



Perspectives on Emerging Trends in Clinical Technology

Q3 2022

Assessing the Opportunities for Clinical Trial Technology

Substantial technological innovation is driving a growing ecosystem of technology solutions across the clinical trial landscape



Clinical Trials Ecosystem

- › Increasing trial complexity has pushed trial sponsors, contract research organizations (CROs), and site management organizations (SMOs) to leverage a broader array of technology solutions to increase trial efficiency and cost-effectiveness

Market Tailwinds

- › Growing preclinical and clinical pipelines are fueled by a rise in pharmaceutical funding and research expenditures, particularly among small and emerging biotech companies

Challenges Facing Clinical Trials

- › Increasing focus on rare, low-incidence, and complex diseases has compounded challenges around patient recruitment and retention, in turn fueling the decentralization of trials and increasing trial complexity

Accelerating Investor Momentum

- › Significant M&A momentum as point solutions innovate around key workflows and large platforms seek to expand their ability to provide end-to-end solutions to sponsors

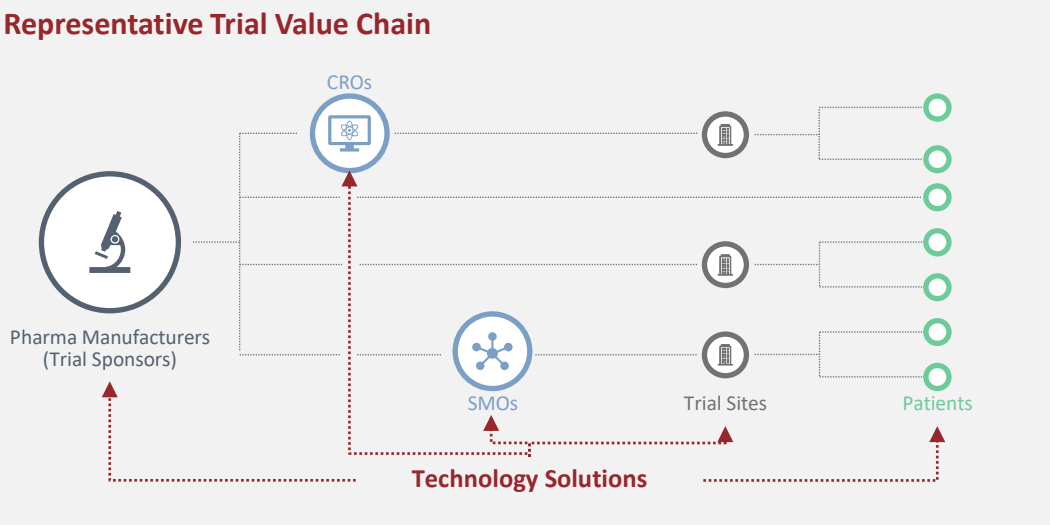
Key Investor Focus Areas

- › Investors in the sector are focused on key platform attributes and business dynamics that will support sustainable growth and solve key clinical trial pain points

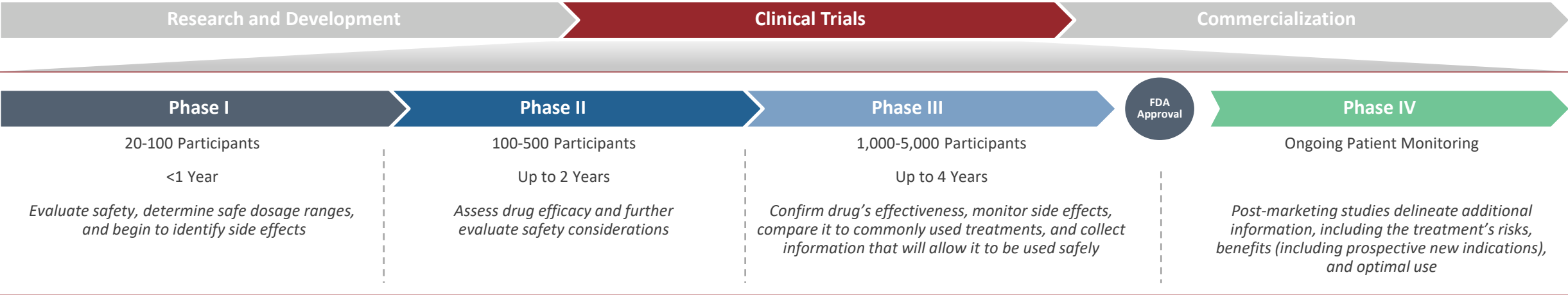
Ongoing Paradigm Shift in Pharma's Commercial Model Has Given Rise to New Challenges in the Clinical Trial Process

Rigorous trial design, execution, and data collection focus on the safety and efficacy of new therapeutic solutions

- Trends in Pharmaceutical Development**
- › Advances in pharmacological and biological science have allowed pharma to shift its focus toward more complex and lower-incidence therapeutic areas in an era when little white space remains for drugs addressing highly prevalent disease states
 - › Over the past decade, drug development efforts have shifted from high-volume, low-cost traditional small-molecule drugs to high-cost, lower-volume, and complex, large-molecule therapies
 - › As manufacturers target more specialized drugs for complex diseases, the addressable patient populations also decline, creating increasing complexity across clinical trials as patients become more difficult to find and the trials themselves incorporate additional complexities and risks
 - › Stakeholders across the development value chain are adopting technology solutions to accelerate time to market, enhance the ability to reach doctors and patients, mitigate trial risk, and better capture and analyze clinical outcomes



Drug Life Cycle Timeline



Framework for Addressing Clinical Trial Challenges

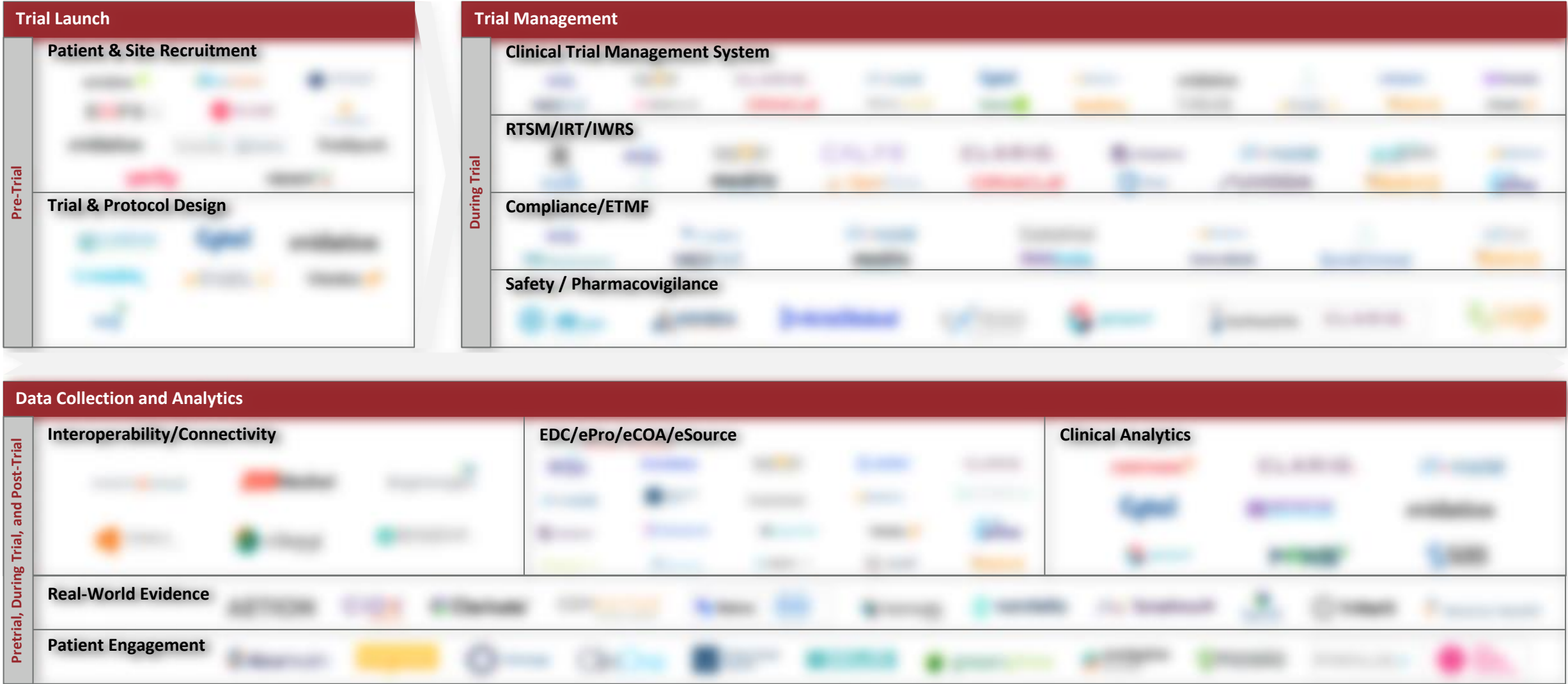
Technology solutions are increasingly focused on increasing speed and minimizing costs at discrete points along the clinical trial value chain

Trial Launch		Trial Management	
Pretrial	Patient & Site Recruitment Solutions enabling sponsors to target appropriate patient populations and sites for trial participation	During Trial	Clinical Trial Management System Centralized platforms used to streamline organizational data, monitor execution against protocol, and report key metrics
	Trial & Protocol Design Solutions that create and test clinical trial designs and protocols		RTSM/IRT/IWRS Systems that enable sponsors to control patient randomization and drug supply in clinical trials
	Compliance/ETMF Solutions enabling secure, accurate, and transparent documentation for clinical trial compliance and regulatory submissions		
	Safety/Pharmacovigilance Solutions that analyze the risks, serious adverse events, adverse drug reactions, and overall safety profile of new treatments		
Data Collection and Analytics			
Pretrial, During Trial, and Post-Trial	Interoperability/Connectivity Solutions enabling the exchange, interpretation, and application of data for clinical trials and patient monitoring	EDC/ePro/eCOA/eSource Solutions designed to collect, clean, and provide real-time data produced from clinical trials	Clinical Analytics Solutions enhancing the ingestion and interpretation of trial data to derive more precise insights from trials and accelerate time to endpoints and/or commercialization
	Real-World Evidence Data tools and services focused on the ingestion and analysis of clinical, claims, and outcomes data derived from observational studies to evaluate safety, new applications, and coverage decisions for on-market therapies		
	Patient Engagement Solutions that facilitate patient engagement and track adherence to trial procedures		

Framework for Addressing Clinical Trial Challenges

To view full market map, please contact:
PharmaServicesandTech@harriswilliams.com

Technology solutions are increasingly focused on increasing speed and minimizing costs at discrete points along the clinical trial value chain

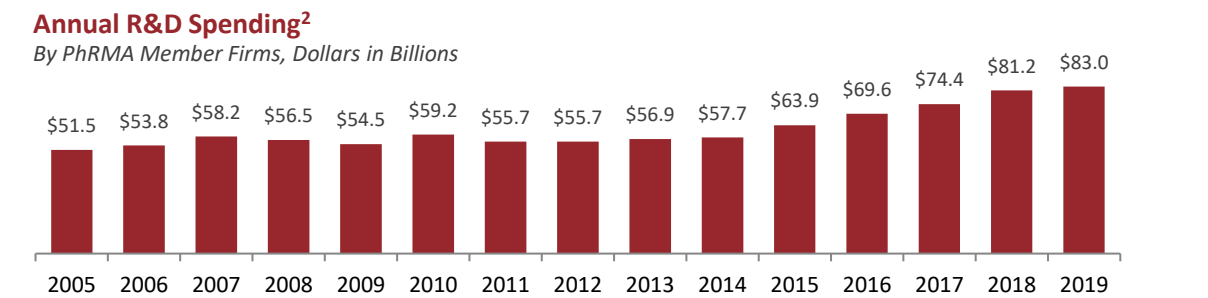


Significant Funding and Pipeline Momentum are Accelerating Clinical Trial Growth

Well-capitalized manufacturers continue to increase their R&D spend, filling the preclinical and clinical pipeline at an accelerating rate

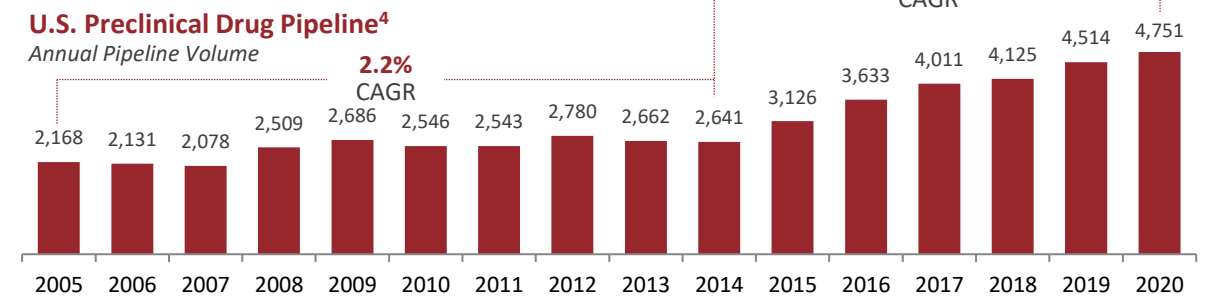
Influx of Capital

Between April 2020 and May 2022, the Life Science industry raised over \$43B in capital through IPOs with significant accompanying private investment¹, fueling sustained increases in preclinical development that will translate to a growth in clinical trial activity over the coming years. R&D expenditures have increased alongside the influx of capital as trials increase in complexity and scale.



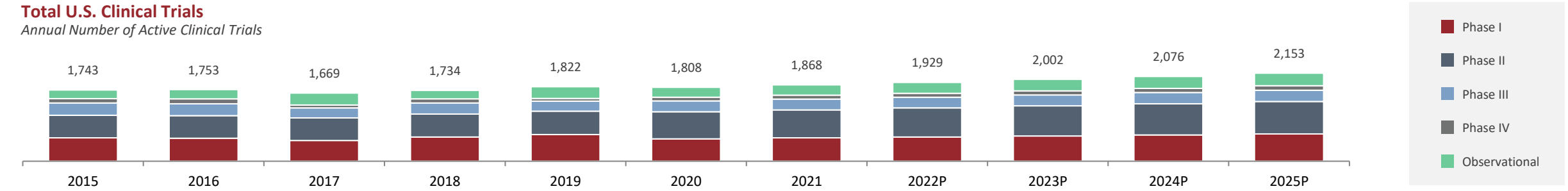
Expanding Pipeline

The volume of preclinical drugs and active clinical trials continues to grow as manufacturers advance new compounds from research to approval. The preclinical pipeline is at an all-time high, providing sightlines to future clinical trial growth as products move to clinical stage after approximately 3-4 years in development. CROs report sustained request volume³ through 2021 as pharmaceuticals deploy capital into the trial pipeline.



Active Independent Launches

Emerging Biopharma companies (EBPs) are increasingly launching new products independently, with small pharma and biotech companies increasingly leading novel compounds through commercialization, driving a new wave of customers for outsourced pharma services and tech providers. 53% of new drugs launched in 2021 were originated by emerging biopharma companies, and 76% of FDA regulatory submissions for novel active substances (NAS) in 2021 were originated and launched by emerging biopharma companies⁵, representing a significant paradigm shift from the era shortly before and after the 2012 “patent cliff,” when large pharma aggressively acquired EBPs with promising therapies in early-stage trials.



Changing Landscape of Drugs in Development and Trials Creates Significant Challenges

Increasing scale and complexity of trials adds cost, time, and potential for delays, which can have significant financial impact for trial sponsors

Increasing Trial Complexity

- As protocols become more complex, so does the potential to add unpredicted cost and time to trials as they progress, with amendments and deviations requiring enrollment suspension, additional approvals, and oversight over relaunch
- CSSD estimates that each Phase III protocol amendment costs over \$535,000 in direct, unbudgeted costs and results in three additional months of implementation time. The ability to rapidly identify and quickly act on patterns in data to adjust trials is a critical advantage in avoiding substantial delays and added cost, especially as average time to Phase III completion has increased from just over 2 years in 2010 to 3.5 in 2022.¹ Each day of delay in a trial can add between \$0.6M and \$8.0M to overall cost per day²

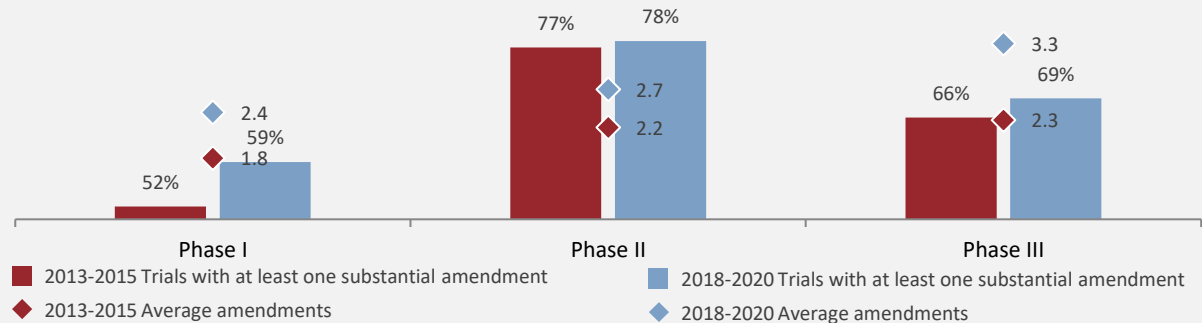
Patient Enrollment and Retention

- Patient recruitment is the single largest cost driver of clinical trials, representing approximately 30% of total cost.³ 80% of clinical trials fail to meet their enrollment goals in stated timelines⁴ and experience average dropout rates of 30%.⁵ Enrollment forecasting is the foremost reason for trial discontinuity and is estimated to have cost the industry \$40B⁶
- Finding and reaching relevant patient populations requires data-driven solutions to better target and retain participants. The imperative of finding a diverse panel of participants has been compounded by the FDA’s recent guidance recommending adequate enrollment of underrepresented groups in trials

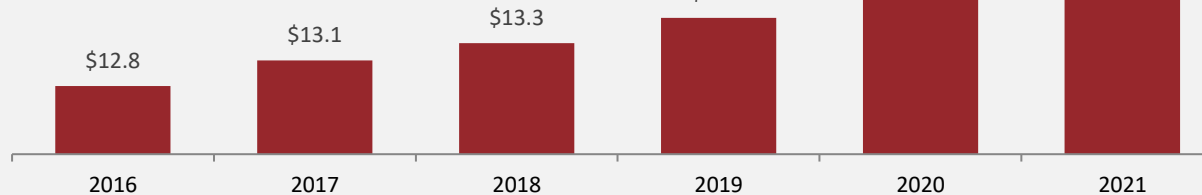
Decentralization

- 70% of patients live more than two hours from trial sites⁷, and patients who drop from clinical trials most frequently cite the volume of visits to the study center as the key reason for leaving.⁸ This underscores the need for decentralized or hybrid clinical trial designs that are better able to meet participants where they are. As trials target increasingly rare disease states with broadly dispersed patient populations, this dynamic becomes a critical imperative to support successful trials
- Greater decentralization requires innovative adherence, monitoring, and data solutions to capture and centralize results

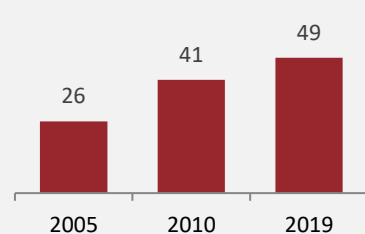
Incidents of Substantial Protocol Amendments⁹
U.S. Clinical Trials



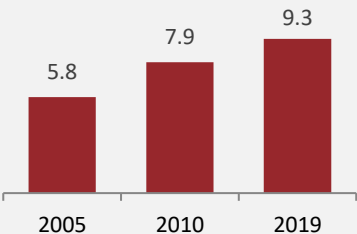
Average Cost per Clinical Trial¹⁰
Phases I-III, dollars in millions



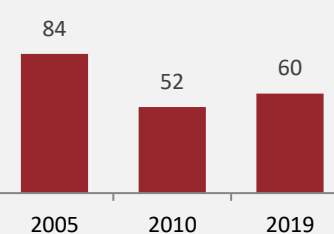
Average Sites per Trial¹¹
Phase III



Average Outcomes per Trial
Phase III



Median Patients per Trial
Phase I-III



(1) RSM
(2) Antidote.me
(3) Deloitte

(4) NIH
(5) CISCPR
(6) Cytel

(7) McKinsey
(8) CISCPR
(9) CenterWatch

(10) Industry research
(11) Industry research

Shift to Decentralized Trials Enhances Patient Access but Increases Complexity

Increasing Reliance on Decentralized Trials

- Historically, Academic Medical Centers (AMCs) hosted most clinical trials. However, most Americans are over two hours away from their nearest clinical trial site¹ and increasingly seek primary and specialized care outside of AMCs, making them harder to reach for AMC-run trials and emphasizing the need for more flexible or localized trial design
- 18% of patients drop out of conventional clinical trials after enrolling, citing clinic attendance as a major factor. As a result of enrollment and retention challenges, 86% of all trials do not meet enrollment timelines and 30% of Phase III trials fail²
- Recent data on decentralized trials shows a 30-50% reduction in patient recruitment time, a 90% increase in retention rates, and a 97% increase in patient interest³. 83% of sites and 80% of sponsors have invested in decentralized study capabilities such as remote patient monitoring and telemedicine applications
- 1,300 decentralized clinical trials are expected for 2022, which indicates a 28% increase from 2021 and a 93% increase from 2020⁴

Benefits of Decentralized Trials

- Decentralized trials enable the recruitment and retention of previously out-of-reach patient populations, creating access to and engagement with patients with rare diseases and diverse backgrounds, while enhancing efficiency in recruitment timelines
- Decentralization allows patients to visit their existing providers, enhancing patient engagement, decreasing burdensome travel demands, and reducing patient dropout rates
- Oncology and rare disease sponsors are increasingly focused on protocols with more encompassing population reach; 73% of oncology executives plan to run a hybrid or decentralized trial in the next 12 months, compared to 49% in the previous 12 months⁵

Opportunities for Technology Solutions

Electronic clinical-outcomes assessments

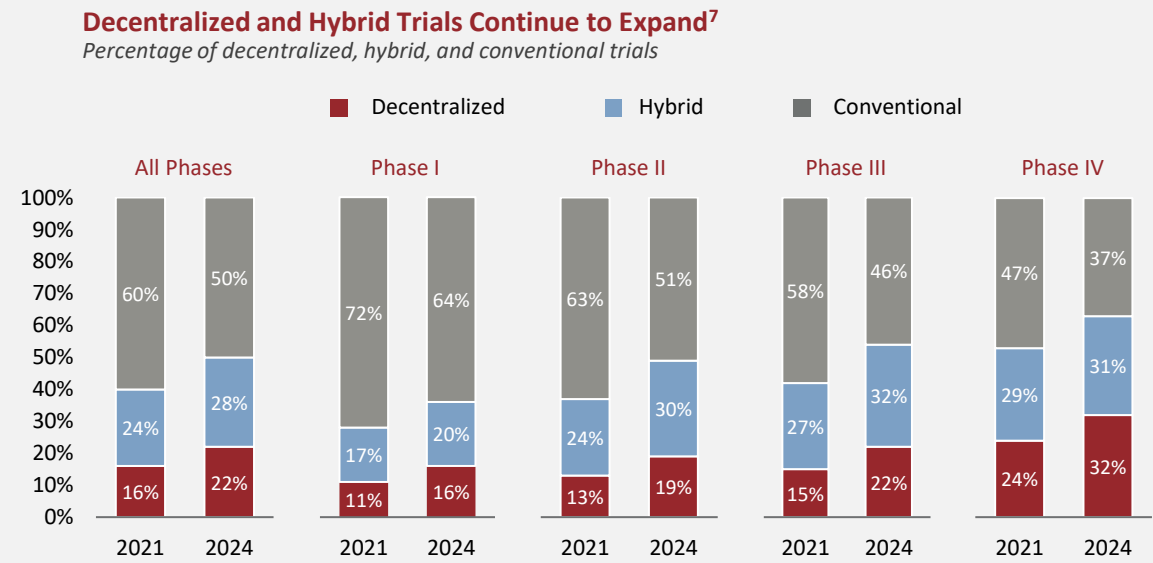
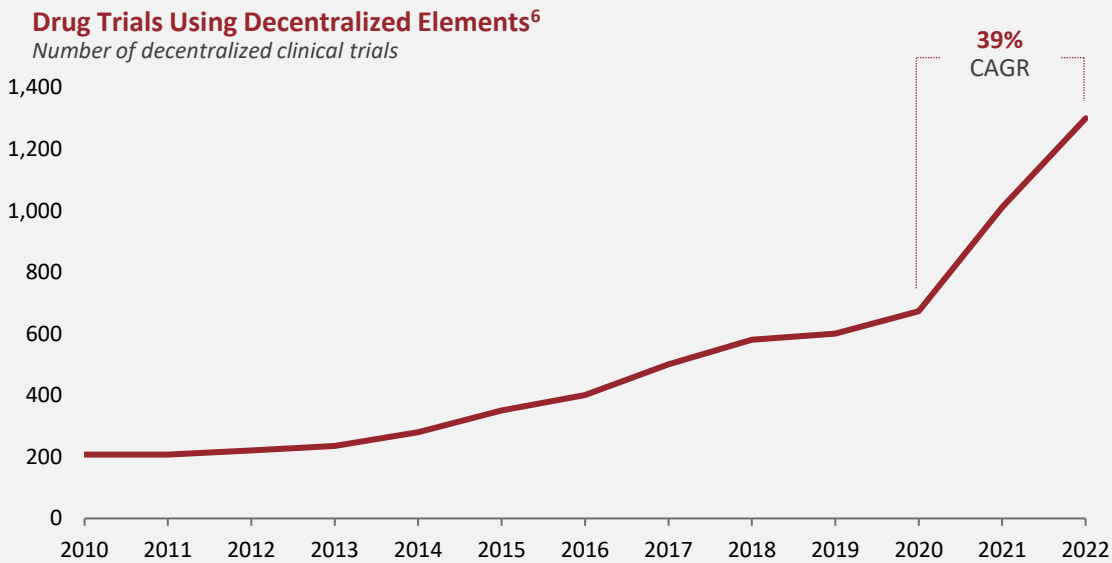
Wearables

Remote patient monitoring

Telemedicine

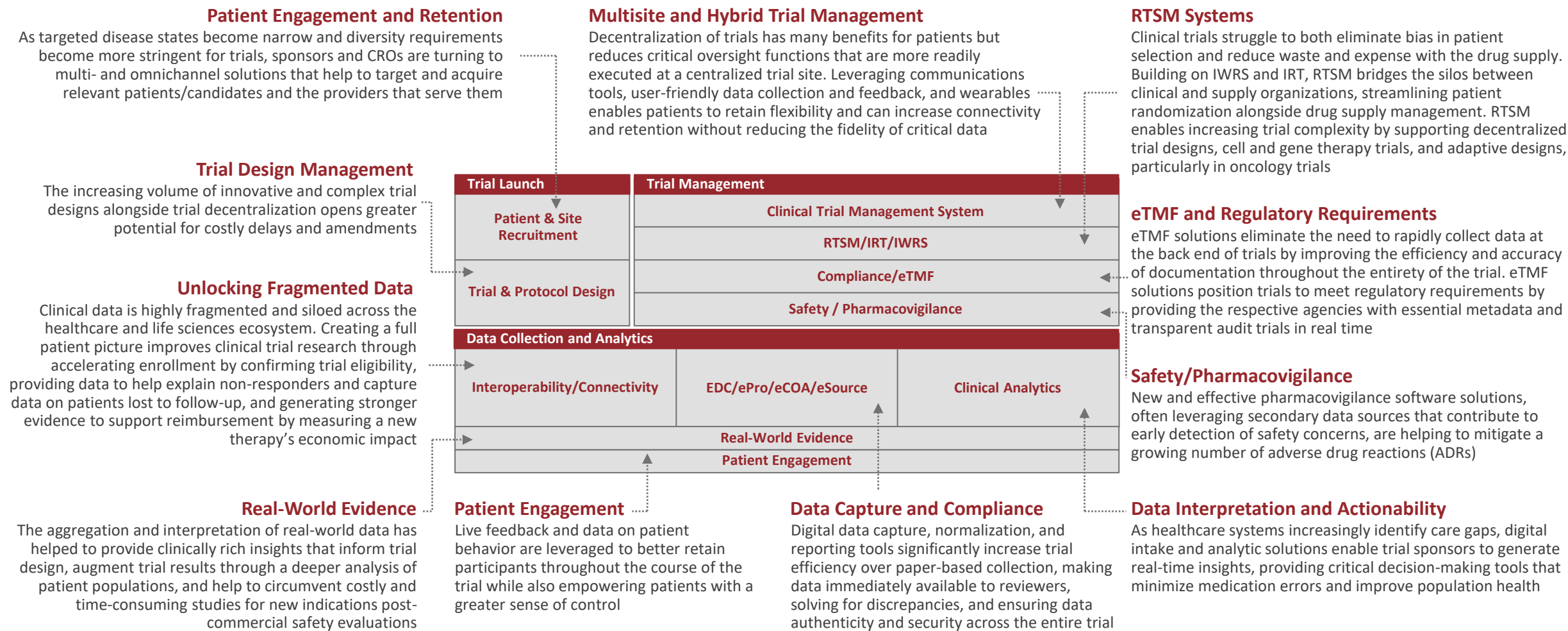
Digital consent

Diagnostic testing



Clinical Trial Technology Manages Trial Complexity and Improves Efficiency

Across the clinical trial landscape, emerging trends in technology are helping to improve speed, safety, and cost



Accelerating Investor Interest in Clinical Trial Technology





To view full timeline, please contact:
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Industry tailwinds are driving significant and accelerating investor momentum across clinical trial technology



What to Look for in Clinical Trial Tech Platforms

Investors are interested in several attributes of clinical trial software companies that provide the greatest opportunity for sustainable growth

	Description	Harris Williams Observations
<div><div>High-Value Therapeutics</div></div>	Pharma evolution from high-volume, low-cost drugs to high-cost, low-volume specificities has prompted clinical trial technology focused on highly specific therapeutic areas	Investors prioritize solutions in high-revenue, often complex therapy areas such as oncology, cardiology, and musculoskeletal; hard-to-reach patient populations provide an opportunity for tech solutions to provide meaningful value to pharma for these high-cost treatments
<div><div>Differentiated Data Capabilities</div></div>	The ability to collect and analyze data with potentially proprietary algorithm, or exclusive right or access to hard-to-amass or rare data sets. Analytics may be driven by machine learning or AI, with a virtuous flywheel improving the analytics as the data assets continue to grow	Investors prefer differentiated data capabilities that enhance trial workflows and outcomes reporting, providing decision-driving analytics rather than simple reporting, as they provide a competitive moat; investors are also focused on ability to monetize unique data assets
<div><div>Recurring/ Reoccurring Revenue</div></div>	Business models are typically project-based, focused on a specific trial, with solutions for larger, later-stage, and more-complex trials commanding higher ticket prices than solutions serving shorter-duration, Phase I studies	Clinical trial software businesses with entrenched, diversified customer relationships have been able to migrate from per-study or per-enrollee pricing to a true subscription model, underpinning long-term revenue visibility
<div><div>Diverse Customer Base</div></div>	Companies that serve Big Pharma often have meaningful customer concentration, but often have lower customer acquisition costs compared to those that target the long tail of small to midsize pharma and biotech	Investors within pharma technology and services prefer a diversified customer base but can gain comfort and confidence in top-level customer concentration by understanding top customer tenure, contractual agreements, and diversification across therapeutic areas and multiple studies within the same trial sponsor

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