Perspectives on Emerging Trends in Clinical Technology

Q3 2022

Harris Williams

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

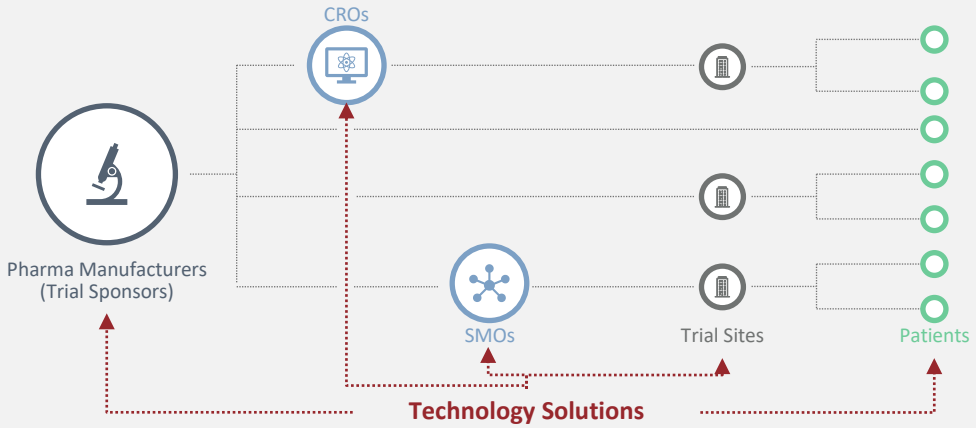
Ongoing Paradigm Shift in Pharma's Commercial Model Has Given Rise to New Challenges in the Clinical Trial Process

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

Representative Trial Value Chain



Drug Life Cycle Timeline

Research and Development | Clinical Trials | Commercialization

Phase I	Phase II	Phase III	FDA Approval	Phase IV
20-100 Participants	100-500 Participants	1,000-5,000 Participants		Ongoing Patient Monitoring
<1 Year	Up to 2 Years	Up to 4 Years		
Evaluate safety, determine safe dosage ranges, and begin to identify side effects	*Assess drug efficacy and further evaluate safety considerations*	*Confirm drug's effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow it to be used safely*		*Post-marketing studies delineate additional information, including the treatment's risks, benefits (including prospective new indications), and optimal use*

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

Pretrial

Patient & Site Recruitment

Solutions enabling sponsors to target appropriate patient populations and sites for trial participation

Trial & Protocol Design

Solutions that create and test clinical trial designs and protocols

Trial Management

During Trial

Clinical Trial Management System

Centralized platforms used to streamline organizational data, monitor execution against protocol, and report key metrics

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

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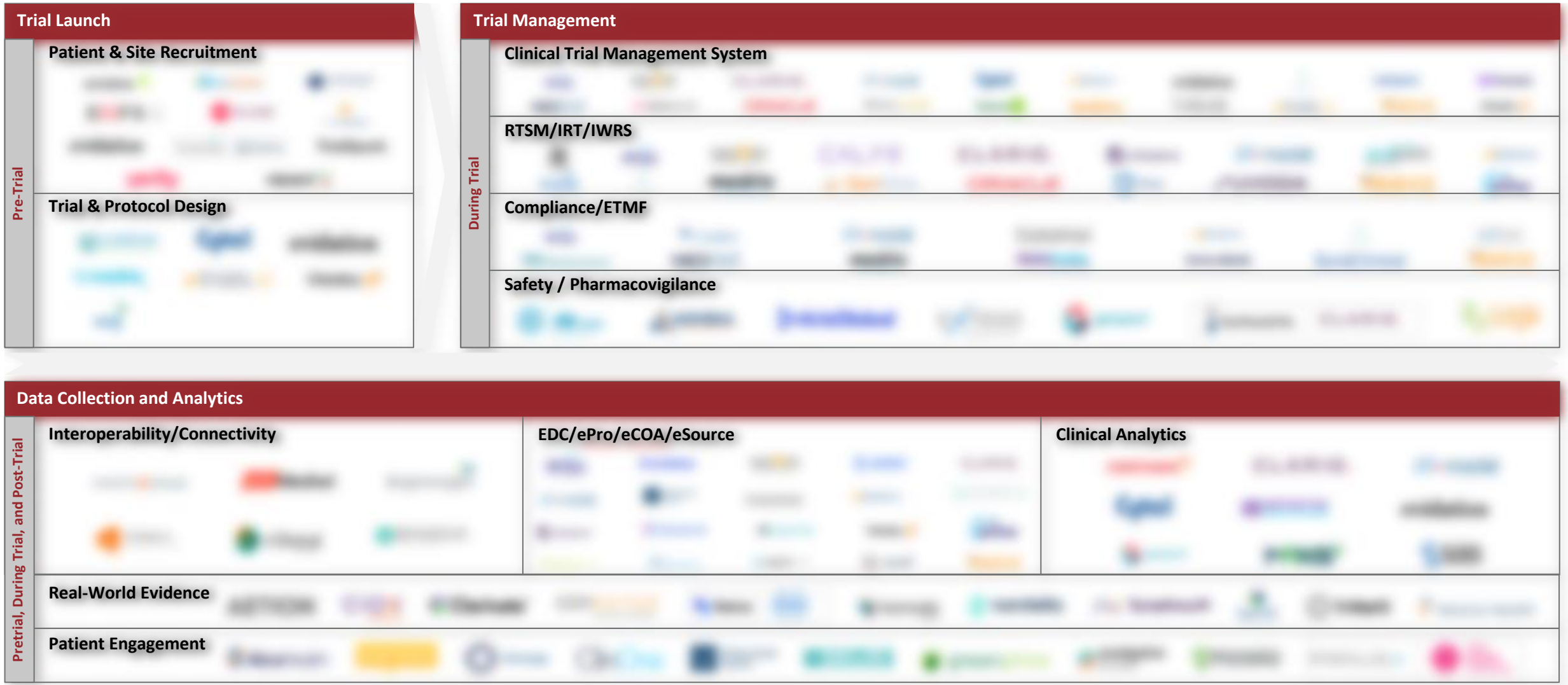


Significant Funding and Pipeline Momentum are Accelerating Clinical Trial Growth

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 investment[1], 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.

Annual R&D Spending[2]

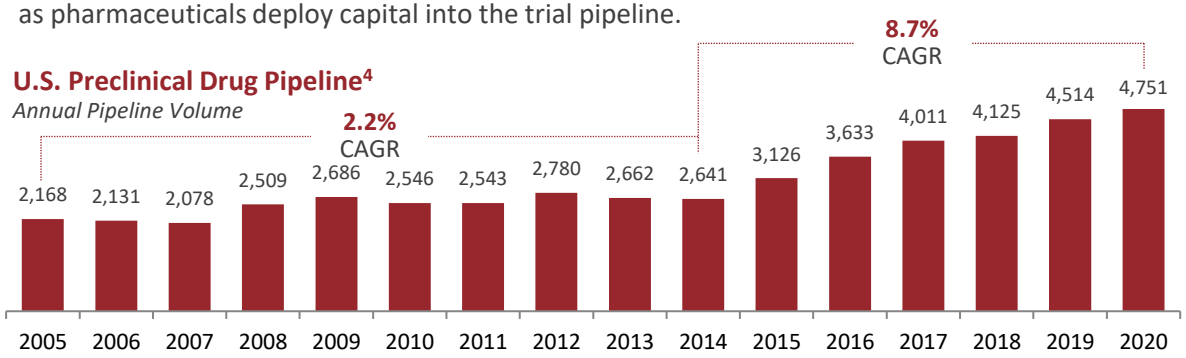
By PhRMA Member Firms, Dollars in Billions

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 volume[3] through 2021 as pharmaceuticals deploy capital into the trial pipeline.

U.S. Preclinical Drug Pipeline[4]

Annual Pipeline Volume

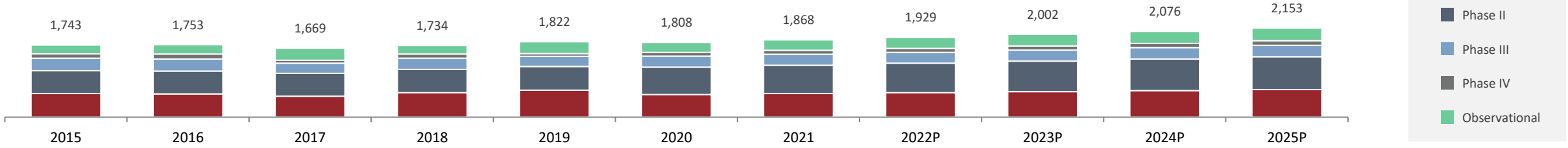


Active Independent Launches

- 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 companies[5], 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.

Total U.S. Clinical Trials

Annual Number of Active Clinical Trials



(1) RSM
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(3) RSM
(4) Industry research
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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 day[2]

Patient Enrollment and Retention

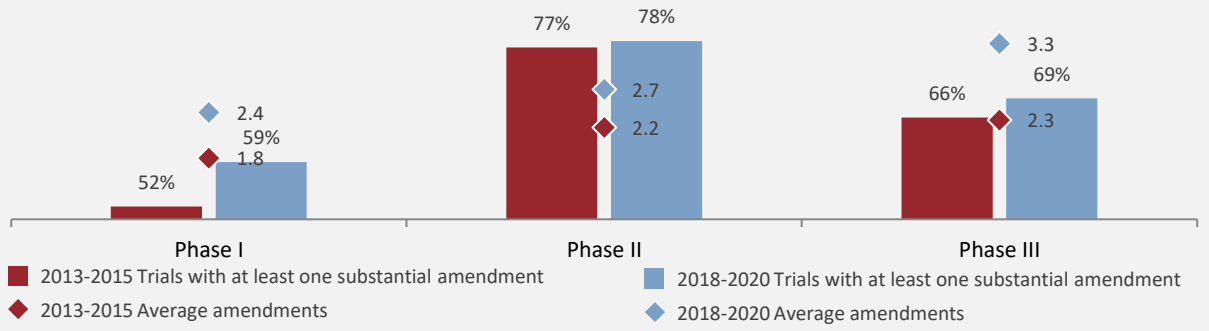
- Patient recruitment is the single largest cost driver of clinical trials, representing approximately 30% of total cost.[3] 80% of clinical trials fail to meet their enrollment goals in stated timelines[4] and experience average dropout rates of 30%.[5] Enrollment forecasting is the foremost reason for trial discontinuity and is estimated to have cost the industry $40B[6]
- 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 sites[7], 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

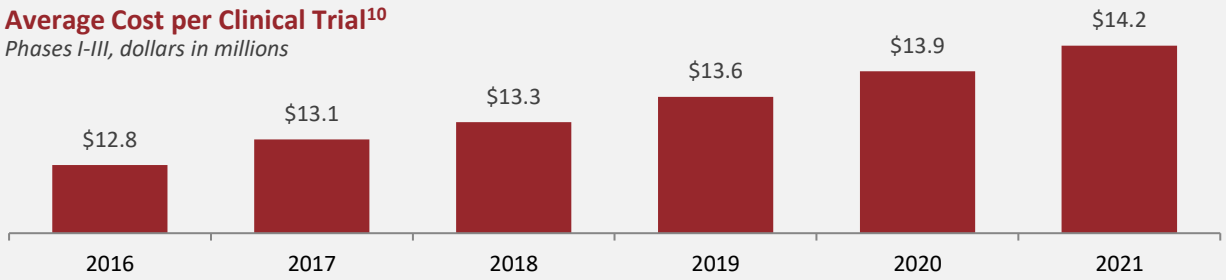
Incidents of Substantial Protocol Amendments[9]

U.S. Clinical Trials



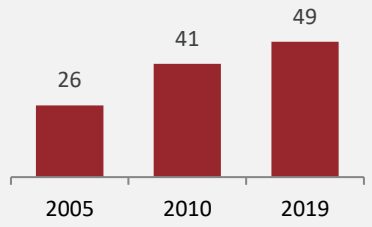
Average Cost per Clinical Trial[10]

Phases I-III, dollars in millions



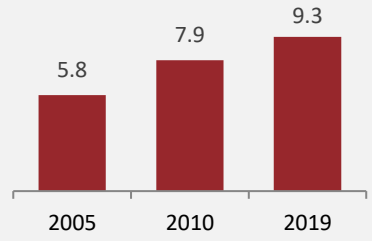
Average Sites per Trial[11]

Phase III



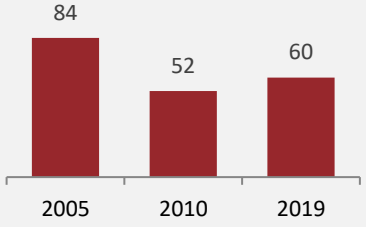
Average Outcomes per Trial

Phase III



Median Patients per Trial

Phase I-III



(1) RSM
(2) Antidote.me
(3) Deloitte
(4) NIH
(5) CISCRP
(6) Cytel
(7) McKinsey
(8) CISCRP
(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 site[1] 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 fail[2]
- 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 interest[3]. 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 2020[4]

Benefits of Decentralized Trials

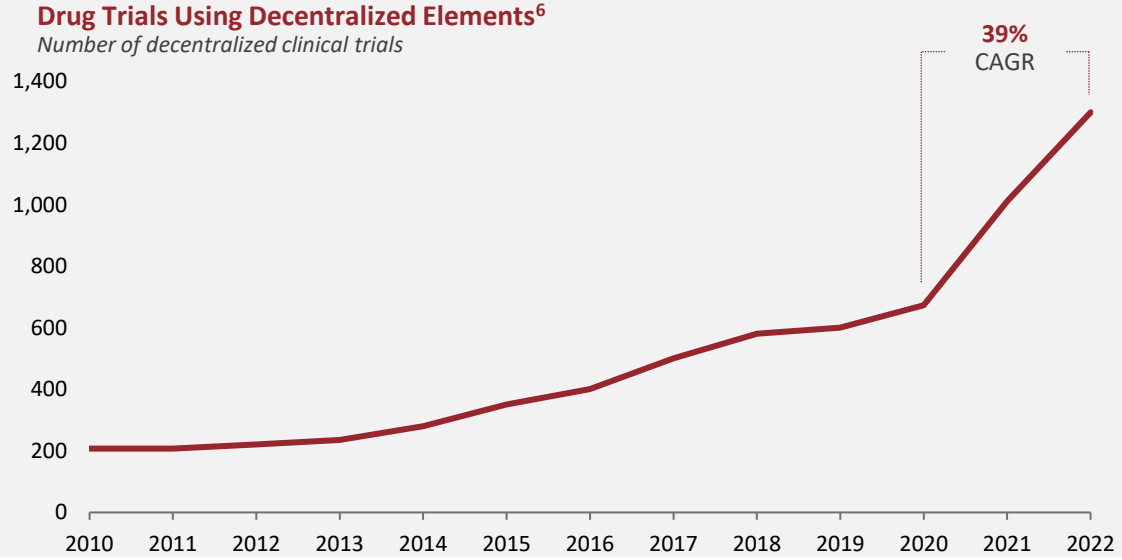
- Decentralized trials enable the recruitment and retention of previously out-of-reach patient populations, creating access to and engagement with patients with rare diseases and diverse backgrounds, while enhancing efficiency in recruitment timelines
- Decentralization allows patients to visit their 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 months[5]

Opportunities for Technology Solutions

- Electronic clinical-outcomes assessments
- Wearables
- Remote patient monitoring
- Telemedicine
- Digital consent
- Diagnostic testing

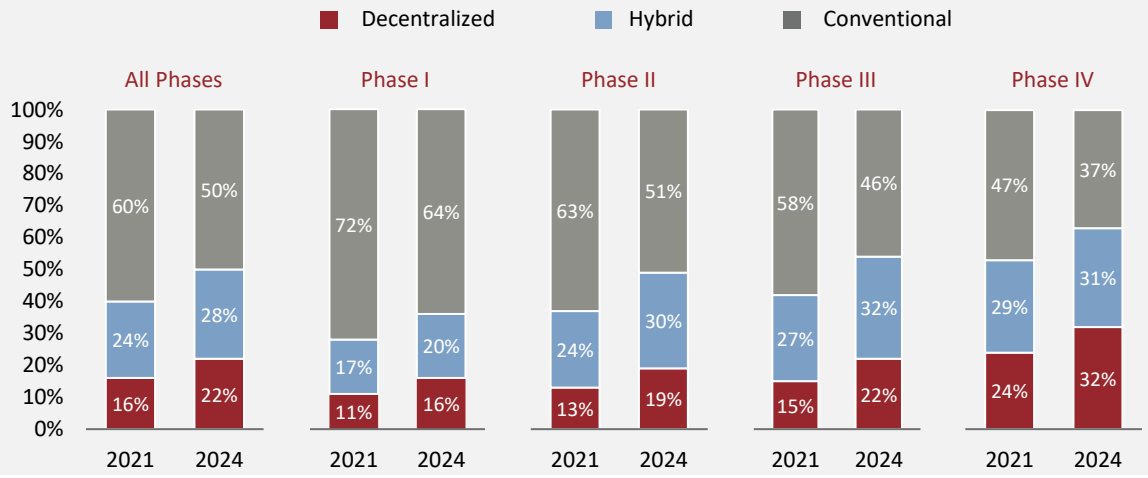
Drug Trials Using Decentralized Elements[6]

Number of decentralized clinical trials



Decentralized and Hybrid Trials Continue to Expand[7]

Percentage of decentralized, hybrid, and conventional trials



(1) Sanofi
(2) Deloitte
(3) Florence Healthcare
(4) GlobalData
(5) Science 37
(6) GlobalData
(7) EY - Parthenon

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

Patient Engagement and Retention

As targeted disease states become narrow and diversity requirements become more stringent for trials, sponsors and CROs are turning to multi- and omnichannel solutions that help to target and acquire relevant patients/candidates and the providers that serve them

Multisite and Hybrid Trial Management

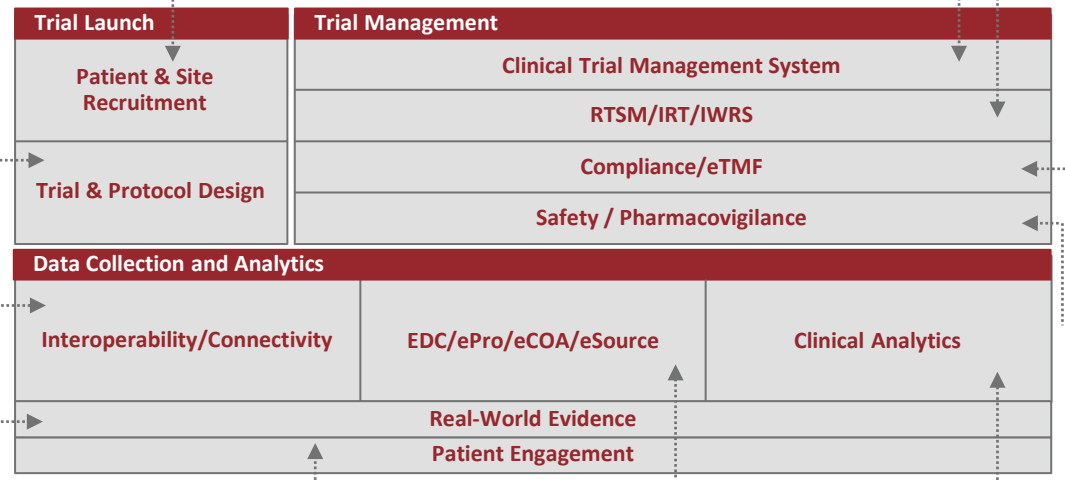
Decentralization of trials has many benefits for patients but reduces critical oversight functions that are more readily executed at a centralized trial site. Leveraging communications tools, user-friendly data collection and feedback, and wearables enables patients to retain flexibility and can increase connectivity and retention without reducing the fidelity of critical data

RTSM Systems

Clinical trials struggle to both eliminate bias in patient selection and reduce waste and expense with the drug supply. Building on IWRS and IRT, RTSM bridges the silos between clinical and supply organizations, streamlining patient randomization alongside drug supply management. RTSM enables increasing trial complexity by supporting decentralized trial designs, cell and gene therapy trials, and adaptive designs, particularly in oncology trials

Trial Design Management

The increasing volume of innovative and complex trial designs alongside trial decentralization opens greater potential for costly delays and amendments



eTMF and Regulatory Requirements

eTMF solutions eliminate the need to rapidly collect data at the back end of trials by improving the efficiency and accuracy of documentation throughout the entirety of the trial. eTMF solutions position trials to meet regulatory requirements by providing the respective agencies with essential metadata and transparent audit trials in real time

Unlocking Fragmented Data

Clinical data is highly fragmented and siloed across the healthcare and life sciences ecosystem. Creating a full patient picture improves clinical trial research through accelerating enrollment by confirming trial eligibility, providing data to help explain non-responders and capture data on patients lost to follow-up, and generating stronger evidence to support reimbursement by measuring a new therapy's economic impact

Safety/Pharmacovigilance

New and effective pharmacovigilance software solutions, often leveraging secondary data sources that contribute to early detection of safety concerns, are helping to mitigate a growing number of adverse drug reactions (ADRs)

Real-World Evidence

The aggregation and interpretation of real-world data has helped to provide clinically rich insights that inform trial design, augment trial results through a deeper analysis of patient populations, and help to circumvent costly and time-consuming studies for new indications post-commercial safety evaluations

Patient Engagement

Live feedback and data on patient behavior are leveraged to better retain participants throughout the course of the trial while also empowering patients with a greater sense of control

Data Capture and Compliance

Digital data capture, normalization, and reporting tools significantly increase trial efficiency over paper-based collection, making data immediately available to reviewers, solving for discrepancies, and ensuring data authenticity and security across the entire trial

Data Interpretation and Actionability

As healthcare systems increasingly identify care gaps, digital intake and analytic solutions enable trial sponsors to generate real-time insights, providing critical decision-making tools that minimize medication errors and improve population health

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
High-Value Therapeutics	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
Differentiated Data Capabilities	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
Recurring/ Reoccuring Revenue	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
Diverse Customer Base	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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