SCRS
Society for Clinical Research Sites

Site Landscape:
Benchmark Your Site

Tuesday, September 30th

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Site Solutions Summit™

Site Landscape: Benchmark Your Site

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SCRS

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Faculty Disclosure

In compliance with ACCME Guidelines, I hereby declare:

I do not have financial or other relationships with the manufacturer(s) of any commercial services(s) discussed in this educational activity.

Jimmy Bechtel, SCRS

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MOREHOUSE SCHOOL OF MEDICINE

Criteria for Awarding Contact Hours

Applicants must be present during the “live” event, contact hours are not issued for recordings.

Applicants must attend the activity the whole time, missing no more than ten minutes of the activity.

Applicants must complete the post-meeting survey with a score of at least 70%.

Applicants must complete the post meeting survey evaluation questions.

Society for Clinical Research Sites, Inc. is accredited as a provider of nursing continuing professional development by the American Nurses Credentialing Center’s Commission on Accreditation.

Two Perspectives, One Truth

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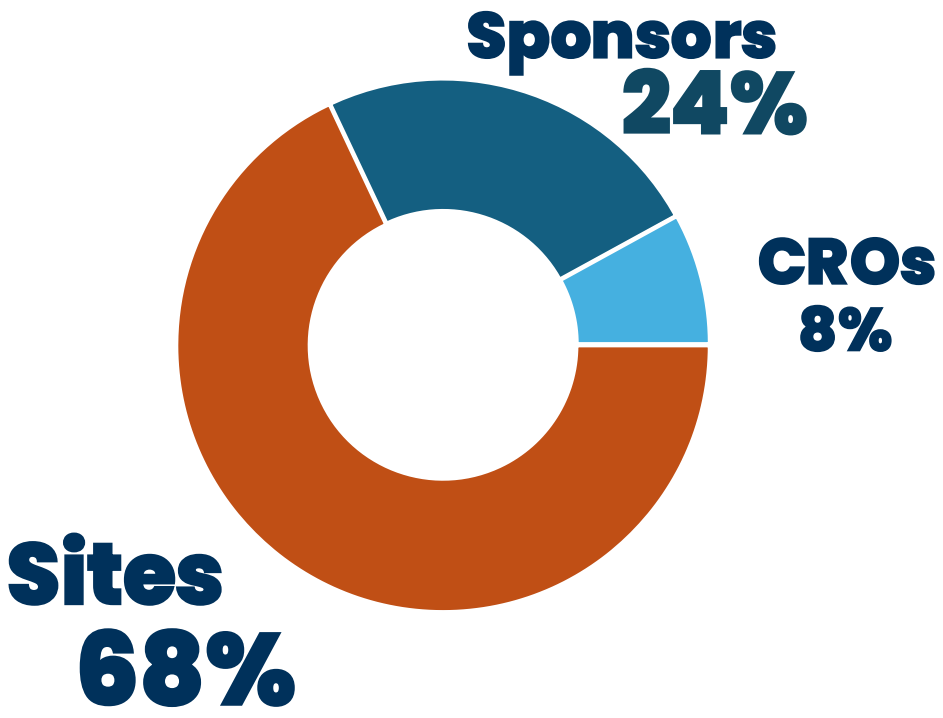
SCRS Global Survey Says...

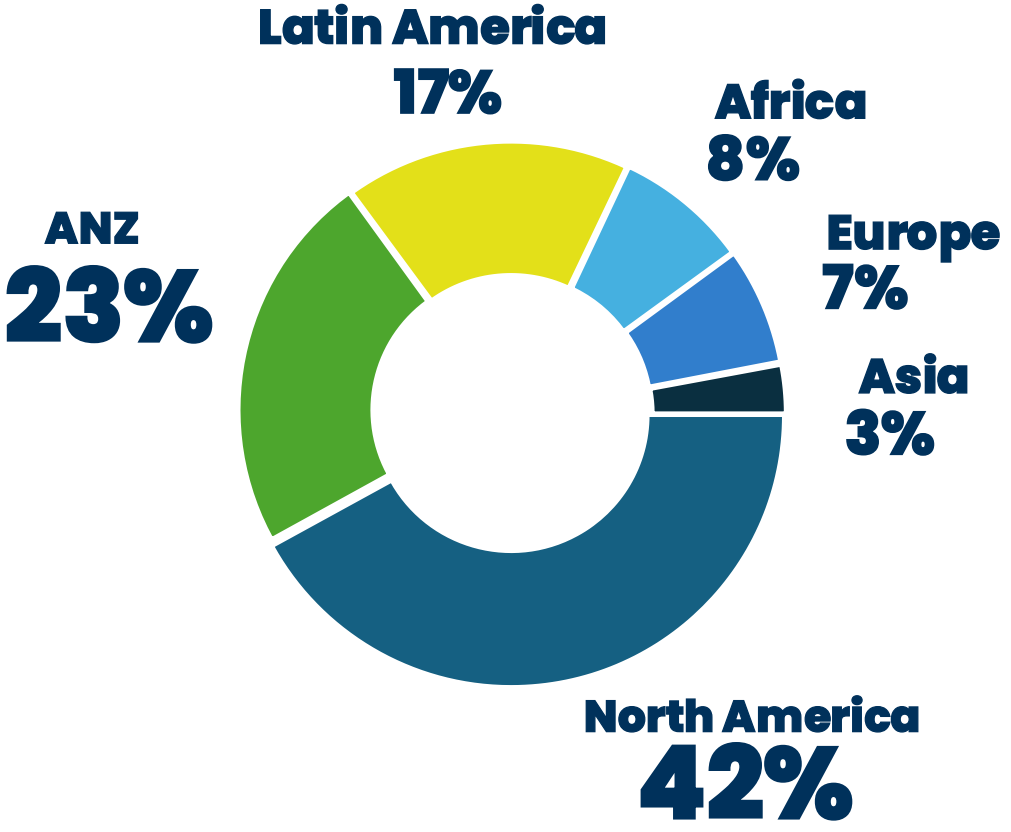
- **69.2%** struggle with salary cost increases
- **40.5%** experienced decline in study opportunities
- **26.2%** identify protocol complexity as #1 industry issue

Tufts CSDD Research Shows...

- **160%** more patients enrolled per site with DCT
- **6 months** faster trial completion with technology
- **71%** of sites request better communication processes
- **88%** of trials successfully using DCT solutions

Our Data Sources





Our Data Sources

Tufts CSDD Research Portfolio

- 69 global clinical trials analyzed for DCT impact
- 301 patients surveyed on direct-to-patient experiences
- 290 investigative sites assessed for operational efficiency
- 15+ years of clinical trial performance data

Global Ecosystem Under Pressure

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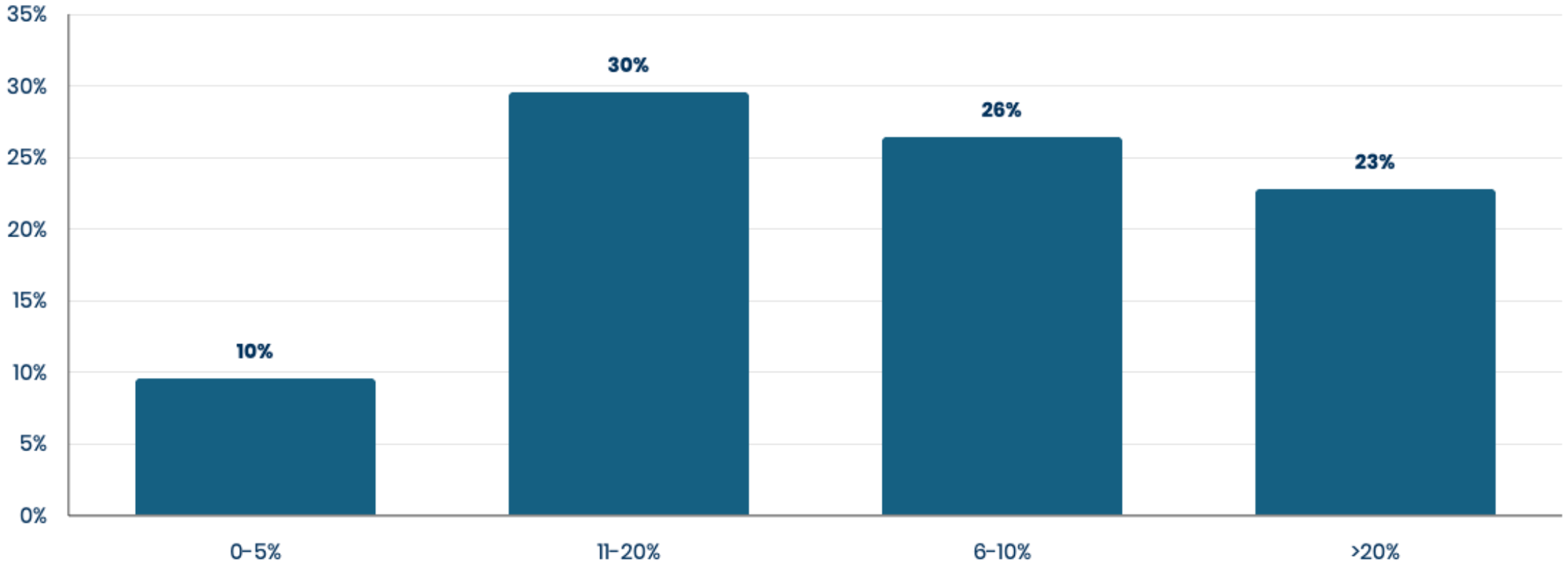
SCRS Landscape

82% of sites experienced a >6% cost increase in 2024



Tufts: Top Site Reported Pain Points

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Percent Rating Activities that have Worsened 'Greatly' or 'Somewhat' Over the Past 5 Years

	Overall	Clinical Staff	Administrative Staff	Integrated Care / Research Site	Dedicated Site / Site Network
Study Start Up					
Budgets & Contracts	65%	65%	68%	65%	71%
Communication and Coordination	64%	61%	68%	64%	62%
Study Execution					
Patient Recruitment	54%	56%	51%	54%	57%
CRA Quality and Turnover	49%	43%	59%	48%	54%
Other Operating Activities					
Hiring & Retaining Personnel	70%	66%	78%	69%	74%
Implementing New Technologies	42%	42%	44%	45%	35%

SCRS: Primary Cost Drivers

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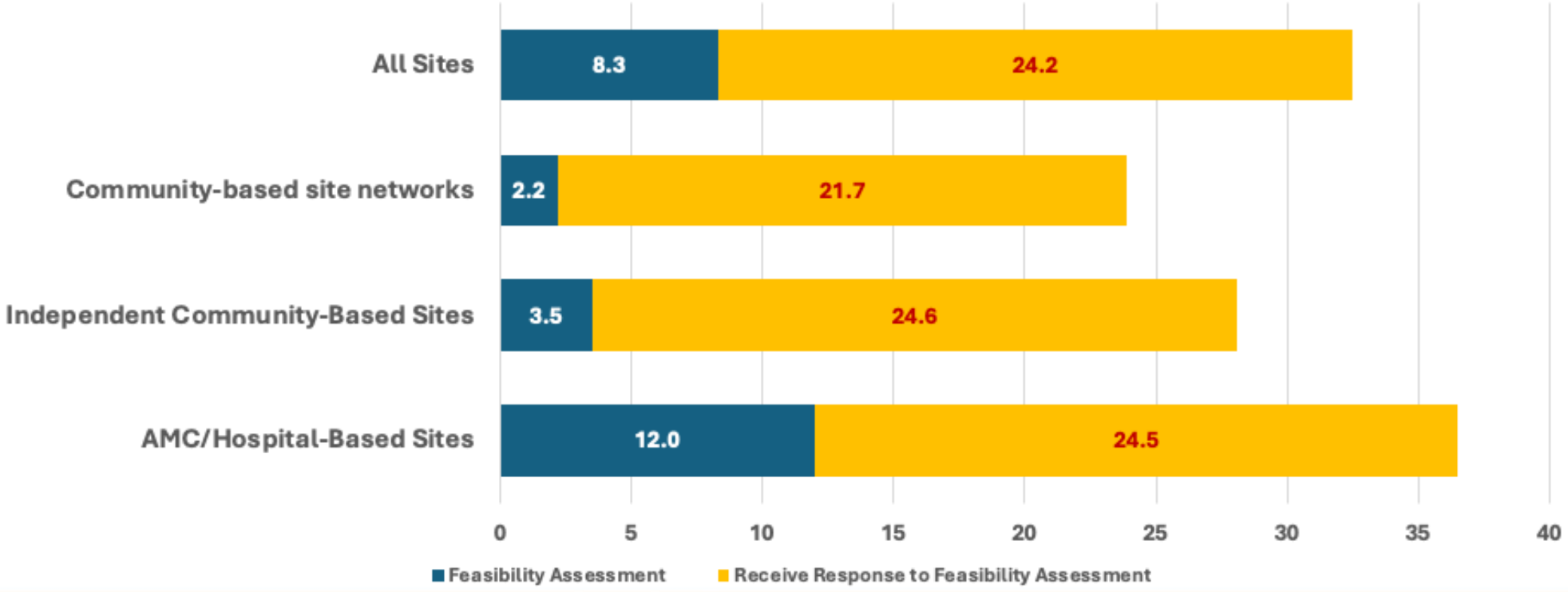
1. Regulatory Fees: 15%
2. Insurance: 25.9
3. Technology: 25.9%
4. Salaries: 69.2%

41.2% of sites indicate they have been unable to mitigate costs

Feasibility Challenges

Tufts CSDD

Each feasibility assessment takes approximately 33 business days on average



Feasibility Challenges

Tufts CSDD

More than half of sites complete feasibility assessments without the benefit of a full protocol

	All Sites	AMC/ Hospital Based Sites	Independent Community-Based Sites	Community-based Site Networks
Percent of feasibility assessments during which a full protocol was provided	43%	46%	41%	37%
Percent of feasibility questions that are deemed 'irrelevant'	27%	28%	24%	32%
Percent of time that sites receive feedback after the feasibility assessment process	43%	47%	36%	38%
Percent of sites that consider feedback somewhat or very useful	49%	52%	49%	38%

Feasibility Challenges

Tufts CSDD

Sites participate in an average of 15 feasibility assessments and 10 qualification visits annually

Mean number and outcomes overall and by site type

	All Sites	AMC/Hospital Based Sites	Independent Community-Based Sites	Community-Based Site Networks
Number of annual feasibility assessments	15	12	22	30
Percent of time asked to provide more information after feasibility assessment	46%	51%	46%	21%
Number of annual Qualification Visits	10	10	8	12
Percent of time selected	67%	76%	57%	50%
Percent of time invited to rebid	14%	15%	9%	24%

Budgets and Contracts

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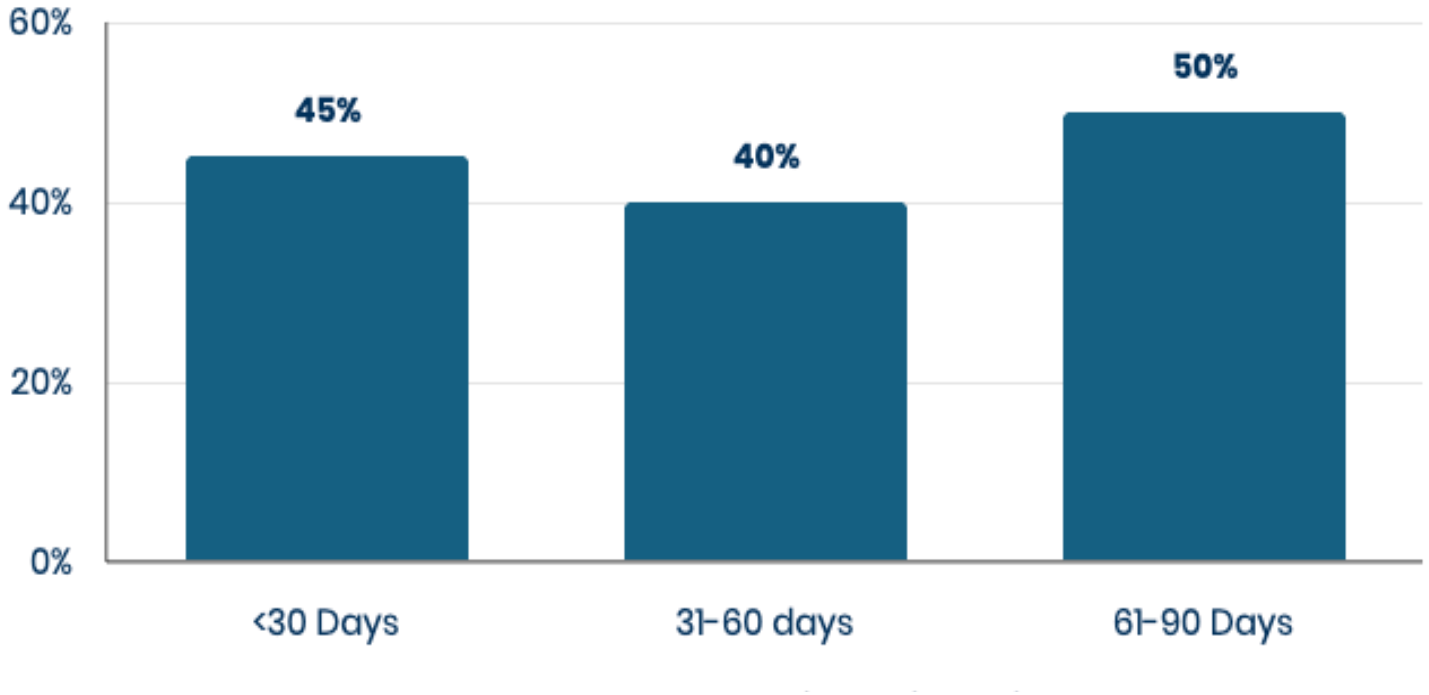
SCRS Landscape: Timelines



Budget Completion Timelines

Top Delay Factors

- Large Budgetary Misalignment: 38.9%
- Lack of Sponsor Responsiveness: 26.4%
- No Initial Fair Market Value offering: 26.7%

Budgets and Contracts

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Tufts CSDD Validation

Full protocols, focused information and draft budgets are top improvement recommendations

Top Recommendations to Improve the Feasibility Assessment Process (select 3)	All Sites	AMC/Hospital Based Sites	Independent community-Based Sites	Community Based Site Networks
Provide full protocol versus synopsis at time of feasibility assessment	71.3%	68.0%	75.6%	75.0%
Focus on study-specific aspects and use previously gathered data to pre-populate the assessment	53.9%	56.4%	48.9%	56.3%
Provide draft budget at time of feasibility assessment	35.7%	35.9%	40.0%	31.3%
Provide feedback on site selection decision and the reasons for not being selected	35.0%	28.2%	46.7%	37.5%
Provide compensation for the time and effort to complete the feasibility assessment	32.2%	35.9%	24.4%	18.8%
Conduct the assessment live instead of via questionnaires	25.2%	26.9%	26.7%	12.5%
Ensure a person is available to answer questions during the assessment	18.2%	16.7%	17.8%	31.3%
Provide more timely response to the feasibility assessment	18.2%	21.8%	13.3%	18.8%

Improving Finalization Timeline

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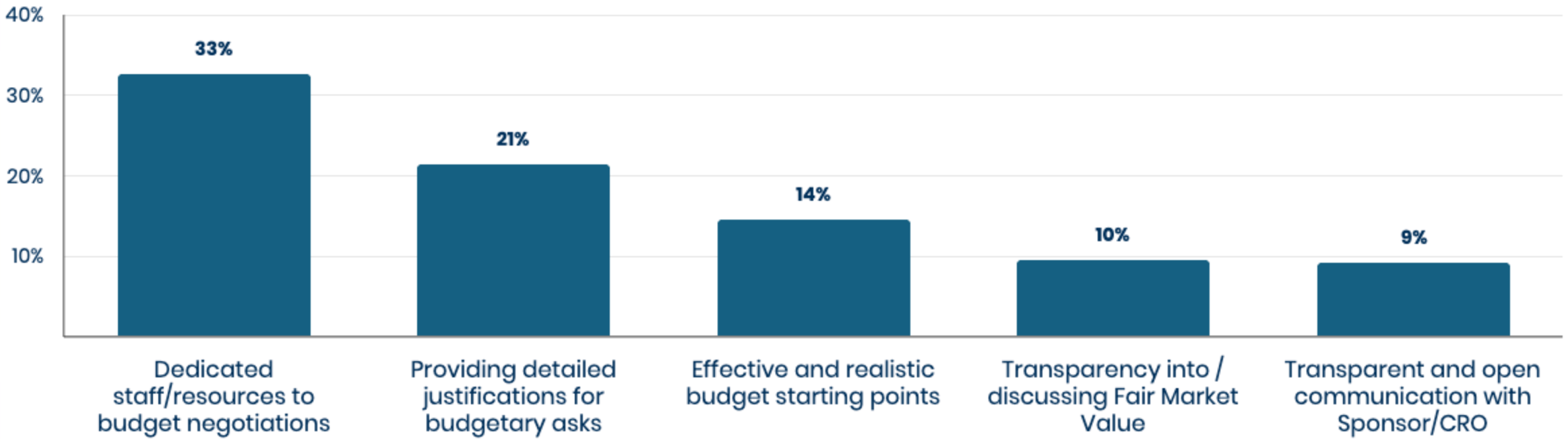
SCRS Landscape

Dedicated staff and resources to budget negotiations



Improving Finalization Timeline

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SCRS Landscape

#1 Industry challenge for 2025 - 27%

Slightly ahead of Rising Costs at 25%

SCRS: Impact on Operations

- **24.1%: Decline trials due to complexity**
- **21.2%: Decline due to budget disagreements**
- **19.7%: Decline due to staffing challenges**

SCRS: Study Disruption Reality

- **49.2%: Cite sponsor driven causes as top delay cause**
- **40.5%: Experienced a decline in study opportunities**
- **34.6%: Report 1-5% cancellation rate**

Protocol Complexity

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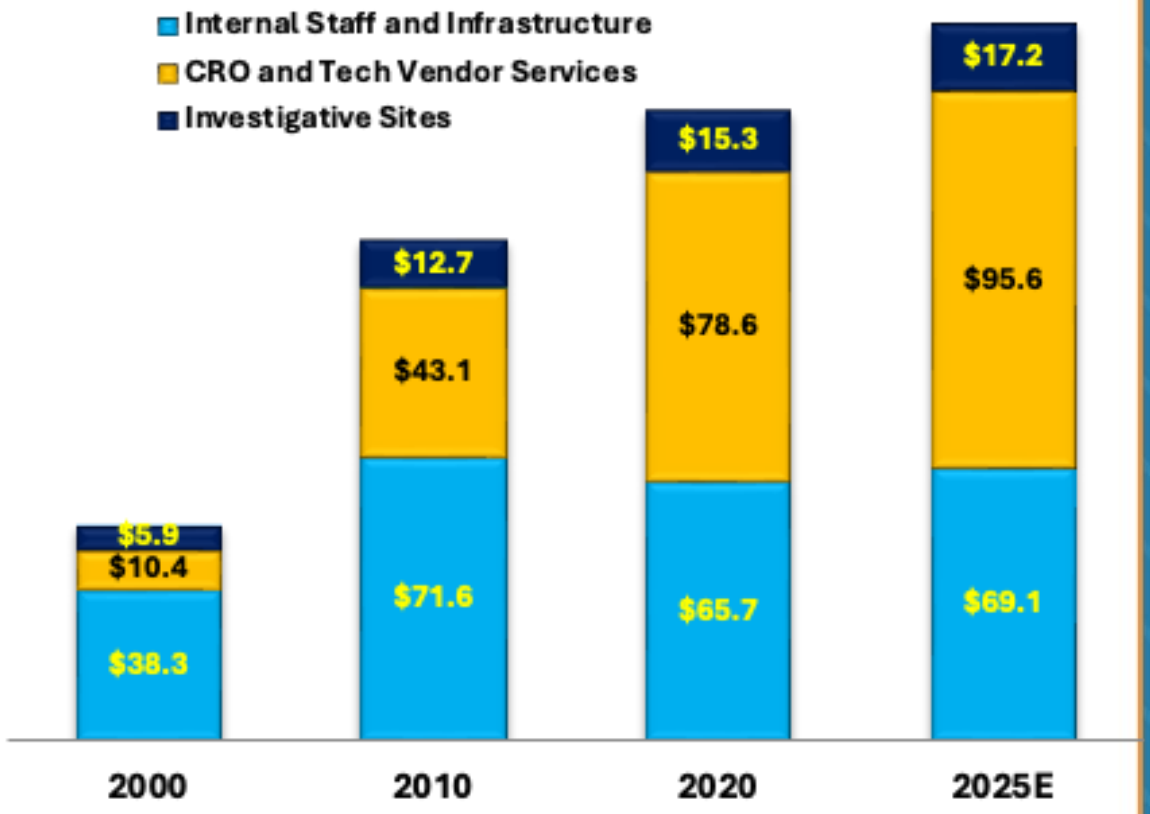
Protocol Design

Phase III Pivotal Trials *(Means per Protocol)*	Overall	
	2015	2025
Total Endpoints	14	18
Total Eligibility Criteria	31	35
Total Procedures	187	301
Total Countries	9	13
Total Investigative Sites	65	106
Total Patients Randomized	597	737
Total Data Volume	1.8 million	~4.9 million

Source: Tufts CSDD

Executional Fragmentation

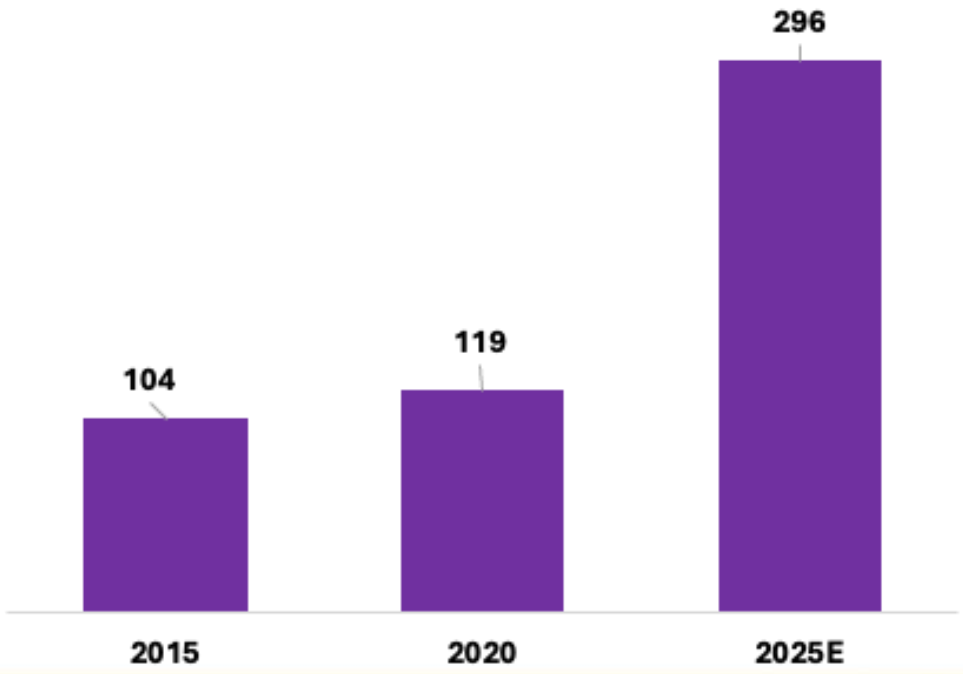


Protocol Complexity

Tufts CSDD

Deviations and Amendments per Protocol

Mean Deviations per Pivotal Trial



Substantial Amendments per Pivotal Trial

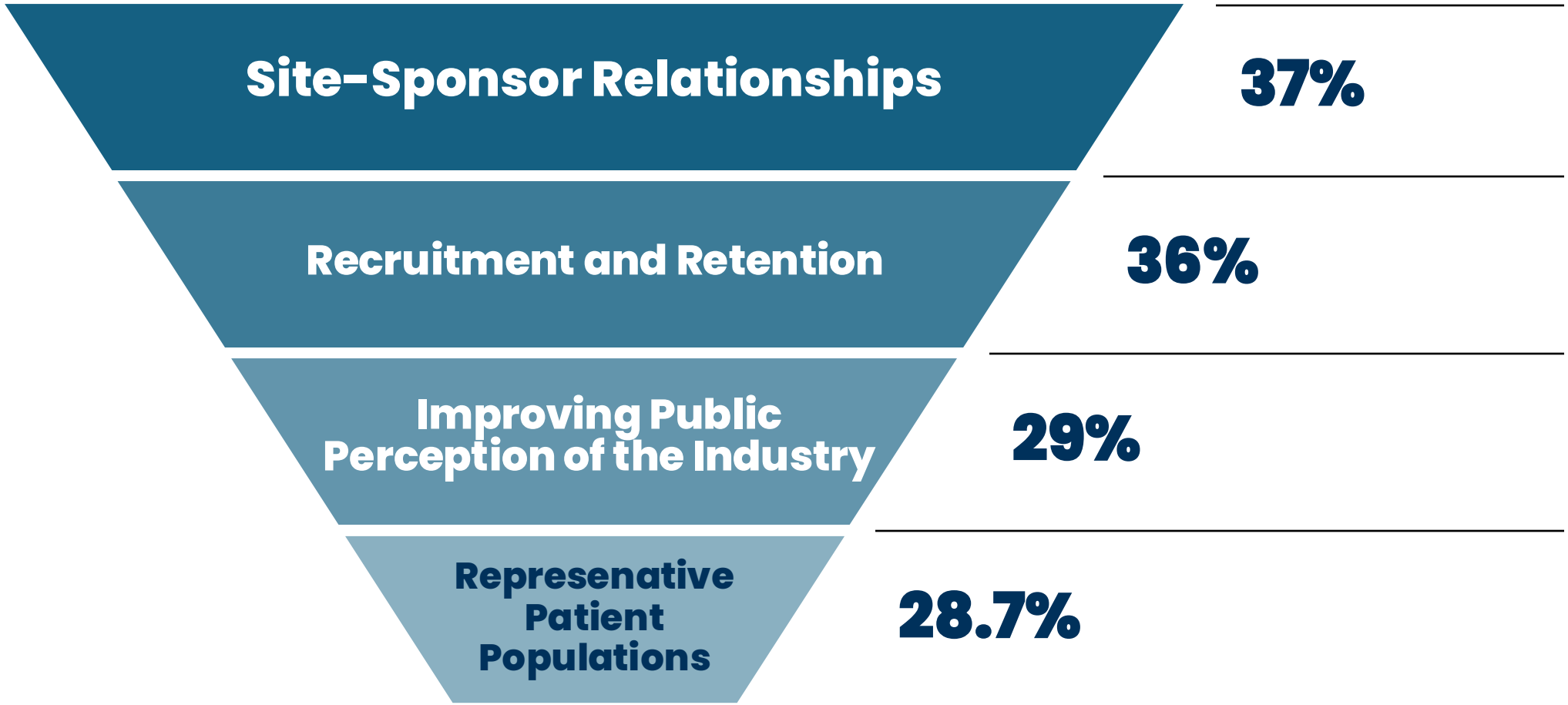
	2013-2015 (N=836)		2018-2021 (N=952)	
	Percent with at least 1 amendment	Mean Number	Percent with at least 1 amendment	Mean Number
Phase I	52%	1.8	67%	3.1
Phase II	77%	2.2	89%	3.3
Phase III	66%	2.3	82%	3.5

Patient Community Benchmarks

Tufts CSDD

Phase II/III Protocols *(Mean Days and Percents)*	Non-Oncology	Oncology	Rare Diseases
Total Duration (Final Protocol to DBL)	1,080.9	1,598.7	1,304.8
Study Initiation (Final Protocol to FPFV)	146.4	148.3	173.3
Enrollment Duration (FPFV – LPLV)	852.1	1,327.2	1,073.6
Close-Out Duration (LPLV – DBL)	59.9	68.5	61.4
Randomization Rate (Enrolled/Screened)	70.9%	67.1%	76.3%
Completion Rate (Completed/Enrolled)	80.0%	31.4%	48.8%

Patient Community Benchmarks



Patient Community Benchmarks

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Demographic Disparities in Pivotal Trials

1,165 pivotal trials for all drugs and biologics approved between 2007 and 2021	Distribution	Proportional disparity based on disease prevalence
Black	8.6%	-64.2%
Asian	9.6%	-31.7%
Other	4.1%	-73.3%
White	77.2%	+12.9%
Hispanic/Latino	13.1%	-32.1%

SES Disparities in Clinical Trial Experience

4,006 US-Based Individuals with a Medical Condition	Interest in Participating in Clinical Trials	Asked by HCP to Participate
Up through HS	38.2%	8.0%
College	39.8%	10.1%
Graduate	48.5%	16.2%

Technology-Enabled Solutions

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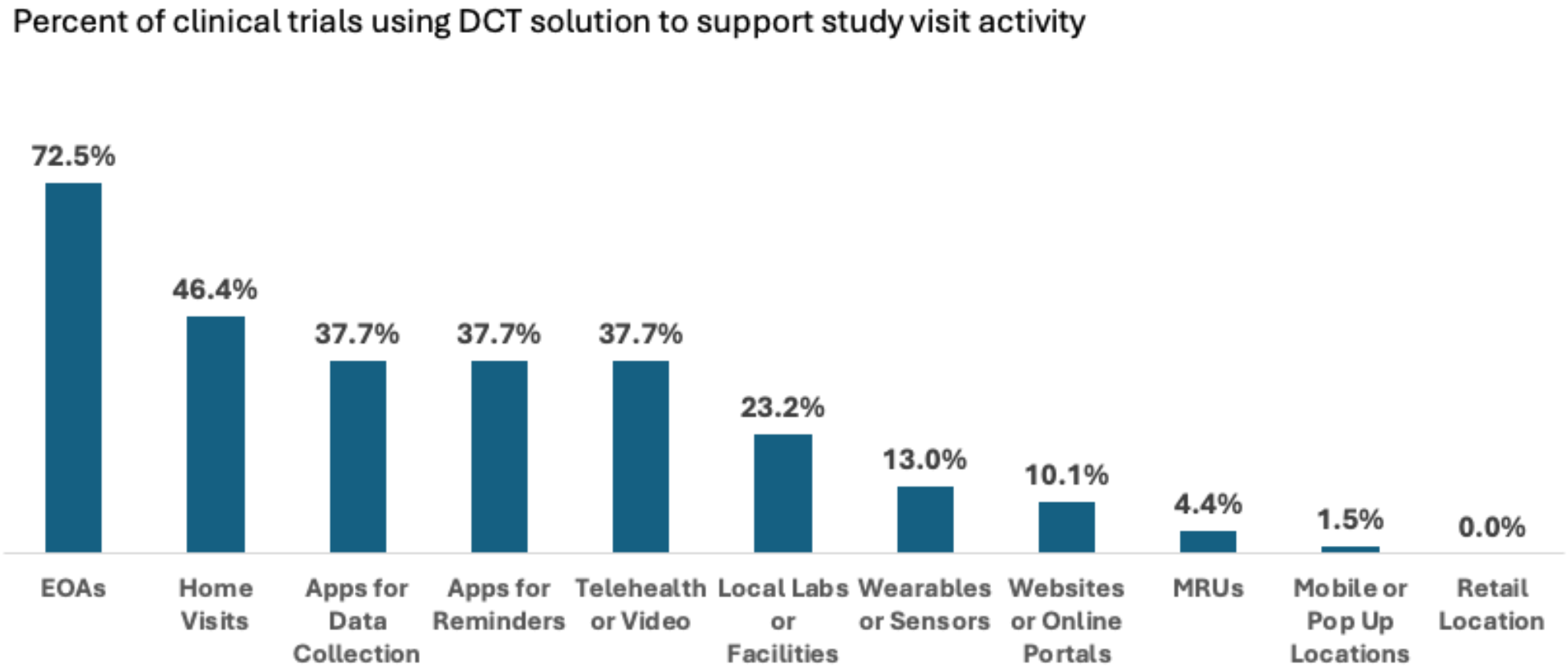
Tufts CSDD

Electronic outcome assessment and home visits are top solutions supporting study visits



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DCT solutions use is associated with fewer but more productive investigative sites

SCRS Landscape

33.2% - Shortening timelines to improve outcomes

Comparing enrollment performance between clinical trials using and not using DCT solutions

Phase II and III Clinical Trials	Used DCT Solutions Mean (CoV)	No DCT Solutions Used* Mean (CoV)
Sites Enrolling ≥ 1 Participant	43.2 (1.08)	72.9 (1.01)
Percent of Sites Enrolling ≥ 1 Participant⁺	76.8% (0.34)	83.7% (0.20)
Participants Screened	853.3 (1.98)	837.9 (2.44)
Participants Enrolled	580.7 (2.43)	411.7 (1.85)
Participants per Site	15.6 (1.46)	6.0 (1.34)

*Drawn from 2020 and 2022 Tufts CSDD studies of Phase II and Phase III clinical trials that reported no DCT Solution use.

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Tufts CSDD

Clinical trials using DCT solutions have higher proportional patient community representation

Comparing patient demographic distributions between phase II and III clinical trials using and not using DCT solutions

Demographic	Used DCT Solution Mean (CoV)	No DCT Solutions Used* Mean (CoV)
Sex		
Male	44.3% (0.57)	51.0% (0.41)
Female	55.7% (0.45)	49.0% (0.43)
Racial Identity		
American Indian or Alaska Native	1.9% (1.74)	0.5% (2.37)
Asian	20.9% (1.01)	14.2% (1.72)
Black	7.3% (2.19)	7.0% (1.13)
Native Hawaiian or Pacific Islander	0.3% (1.21)	0.1% (2.16)
White	72.6% (0.27)	81.3% (0.23)
Ethnicity		
Hispanic or Latino	14.9% (0.96)	12.6% (1.02)

*drawn from 2023 Tufts CSDD Study – Phase II and III clinical trials that reported no DCT Solution use.

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Tufts CSDD

Select virtual and remote solutions are associated with higher proportional representation

Average patient demographic distribution in phase II and III clinical trials by specific DCT solution used

	No DCT Solution Used*	Home Visits	Local Labs	Mobile Devices and Wearables	Virtual Visits
Sex					
Male	51.0%	52.6%	54.0%	48.3%	53.4%
Female	49.0%	47.4%	46.0%	51.7%	46.6%
Racial Identity					
American Indian or Alaska Native	0.5%	0.2%	0.9%	0.6%	0.4%
Asian	14.2%	13.8%	15.5%	16.2%	18.3%
Black	7.0%	3.6%	11.0%	8.6%	5.5%
Native Hawai'ian or Pacific Islander	0.1%	0.0%	1.8%	0.9%	0.2%
White	81.3%	80.8%	70.5%	76.6%	76.1%
Ethnicity					
Hispanic or Latino	12.6%	13.3%	13.5%	11.4%	13.3%

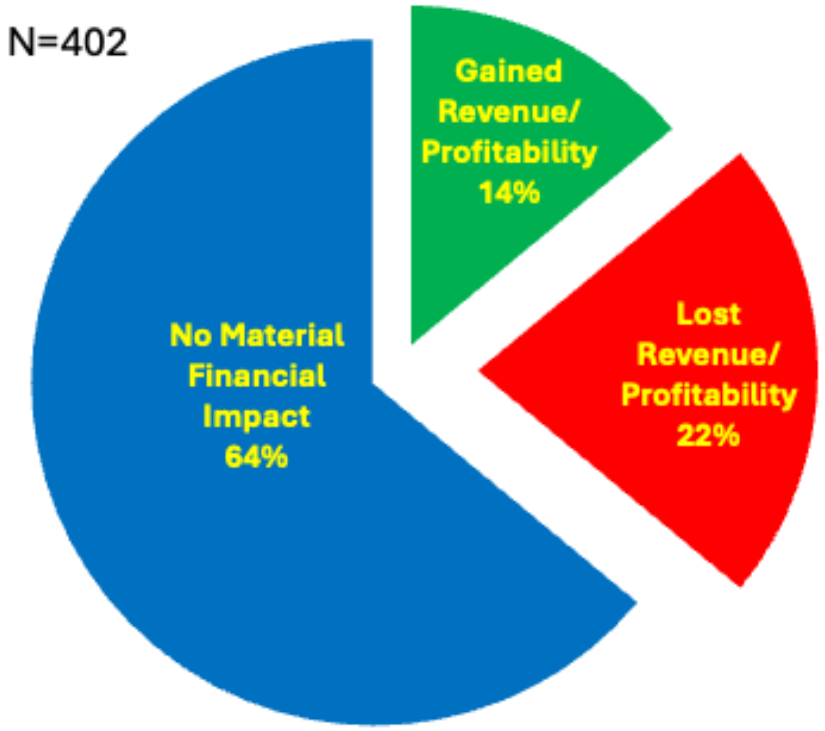
*drawn from 2023 Tufts CSDD Study – Phase II and III clinical trials that reported no DCT Solution use.

Technology-Enabled Solutions

Tufts CSDD

Site Perceived Financial Impact of Digital Solutions

Overall Financial Impact Reported



Top Causes of Revenue/Profit Loss

N=88 sites that reported revenue/profit lost	Percent Report
Difficulty coordinating technology	86%
Time troubleshooting technical issues	75%
Time spent with help desk	74%
Additional site personnel training required	65%
Time and effort training study volunteers	65%
Device shipment issues and delays	65%
Password and logging-in issues	60%

Technology-Enabled Solutions

SCRS Landscape

Technology ROI and Financial Priorities

- **63% – Want better knowledge of technology costs**
- **29.9% – Focusing on finance innovation**
- **22.5% – Are using AI/Technology to find efficiencies**

Joint Insight:

Technology investments can and are offsetting salary inflation through productivity gains.

Direct to Patient Shipments

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Solving for Recruitment and Retention

SCRS Landscape

23.6% of sites prioritize recruitment and retention as a "pressing issue to address in 2025"

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Topical and oral medications are viewed by sites as the most feasible for DTP Shipment

Percent of sites rating feasibility of route of administration

	Very Feasible	Somewhat Feasible	Not Very/Not Feasible
Topical	81.1%	17.3%	1.6%
Oral	79.5%	18.9%	1.6%
Parenteral Injection	17.3%	44.9%	37.8%
Parenteral Infusion	2.4%	8.7%	88.9%

Direct to Patient Shipments

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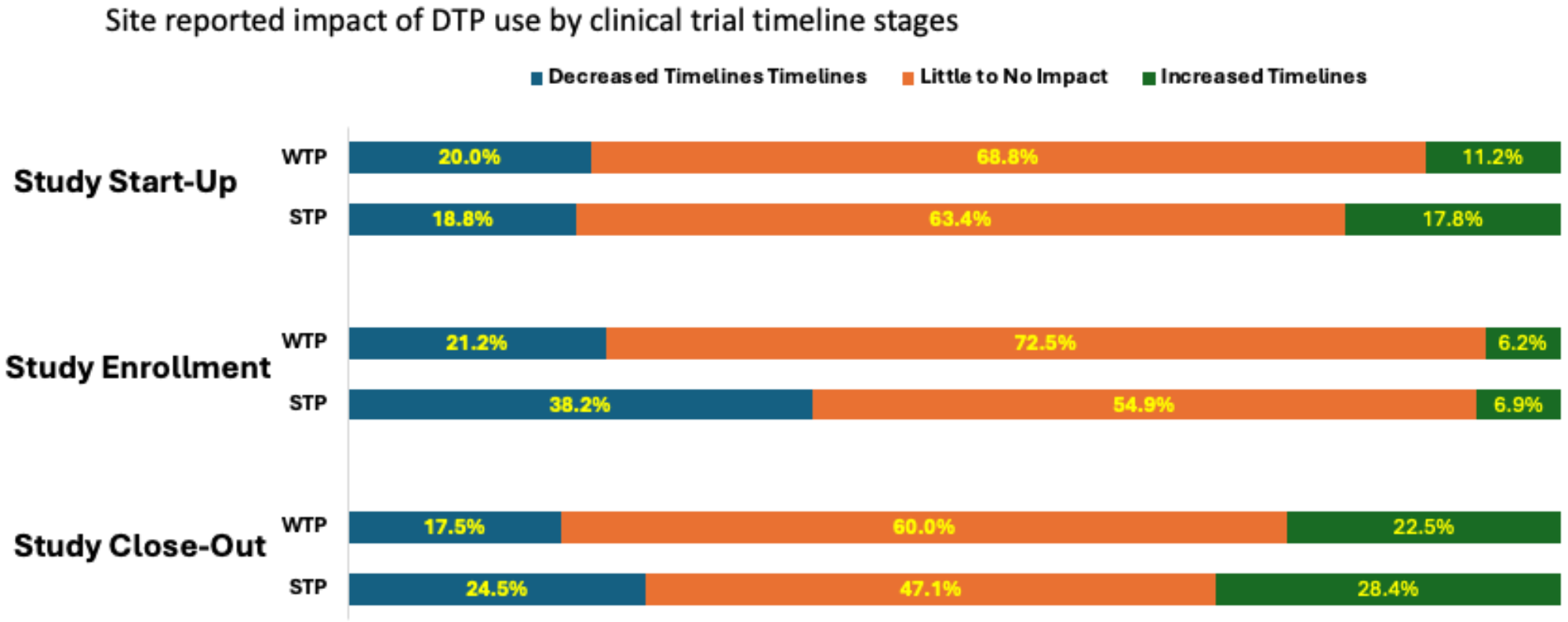
Tufts CSDD

Impact of Direct-to-Patient shipments on timelines compared to traditional clinical trials



WTP: Warehouse to Patient; STP – Site to Patient

Direct to Patient Shipments

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Tufts CSDD

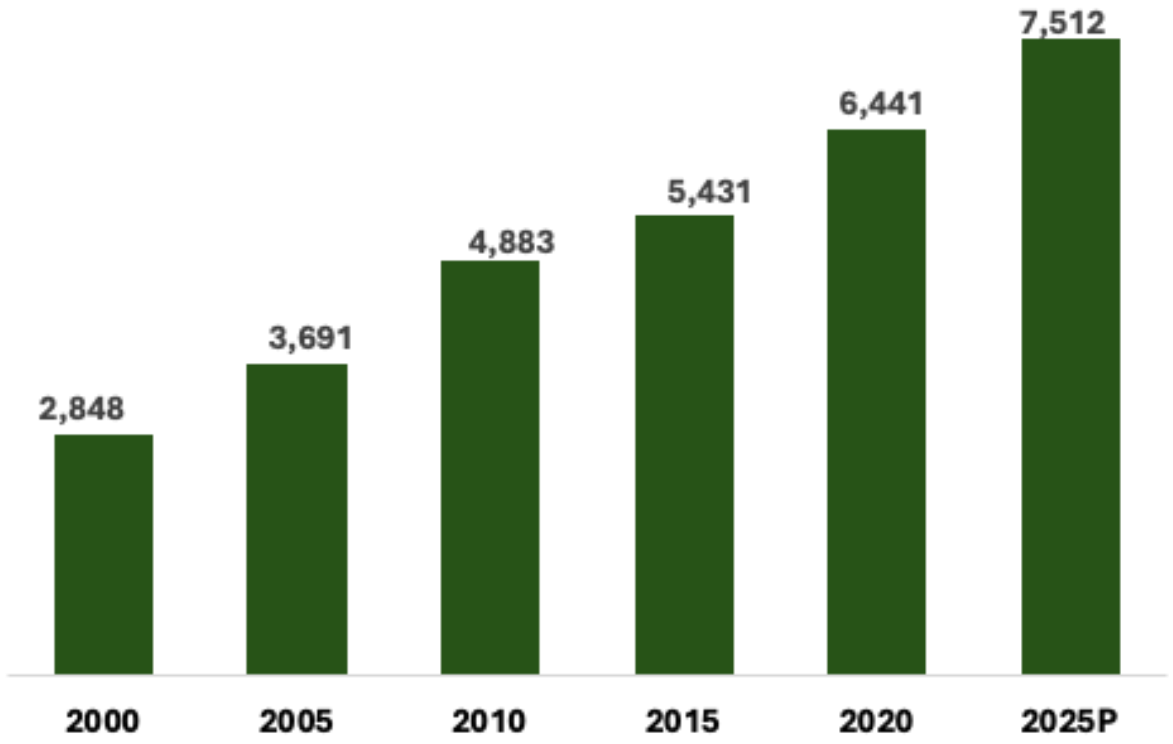
Patients very positive about DTP impact on convenience and willingness to participate and stay in clinical trials

Percent of patients agree by age, housing situation and travel time to the site

		More Convenient	It will increase my willingness to participate	It will increase my willingness to stay in my clinical trial
OVERALL		**92.8%**	**85.5%**	**90.4%**
Age	18-30	90.9%	88.6%	88.6%
	31-50	92.5%	89.2%	91.4%
	51+	96.6%	69.0%	89.7%
Housing Situation	Single Family Home	95.3%	85.9%	92.9%
	Apartment	88.6%	97.7%	88.6%
	Mobile Housing/Other	88.9%	66.7%	77.8%
Travel time to the Site	Less than 45 minutes	96.2%	88.6%	94.9%
	More than 45 minutes	84.6%	76.9%	76.9%

Tufts: Global R&D Pipeline

Total Drugs and Biologics in R&D



Worldwide R&D Spending ($s US Billions)	
2012	$136
2014	$145
2016	$159
2018	$181
2020	$188
2022	$202
2024	$221

Tufts: Use and Reported Impact of AI-Enabled Activities

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Clinical Domain	Average percent of companies reporting AI/ML partially or fully implemented	Average Reported Cycle Time Reduction	Top activities partially and fully implemented	Percent reporting partially & fully implemented
Planning and Design	29.2%	13%	Identification of diverse patient populations Content development of educational materials	51.6% 39.6%
Clinical Trial Execution	32.0%	20%	Analysis of genetic data Patient narratives	50.0% 47.9%
Regulatory Submission	27.1%	22%	Trial Master File (TMF) Filing Clinical Study Report (CSR) Writing	38.4% 31.7%

Workforce Optimization

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SCRS Landscape:

- 50% of sites increased their workforce in 2024
- 42.1% Struggle with salary competition
- 36% face career progression challenges

Tufts Data:

- Higher productivity through DCT (160%)
- Specialized skill development (tech focus)
- Career advancement through innovation leadership

Workforce Optimization

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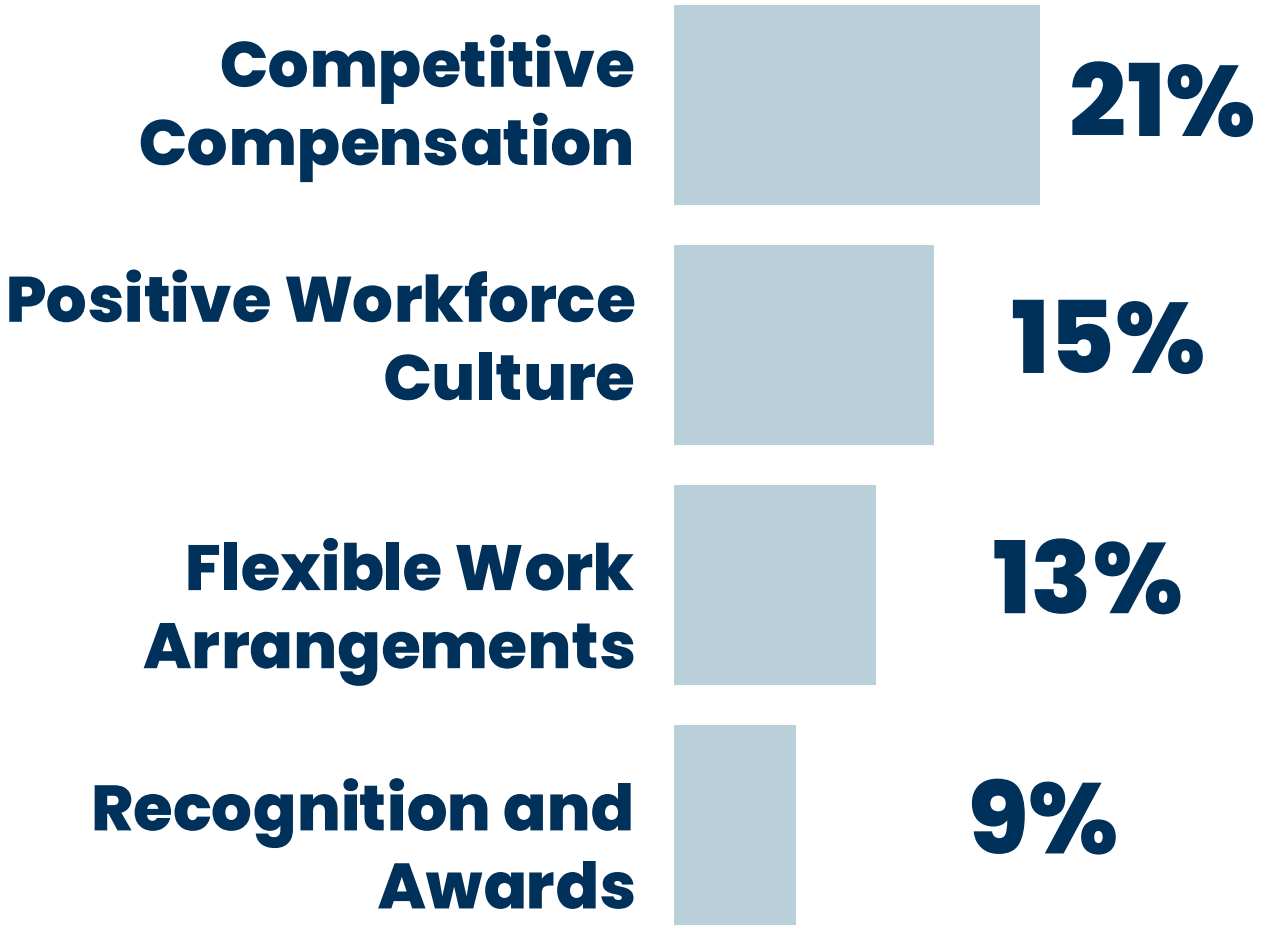
Most Effective Strategies



Tufts: Regulatory Tailwinds: Final R3 Guidelines

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- Encourage shift from compliance-driven to risk-based approaches
- Support flexibility to accommodate increasing customization
- Optimize data while minimizing site and patient burden
- Leverage current and emerging technology solutions
- Advance QbD instead of reactive, protective designs
- Promote proportional response to risk

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Immediate Actions

Communication Protocols

- Implement single points of contact
- Standardize response timelines
- Create effective and complete feedback loops

Feasibility Improvements

- Provide full protocols (not synopsis)
- Include draft budgets up front
- Focus on study-specific criteria

Contract and Budgets

- Deploy dedication negotiation teams
- Standardize budget templates
- Implement Fair Market Value frameworks that are FAIR

SCRS Global Data Evidence: 42% success rate with communication improvements

Integrated Transformation

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Site Facing: 15% increased costs, 30% staff turnover, and declining study opportunities

Short Term

- Standardized communication protocols
- Reduced contract timelines by 40%
- Dedicated budget team
- Fix Training Challenges

Mid Term

- DCT and technology implemented for 60% of appropriate trials
- 120% improvement in patient enrollment
- 25% reduction in study start-up time

Financial Impact

- ROI: 3:1 on technology invesement
- Cost Savings: 18% reduction in operational burden
- Staff retention: improved by 45%

Cut 25 Commitment

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These companies have committed to reducing training burden on sites.

- Advarra
- AstraZeneca
- Bayer
- Cognizant
- IQVIA
- LabCorp
- Lilly
- Medidata
- Merck
- Novo Nordisk
- ProofPilot
- ThermoFisher/PPD
- Sanofi
- Simulations Plus
- Scout
- TPS Global

Key Takeaways

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The Evidence is Clear

Industry Challenges are Global

- 82% facing significant cost increases
- Protocol complexity #1 priority concern
- Traditional processes unsustainable

Solutions are Proven

- 160% enrollment improvement with DCT Technology
- ROI through efficiency gains
- Communication improvements deliver results

Action is Needed

- Process standardization immediate opportunity
- Technology integration strategic necessity
- Industry collaboration competitive advantage

Connected Globally

Visit the SCRS Hub to learn more

SCRS AMBASSADOR

SCRS Society for Clinical Research Sites MEMBER

Looking Ahead

- Breakout Sessions

- Networking Breaks In The Exhibit Hall

- Eagle Awards Gala & Site Appreciation Reception
  7:00pm

Clinical Connections Lunch

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