would seem to broadly validate the use case for an integrated/holistic information technology platform.



Source: Medidata Solutions (Preparing for ICH E6 (R3) Good Clinical Practice Changes) and Bourne Partners

Breaking Down the Clinical Trial Software/Tech Stack

Key Sub-Verticals within Clinical Trial Software/Tech

We consider the clinical trial software/technology space as a compilation of a variety of sub-verticals, each of which has its own independent set of vendors, growth considerations, and regulatory issues.

1) Clinical Trial Management System (CTMS). The CTMS is the core of the clinical trial tech stack, in our view. Procurement decisions are driven by scalability, interoperability, and customizability -- as well as an ongoing shift from on-premise to cloud-based solutions.

2) Electronic Data Capture (EDC). Adoption of EDC software is near 100% with three top vendors representing about two-thirds of the market. Differentiators include interoperability, ease of set-up and use, and the ability to support complex trial designs.

3) Randomization and Trial Supply Management (RTSM). We consider RTSM software to be essential to support complex protocols and the use of adaptive study designs, which are often used in oncology, rare diseases, and other medically challenging areas.

4) Risk-Based (Remote) Monitoring. About half of all clinical trials include at least one element of a risk-based monitoring program, and we expect this to significantly increase in the coming years as protocols become more complex and data intensive.

5) Study Feasibility and Patient Recruitment. Software applications are increasingly necessary for clinical trial feasibility analysis, i.e., to identify target niche patient populations and sites as well as to generally predict the practicality of a study protocol.

6) eConsent. We believe that eConsent software can improve both regulatory compliance and patient engagement. In our view, poor clinical trial patient retention is often mainly due to the patient not having a full understanding of what is expected of him/her.

7) ePRO/eCOA. ePRO software allows participants to self-report data from the convenience of their homes without having to manage physical forms or physically visit trial sites. We think ePRO software can also materially improve study data quality.

8) Payments. Compensating clinical trial patients appropriately is critical to patient retention and data quality. The need for clinical trial payments and patient logistics software has increased significantly due to inflationary pressures, in our opinion.

9) Pharmacovigilance (Safety). We see an increasing use case for pharmacovigilance software applications as a result of the rising therapeutic complexity of many of the new experimental precision medicines coming to market.

10) Information Technology Outsourcing. Ongoing shortages in skilled labor will compel pharma companies to look to outsourcing partners, particularly in newer areas such as generative artificial intelligence and large language models.

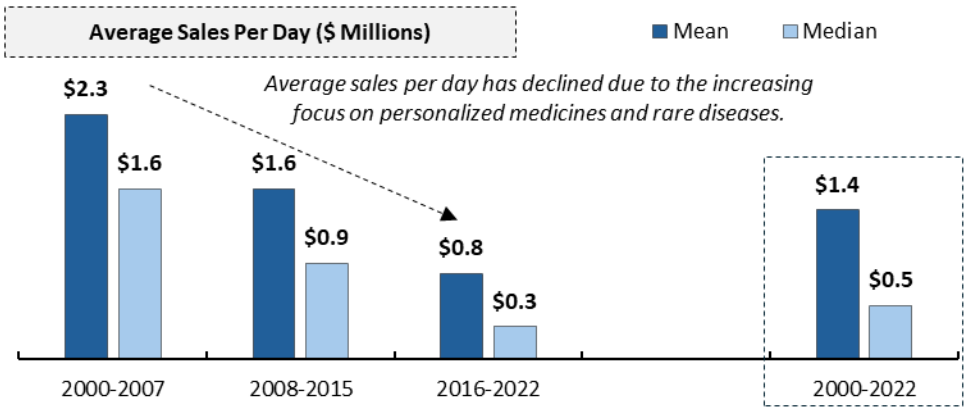
Source: Bourne Partners

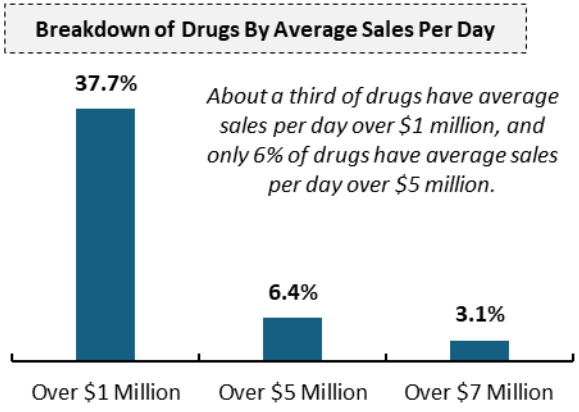
The Value of TIME in a Clinical Trial

The primary driver of ROI for any software application in the clinical trial space is its ability to accelerate time-to-market. This is because -- the greatest single cost for a drug developer, by far, is a day delayed in a clinical trial. New drugs have a defined period of exclusivity, during which the drug manufacturer enjoys significant premium pricing. Accelerating time-to-market by even just one day will often "pay for" the entire software/technology budget for a clinical trial.

Each day that a clinical trial is delayed represents, on average, lost sales revenue of $1.4 million per day (mean) or $0.5 million per day (median) for the drug manufacturer, according to a recent analysis by the Tufts Center for the Study of Drug Development. Of course, this will vary by therapeutic area and by specific drug. For drugs with more significant end markets (the top-10% of drugs), a day delayed can represent lost sales revenue of upwards of $5 million per day.

The most common source of delays in clinical trials are poor patient recruitment, onboarding, and retention, in our view. Also, data quality issues can slow regulatory approvals by months. A few week delay in a clinical trial can easily result in a greater economic cost for the sponsor (measured in lost sales) than the entire budget for the clinical trial itself. This includes the total cost of software implementation, licenses, and related fees. The average cost of a clinical trial has remained stable over time at $24.8 million (mean) or $9.4 million (median), varying by therapeutic area with immunology, respiratory, and dermatology being the most expensive.





Source: The Tufts Center for the Study of Drug Development, and Bourne Partners

1) CTMS Vendors Serve as the Core of the "Tech Stack"

The adoption of software and information technology can materially accelerate clinical trial completion and time-to-market for new drugs. The core of the "information technology stack" for clinical trials is the clinical trial management system (CTMS). In our view, CTMS procurement decisions are driven by scalability, interoperability, and customizability.

A CTMS is an enterprise software system that serves as the "hub" of the research operations for a biopharma company, a contract research organization (CRO), a research site network, and/or any other organization involved in clinical trials. Essentially, a CTMS organizes all clinical trial operational data -- e.g., study, participant, and staff information, budget/financial information, and regulatory/billing information -- into a common location ("single source of truth") allowing users to generate reporting and analytics.

The CTMS marketplace is mature with most of the new sales in recent years being driven by the proliferation of small/mid-sized biopharma sponsors. The vendor landscape is fragmented, but we see Veeva Systems (VEEV-NASDAQ) as an emerging leader with a ~30% market share. We estimate Veeva now has ~200 CTMS customers, including the majority of the top-20 pharma companies and top-10 CROs. Much of Veeva's strength in CTMS came as an extension of its leadership in eTMF software where it has a dominant ~70% market share.

Looking ahead, **we expect procurement/replacement decisions in the CTMS space will be driven by the growing complexity of clinical trials**, a greater need for data-driven decision-making, and increasing regulatory burdens, including mandates for patient diversity. Also, a large percent of the deployed CTMS systems are still on-premise, limiting their ability to connect with third-party software systems and to support decentralized designs. We believe many organizations have put-off the movement to a cloud-based CTMS due to internal disruptions/inertia that can be caused by a large system migration.

Key Features of a Clinical Trial Management System (CTMS)


Clinical trial participant tracking and EDC software integration


Document management, filing, and storage


Contract management (sites and teams)


Scheduling and monitoring


Contract and payment System


Reporting and business analytics


Visit report authoring and letter generation


Project planning (study milestones and tasks)

Source: Bourne Partners

2) Electronic Data Capture (EDC) Software

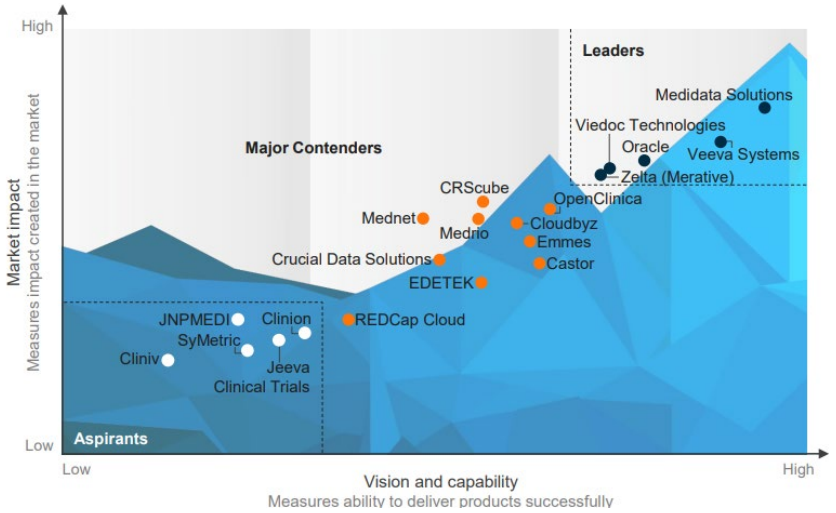
Electronic data capture (EDC) software is another key foundational element of the clinical trial "tech stack," and is generally one of the first software decisions a biopharma sponsor would make. Today, EDC adoption is near 100% with a few clear market share leaders. However, a number of smaller solutions are looking to break into the space.

EDC software is used to collect clinical trial data in a digital format, replacing paper-based case report forms that investigator sites would otherwise use to collect data on clinical trial patients and participants. Use of EDC software improves data accuracy/quality with checks at the point of data entry, immediately highlighting errors and missing data.

In our view, **EDC software adoption is ubiquitous across the pharma and biotech space.** Medidata Solutions (a division of Dassault Systèmes) is, by far, the market leader (used in 30k+ clinical trials to date) followed by the life sciences business of Oracle Corporation and Veeva Systems.

Competitively, **EDC software tends to be "sticky," and most users tend to purchase EDC software on an enterprise basis** for all of their trials. This helps to minimize start-up/training costs. Differentiators include the ability to integrate with other applications and wearables, ease of set-up and use, and the ability to support complex trial designs and protocol amendments. Also, most modern EDC software is designed to be interoperable with electronic health record and laboratory information systems allowing for a seamless flow of data.

Phase III Pivotal Trials (Mean)	2010		2020
Total Endpoints	13	→	22
Total Eligibility Criteria	34	→	30
Total Procedures	187	→	263
Total Countries	9	→	15
Total Investigative Sites	65	→	104
Procedures Per Visit	11	→	13
Total Patients Randomized	597	→	632



Source: Everest Group (Peak Matrix Assessment; September 2024), and Bourne Partners

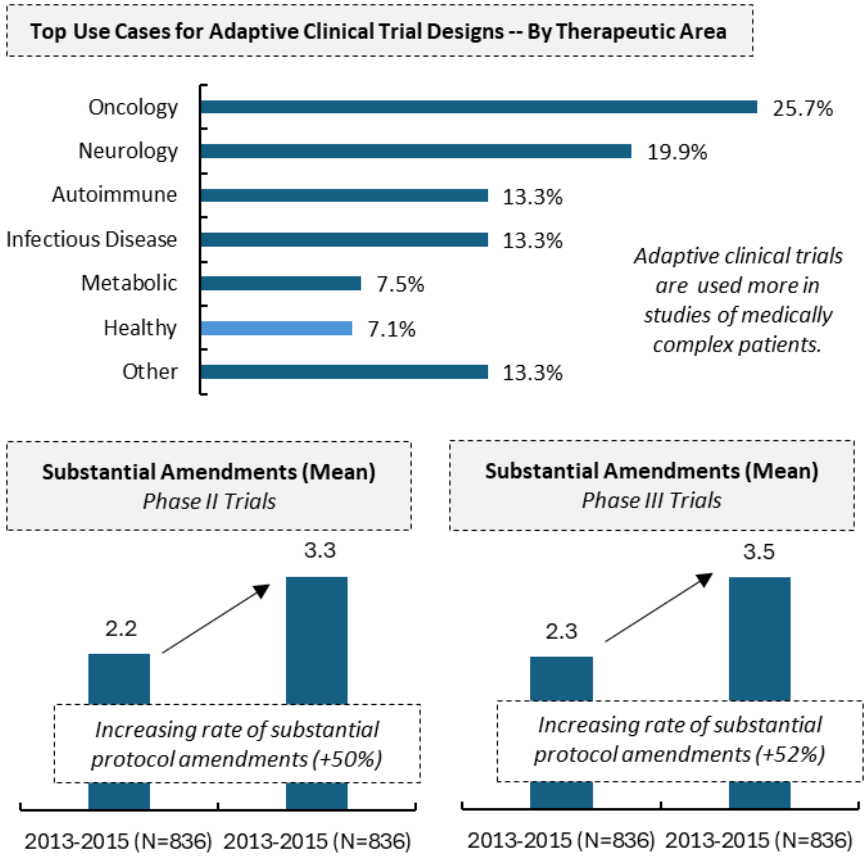
3) RTSM / IRT Software to Address Adaptive Study Designs

We see an increasing need for Randomization and Trial Supply Management (RTSM) and Interactive Response Technology (IRT) software to address the increasing complexity of clinical trials, including the increasing mix of oncology and rare disease studies. Today, upwards of 20% of clinical trials include adaptive study designs, and this will likely increase in the coming years.

Modern RTSM software is essential to efficiently address protocol amendments and to support adaptive clinical trials by enabling real-time data integration, dynamic randomization, and supply chain flexibility. In our view, these efficiencies are maximized when RSTM is integrated within a broader tech platform including EDC software.

Rising clinical trial complexity has led to an increasing prevalence of protocol amendments. For instance, Phase III protocols for oncology generate 40% more protocol amendments (than do non-oncology protocols). Similarly, Phase III protocols for rare diseases generate 19% more amendments. A single amendment in a typical Phase III trial can cost an average of $450,000 and delay a study by an average of 30 days (translating to $42M of potential lost sales revenue for the sponsor -- refer to Slide 19).

We have seen a steady growth in the use of adaptive trial designs, particularly for Phase II oncology studies. Today, upwards of 20% of clinical trials use some form of adaptive design, such as treatment selection and seamless phases, and this percent has increased steadily over time.



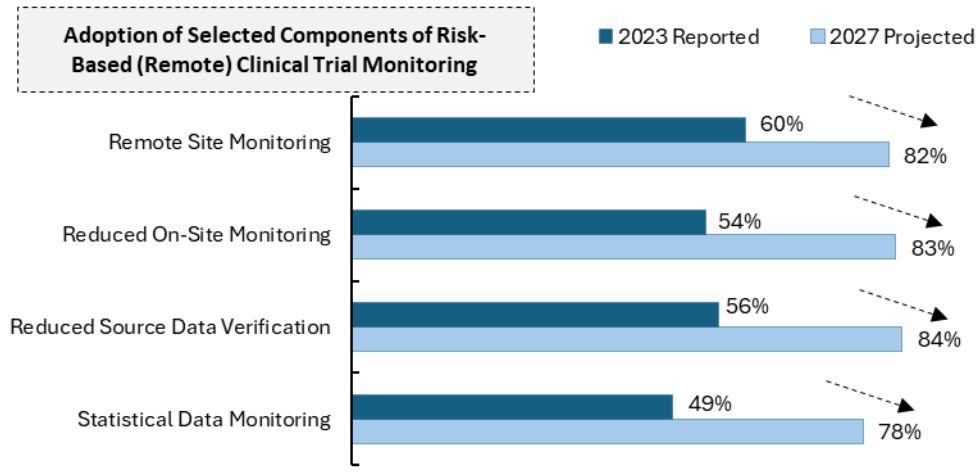
Source: The Tufts Center for the Study of Drug Development and Bourne Partners

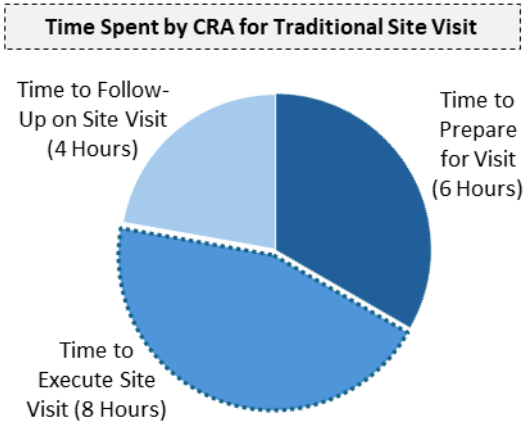
4) Momentum Towards Risk-Based (Remote) Monitoring

Data and risk surveillance technologies are becoming more and more critical in clinical trials as protocols become more complex with larger datasets. Survey data suggests that over 50% of clinical trials now include at least one element of a risk-based monitoring program, and this percentage is expected to materially increase in the coming years.

Risk-based monitoring involves a system of analytics to proactively identify data quality and patient safety concerns in real-time during a clinical trial in order to head-off issues before they snowball into more serious systemic problems that might threaten the integrity of an entire study. Increasingly, sponsors and CROs are employing artificial intelligence/machine learning algorithms that can interrogate large quantities of clinical trial data for outliers, anomalies, and trends in real-time.

We believe the primary economic value of a risk-based monitoring program is the potential for accelerated time to database lock due to reduced delays from data quality and patient safety problems. There are direct cost savings as well. In our view, traditional site monitoring with on-site clinical research associates (CRAs) can account for as much as 25%-30% of a typical Phase III trial. With the median clinical trial costing $9.4 million, total site monitoring related costs over the course of a trial might equate to upwards of $2.0 million. So, reduced CRA travel/site visits could comfortably save multiple hundreds of thousands of dollars per trial.





Source: American Pharmaceutical Review, Dirks, A., Florez, M., Torche, F. et al. Comprehensive Assessment of Risk-Based Quality Management Adoption in Clinical Trials. Ther Innov Regul Sci 58, 520–527 (2024) and Bourne Partners

5) Software Use Cases in Recruitment and Feasibility

We see strong demand for software applications that can support feasibility studies for clinical trials addressing niche, tough-to-reach, and tough-to-retain patient populations in areas like oncology, genetic conditions, and rare diseases. Poor decisions around feasibility can lead to an increased volume of costly protocol deviations and amendments.

A feasibility study evaluates the practicality of a clinical trial protocol with respect to its likelihood of achieving completion within a targeted time period and/or budget. This includes an evaluation of the inclusion/exclusion criteria, the procedures involved, and availability of staff, facilities, and equipment, among other factors. Often feasibility studies are done in a short period of time during the "pre-award phase" of a study. Poor feasibility can result in costly protocol deviations and amendments over time.

Software applications are often adopted and used to accelerate feasibility analysis by aggregating and normalizing large volumes of data (from electronic health record software systems, patient registries, and demographics databases) to more accurately identify targeted patient populations and investigator sites and predict the practicality of a study protocol.

More complex therapeutic areas require the ability to partner with medical providers in order to proactively search EHR software systems, laboratory systems, and medical claims, to match specific patients (on a de-identified basis) to a specific clinical trial protocol. This often involves the use of artificial intelligence algorithms and natural language processing (NLP) software that can evaluate non-structured data (physician notes) to alert study design teams of potential candidates.

Protocol Design Considerations

- Number of Patients Required
- Inclusion / Exclusion Criteria
- Type of Procedures
- Required Staff and Equipment

Country and Site Selection

- Local Patient Demographics
- Availability of Specialized Staff
- Political and Regulatory Environment
- Information Technology Infrastructure

Site Activation Assessment

- Track Record of Site Start-Up
- Staffing Shortages
- Existing Technology Stack
- Financial Issues

Source: Bourne Partners

6) eConsent Software Linked to Improved Retention

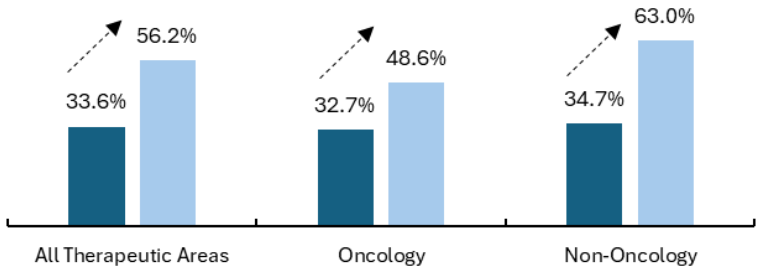
eConsent software applications can be used to improve both regulatory compliance and patient engagement. Survey data suggests that patient retention in clinical trials has declined over time. Much of this can be addressed by improving the informed consent process at the beginning of the trial to better educate patients on what is expected of them.

eConsent software allows clinical trial participants to review informed consent forms in a digital format including the capture of e-signatures. Informed consent is a critical regulatory requirement that must be obtained (in writing) from each participant prior to the start of a trial. This ensures an understanding of the protocol, visit schedules, and any risks associated with the treatment.

The use of eConsent software reduces the compliance burden related to managing paper documents. This is particularly relevant for complex clinical trials, which tend to have multiple protocol amendments (each of which requires informed consent). Studies show that the use of eConsent reduces consent-related major and critical protocol deviations from an average of 14% to only 6%.

However, in our view, **the greatest value of eConsent software (vs paper-based consent) is that it improves patient retention** (and recruitment), which are two primary causes of clinical trial delays. In almost every survey we have seen on clinical trial patient retention, poor understanding of expectations is one of the top reasons for early patient drop-outs.

Clinical Trial Drop-Out Rates Have Increased
Percent of Total Drop Outs in Phase II and Phase III Trials Due to Participant Choice



18% *of patients randomized in a clinical trial end up dropping-out prior to the completion of the study*

35% *of patients who dropped-out of a study early say it was difficult to understand the consent form (versus 16% of those who completed the trial)*

64% *of patients who dropped out of a study early were satisfied that their questions were answered during the consent process (versus 89% of those who completed the trial)*

Source: Advarra (Retention in Clinical Trials: Keeping Patients on Protocols; 2021), the Tufts Center for the Study of Drug Development, and Bourne Partners

7) eCOA / ePRO Software Linked to Data Quality

The use of eCOA and ePRO software applications has grown significantly over time, and we expect these applications to continue to grow in relevance as sponsors must compete in an increasingly consumer-driven healthcare environment in which "quality of life" measures and patient preferences become key product differentiators.

Electronic clinical outcome assessment (eCOA) software collects data directly from patients in real-time via an Internet-enabled mobile device (e.g., an iPhone or an Android). The most common form of eCOA is patient reported outcomes (or ePRO). ePRO software, in turn, allows clinical trial participants to record their personal assessment of their wellness (e.g., symptoms, moods, side-effects, pain intensity, etc.) often on their own personal mobile device.

ePRO software can increase clinical trial data quality by improving patient compliance with prompts and branching logic as well as the elimination of 'double-data entry' (e.g., capturing data directly from the patient in digital form and flowing it directly into the study EDC software). This accelerates the accumulation of quality/relatable data and accelerates clinical trial completion. Also, ePRO software can improve the clinical trial experience by allowing participants to self-report data from the convenience of their homes without having to manage physical forms or physically visit trial sites.

eCOA Modality	Definition	Use Cases	Example End Points
ePRO *(Patient Reported Outcomes)*	Data self-reported electronically directly verbatim by the clincal trial participant/patient	Trained health professional is not needed; Deals with unobservable concepts (e.g., feelings and	Pain Intensity Mood / Feelings Eating Habits
ClinRO *(Clinician Reported Outcomes)*	Data reproted by a healthcare professional observing a clinical trial participant	Judgment of a trained healthcare professional is needed	Tumor Size Parkinson's patient who cannot speak/comment
ObsRO *(Observer Reported Outcomes)*	Data based on an observation by someone other than the patient or medical professional	Trained helathcare professional is not needed and self-reporting is not appropriate/feasible	Infant/young child Dementia patient
PerfO *(Performance Outcomes)*	Performance of a task by the participant based on instructions administered by a healthcare	The specific task is required by the clinical trial protocol	Six minute walk test Memory recall

Source: Bourne Partners

8) Modern Payments Systems Key to Patient Retention

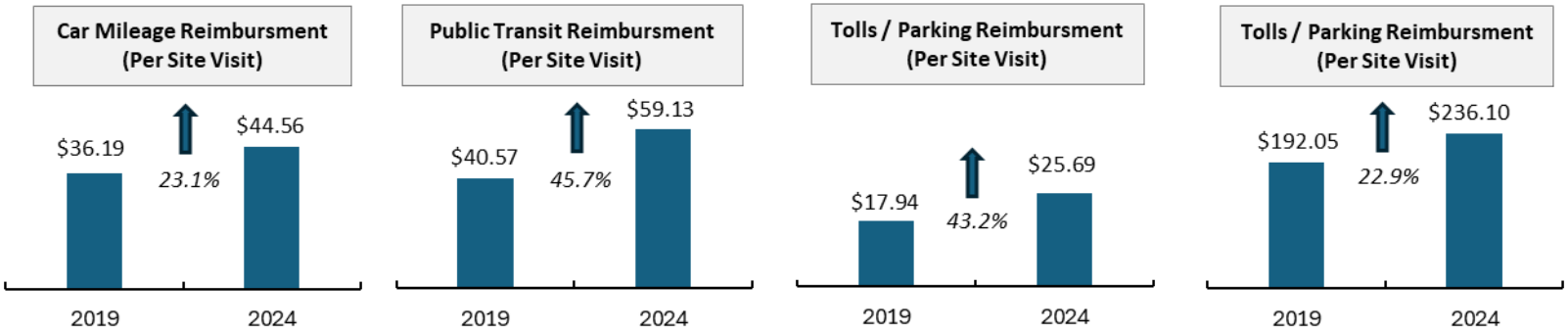
We believe that the demand for clinical trial payments and patient logistics software has increased significantly over the past decade due to inflationary cost pressures on participants. Even with inflation now subsiding, timely and accurate participant reimbursement is critical for patient retention, particularly in niche/targeted disease areas.

It is increasingly expensive to be a patient in a clinical trial. Each visit to a clinical trial site might represent $70 to $100 of out-of-pocket expenses with respect to transportation, meals, parking, and tolls, etc. These expenses may increase significantly if air (or train) travel is required. Also, for many patients, there is a need for childcare and time off-of-work. Finally, for some studies (in oncology, for instance), there might be a need for an overnight stay due to an infusion therapy.

On top of this, **clinical trial sites that lack a modern payments system sometimes wait months before receiving their grant payments in order to cut a physical check** to their patients. The patient, in turn, must then carry out-of-pocket expenses. Then, depending on the circumstances, these reimbursements can sometimes be taxable to the patient, resulting in a tax reporting burden.

Finally, **absent a modern payments system, clinical trial sites must bear the administrative burdens** of managing the logistics of patient travel, tracking reimbursements, and writing checks. Adopting a modern/automated payments solution can reduce overall administrative costs by 20% for the site (and the sponsor) and accelerate recruitment timelines (by reducing patient drop-outs).

Inflation Has Financially Weighed Heavily on Clinical Trial Participants



Source: Greenphire Patient Experience Dataset (U.S. Only) and Bourne Partners

Sources of Poor Patient Retention Due to Poor Payments

Adopting a modern clinical trial patient payments/logistics software or service can significantly accelerate enrollment (and study completion) timelines by reducing early patient drop-out rates. Also, financially, a single patient drop-out can often add tens of thousands of dollars of incremental recruitment costs for the sponsor.

Frequent and/or Lengthy Travel. Clinical trial participation declines as the distance to a trial site increases. Specifically, enrollment rates can decline as much as 10% for every 30 miles a clinical trial participant must travel to a study site. In addition to transportation costs, there are logistical burdens on the patient, such as arranging travel services and accessing hotel accommodations, if needed.

Out-Of-Pocket Costs. Patients do not want to bear financial costs when participating in a clinical research study. Data from Scout Clinical suggests that 11%-13% of patients drop out of trials because they have not been paid accurately and/or on a timely basis. Because of this, lower income patients, in particular, are less likely (30%) to enroll in clinical trials. This is often bad for sponsor and site diversity objectives, which, in turn, can impact regulatory approvals.

Cross-Border Logistics. Clinical research on genetic conditions and/or rare diseases often relies on faraway patients, sometimes from foreign countries. Travel between countries is expensive and involves unique complexities -- e.g., medical/travel visas, health and travel insurance, and other factors. In these situations, navigators are often employed by sponsors and sites to help patients navigate cultural differences.

Scout

10%

Enrollment rates decline 10% for each 30 miles patients much travel to a trial site

greenphire

15%

Increase in clinical trial patient retention by using a modern payments system

MEDIDATA

61%

Most patients seek reimbursement detail before participating in a clinical trial

florence

23%

Patients who enroll in a clinical trial and do not complete the protocol

NIH National Institutes of Health
Turning Discovery Into Health

More than 90% of the clinical trials experience unexcepted delay due to failed and under-enrollment as well as challenges to participant retention, which includes loss of participants to follow-up

Source: Scout Clinical and Bourne Partners

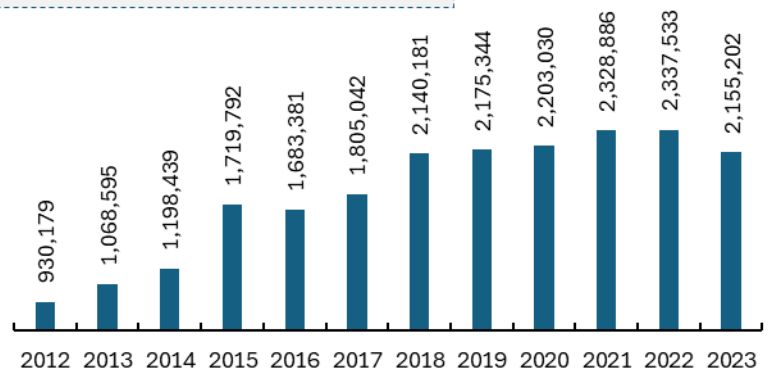
9) Rising Focus on Pharmacovigilance (Safety)

We see an increasing use case for pharmacovigilance software applications driven by the therapeutic complexity of many new precision medicines coming to market. We also see opportunities for vendors to develop and offer new artificial intelligence and machine learning applications that can help analyze unstructured medical data.

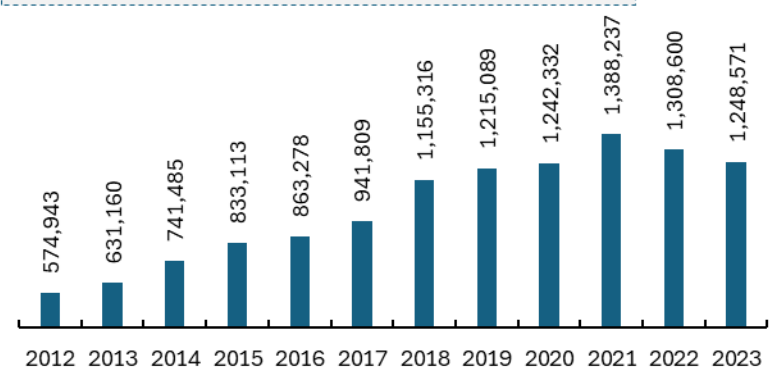
Pharmacovigilance software solutions help detect, track, and document patient safety related issues (adverse events) related to drug therapies. Regulatory authorities (e.g., the FDA and EMA) require the implementation of pharmacovigilance systems to report adverse events, and pharma and biotech companies want to be able to proactively address patient safety concerns before they snowball into more significant liabilities and public relations issues.

By our experience, **pharmacovigilance software procurement decisions are driven by usability, customizability, and interoperability** as well as the perception of the strength of the vendor. Also, we think sponsors generally prefer to have their safety operations working on the same technology platform as their regulatory and clinical operations. This allows for volume-based pricing and a more seamless flow of information, reducing the risk of manual entry errors. So, we think vendors who can offer pharmacovigilance software as part of a broader enterprise technology platform have an inherent competitive advantage.

Total Number of Adverse Safety Events
Reported to the U.S. FDA



Total Number of Expedited (Serious) Adverse Safety Events
Reported to the U.S. FDA



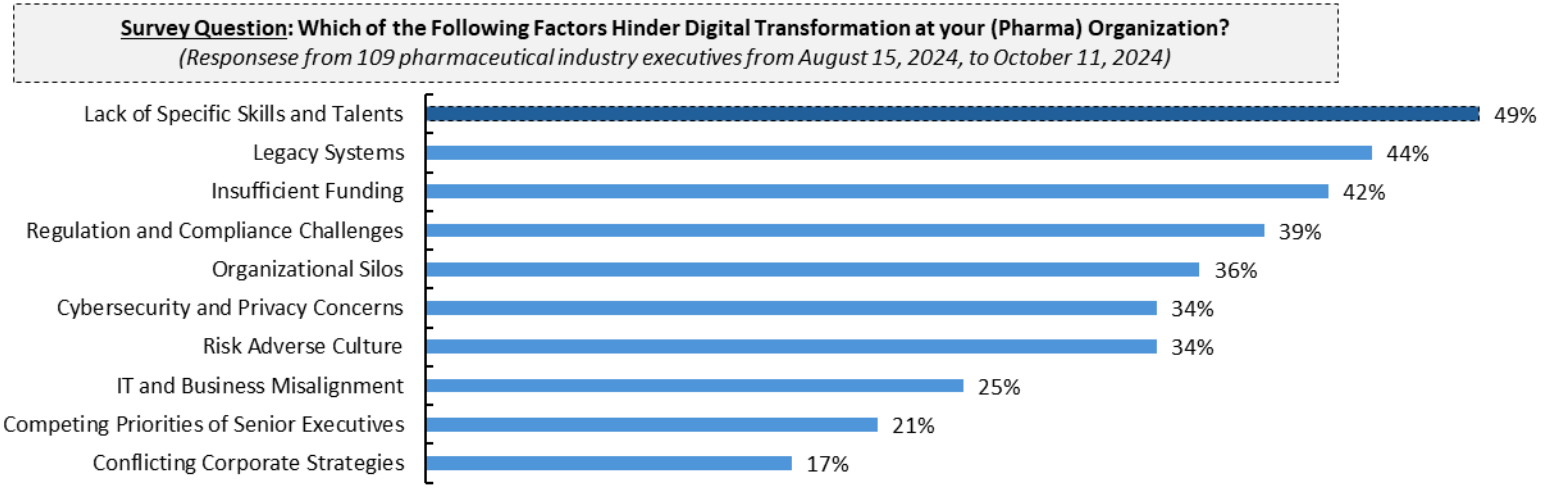
Source: FDA Adverse Events Reporting System (FAERS) and Bourne Partners

10) Overcoming Challenges of Digital Transformation

We see growing demand for outsourced (and offshored) information technology services as pharma companies face an expanding "skills gap" for skilled labor -- against the rising demands of data science and artificial intelligence. This sets up a strong demand environment for consulting firms to effectively implement digital transformation strategies.

We continue to see shortages of skilled labor in the life sciences for information technology staff. Essentially, the rapid pace of technological innovation, including advances in generative artificial intelligence, has outstripped the ability of pharma company training programs to keep up -- creating a growing "skills gap." For the second year in a row, the "lack of specific skills and talents" was named as the top barrier to digital transformation efforts in the pharma industry by 49% of respondents in a GlobalData survey.

In our view, **there is no quick solution to this problem.** Over the last five years, pharma companies have turned to outsourcing for all or part of their information technology functions, including governance, change management, implementation, and application maintenance. We expect this shift to "shared services" will continue for the foreseeable future.



Source: FDA Adverse Events Reporting System (FAERS) and Bourne Partners

Consolidating Vendor Landscape

Benefits of an Integrated Information Tech Platform

We expect significant consolidation across the clinical trial software and technology space in the coming years. This is due to a broad understanding that integrated technology platforms can help accelerate clinical trial timelines, enhance data quality, generate scale efficiencies, and improve collaboration -- as well as allow for volume-based pricing.

There are currently many dozens of categories of software and services that have evolved over the years that help to accelerate and enhance clinical research related activities. This has led to a fragmentation of "point" solution vendors.

In our view, **there is a strong preference by pharma companies, CROs, and clinical trial sites for a "one-stop-shop approach" with respect to software procurement.** With integrated software applications, data is captured and updated in one place, improving data consistency and creating a single source of truth across various clinical trial activities. Also, integrated software platforms reduce the risk of lost and erroneous data that can occur due to double-data entry and the interfacing of disparate software applications. This improves data quality and facilitates the use of artificial intelligence and machine learning -- ultimately, accelerating time to market.

Integrated technology platforms allow for increased efficiencies, greater collaboration and improved decision-making. With a single data set, there can be a more holistic view of clinical trial activities, enabling better monitoring and tracking of processes. Working from a single data set streamlines communication and issue resolution, allowing for minor issues to be dealt with in real time before they fester into larger/systemic challenges that could threaten an entire clinical trial.

Finally, **enterprise purchasing simplifies the contracting process and allows for volume-based pricing.** Most vendors offer tiered pricing schemes in which customers are placed in different tiers based on their usage levels/volume, with each tier consisting of a progressively lower price per unit. It also tends to improve customer service/satisfaction.

Example IRB-Based Technology Platforms

ADVARRA advancing better research | wcg™

Example Software Technology Platforms

MEDIDATA | greenphire | Veeva | ORACLE

Example CRO-Based Technology Platforms

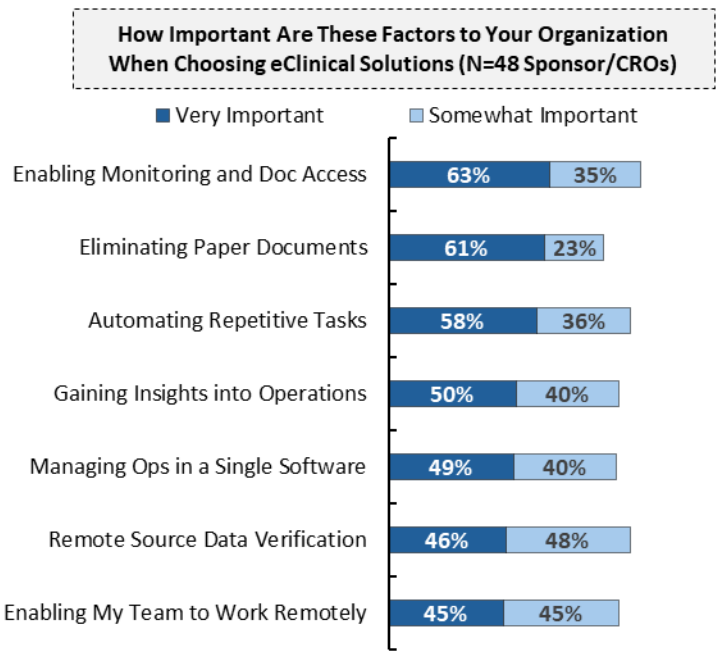
ICON | IQVIA™

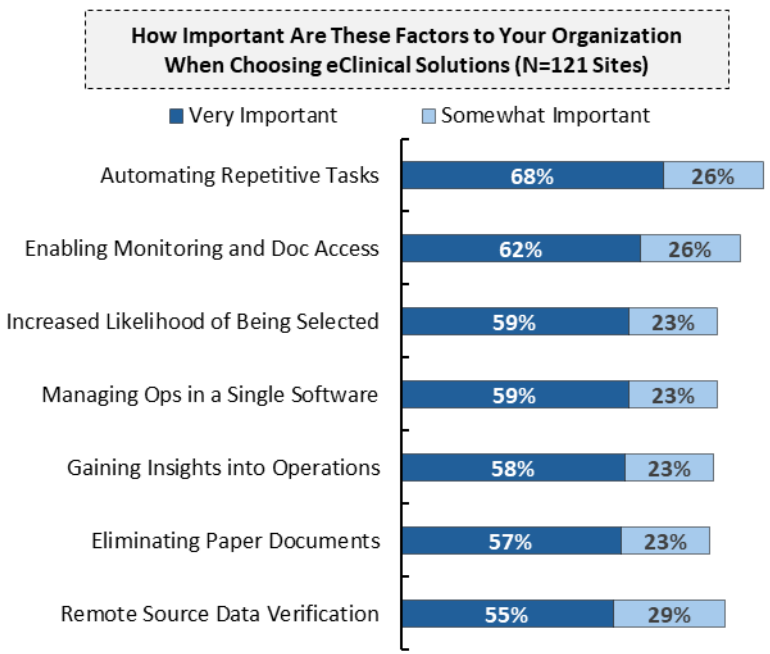
Source: Bourne Partners

What the Industry is Saying it Wants from Software/Tech

Operating on a single/integrated technology platform is commonly cited in many surveys as one of the top (if not the top) factors in selecting a particular software application. We would argue that many of the other factors cited in surveys for preferring one software (vs another) -- e.g., performance monitoring, streamlining documentation, automating manual tasks, and gaining insights -- are also (implicitly) advanced with greater technology integration as well.

Enabling remote monitoring and document exchange was reportedly the top reason to invest in information technology among sponsors and CROs, per the *Florence Healthcare 2024 State of Technology Enabled Clinical Trials Report*. In our view, this is very consistent with the draft ICH E6 guidelines, which emphasized the importance of risk-based quality monitoring in clinical trials.





Source: Florence Healthcare (2024 State of Technology Enabled Clinical Trials Report; November 2024) and Bourne Partners

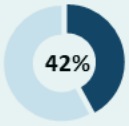
Benefits of Integrated Technology Platforms (for Sites)

In our view, **the ability to create positive experiences for clinical trial sites is critical to a sponsor's (and CRO's) ability to bring new therapies to market in a timely manner.** Quality trial sites are in short supply, and sites who have had a good experience with a particular sponsor tend to be much more open to doing more clinical trials with that sponsor.

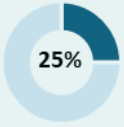
One of the top sources of frustration that we consistently hear from clinical trial sites is the volume of disparate/fragmented software applications that sponsors and CROs thrust upon them -- many of which duplicate their own existing software. Today, sites need to manage dozens of overlapping software applications. Specifically, a poll of clinical research sites found that 60% of sites are using 20+ overlapping software applications each with their own usernames and passwords and training requirements. Storing passwords in excel worksheets is not secure and navigating these various software applications is a challenge. According to data from *the Society for Clinical Research Sites*, 40% of site staff report spending 5 to 15 hours of training per study per month, which is time taken away from patient-facing (engagement related) activities.

Adding to this, **the post-COVID rise of decentralized clinical trial (DCT) designs has led to even greater operational burdens.** DCTs greatly improve patient access, in our opinion; however, this has come at the expense of clinical trial sites. Sites are increasingly forced to juggle a range of digital patient engagement technologies -- e.g., telemedicine, eConsent software, etc. Also, clinical trial sites typically do not have the personnel to visit patients in the community and collect data, so this creates a new need to coordinate with multiple third-party services companies (e.g., home nursing, infusion, and phlebotomy).

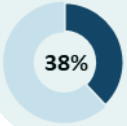
Clinical Trial Sites Are Feeling the Burden of Fragmented Information Technology



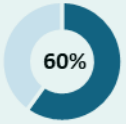
of trial sites stress the need for sponsor/CRO acceptance of their tech in study participation



of independent clinical trial sites and networks ranked sponsor-provided tech as a top challenge



of clinical trial sites find sponsor/CRO provided technology to be inadequate (difficult to use)



of clinical trial sites report using more than twenty software systems on a daily basis

Source: Florence Healthcare, the Society for Clinical Research Sites, and Bourne Partners

Fragmented Vendor Landscape in Need of Consolidation

The competitive landscape for clinical trials software and technology is highly fragmented with hundreds of high-quality vendors targeting different functional areas. It is difficult to neatly categorize vendors since most vendors address multiple pain points. In our view, many of these solutions create exceptional outcomes for their users.

To access the full unblinded report, contact:
research@bourne-partners.com

Source: Bourne Partners

Vendor Profile: Advarra

Advarra is one of the largest providers of Institutional Review Board (IRB) services, working with 3,500+ institutions, hospitals, health systems, and academic medical centers. Over the years, Advarra has used its IRB customer relationships as a channel to cross-sell various internally-developed and acquired software and services.

Advarra was created in 2017 from the merger of two institutional review board (IRB) providers: *Chesapeake IRB* and *Schulman IRB*. This merger was catalyzed by a new mandate from the National Institutes of Health (NIH) that required all multi-site clinical research studies to use a single IRB for ethical review to improve consistency and efficiency.

In June 2022 Blackstone and the Canada Pension Plan Investment Board together acquired a majority equity stake in Advarra with minority investments from Genstar Capital (an investor since 2019) and Linden Capital Partners (an investor since 2017), among others. This capital infusion should allow Advarra to continue to build out its portfolio of clinical trial software and services through acquisitions.

Advarra continues to introduce innovations into the market. This year, for instance, Advarra has launched software that aggregates data on patient outreach and enrollment trends into a single dashboard to help sponsors, contract research organizations, and sites track progress towards patient recruitment goals. This follows the release of a single sign-on (SSO) solution, which allows clinical trial sites to access disparate software technologies through one log-in pathway. Finally, in early 2024, Advarra launched a new eConsent software application that is integrated with the company's IRB and eRegulatory software.

Recent Selected Acquisitions

Quorum Review IRB (March 2019) Adds IRB services in the U.S. and Canada and research/tech consulting	**Forte (September 2019)** Adds suite of clinical trial software including an enterprise CTMS solution
The IRB Company (April 2020) Adds an AAHRPP-accredited central IRB in the U.S. since 1981	**IntegReview IRB (November 2020)** Adds IRB services in the southern U.S. and in early phase research
Longboat (November 2020) Adds tech for site training, protocol compliance, and patient engagement.	**YourEncore (December 2020)** Adds drug development and commercialization consulting services
Bio-Optronics (March 2021) Adds a suite of clinical trial software apps, including a CTMS system	**Watermark Research Services (July 2021)** Adds consulting in biostatistics, protocol design, and safety

Source: Advarra and Bourne Partners

Vendor Profile: Greenphire

Greenphire is the largest vendor of site/patient payments and logistics services for clinical trials. Of note, this includes the February 2024 acquisition of Clincierge, a provider of high-touch patient travel/logistics, and the January 2025 acquisition of Sudova, a vendor of randomization and trial supply management, and consent software.

Founded in 2008, Greenphire is a leading vendor of clinical trial site/patient payments, patient travel and logistics, and budgeting and benchmarking services. These software/tech-enabled services, together, are able to materially improve patient retention and accelerate clinical trial timelines. Greenphire is broadly viewed as a market leader in the payments space having executed upwards of $8 billion in payments made over the course of 1,300 studies in nearly 80 countries. Today, Greenphire does business with the majority of the top 30 pharmaceutical companies and the top CROs -- as well as leading research site networks.

One of the more interesting recent developments at Greenphire, in our view, was the launch of the company's new Patient Experience Dataset. The Patient Experience Dataset is a repository of global patient-level insights by phase, therapeutic area, and country, including average stipends and reimbursements. This data asset is being brought to life through a partnership with Citeline (announced September 2024) in which Greenphire's dataset of financial transactions is being combined with Citeline's data on investigator sites and protocols using the data science capabilities of Citeline.

In July 2021, Thoma Bravo acquired a majority equity stake in Greenphire (from The Riverside Company) through a $1.1 billion leveraged buyout following a prior capital infusion from Saratoga Investment in March 2021.

Site Payments

- Centralized portal for automated invoicing & payments
- Integration with any data source (EDC, CTMS, ERP, etc)

Patient Payments

- Reimbursements, stipends, data-triggered payments
- Physical card, virtual card, bank transfer
- Easy-to-use site portal

Patient Travel and Logistics

- Air, rail, and ferry travel
- Car services and rideshares
- Visa & passport services

Budgeting and Benchmarking

- Copy/paste protocol SOA from excel
- Create multiple scenarios, treatment arms, cohorts
- Easily process & track amendments

Analytics and Insights

- Patient Experience Dataset
- Payment management analytics
- Study forecasting

Source: Greenphire and Bourne Partners

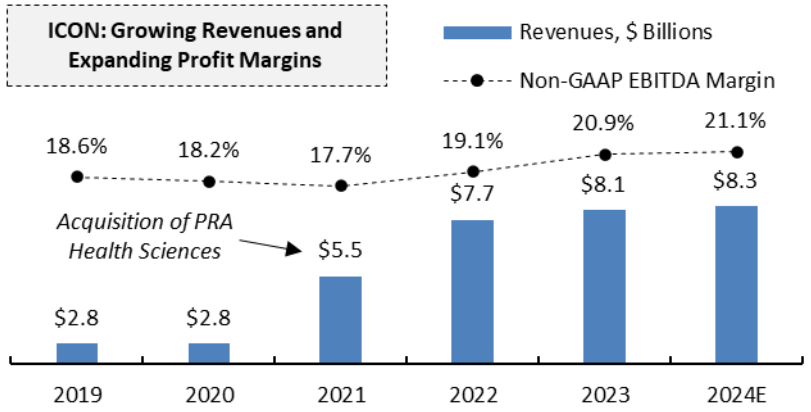
Vendor Profile: ICON

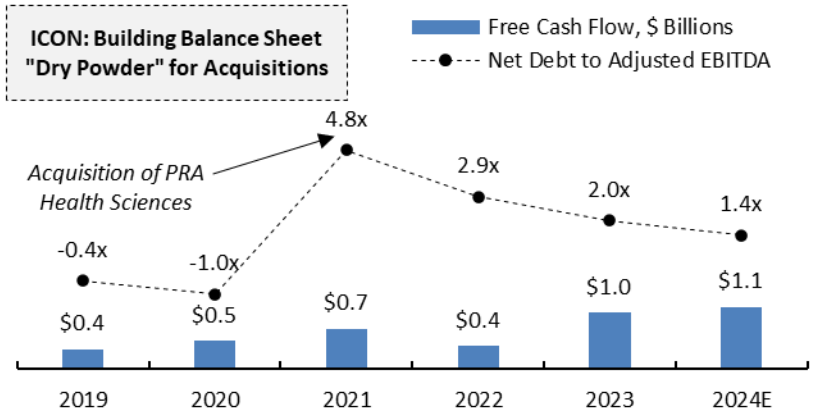
ICON is one of the largest contract research organizations (CROs) in the world with ~$8.5 billion of annual revenue. In our view, ICON has always positioned itself at the "cutting edge" of information technology both through partnerships with third-parties and through the direct ownership of proprietary software and data applications.

ICON is a technology-enabled CRO with a broad suite of proprietary software applications and data supporting both clinical development and drug commercialization. Today, ICON invests upwards of $200M annually in technology, and the company has significant balance sheet "dry powder" to pursue acquisitions. In the area of information technology, most recently, ICON acquired *Human First*, a provider that helps sponsors with digital health technology selection.

Notably, **ICON houses one of the largest healthcare data repositories in the United States** as a result of its acquisition of Symphony Health in 2017. This data repository, the "Integrated Dataverse," includes data on 307 million patients, 2 million active prescribers, and 85% of all retail prescriptions. Also, this data helps inform a variety of business intelligence tools that help life sciences companies evaluate the U.S. pharmaceutical marketplace.

Finally, **ICON has developed a variety of software solutions**, including *One Search*, an artificial intelligence application for patient recruitment, and *Firecrest*, a software for site activation and patient engagement -- as well as various eConsent, eCOA, eSource, and telemedicine applications.





Source: ICON and Bourne Partners

Vendor Profile: IQVIA Holdings

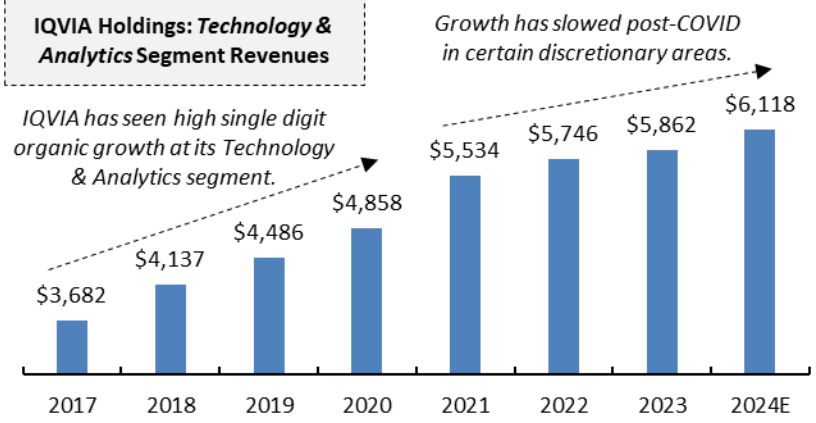
IQVIA is the largest provider of outsourced services, software, and advanced analytics for the biopharma industry with upwards of $15 billion of consolidated revenue. This includes over $6 billion of revenue from the company's *Technology & Analytics* segment, which consists of its software and data products as well as its tech-enabled service offerings.

The foundation of IQVIA's *Technology & Analytics* business is the legacy IMS data business, which represents ~$1.8 billion of annual revenue. Here, IQVIA owns and manages 61 petabytes of proprietary data sourced from ~150k sources globally. These data assets, in turn, are used by almost every biopharma company, to some degree, to make more informed clinical and commercial decisions.

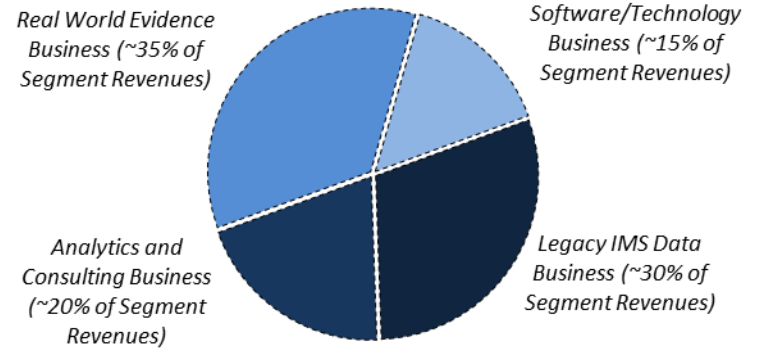
On top of these data assets, **IQVIA offers a broad range of software and services offerings.** In particular, IQVIA has invested heavily in artificial intelligence (AI) to support clinical development and commercialization. Most recently, this includes the *IQVIA AI Assistant,* a generative AI decision support software that addresses brand and territory performance, competitive intelligence, and prescription drivers, among others. There has also been elevated focus on the development of patient engagement solutions.

Finally, **IQVIA has had a deep partnership with salesforce.com for many years.** Recently, IQVIA and salesforce.com have expanded their relationship to co-develop/launch a new end-to-end CRM software platform, which is expected to be available in late 2025.

IQVIA Holdings: *Technology & Analytics* Segment Revenues



IQVIA Holdings: Breakdown of the *Technology & Analytics* Segment



Source: IQVIA Holdings and Bourne Partners

Vendor Profile: Medidata Solutions

Medidata Solutions is a leading vendor of cloud/SaaS-based solutions for the life sciences with market share leadership in clinical trials and drug development. Owned by the French conglomerate Dassault Systèmes, Medidata has significant access to financial resources to develop and acquire new information technology solutions in the coming years.

Medidata Solutions was acquired by Dassault Systèmes in October 2019 for $5.8 billion. Dassault Systèmes develops design, modeling, and visualization software for the aerospace, defense, and consumer goods industries as well as for the life sciences. In the life sciences, Dassault Systèmes was primarily focused on drug discovery, manufacturing, and supply chain planning. The acquisition of Medidata Solutions expanded Dassault Systèmes's into the clinical trials space.

Core to Medidata's value proposition is its electronic data capture (EDC) software, which, we believe, accounts for the bulk of its revenue base. As the EDC marketplace matured, Medidata has expanded into adjacent software applications and analytics in areas such as clinical trial design, eConsent, regulated content management, and real-world evidence, among others.

Recent innovations have included an end-to-end platform for decentralized clinical trials, which Medidata launched during the COVID-19 pandemic. Also, Medidata has built out its *Medidata Sensor Cloud* to support the collection of patient data from mobile devices, and its *myMedidata* portal to improve patient recruitment, payments, and engagement.

The Medidata Platform

Patient Engagement	Clinical Data Management	Clinical Operations	Trial Design and Evidence Generation
Decentralized Clinical Trials	Rave EDC	Clinical Data Studio	Integrated Evidence
eCOA	Clinical Data Studio	Adjudicate	Intelligent Trials
eConsent	Health Record Connect	CTMS	Medidata Link
myMedidata	Coder+	eTMF	Trial Design
Patient Insights Program	Imaging	Grants Manager	Synthetic Control Arm
Sensor Cloud	RTSM	Site Payments	Research Alliance
Patient Payments	Safety Gateway	Planning	

Source: Medidata Solutions and Bourne Partners

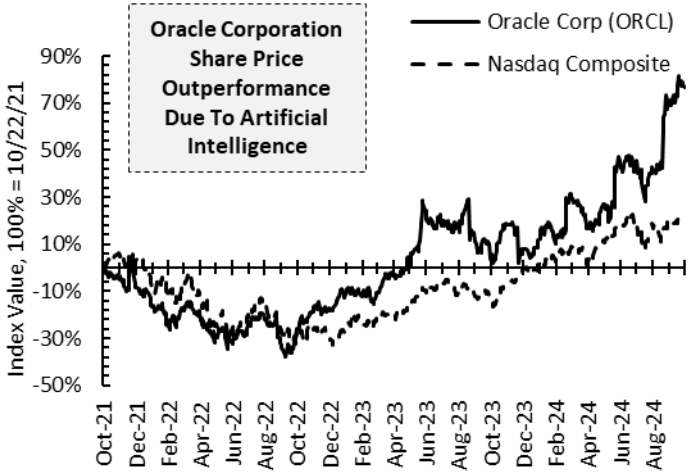
Vendor Profile: Oracle Corporation

We view Oracle Corporation as a major player in the life sciences industry, offering a wide range of software, data tools, cloud infrastructure, and services -- backed by the balance sheet of a $450 billion corporation (market cap). Most recently, Oracle acquired Cerner Corporation, the leading global vendor of EHR software for healthcare providers.

Oracle is a multinational information technology company that provides a range of products and services, including cloud applications/infrastructure, database software, and enterprise software, among others. Oracle is particularly known for its cloud-based enterprise resource planning (ERP) as well as for systems such as Solaris, Java and Oracle Linux. Also, Oracle manufactures purpose-built servers and network solutions to run its platforms and databases.

Oracle has a large healthcare business with a significant footprint in the life sciences industry. This business was built off of a series of acquisitions over the past fifteen years, including Phase Forward in 2010 (clinical trial software applications), goBalto in 2018 (clinical trial patient recruitment), and Cerner Corp in 2022 (electronic health record software), among others. Cerner, in turn, had developed its own life sciences business based on its acquisition of Kantar Health in 2021.

For the life sciences, **Oracle offers a full continuum of software applications supporting clinical trials, real-world evidence, and safety studies** with complementary research services. Also, Oracle offers cloud infrastructure and artificial intelligence solutions for large biopharma organizations. Finally, through its acquisition of Cerner, Oracle Health has access to significant clinical data assets.



Oracle Partner Network (Sample Companies)

Source: Oracle Corporation and Bourne Partners

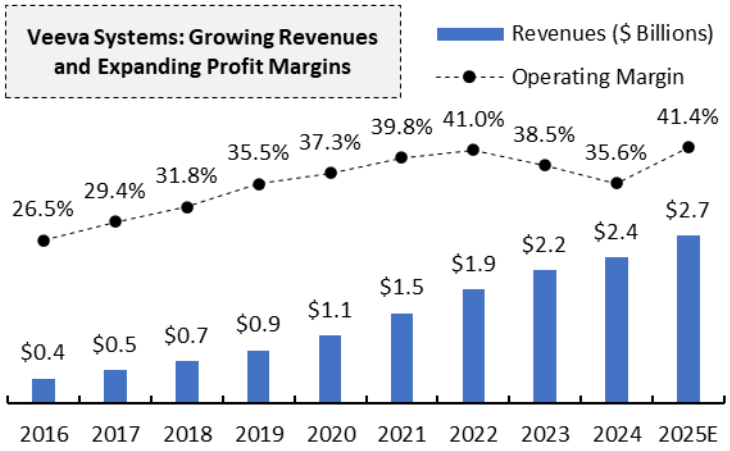
Vendor Profile: Veeva Systems

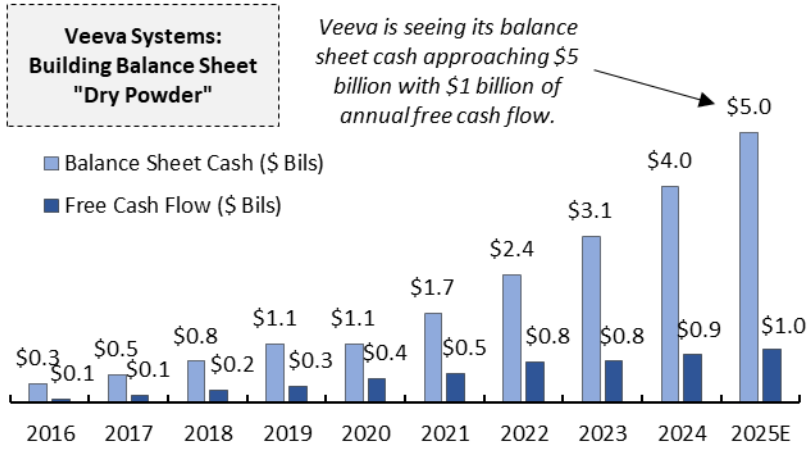
Veeva Systems is an enterprise vendor of software, data, and services for the life sciences industry. In the past, Veeva Systems was primary known for its CRM software where it has established a dominant market share (~80%). However, over the years, Veeva has also grown to become one of the leading software vendors for clinical trials and operations.

Key to Veeva's competitive differentiation is the integration of its software, data, and services into a unified offering. This reflects Veeva Systems's historical reliance on (and success with) in-house/organic innovation to fuel its growth -- with the company spending $700M+ annually on research and development activities.

Today, **Veeva holds ~$4.9 billion in balance sheet cash (no debt) with $1B of run-rate free cash flow**. This represents significant "dry powder" for acquisitions, and the company has, at times, used acquisitions to accelerate development in certain niche areas. Notable recent acquisitions have included *Veracity Logic* (2021), *Crossix* (2019), *Physician's World* (2019), and *Zinc Ahead* (2015).

To date, **Veeva's strategy for artificial intelligence (AI) has been to be an "enabler" for third-party developers** through its "AI Partner Program." Today, Veeva Systems partners with over ten AI developers supporting roughly 30 use cases. Looking ahead, we suspect that this AI Partner Program represents an ideal nesting ground for future acquisitions.





Source: Veeva Systems and Bourne Partners

Vendor Profile: WCG Clinical

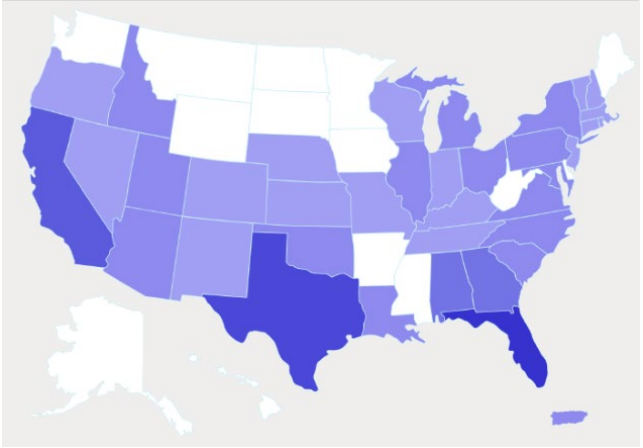
WCG Clinical is one of the largest commercial Institutional Review Boards (IRBs) in the United States having reviewed 70,000+ studies at 300,000+ sites across North America over the past 25 years. Also, over the years, WCG has used its IRB business as a platform to develop, acquire, and cross-sell software and services that accelerate clinical trials.

WCG was founded in 2012 via the merger of WIRB and Copernicus Group IRB. This created the largest commercial IRB at that time. WCG has used its leadership in the IRB space to develop adjacent software, data, and services businesses that support clinical trial activities for the benefit of sponsors, contract research organizations (CROs), and trial sites.

WCG's revenues are roughly split between its ethical review (e.g., IRB) business and its clinical trial solutions business. The clinical trial solutions business includes a continuum of software and services that address key pressure points such as study planning, patient engagement, and scientific/regulatory review. Much of the clinical trial solutions business was built through acquisitions. Most recently, in August 2024, WCG acquired *Array*, a provider of training content and services for clinical trial investigators.

Of note, **WCG operates the "WCG Site Network," which is a virtual network of 470+ independent clinical trial sites** and 1,000+ investigators. This gives sponsors and CROs a single point of contact to streamline contracting, budgeting, and payments for multiple sites. Also, WCG embeds site support teams dedicated to optimizing patient enrollment and study execution, resulting in accelerated timelines and improved patient access. Finally, WCG can use its site network to scale its clinical trial solutions business. Over the past five years, WCG has placed 1,300+ clinical trials through its site network.

The WCG Site Network Includes 470+ Sites Across the United States



29%	*faster study start-up timelines when working with the WCG Site Network*
27%	*faster contracting timelines when working with the WCG Site Network*
34%	*increase in enrollment when working with the WCG Site Network*

Source: WCG Clinical and Bourne Partners

Profiles of Selected Clinical Trial Software Vendors (1 of 3)

Citeline (Norstella)
Morrisville, Pennsylvania
www.norstella.com

In our view, Citeline is best known for its analytical software that provides sponsors and CROs with insights into clinical trial patient enrollment, patient demographics, and clinical trial site performance. Also, Citeline has launched a variety of artificial intelligence applications that optimize clinical trial feasibility studies (e.g., protocol design and site selection).

In November 2022, Citeline was merged with Norstella, a $5 billion-plus vendor of data, business intelligence software, and consulting services for the global biopharma industry.

Norstella, in turn, is backed by a variety of investors, including Welsh Carson, Ardan Equity, and Ardian.

CluePoints
Louvain-la-Neuve, Belgium
www.cluepoints.com

Founded in 2012, CluePoints is best known for its cloud-based software platform that supports risk-based quality management programs for sponsors and CROs. Also, CluePoints is used by the U.S. Food and Drug Administration and other regulators to prioritize and execute site inspections.

CluePoints continues to develop new applications to build out its software offerings. Most recently, CluePoints released a Medical & Safety Review software that detects patient safety issues during a clinical trial.

In June 2024, private equity firm EQT acquired a majority equity stake in CluePoints with Summit Partners retaining a minority ownership position.

CRIO
Boston, Massachusetts
www.clinicalresearch.io

CRIO was founded in 2015 to develop software and technologies to support the workflows of clinical trial sites. Today, CRIO offers a continuum of integrated software tools used by clinical trial sites, including eSource, CTMS, and eConsent software, among other applications.

Of note, CRIO recently announced a partnership with Pluto Health to help clinical trial sites integrate with third-party EHR software systems and get a fuller clinical context on the patients that they are treating.

In May 2024, Riverside Company, a private equity firm, acquired CRIO to provide funding for new organic software innovation and acquisitions.

Source: Company reports and Bourne Partners

Profiles of Selected Clinical Trial Software Vendors (2 of 3)

eClinical Solutions
Boston, Massachusetts
www.eclinicalsol.com

Founded in 2012, eClinical Solutions markets data infrastructure services and analytics that support the clinical development programs of pharma and biotech companies. Today, eClinical Solutions does business with 16 of the top 50 biopharma companies.

Recently, in September 2024, GI Partners acquired a majority equity stake in eClinical Solutions. Summit Partners, an investor since 2020, will retain a minority stake along with the company's original founders.

In November 2024, eClinical Solutions has recognized as a sector leader in the Life Sciences Clinical Data and Analytics Platform space by the Everest Group for its "elluminate Clinical Data Cloud."

Florence Healthcare
Atlanta, Georgia
www.florencehc.com

Florence Healthcare is a leading vendor of software solutions that support the operations of clinical trial sites. Today, Florence is deployed at 20,000 trial sites in 90 countries worldwide. Most recently, the company launched "Florence eNcounter," which automates the pre-screening processes and documentation associated with clinical trial patient enrollment.

In May 2021, Insight Partners acquired a majority equity position in Florence. Other investors include Fulcrum Equity Partners, Bee Partners, and Flashpoint.

Subsequently, in September 2023, Florence acquired VersaTrial, a developer of patient engagement software for clinical trial sites.

Ledger Run
Tiburon, California
www.ledgerrun.com

Ledger Run offers a tech-enabled suite of financial management services that help clinical trial sponsors and CROs with budgeting, contract management, investigator payments, and business intelligence analytics. The company currently supports three of the top ten global pharma companies and two of the largest CROs.

Ledger Run was acquired by Blue Star Innovations Partners, a growth oriented private equity firm, in August 2024.

Shortly thereafter, in October, Ledger Run acquired Assentia, a global vendor of clinical trial contract negotiation software and services and investigator payments for biopharma sponsors and CROs in over 60 countries.

Source: Company reports and Bourne Partners

Profiles of Selected Clinical Trial Software Vendors (3 of 3)

OpenClinica
Needham, Massachusetts
www.openclinica.com

OpenClinica offers a suite of technologies and services, including electronic data capture software, data management, patient-reported outcomes, randomization, and supply management, among others.

OpenClinica was recently recapitalized by Thompson Street Capital Partners in February 2023.

Most recently, in December 2024, OpenClinica acquired BuildClinical, adding patient recruitment capabilities. BuildClinical also complements OpenClinica's historical focus on biopharma sponsors and CROs with a customer base of academic medical centers. We think this potentially sets up cross-selling opportunities.

RealTime eClinical Solutions
San Antonio, Texas
www.realtime-eclinical.com

RealTime eClinical Solutions develops a continuum of cloud-based software for clinical research, anchored by its flagship clinical trial management system. Recently, RealTime has reported success with site networks, academic medical centers, and CROs, and the company is now deployed at 3,000+ clinical trial locations.

RealTime recently acquired Complion in December 2022 (regulatory software) and Devana Solutions in July 2023 (trial site operations software).

RealTime has been financially backed by private equity firm LLR Partners since early 2022. Of note, LLR Partners also owns Suvoda, a leading vendor of IRT/eCOA software solutions.

YPrime
Malvern, Pennsylvania
www.yprime.com

Founded in 2006, YPrime is a well-known vendor of eCOA, IRT, and eConsent software applications as well as consulting and integration services. These software and services, wrapped together, have been shown to mitigate clinical trial delays, protocol amendments, and data quality issues.

Recently, YPrime was recognized as a "Trailblazer" in the Everest Group's Clinical Trial Patient Engagement Products Assessment.

YPrime has been backed by private equity firm Flexpoint Ford since 2019. Ballast Point Ventures has also been an owner since 2013. In February 2022, YPrime acquired Tryl, a patient engagement solution.

Source: Company reports and Bourne Partners

Valuation Considerations

Information Technology / SaaS Trading Comparisons

Company Name	Ticker	Enterprise Value	Projected CY2025 Revenue	Growth	Multiple	Projected CY2025 EBITDA	Margin	Growth	Multiple	Debt Ratio
Technology / SaaS Comparisons										
Autodesk	ADSK	$64,391	$6,884	11.4%	9.4x	$2,580	37.5%	13.4%	25.0x	0.2x
Salesforce	CRM	312,207	41,397	9.7%	7.5x	15,613	37.7%	8.0%	20.0x	0.0x
Datadog	DDOG	44,788	3,240	22.7%	13.8x	858	26.5%	30.8%	52.2x	-2.6x
DocuSign	DOCU	17,642	3,150	7.6%	5.6x	1,091	34.6%	10.3%	16.2x	-0.7x
Dynatrace	DT	14,961	1,852	16.6%	8.1x	537	29.0%	23.2%	27.9x	-1.7x
Fortinet	FTNT	71,875	6,633	13.2%	10.8x	2,265	34.2%	14.4%	31.7x	-1.2x
HubSpot	HUBS	36,303	3,006	16.7%	12.1x	643	21.4%	24.8%	56.5x	-1.8x
Cloudflare	NET	40,759	2,096	25.4%	19.4x	447	21.3%	37.3%	91.3x	-0.8x
ServiceNow	NOW	219,420	13,231	20.2%	16.6x	4,759	36.0%	24.6%	46.1x	-1.4x
Okta	OKTA	14,031	2,802	10.0%	5.0x	628	22.4%	17.6%	22.3x	-2.1x
Palo Alto Networks	PANW	118,127	9,800	14.1%	12.1x	3,003	30.6%	11.3%	39.3x	-0.8x
Paycom Software	PAYC	11,450	2,055	9.8%	5.6x	814	39.6%	10.3%	14.1x	-0.3x
RingCentral	RNG	4,459	2,575	7.0%	1.7x	666	25.9%	12.3%	6.7x	2.1x
Atlassian Corporation	TEAM	65,748	5,568	18.4%	11.8x	1,377	24.7%	20.6%	47.7x	-0.7x
Veeva Systems	VEEV	31,219	3,056	12.6%	10.2x	1,277	41.8%	14.4%	24.4x	-3.9x
Workday	WDAY	62,898	9,524	13.8%	6.6x	2,940	30.9%	22.0%	21.4x	-1.3x
Wix.com	WIX	13,335	2,019	13.4%	6.6x	498	24.7%	22.1%	26.8x	0.0x
Zscaler	ZS	27,962	2,891	20.4%	9.7x	736	25.5%	27.7%	38.0x	-2.0x
Median (Technology / SaaS)				***13.8%***	***9.7x***		***29.0%***	***20.6%***	***27.9x***	***-1.2x***
Pharma / Healthcare IT Comparisons										
Certara	CERT	$2,105	$422	10.5%	5.0x	$136	32.1%	11.1%	15.5x	0.6x
Clarivate	CLVT	8,162	2,568	2.8%	3.2x	1,052	41.0%	4.0%	7.8x	4.1x
Definitive Healthcare	DH	460	241	3.7%	1.9x	67	27.9%	7.3%	6.8x	-0.7x
GoodRx	GDRX	1,933	826	7.1%	2.3x	277	33.6%	9.9%	7.0x	0.4x
Health Catalyst	HCAT	323	339	10.4%	1.0x	39	11.5%	35.5%	8.3x	-0.6x
HealthStream	HSTM	893	306	6.6%	2.9x	70	23.0%	6.1%	12.7x	-1.1x
Hims & Hers Health	HIMS	6,270	2,078	13.7%	3.0x	264	12.7%	21.5%	23.8x	-0.9x
IQVIA Holdings	IQV	49,573	16,054	5.9%	3.1x	3,860	24.0%	6.9%	12.8x	3.2x
OptimizeRx Corp	OPRX	119	100	9.3%	1.2x	12	11.6%	20.8%	10.3x	1.7x
Phreesia	PHR	1,529	477	12.0%	3.2x	81	17.0%	39.3%	18.8x	-0.7x
Schrodinger	SDGR	1,286	256	17.8%	5.0x	(165)	-64.7%	-4.5%	-7.8x	1.6x
Simulations Plus	SLP	619	103	16.4%	6.0x	35	33.6%	-100.0%	17.9x	-0.5x
Tempus AI	TEM	7,506	963	21.5%	7.8x	(12)	-1.3%	-679.2%	-619.7x	-0.4x
Veradigm	MDRX	1,252	631	3.0%	2.0x	161	25.6%	-14.2%	7.8x	-1.7x
Weave Communications	WEAV	1,108	236	15.3%	4.7x	10	4.2%	67.8%	111.4x	-4.2x
Median (Pharma / Healthcare IT)				***10.4%***	***3.1x***		***23.0%***	***7.3%***	***10.3x***	***-0.5x***

Note: Market values are as of the close of business January 21, 2025.
Source: S&P Global Market Intelligence and Bourne Partners

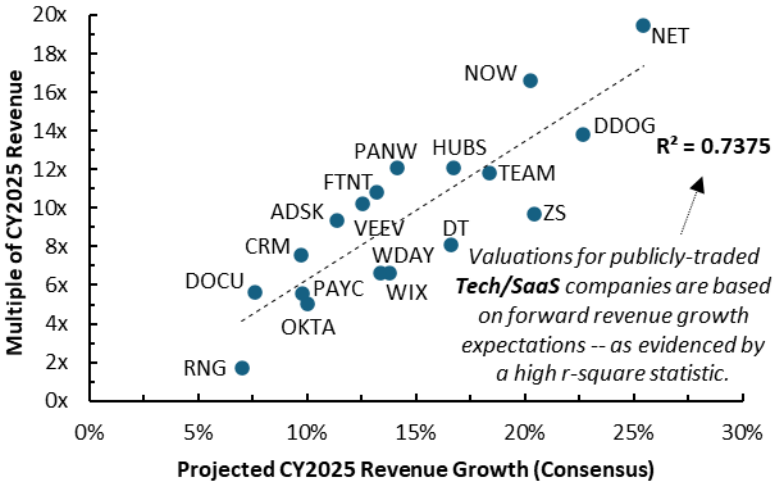
Valuations Are a Direct Function of Revenue Growth

In our view, **market valuations for technology/SaaS companies are a direct function of forward revenue growth expectations.** This reflects the significant operating leverage inherent in the SaaS-model, which often allows for very high contribution margins (often 80%+) on each incremental dollar of revenue -- coupled with limited capital requirements.

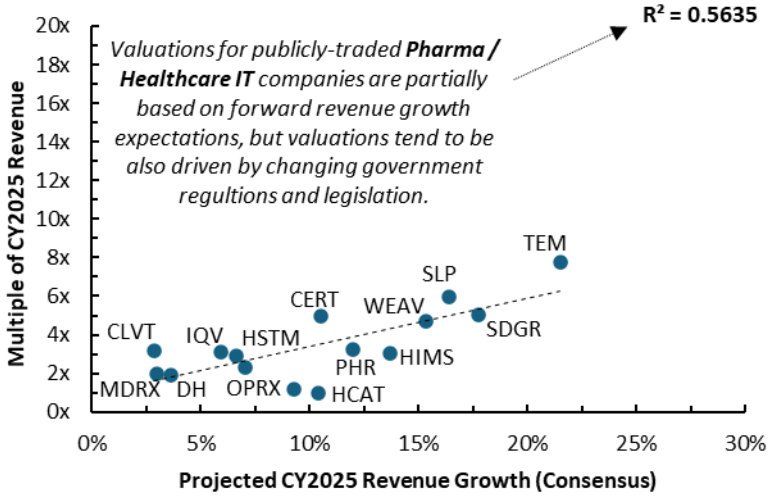
Many publicly traded technology/SaaS vendors now operate from single-instance, multi-tenant platforms, which allow for maximum economies of scale and efficiency introducing new innovation and updates to existing products. Also, in healthcare, there has been a broad acceptance of public cloud as public cloud environments have proven to be safe stores of data from a cybersecurity standpoint -- on top of being much less expensive (and more scalable).

Finally, **vendors are now selling themselves as operating expense line items (i.e., subscriptions)** that can be rapidly and nimbly scaled up-and down with little, if any, upfront capital or financial commitment by the end user. This creates greater visibility for investors and facilitates easier budgeting/planning for the vendor.

Technology / SaaS Comparisons



Pharma / Healthcare IT Comparisons



Note: Market values are as of the close of business January 21, 2025. Refer to Slide 48 for background data on trading comparisons. Source: S&P Global Market Intelligence and Bourne Partners

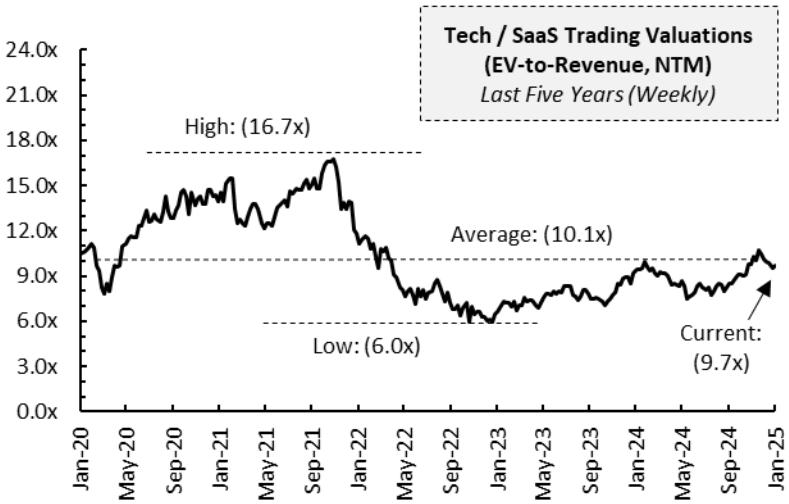
Significant Recovery in Valuations in Recent Years

We have seen a significant recovery in tech/SaaS valuations over the past two years. Specifically, valuations for publicly traded tech/SaaS vendors have recovered almost 80% from their low in November 2022, and they are near their five-year average. The recovery in healthcare IT valuations has lagged, in our view, due to company-specific challenges.

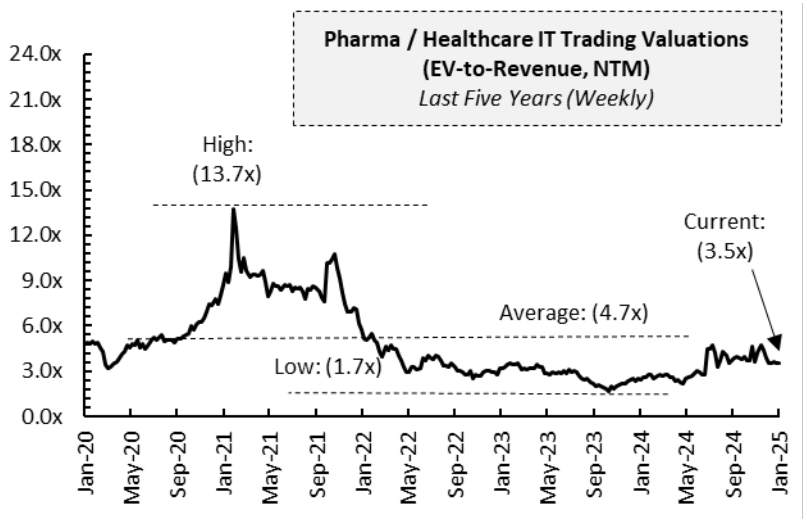
Valuations for publicly traded tech/SaaS companies have proven to be very sensitive to interest rates and general capital market conditions. Valuations fell by well over 50% as the U.S. Federal Reserve Bank began ramping its interest rate target in 2022. This was followed by a sharp recovery in valuations as expectations for Federal Reserve rate cuts increased in 2023 and 2024.

Healthcare IT valuations, as a group, have tended to trade at a discount to the broader tech/SaaS space over time. In our opinion, this reflects the fact that they are often selling their solutions into smaller end markets consisting of customers that tend to be less financially viable and less sophisticated. Also, many healthcare IT companies have significant "services" businesses that support the adoption and execution of their software offerings. This results in relatively less scalable business models.

Technology / SaaS Comparisons



Pharma / Healthcare IT Comparisons



Note: Market values are as of the close of business January 21, 2025. Refer to Slide 48 for background data on trading comparisons. Source: S&P Global Market Intelligence and Bourne Partners

Selected Recent Pharma Tech Acquisitions (1 of 2)

Over the past year, despite otherwise rocky capital markets, **strategic and sponsor demand for pharma tech and services providers has remained strong with both buyer groups often willing to pay premium valuations for quality assets.**

To access the full unblinded report, contact:
research@bourne-partners.com

Selected Recent Pharma Tech Acquisitions (2 of 2)

Over the past year, despite otherwise rocky capital markets, **strategic and sponsor demand for pharma tech and services providers has remained strong with both buyer groups often willing to pay premium valuations for quality assets.**

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Appendix: Bourne Partners Overview

Bourne Partners Overview

Our Service Offering

For over twenty years, Bourne Partners has focused exclusively on providing investment banking advisory services and making direct investments in the Pharmaceutical, Pharma Tech/Services, Healthcare IT/Services, and Consumer Health spaces.

Since 2015, we have successfully executed on **over $15B** in transactions, having worked with many leading companies and private equity investors in these core focus areas.

Investment Banking

Mergers and Acquisitions
Sell-side and buy-side assignments
Transaction Experience: $30M - $3.5B

Capital Sourcing
Debt / Equity / Hybrid
$10 - $500 million raises

Business Development Support
Development stage and approved products
Local and international

Strategic Capital

Investment Focus
Direct investments in private companies
Selective approach in vital focus areas

Other Criteria
Cash flow positive opportunities
Complex situations with creative structures
Actionable growth stage or middle market business
Flexible investment targets with established private equity relationships

Geographic Coverage

Sector Expertise

Pharmaceuticals

Pharma Services & Technology

Healthcare Services

Digital Health & HCIT

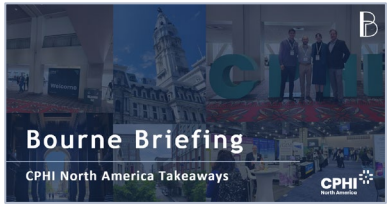
Thought Leadership

Bourne Perspective

After 20+ years of exclusive industry and capital markets coverage, we know the space and we are committed to providing insights to clients. We provide cutting-edge thought leadership on all things Pharma, Pharma Services, Healthcare Services, and Consumer Health.

Through leveraging resources and insights of both Bourne Partners Strategic Capital and Investment Banking divisions, **we provide differentiated perspectives to our clients from our unique vantage point**. Our goal is to deliver heavy-hitting, timely reports in an easy-to-read format tailored specifically for executives within our industry coverage.

Conference Commentary



Industry Update Posts

Weekly Newsletter

White Papers

Marketplace Deep Dive Reports

Bourne's Leadership in Pharma Services

Proven Expertise

Over recent years, Bourne has successfully completed numerous key transactions, solidifying its position as a leading M&A advisor in the pharma services, pharma, consumer health, and healthcare services verticals.

Sector Expertise

Clinical & Drug Discovery Services

- Full-Service & Specialty CROs
- Site Networks & SMOs
- IRB & IBC Services
- Patient Recruitment
- Patient / Provider Engagement & Retention
- Patient Logistics & Payments
- Hub Services & Patient Support Services
- eClinical & Tech-Enabled Trial Automation
- eLearning and Clinical Education
- Safety & Pharmacovigilance
- Clinical Data Services
- RWD, RWE, & Data Analytics
- Life Sciences Consulting

Commercialization

- Medical Communications
- Medical Affairs
- Pricing & Market Access
- Launch Strategy
- HEOR
- Healthcare Marketing / Advertising
- Patient / Provider Engagement & Retention
- Medical Education & eLearning
- RWE, Data, & Analytics
- Post-Market Safety & Pharmacovigilance
- Regulatory & Compliance Services
- Life Sciences Consulting

Supply Chain Services

- CMO / CDMO
- Biopharma and Cold Chain Storage
- Packing / Labeling / Logistics / Distribution
- Software and Tech-enabled Services

Relevant Recent Tombstones

Clincierge has been acquired by greenphire, a portfolio company of THOMABRAVO

BOURNE STRATEGIC CAPITAL has completed a growth investment in Eximia Clinical Research

optimal research has been acquired by PPD

SYNEXUS has been acquired by accelovance (ACCELERATE. ADVANCE. ACHIEVE.)

accelovance has been acquired by Clinical Development Partner Linical

reverba, a portfolio company of 424 CAPITAL, has acquired Six Degrees Medical

spencer health solutions has received a growth investment from RCT Research Corporation Technologies

The Bourne Team

Senior Leadership

Banks Bourne
Founder & CEO

Jeremy Johnson
Senior Managing Director

Aaron Olson
Managing Director

Xan Smith
Managing Director

Todd Bokus
Director

Robert Stanley
Director

Strategic Advisory & Administration

Matt Bullard
Strategic Advisor

Scott Emerson
Strategic Advisor

Bruce Montgomery
Strategic Advisor

Paul Campanelli
Strategic Advisor

Martin Zentgraf
Strategic Advisor

Minor Hinson
CIO, BPSC

Chris Inklebarger
Chief Operating Officer

Calli Lewis
Chief of Staff

Transaction Execution Team

Vice Presidents




Associates




Analysts





Deep Industry Expertise

Excellent M&A Execution

Thorough Sponsor Coverage

Broad Senior Support

Detailed Thought Leadership

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