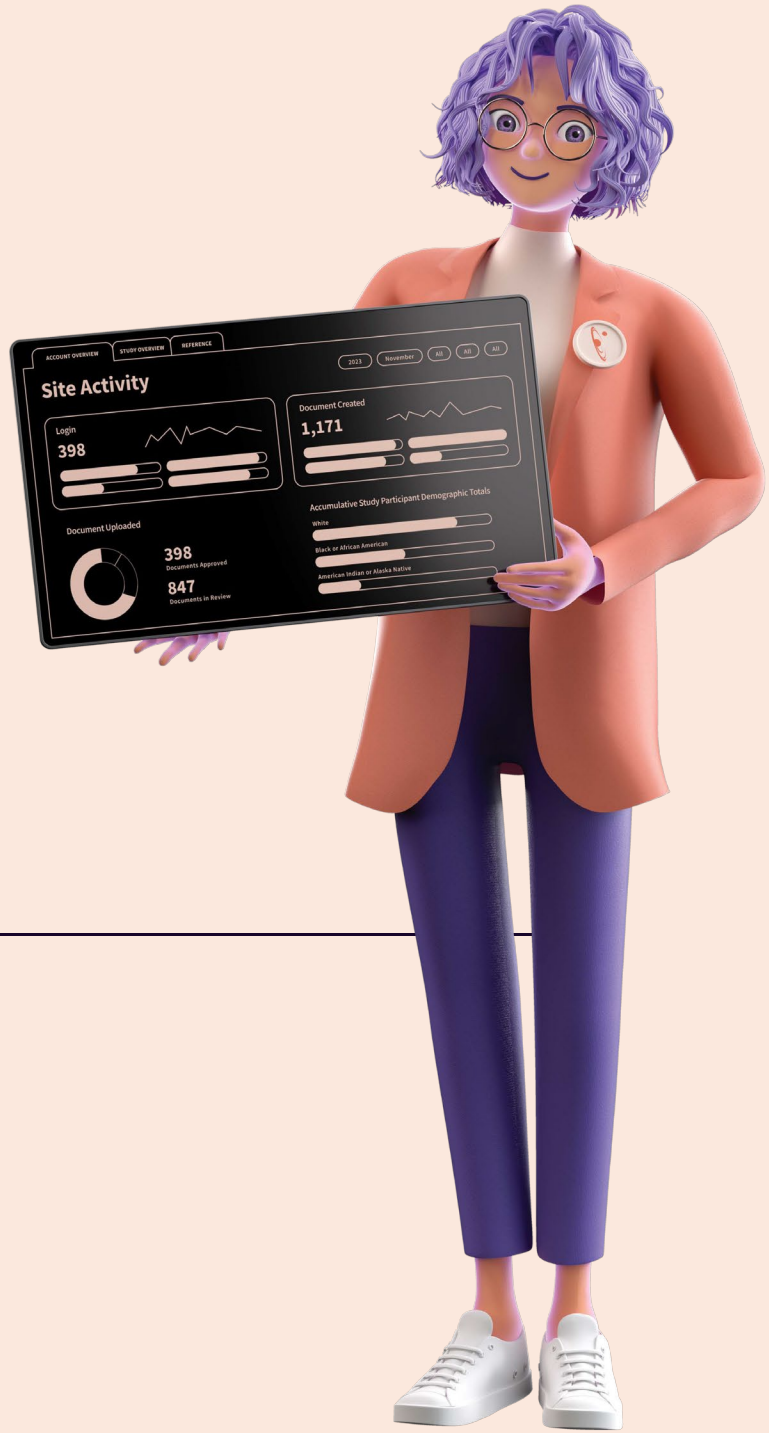
2024 State of Tech-Enabled Clinical Trials Report



Data, trends and insights into how technology is transforming clinical trial operations between sites and sponsors from Florence's fifth annual industry survey.

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Contents

Introduction to the Top 2024 Trends and Insights

Welcome to the 2024 Report

The 5th annual edition of our report draws from the insights of 212 clinical research leaders who participated in our survey in 2023. This year, we focus on the crucial theme emerging of 'Site Enablement Digital Mandates,' underscoring the shift towards a more connected, efficient, and site-centric clinical trial approach.

We observe an acceleration in Site Enablement, characterized by a flexible digital mandate that deviates from past practices. This approach is defined by two key strategies: integrating with existing technology stacks at sites and deploying genuinely site-centric solutions like eISF to digitally under-served sites.

Despite Sponsors indicating they are deploying a more site-centric technology strategy in 2023, with 70.3% stating they distribute site-centric eISFs, research shows 37.5% of sites find sponsor-provided technology inadequate and 41.4% of sponsors report that sites don't accept their technology, indicating that sponsors' perceptions are different from site realities.

We suggest a strategic reorientation for 2024. Both sponsors and CROs should embrace site-centric strategies, while sites should advocate for technologies that meet their needs.

Discover this year's insights and data in the report. Sponsors, CROs, and sites must engage in this essential evolution, which will drive the clinical trial industry towards a more innovative, efficient, and successful future.

> **Our fifth annual report highlights a continued focus on Site Enablement as the key strategy pillar for digitizing the workflows between sites and sponsors.**
>
> **Blake Adams - SVP Marketing, Florence**

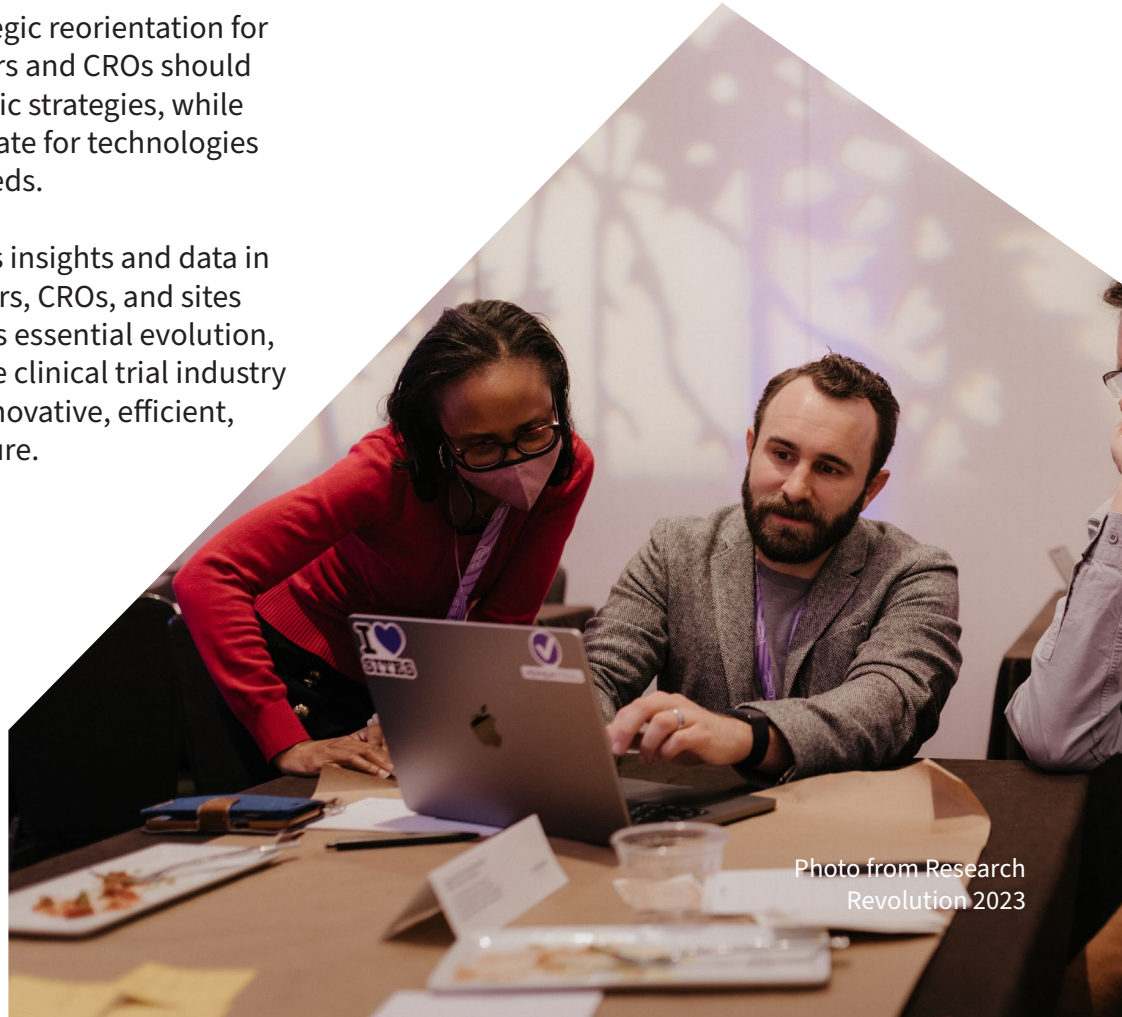


Photo from Research Revolution 2023

Photo from Research Revolution 2023

Recommendations for Leaders Emerging from the 2024 Report

Shift to Digital Site Mandates; Not Forced Sponsor Technology Platforms

As sponsors deploy more technology to their sites, a perception gap emerges: 95.24 % of sponsors believe sites value their software, but only 62.5% believe it meets their needs. To bridge this gap, sponsors/CROs must develop digital mandates that provide site-centric technology to sites when needed, yet integrate with sites that have existing technology stacks.

Emphasize Site Autonomy and Sponsor Collaboration

66.42% of sites surveyed in this years report own an eISF in 2024, while 32.38% own eConsent. 41.67% of sites stress the need for sponsor acceptance of their technology in study participation. Meanwhile, 42.86% of sponsors view their software's adoption as a key selection criterion. To succeed, sponsor/CRO leaders must prioritize site experiences and integration in their technology choices.

Prioritize Integration and Flexibility in Technology Solutions

In 2024, only 16.35% of sites will use sponsor-deployed portals, down from 38.30% in 2022. 60.38% of sites and 56.66% of sponsors also cite integration as a major barrier to tech investment. In order to meet the diverse needs of both sponsors and sites, leaders should prioritize systems that allow seamless and vendor agnostic integration.

Top Trend Alert: The Year of Digital Mandates

/ How Data Shows Agreement Between Sites and Sponsors on the Strategy of Site Enablement, but Signals Gaps in Alignment

2024 Will Build on Early Signs of Success with New Approach to Sponsor-Site Workflow Digitization

A Continued Focus on Site Digitization and Always-on Connectivity

Digitalizing workflows at every site and establishing always-on connectivity between sites and sponsors will remain a core focus in 2024, which has been on everyone's priority list since 2020.

Sponsor mandated portals failed to accomplish the goal in the past so now the focus has shifted to Site Enablement, which emerged as a key goal in 2023. Site Enablement emphasizes the enhancement of the site experience and the enhancement of workflows as the cornerstone of technology implementations.

Early adopters of this strategy have seen significant progress over the last three years; achieving faster timelines, increased capacity, and significant risk reduction across portfolios.

Acceleration of Site Enablement in 2024 with a Flexible Digital Mandate

Unlike past practices, the 2024 push for Site Enablement adopts a flexible digital mandate. Two key differences define this new strategy:

First, it emphasizes integration with existing technology stacks at sites, enabling them to maintain their existing workflows. As a result, there is no need for unique processes for each study, which has been a challenge in the past.

Second, it involves deploying genuinely site-centric solutions to sites lacking digital capabilities, like eISF. In contrast to previous sponsor-centric models, these solutions are designed for ease of use and adaptability across diverse studies.

2024 Key Supporting Data

Death of Sponsor Portals

Use of sponsor-deployed document portals significantly decreased from 38.30% in 2022 to 16.35% in 2024, and the demand for sponsors to provide remote document and information exchange decreased, from 13.87% in 2023 to 5.83% in 2024.

Sponsor Supplied eConsent Decline

Reliance on sponsor-deployed eConsent is declining, with its usage dropping to 27.62% in 2024 from 48.78% in 2022 and 32.38% of sites now indicating they own the technology, up from 19.72% in 2022.

Site-Owned Feasibility Dramatic Increase

Site investment in their own feasibility platforms increased dramatically from 22.54% in 2020 to 43.88% in 2024

Site-Owned Tech is Here to Stay

Site investment in tech dramatically increased previous three years:

- eISF: 64% 2024 | 41% in 2020
- eSource: 14% in 2024 | 33% in 2020
- eConsent: 32% in 2024 | 20% in 2020
- Feasibility: 44% in 2024 | 23% in 2020

Photo from Research Revolution 2023

> **Site digitization mandates are here, but this time it must be different - it must actually help the sites.**
>
> **Catherine Gregor, CCTO, Florence**

Caution: The Gap Between Sponsors Perception and the Site Reality

Data suggests some sponsors may be repackaging old sponsor-centric models for Site Enablement in 2024, rather than rethinking their strategies.

Despite 70.73% of sponsors reporting increased eISF distribution, a cornerstone of site-centric technologies, there is still a significant gap in site experience. 37.5% of sites find the technologies provided inadequate, 50% of sponsors complain about document management and exchange with sites, and 41.4% experience technology adoption challenges at their sites, all of which should be resolved by a truly site-centric strategy, highlighting ongoing misalignment.

Although sponsors and CROs seem to prioritize site experience, many still use re-branded, sponsor-centric solutions with site modules added.

Building a Digital Mandate Strategy that Works

For successful digitization in clinical trials, sponsors and CROs need a comprehensive approach:

Prioritizing Site Experience: It's vital to provide advanced technologies tailored for sites. A notable 41.67% of sites rank a sponsor's use of their technology as their top criterion. Moving beyond merely repackaged sponsor software to genuinely enhance site workflows is essential.

Embracing Interoperability: Integrated systems are key, as recognized by 60.38% of sites and 56.66% of sponsors. These systems should integrate smoothly with existing site technologies.

Focusing on Site Autonomy: Supporting the trend towards site autonomy is crucial. In 2024, 64.42% of sites have their eISF, and 32.38% use eConsent.

As 2024 unfolds, sponsors and CROs must actively embrace site-centric strategies in clinical trials, focusing on genuine site needs and technology integration.

Eight Key Insights in This Years Report

1

Consistent Emphasis on Automation

68% of sites in 2024 continue to prioritize automating repetitive tasks, showing stable recognition of its efficiency benefits, though slightly down from 73% in 2022.

2

Unified Focus on Remote Monitoring

62% of sites and 62.50% of sponsors rate remote monitoring extremely important, aligning towards a continued move to remote-first clinical trials operations.

3

Technology as a Competitive Advantage

59% of sites in 2024, up from 54% in 2023, view investing in technology as essential for being selected for a study, highlighting its growing importance in selection competition.

4

Shift Towards Flexible Platforms

The preference for managing trials on a single platform declines to 59% in 2024, suggesting a sponsors/CROs realize forcing all sites into a single platform is not a viable long-term option.

5

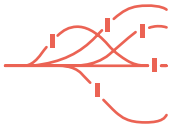
Rising Site Autonomy and Sponsor Integration

65.42% of sites own an eISF and 32.38% own eConsent, reflecting the move towards site tech ownership, with 41.67% emphasizing sponsor acceptance of their technology.

6

Increase in Sponsor eISF Distribution

There's a rise in sponsors providing eISF to sites, reaching 70.73% in 2024, signifying a shift towards enhanced sponsor-driven site enablement, specifically for sites without tech.



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Integration Challenges Amplify

Integration emerges as a significant barrier, with 60.38% of sites and 56.66% of sponsors identifying it as a concern, underscoring the complexity of merging technology systems.

8

Growing Gap in Technology Appreciation

95.24% of sponsors believe sites value their software, yet only 62.5% of sites feel that sponsors adequately address their technology needs.

Ryan Jones
Chief Executive Officer
Florence

"Looking ahead, I see the rise of a 'Sponsor Digital Mandate' as a key catalyst in clinical research. This mandate will accelerate the digitization of sites, respecting their technological preferences while encouraging a more unified and efficient approach to clinical trials."

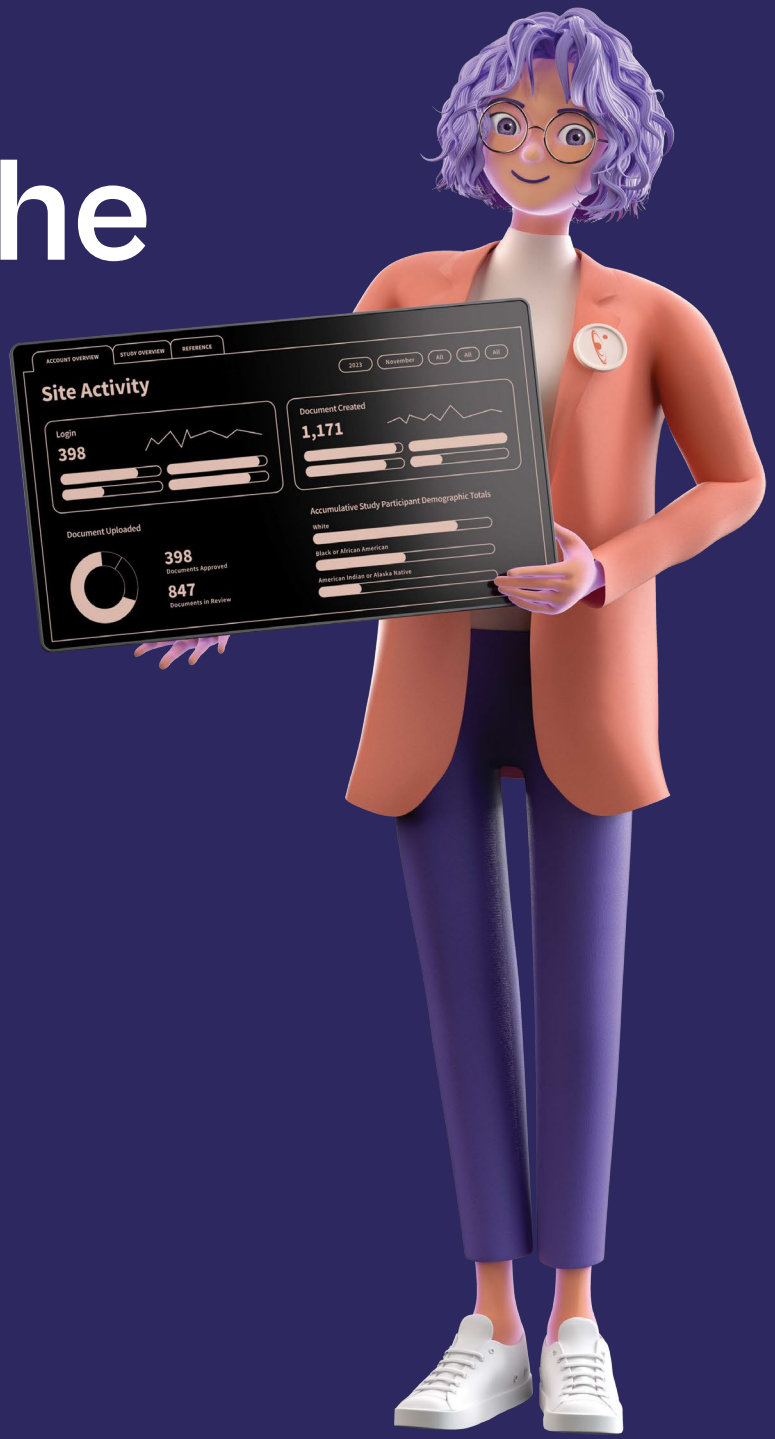
Catherine Gregor
Chief Clinical Trial Officer
Florence

"The past has shown us the value of digital workflows. In 2024, we will see a movement towards site autonomy to decide which digital tools they want to work in. While Sponsors will focus on tech that can aggregate site data across disparate systems, creating an integrated digital landscape. "

Kristin Surdam
Principal Thought Leader
Florence

"In 2024, I envision a transformative year in clinical research where technology moves beyond its traditional roles. We're moving towards a future where tech partnerships, integrations, and solution optionality take center stage, fostering an environment where collaborative innovation thrives over isolated efforts."

Deep Dive into the 2024 Data



/ Analysis of the Trends and Data from this Years Report and Recommendations for 2024 and Beyond Planning

Where Sites and Sponsors are Investing in Technology in 2024

/ Where Should Sites and Sponsors be Making Strategic Technology Investments in 2024 and Beyond to Maximize Workflow Digitization and Connectivity

2024 Technology Adoption and Investment Trends at Sites and Sponsors

In this section we analyze the responses sites and sponsors/ CROs provided to their current adoption and future investment plans for key technologies.

eISF Ownership Surge Signifies Digital Adoption and Market Maturity at Sites

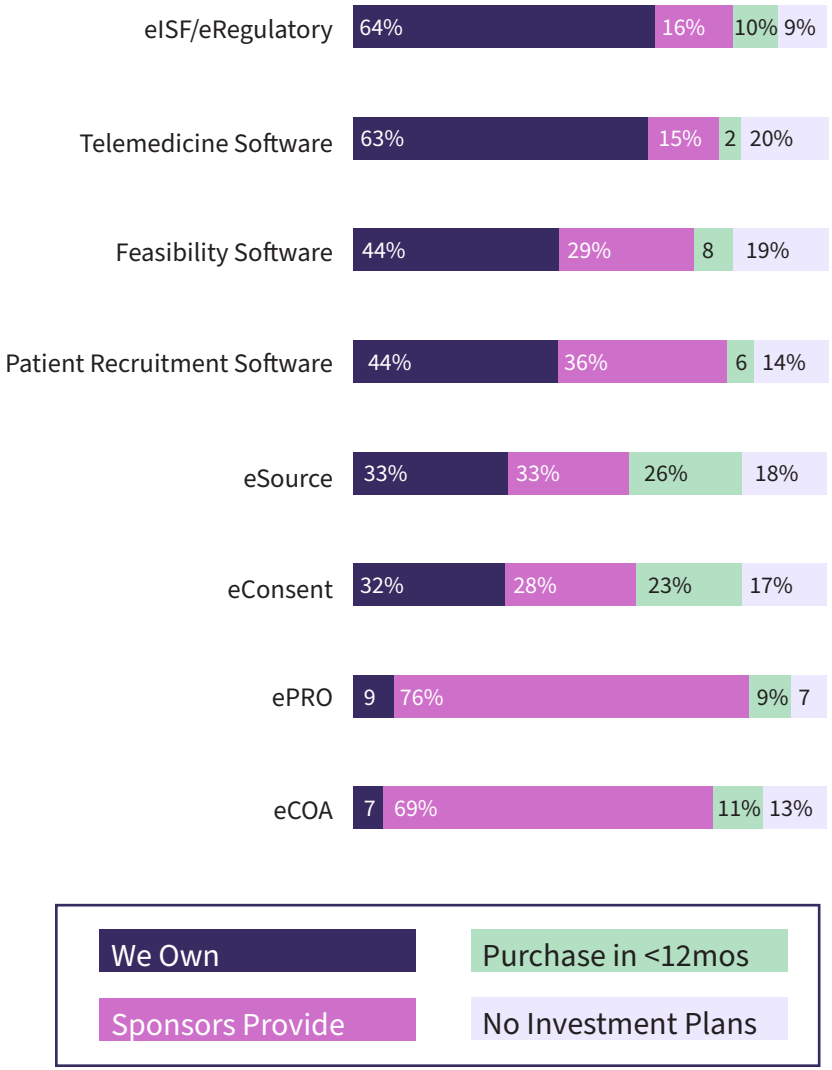
Clinical trial site ownership of eISF (Electronic Investigator Site File) markedly increased, climbing from 40.85% in 2020 to 64.42% in 2024, signaling a shift towards widespread digital document management. Simultaneously, site plans to invest in eISF over the next 12 months declined, dropping from a peak of 19.72% in 2020 to 9.62% in 2024. This indicates a nearing saturation point in the eISF market, particularly among established and large enterprise sites.

Furthermore, the use of sponsor-deployed document portals significantly decreased from 38.30% in 2022 to 16.35% in 2024, reflecting a growing trend where sites prefer to own and manage their eISF platforms.

This shift highlights an emerging need for sponsors to integrate with existing site eISFs while deploying eISFs in sites that currently lack the technology.

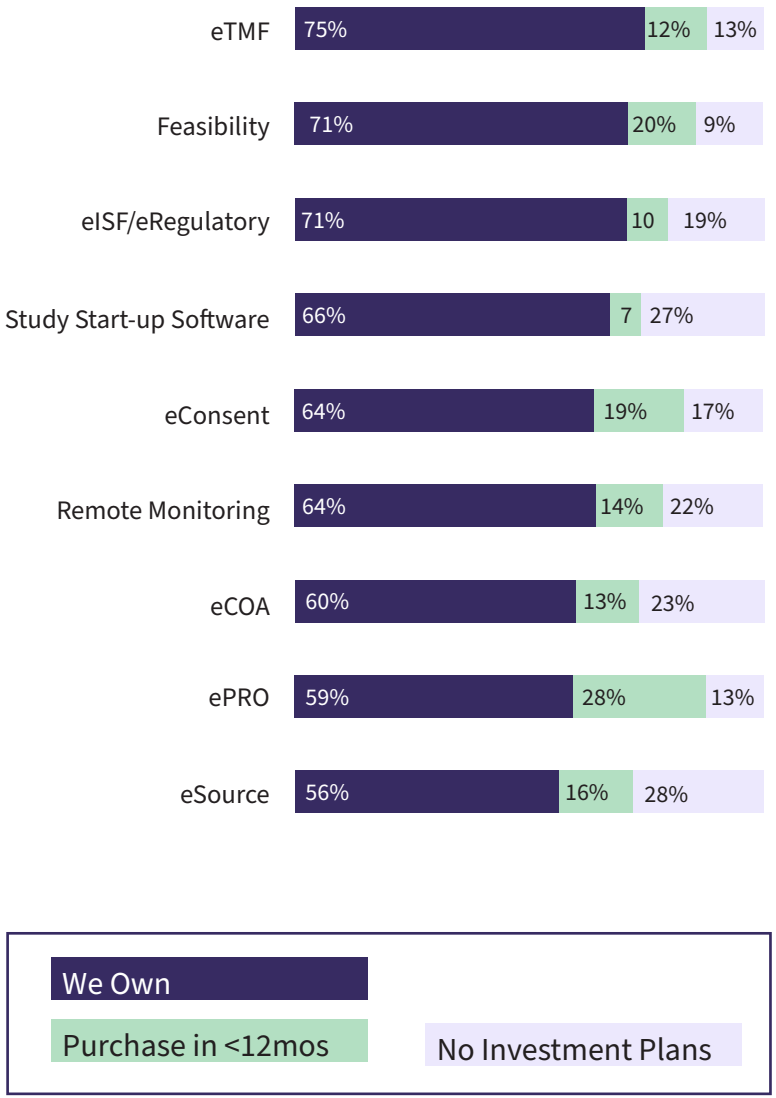
The 2024 Data Behind the Trends

Current Site Technology Adoption and Investment
(N=104 Sites)



The 2024 Data Behind the Trends

Current Sponsor Technology Adoption and Investment (N=41 Sponsor/CROs)



Sponsors Increasingly Distributing eISF Platforms to Sites as Part of Enhanced Site Enablement Strategy

In 2024, a significant shift is evident among sponsors, with 70.73% distributing eISF (Electronic Investigator Site File)/ eRegulatory platforms to study sites, marking a notable increase from 62.50% in 2023, 53.85% in 2022, and just 12.12% in 2021.

Conversely, the decline in sponsors not investing in eISF – down to 19.51% in 2024 from 75.16% in 2021 – highlights an increased recognition of the importance of digitizing document workflows at sites and providing comprehensive site enablement solutions, particularly to sites without their own eISF platforms.

This trend reflects sponsors' commitment to streamlining and enhancing the efficiency of document management in clinical trials.

eConsent Emerges as a Key Focus for Site Investment with Increasing Site Ownership

The ownership of eConsent by clinical trial sites shows significant growth, increasing from 19.72% in 2022 to 32.38% in 2024. Concurrently, plans to invest in eConsent rose, reaching 22.86% in 2024, up from 15% in 2023. This trend underscores a clear preference among sites for managing their consent processes.

Meanwhile, reliance on sponsor-deployed eConsent is declining, with its usage dropping to 27.62% in 2024 from 48.78% in the post-pandemic period, indicating a shift towards consent processes owned and controlled by the sites themselves.

Technology Usage, Indicating a Push for Site Data Control

The use of site feasibility platforms dramatically increased, rising from 22.54% in 2020 to 72.45% in 2024. Alongside this surge, 43.88% of sites now manage their own feasibility platform, demonstrating a clear desire to control their data and insights. On the sponsor side, feasibility software became a top technology, with 71.43% of sponsors using it in 2024, and an additional 20% planning investments. This is a substantial rise from 53.09% in 2023 and 41.94% in 2021, emphasizing a concerted effort to enhance the site selection process.

Sites are asserting their need for ownership and control over their data, while also seeking to streamline the protocol feasibility process, which often involves filling out numerous questionnaires. In response, tech vendors are expected to develop solutions over the next 12 months that address these evolving site needs.

Continued Growth and Stability in eSource, eCOA, and ePRO Deployment Post-Pandemic

In 2024, the deployment of eSource technology stabilizes, with 56.25% of sponsors using it, steady from 45% in 2023 and 53.85% in 2022, and a notable rise from 21.21% pre-pandemic. This trend underscores the lasting impact of digital collaboration tools introduced during COVID.

On the site front, 32.99% now own an eSource platform, a significant increase from 14.08% in 2020. Additionally, 25.77% of sites are using sponsor-deployed eSource platforms, and 23.71% plan to invest in this technology in 2024, up from just 10% in 2022.

Alongside eSource, the deployment of eCOA (Electronic Clinical Outcome Assessments) and ePRO (Electronic Patient-Reported Outcomes) technologies continue to be robust. In 2024, 60% of sponsors are deploying eCOA, up from 56.45% in 2023, while ePRO maintains a steady deployment rate of 59.38%, consistent with the 63.24% observed in 2023.

Telemedicine Usage Solidifies in Clinical Trials: Strong Site Adoption Evident

Telemedicine is now firmly established in clinical trials, with 78.26% of sites utilizing it. Among these, a significant 63.04% own the technology, while 15% use systems provided by sponsors, reflecting a strategic investment in telemedicine by sites. However, the market appears to be nearing saturation, as only 2.17% of sites indicate plans to invest in telemedicine technology in the upcoming 12 months. This trend demonstrates the widespread adoption and integration of telemedicine in current clinical trial practices.

In response to the 2024 trends, both sites and sponsors must actively manage their technology strategies to stay competitive in clinical trials. Where there are technological gaps, it's crucial to connect with key vendors and seek out innovative solutions. A proactive approach in adapting and investing in relevant technologies is essential for enhancing efficiency and success in the dynamic field of clinical research.

Top Challenges to Solve in 2024 with Technology

/ How Sites and Sponsors are Evaluating Where to Invest in 2024 with Technology, and Their Top Priorities to Solve

The Top Priorities Sites Want to Solve with Technology in 2024

This section highlights the primary challenges sites would like to solve in 2024 related to technology. Sites were asked "If you could solve one of these in 2024, which would it be?"

Direct EMR/eSOURCE to EDC Connectivity Tops the List

For the fifth year running, the most pressing technological issue for sites is establishing direct connectivity between EMR/eSOURCE and EDC systems. In 2024, 30.16% of sites identify this as their foremost challenge, indicating a persistent frustration with duplicative data entry and the complexities of integrating disparate data systems. This number has seen a steady emphasis over the years, with 24.27% in 2023, 26% in 2022, and hovering around 25-28% in the preceding years.

Consistent Focus on Automating Regulatory and Study Startup

The automation of regulatory and study startup workflows remains a concern, with 15.08% of sites in 2024 ranking it as their primary issue. This aspect aligns with previous years, which varied from 16% to 22.86%.

The 2024 Data Behind the Trends

Q) If you could only solve one, which of these would you solve in 2024? (N=134 Sites)

30% Direct EMR/eSource to EDC Connectivity for Automated Data

15% Automated Regulatory and Study Startup Workflows

11% Training and Credential Tracking of Study Staff

11% Remote Monitoring and Document Access

10% Site Selection/Site Feasibility Process for New Studies

10% Consenting of Subjects

8% Advanced Patient/Subject Matching Integrated with EMR

6% Remote Source Access Workflows

Emerging Priorities: Training and Credentialing, Remote Monitoring

This year training and credentialing both tied for third place, with 11.11% of sites marking it as their top issue. This marks a rise from its sixth-place ranking in 2023 with 9.62%. Equally important is the focus on remote monitoring and document access, also at 11.11%, highlighting a shift towards enhanced remote capabilities and sponsor workflow integration.

Site Selection and Consent Processes in Focus

Tied for the fifth position, site selection and consenting of subjects each garner 9.52% of sites' top priority for technology solutions. This reflects an increasing emphasis on optimizing site feasibility processes and streamlining patient consent procedures.

Declining Emphasis on Patient and Subject Matching; Remote Source Access

Notably, advanced patient and subject matching, once a higher priority, now ranks seventh with only 7.94% of sites considering it their main concern in 2024. Furthermore, the priority for remote source access for monitors continues to rank lowest, as only 5.56% of sites see it as a top issue, aligning with the finding that 71.88% of sites already possess this technology.

Photo from Research Revolution 2023

2024 Data Highlight

Unanimous Productivity Boost: Every Sponsor (N=51) and 90.48% of Sites (N=141) Agree Technology Makes them More Productive

The Top Priorities Sponsors Want to Solve with Technology in 2024

This section highlights the primary challenges sponsors and CROs would like to solve in 2024 related to technology. Sponsors and CROs were asked "If you could solve one of these in 2024, which would it be?"

Remote Monitoring and Document Exchange at Forefront

Remote monitoring, including document access, exchange, and QC workflows, remains the top priority for sponsors in 2024, with 34% marking it as their main focus. This preference has seen a steady increase from 26.80% in 2023 and aligns with the trends of 2022 and 2021. Additionally, 58.06% of sponsors are utilizing remote monitoring technologies, signifying a strategic shift towards fully integrated workflows that extend beyond basic document access.

Escalating Emphasis on Site Responsiveness

Site Responsiveness to data entry timelines and monitoring for compliance rose significantly, with 26% of sponsors marking it as their top priority in 2024. This marks a major increase from 10.31% in 2023 and a mere 2.86% in 2022, highlighting the evolving role of technology in fostering real-time operational interactions and efficiency with sites.

The 2024 Data Behind the Trends

Q) If you could only solve one, which of these would you solve in 2024? (N=41 Sponsors/CROs)

34% Remote Monitoring, Document Access and QC Workflows

26% Site Responsiveness to Data Entry and Monitoring Needs

14% Advanced Patient/Subject Matching Integrated with EMR

10% TMF Completeness

8% Site Selection

2% Patient Recruitment

0% Site Adoption of Technology

Photo from Research Revolution 2023

2024 Data Highlight

Digital Document Exchange Top of Mind

50% of sponsors say document exchange opportunities are their top concern for 2024

Decreased Focus on Patient Recruitment

Notably, the focus on patient recruitment strategies has diminished, with only 2% of sponsors considering it the top priority in 2024, a sharp decline from 22.68% in 2023 and 22.86% in 2022. This trend might reflect a redirection towards other pressing technological needs or a response to a potential slowdown in patient recruitment demands.

Reduced Emphasis on Site Tech Adoption

Interestingly, the emphasis on site adoption of technology as the top problem to solve has dropped to zero in 2024, down from 5% in 2023 and 14.29% in 2022. This decline contrasts with the 24.53% of sponsors who identified site adoption as a barrier, indicating a complex scenario where sponsors recognize the challenge but do not view it as a primary concern, suggesting they are finding alternative methods to address this issue.

Emerging Focus on Patient Matching and Site Selection

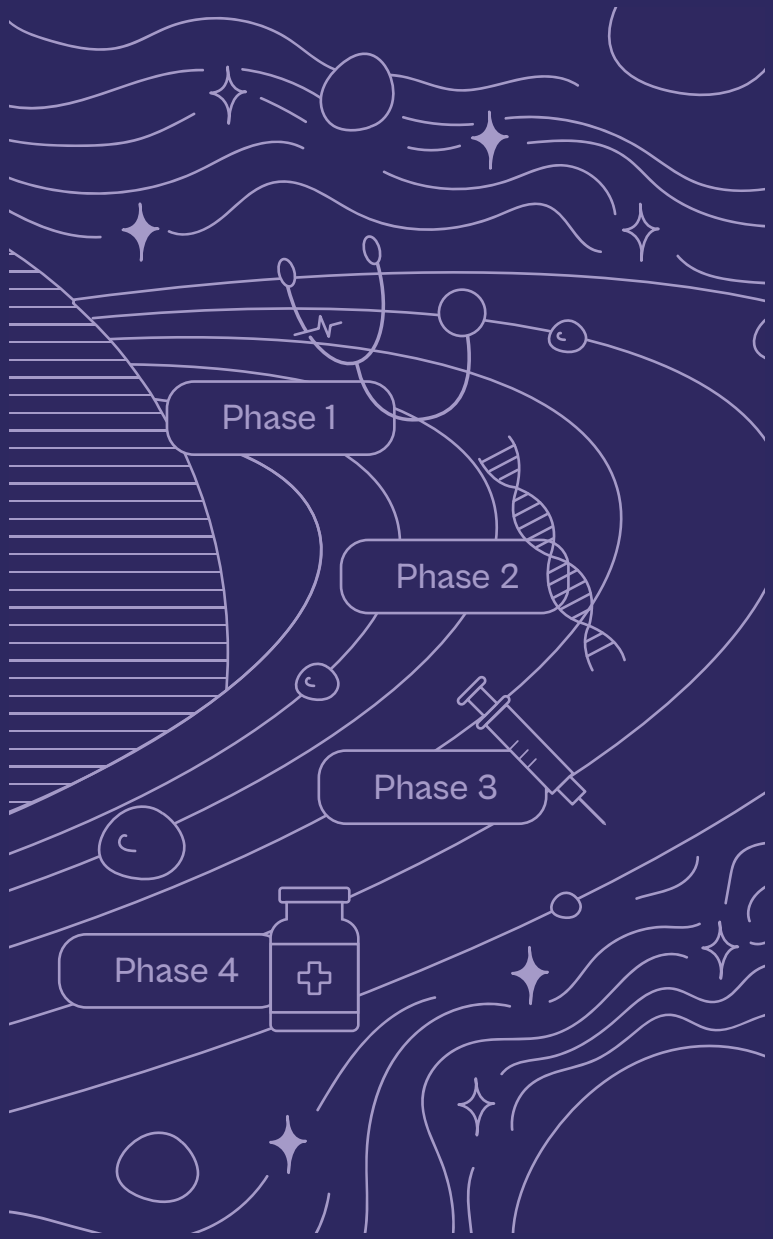
Trends indicate a growing focus on integrating patient matching with EMR, with 14% of sponsors emphasizing it in 2024, up from 9.28% in 2023. Additionally, 6% of sponsors in 2024 are prioritizing site selection processes, up from 3.09% in 2023. Coupled with the decline in patient recruitment priority, these trends point towards a strategic shift. Sponsors are increasingly aiming to equip sites with advanced technology and enhance site selection using predictive analytics, indicating a broader movement towards optimizing clinical trial operations through technology.

Leveraging Technology for Comprehensive Workflow Solutions

Overall, the 2024 landscape reveals sponsors are actively recalibrating their technology strategies to focus more on integration, improving interactions with sites, and streamlining critical aspects of clinical trial management. This shift indicates a clear move towards leveraging technology for more comprehensive and efficient workflow solutions, underscoring the crucial role of sites in patient recruitment and overall data management in clinical trials.

What Sites and Sponsors Care About in Their Technology

/ How Sites and Sponsors Decide What is Important in Their Technology Platforms from a Features and Capabilities Perspective



What Sites Care About When Investing in Technology

In this years report, 121 sites indicated how important they considered certain capabilities and features when selecting new clinical trial technology solutions.

Automating Repetitive Tasks Remains Top Priority

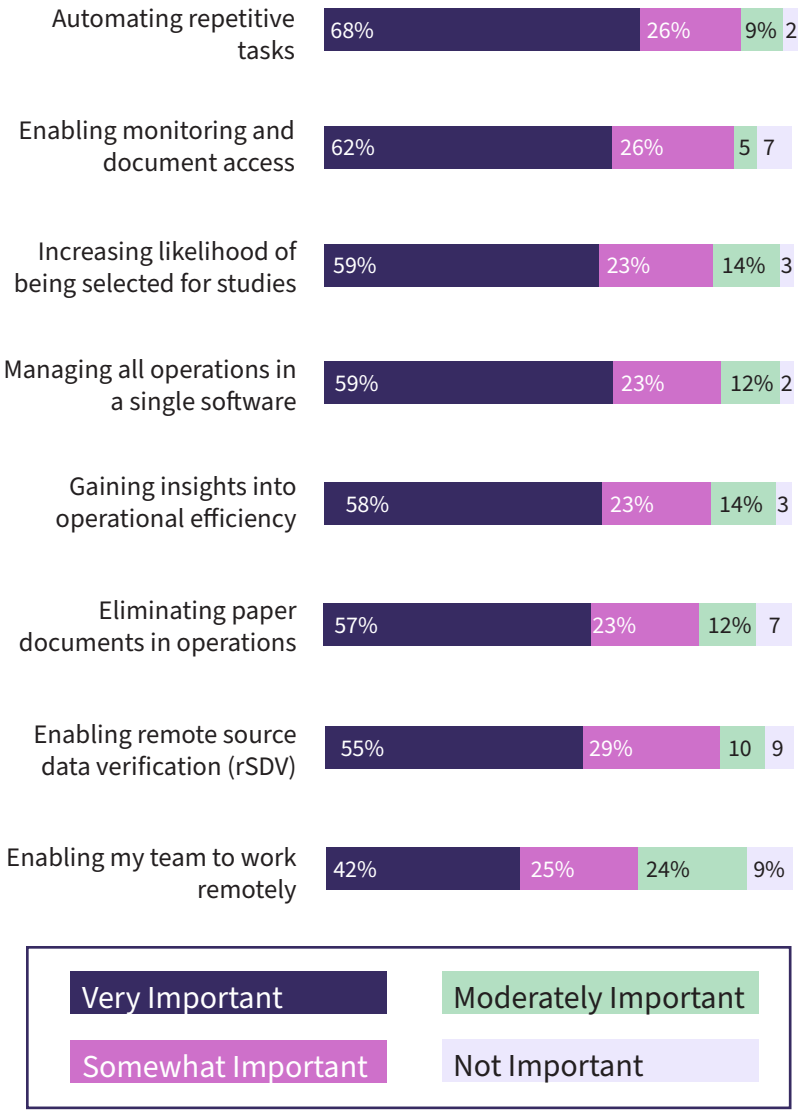
For the fourth consecutive year, automating repetitive tasks is the primary reason sites invest in technology, with 68% of sites ranking it as extremely important in 2024. This is consistent with 65% in 2023, though slightly down from 73% in 2022 and 72% in 2021. Only 2% of sites consider it not important, underscoring the widespread recognition of the value of automation in improving efficiency.

Growing Importance of Enabling Remote Monitoring

Enabling remote monitoring has risen to the second most important factor, with 62% of sites in 2024 considering it extremely important, an increase from 59% in 2023 when it was the third most important. The consistent ranking within the top three over four years reflects the ongoing shift towards decentralized clinical trials and the need for remote capabilities.

The 2024 Data Behind the Trends

Q) How important are these factors to your organization when choosing eClinical solutions? (N=121 Sites)



Increasing Likelihood of Selection by Sponsors/CROs

The importance of increasing the likelihood of being selected by a sponsor/CRO has risen to the third spot in 2024, with 59% of sites ranking it as extremely important, up from the fifth spot in 2023 (54%) and the sixth spot in 2022 (49%). Only 3% consider it not important. This trend indicates a competitive landscape where technology is seen as a key differentiator.

Shift in Priority for Managing Trials on a Single Platform

Managing all clinical trials on a single platform has decreased in priority, moving to the fourth spot in 2024, with 59% of sites considering it extremely important. This is a drop from its third-place ranking in 2022 (53%) and 2021 (66%). The shift suggests an evolving perspective on the importance of integrated trial management systems.

Decline in Priority for Eliminating Paper Documents

The focus on eliminating paper documents has gradually declined, remaining at the sixth spot in 2024, down from the fourth spot in 2021. This trend could reflect a natural progression as more research goes digital, with the initial urgency to eliminate paper lessening as digital processes become more established.

These data points collectively illustrate a clinical trial environment that is adapting to technological advancements, with a clear trend towards automation, remote capabilities, and competitive positioning through technology.

Sites are focusing on technologies that enhance operational efficiency, facilitate remote interactions, and improve their attractiveness to sponsors and CROs, reflecting a strategic approach to technology investment in the clinical trial sector.

Photo from Research Revolution 2023

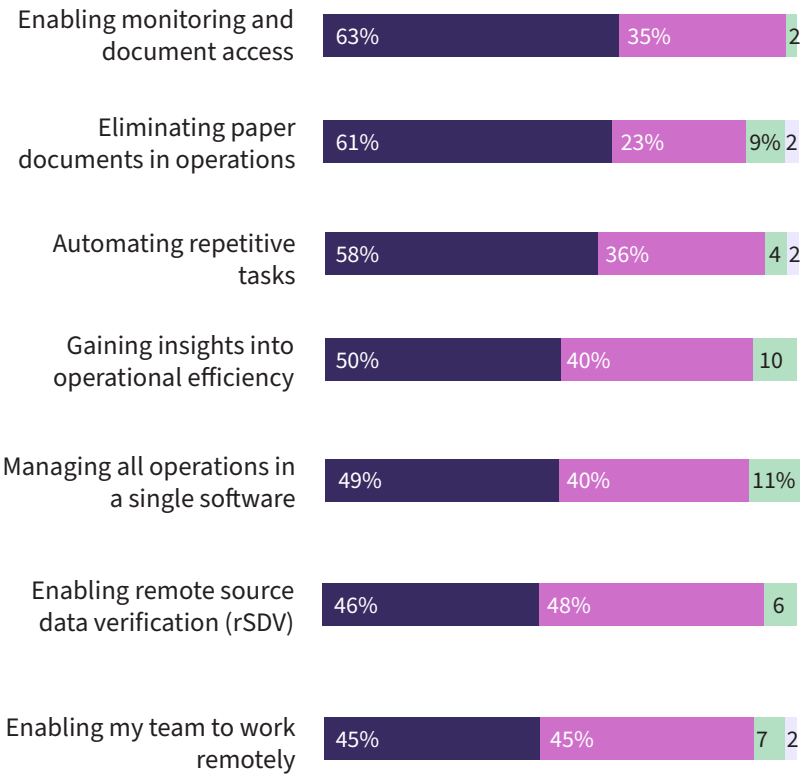
2024 Data Highlight

Email's Dominance Drops

A 55% Decrease in Email Usage for Document Exchange Between Sites and Sponsors from 2020 to 2024.

The 2024 Data Behind the Trends

Q) How important are these factors to your organization when choosing eClinical solutions?
(N=48 Sponsor/CROs)



What Sponsors and CROs Care About When Investing in Technology

In this years report, 48 sponsors and CROs indicated how important they considered certain capabilities and features when selecting new clinical trial technology solutions.

Emphasis on Enhancing Remote Monitoring Capabilities

In 2024, enabling remote monitoring and document exchange emerges as the top ranked reason to invest in technology, with 62.50% of sponsors deeming it extremely important. This emphasis reflects a significant industry shift towards strengthening remote capabilities.

Drive Toward Complete Digitization of Documents and Workflows

The push to eliminate paper documents and workflows is a high priority, indicated by 60.87% of sponsors as extremely important. This trend highlights the industry's commitment to fully digitizing clinical trial operations. The high importance also reflects the reality that the sites in our survey skew towards larger more enterprise sites with paper already mostly replaced (ranking 6th on their list of importance), while sponsors in our report are working with a wide range of sites globally, many of who may still be paper based.

Lower Priority Placed on Unified Platform Management

Integrating all clinical trial operations into a single platform is less critical, with only 48.94% of sponsors rating it as extremely important. This suggests a more diversified approach to technology adoption rather than relying on a singular system.

Standardization of Remote Work in Technology Strategy

The capability for remote work is now a standard expectation in the tech strategy, with 45.45% of sponsors rating it as extremely important, indicating an industry-wide acceptance of remote work as a norm.

Emerging Focus on Operational Efficiency Insights

Surprisingly, only 50% of the sponsors consider gaining insights into operational efficiency as extremely important. This could indicate the focus remains on digitizing processes, and not yet on how to harness the data from the digitized processes.

These insights reveal a nuanced approach by sponsors in technology investment, prioritizing advancements in remote operations and digital documentation while gradually embracing the analytical and efficiency benefits offered by digital transformation in clinical trials.

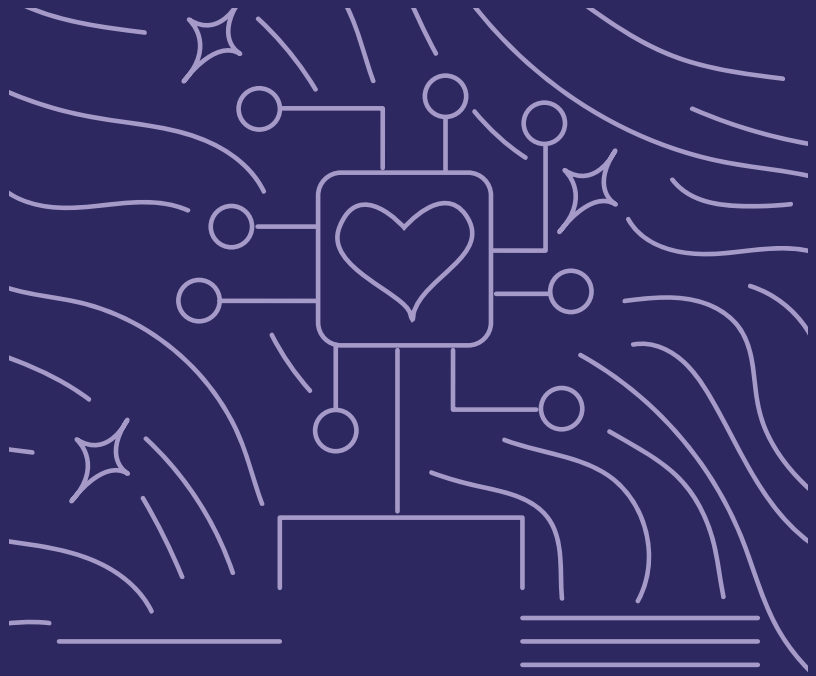
Photo from Research Revolution 2023

2024 Data Highlight

82.76% of sponsors say their organization cares more about the sites technology experience than they did 1 year ago.

Barriers to Site and Sponsor Investments in Technology

/ What Sites and Sponsors Consider the Primary Reasons their Technology Investments Fail



Navigating the Barriers to Technology Investment in Clinical Trials

This report section examines the primary obstacles that clinical trial sites and sponsors encounter when investing in new technologies in 2024. It offers a detailed analysis of challenges such as budget limitations, integration difficulties, adoption hurdles, compliance issues, and the need for vendor training.

Budget and Cost: The Dominant Barriers in 2024's Clinical Trial Technology Investments

Budget and cost remain the top barriers to technology investments in the clinical trial arena for both sites and sponsors in 2024. Site-reported budget concerns slightly decreased to 67.92% from 73.11% in 2023, suggesting cautious optimism, although still higher than previous years (53.33% in 2022 and 67.07% in 2021).

Conversely, sponsors show a growing concern, with 62.75% citing budget as a barrier, up from 53.61% in 2023 and 40% in 2022, highlighting a cautious investment approach and a demand for proven technologies.

The 2024 Data Behind the Trends

Q) What are your biggest barriers to investing in technology? Select all that apply. (N=141 Sites)

68% Budget and cost concerns

60% Integrating with other technologies

44% The transition from current process to new technology

41% IT/Data Privacy/Security process or concerns

25% My team won't adopt or use the technology

24% Compliance concerns

24% Sponsor acceptance of technology

22% Lack of vendor training or role-based implementation support

The 2024 Data Behind the Trends

Q) What are your biggest barriers to investing in technology? Select all that apply. (N=41 Sponsors)

63% Budget and cost concerns

57% Integrating with other technologies

41% The transition from current process to new technology

41% Site teams won't adopt or use the technology

25% Lack of vendor training or role-based implementation support

25% IT/Data Privacy/Security process or concerns

18% Compliance concerns

Integrations: A Growing Challenge in Clinical Trial Technology

Integration issues have become more pressing in 2024, with 60.38% of sites and 56.66% of sponsors reporting these as significant barriers. The increase from 39.06% (sites in 2023) and 46.39% (sponsors in 2023) indicates the challenges brought by the rapid development of new technologies and the need for seamless system compatibility.

Escalating Focus on Site Team Adoption in Technology Deployment

The challenge of site team adoption of new technologies is more acute, doubling to 24.53% in 2024 from 12.74% in 2023. Sponsors echo this concern, with 41.18% emphasizing it in 2024, up from 36.08% in 2023. This trend highlights the need for technologies with a proven record of successful site adoption and high user satisfaction. Additionally, a robust integration and partner ecosystem is essential to facilitate smoother adoption and integration of these technologies within the existing frameworks of clinical trial operations.

Declining Compliance Concerns in Clinical Trial Technology Adoption

Only 23.58% of sites view compliance as an obstacle, a decrease from 31.60% in 2023. Similarly, among sponsors, compliance concerns have dropped to 17.65% in 2024, down from 28.57% in 2022. This decrease suggests growing confidence in newer technologies and the need for solutions with established credibility and compliance capabilities.

Persistent Challenge: Transitioning to New Processes in Clinical Trials

Transitioning to new processes remains a consistent barrier, with 44.24% of sites and 41.18% of sponsors noting it in 2024. For sponsors this represents a considerable increase in concerns related to site adoption from previous years (28.87% in 2023 and 22.86% in 2022), matching the level of concern in 2021 at 42.42% at the height of pandemic technology deployment.

This reflects the shift from replacing old methods with digital solutions to more comprehensive workflow transformations. Collaborative approaches and seeking vendors with specific workflow expertise are essential for smooth transitions.

Elevated Demand for Vendor Involvement in Technology Training

In 2024, there is a noticeable increase in the need for vendor training in the adoption of technology within clinical trials. For sites, 21.70% consider the lack of vendor training as a barrier, a rise from 16.51% in 2023. This need is also becoming more prominent among sponsors, where the concern has escalated from 8.57% in 2022 to 25.49% in 2024. This trend highlights the growing role of vendors not just as technology providers but also as partners in training and consultancy during digital transformations.

Overcoming these barriers necessitates strategic actions by both sites and sponsors. Collaborating with vendors who provide both technology and expertise, prioritizing investments in well-adopted technologies, and focusing on solutions that integrate seamlessly and meet compliance standards are crucial for harnessing technology effectively in future clinical research endeavors.

Photo from Research Revolution 2023

2024 Data Highlight

60.38% of sites and 56.66% of sponsors report integrations are a key barrier to their investment and implementation of technology.

What Sites and Sponsors Expect of Each Other

/ What Sites and Sponsors Care About when it comes to Technology in Their Study Partners

The Technology Capabilities Sites Care about When Working with a Sponsor

This section looks at responses to the question posed to sites “Rank the key things you care about when working with sponsors”.

Priority on Sponsor Acceptance of Site-Owned Tech

Clinical trial sites ranked sponsors accepting and integrating with their existing site technology as their top technology related attributes in 2024, an increase from 35.86% in 2023 and equaling 40% in 2022.

The persistence of this focus is a strong indication of the sites’ preference to retain control over their key technologies. Sites consistently advocate for sponsor flexibility in using site-owned technological solutions, particularly in situations that require duplication of efforts.

Sponsors Conducting Remote Monitoring Critical

25% of sites indicate the sponsors ability to conduct remote monitoring as their primary technological concern in 2024, up from 17% in 2023 and 14% in 2022. Remote monitoring is now a standard practice in clinical trial operations, a practice that gained traction amid the COVID-19 pandemic, and an expectation at trial sites.

The 2024 Data Behind the Trends

Q) Rank the following Sponsor and CRO attributes in the order of most to least important. (N=141 Sites)

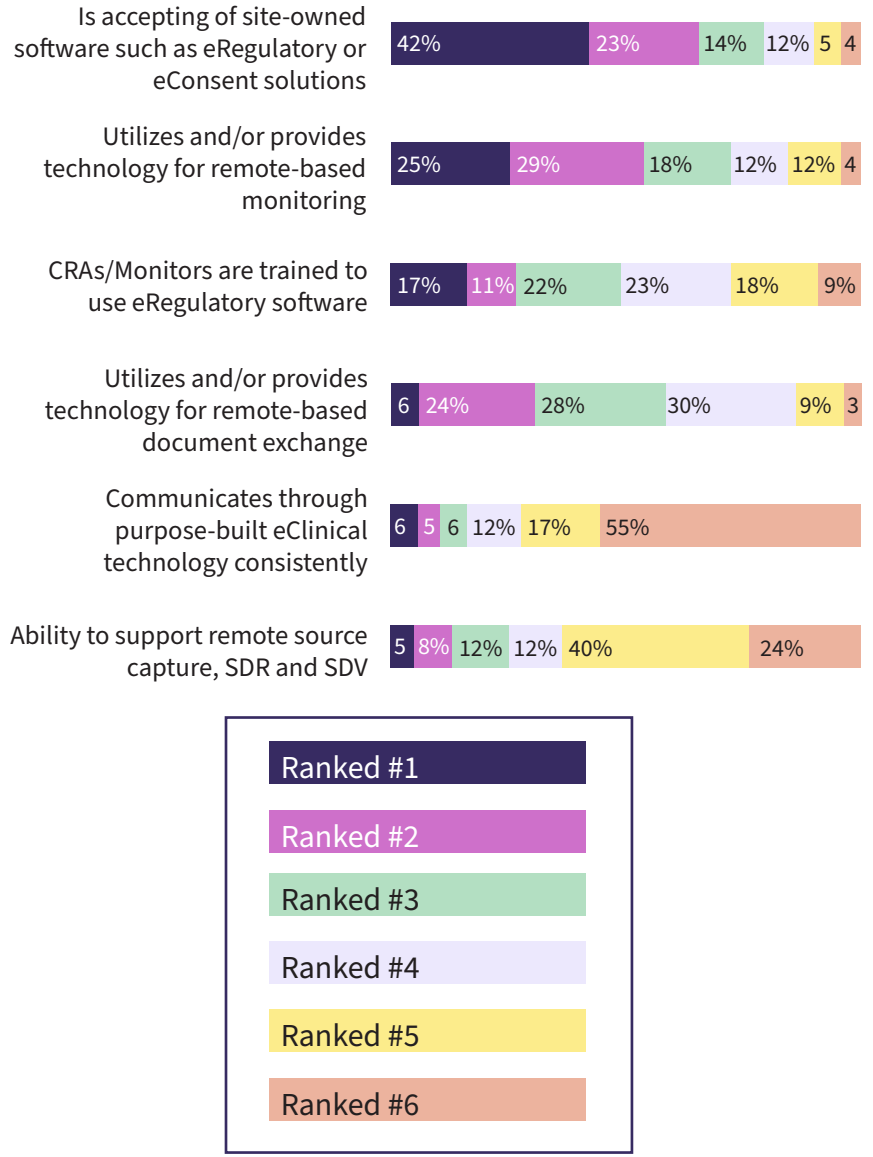


Photo from Research Revolution 2023

43% of sponsors view site acceptance of their tech as crucial, while 42% of sites prioritize sponsor acceptance of their tech, highlighting a major misalignment between the two groups.

Remote Source Data Review and Document Exchange Now an Expectation

The focus on sponsor support for source capture, source data review (SDR), and source document verification (SDV) has seen a marked decline. In 2024, just 5% of sites rank these functions as a top priority, a notable drop from 13.56% in 2023. Additionally, the demand for sponsors to provide remote document and information exchange has similarly decreased, from 13.87% in 2023 to 5.83% in 2024.

This shift indicates that these capabilities are now considered baseline expectations, rather than unique value-adds from sponsors.

Further emphasizing this trend, 55.21% of sites in 2024 offer remote source access. This high percentage reflects a changing site perspective, where remote SDR/SDV and document exchange are integral to the broader scope of remote monitoring, no longer viewed as distinct or additional functionalities. These shifts underline the evolving landscape in clinical trials, where advanced remote monitoring and data management are now foundational elements of sponsor-site collaboration.

Actionable Recommendations for Sites

In response to the shifting technological landscape, sites should actively engage with sponsors favoring the integration of site-owned technology and with an in-depth site enablement strategy. Prioritize the establishment of effective remote monitoring practices to meet industry standards. This proactive stance ensures sites remain technologically adept, contributing significantly to the success of clinical trials.

The Technology Capabilities Sponsors Care about When Working with a Site

This section looks at responses to the question posed to sponsors and CROs “Rank the key things you care about when working with sites”.

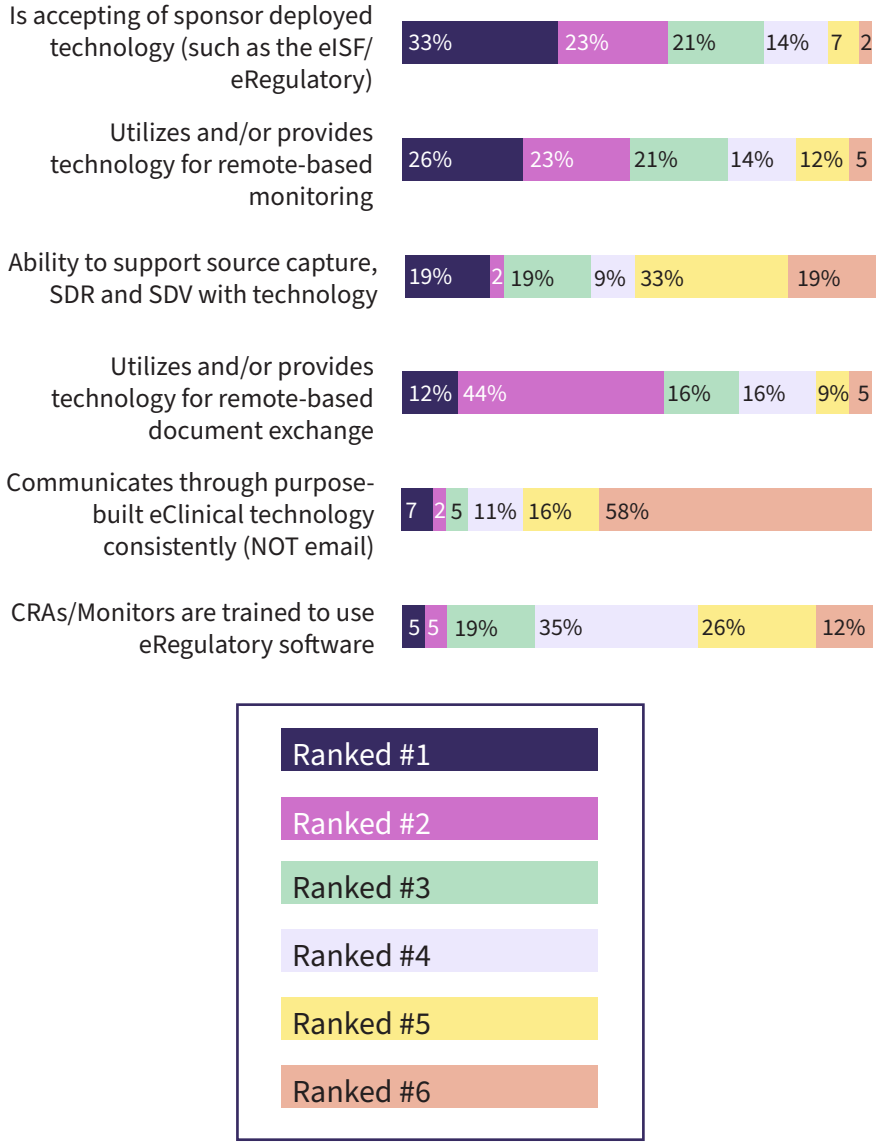
Site Acceptance of Sponsor Technology

The willingness of sites to adopt and use sponsor-provided software has emerged as a crucial factor for sponsors in site selection. 42.86% of sponsors consider this the most critical aspect, marking a significant rise from 25% in 2023 and 28.57% in 2022. This growing emphasis starkly contrasts with the 41.67% of sites that prefer sponsors to integrate with their own site-owned technologies.

This disparity underscores a challenge in aligning technological strategies between sites and sponsors, with 60.38% of sites and 56.66% of sponsors citing integration as a major barrier. This trend highlights the ongoing difficulty in standardizing platforms across diverse studies and sites, emphasizing the need for deeper, more adaptable integrations.

The 2024 Data Behind the Trends

Q) Rank the following Site attributes in the order of most to least important. (N=41 Sponsors/CROs)



Consistent Focus on Remote Monitoring Technologies

Despite shifts in other areas, the utilization of remote monitoring technology remains a stable priority for sponsors. 21.43% of sponsors rate this as their primary technology consideration, slightly lower than the 28.57% in 2022 but still a top priority for 42.86%. This sustained focus indicates that sponsors expect sites to be equipped with remote monitoring capabilities, considering them a standard component of modern clinical trials.

Elevated Importance of Electronic Document Exchange

The importance of electronic document and information exchange technology at sites has gained momentum, rising to the third most significant factor with 14.29% of sponsors emphasizing it. Additionally, 57.15% of sponsors consider it a top-two priority. This marks an uptick from 13.68% in 2023, suggesting a shift from solely focusing on remote document monitoring to a broader embrace of technologies that facilitate real-time collaboration and data exchange.

Bridging the Technology Gap in Clinical Trial Collaborations

The data collectively reveals a landscape where sponsor preferences are evolving towards technologies that foster collaborative and integrated operations with clinical trial sites. While remote monitoring remains an essential requirement, there is a clear move towards technologies that support more comprehensive data and document exchange processes.

The discrepancy between sponsor and site technology preferences underscores the need for solutions that offer deep integration and interoperability, essential for effective and efficient clinical trial collaborations. This environment calls for sponsors and sites to work closely in harmonizing their technological approaches, ensuring mutual benefits and streamlined clinical trial processes.

Photo from Research Revolution 2023

“In 2024, the focus shifts towards streamlined digital workflows and interoperability. This is crucial for more efficient, patient-centered trials, promising faster and more effective medical breakthroughs.”

Blake Adams, SVP Marketing, Florence

Creating a Comprehensive Tech Strategy for 2024 and Beyond

/ How Sites and Sponsors/CROs can Harness the Data and Insights from this Years Report to Strategically Plan for 2024

Creating a Comprehensive Tech Strategy in 2024

As we conclude our insights into the 2024 clinical trials landscape, it's clear that the future hinges on strategic technology integration. The data indicates a significant shift towards site enablement, with sponsors and sites increasingly recognizing the value of technology in streamlining processes. However, challenges in integration and effective technology deployment remain.

This section aims to guide both sponsors and sites in developing a comprehensive and effective tech strategy that aligns with the evolving needs of clinical trials.

For Sponsors

Prioritize Site-Centric eISFs: Emphasize deploying eISFs that genuinely support site workflows. With 70.73% of sponsors claiming to be distributing eISFs, it's crucial to ensure these solutions are more than just digital placeholders and repackaged sponsor tools, but are truly enhancing site efficiency.

Invest in Integration: Tackle the integration challenge head-on, given that 60.38% of sites find this a barrier. Develop solutions that are not only technically sound but also user-friendly and intuitive for site staff.

Partner with Insightful Vendors: Collaborate with vendors who don't just sell a product but understand the nuances of the site experience. Their insights can be invaluable in developing solutions that are both practical and innovative.

Regular Feedback and Adaptation: Establish a feedback mechanism with sites to continually refine and adapt the technology. This ensures that the tech solutions remain relevant and effective.

Photo from Research Revolution 2023

> **In 2024 Sponsors and CROs must embrace hybrid digital mandates through a truly site centric technology strategy that prioritizes the site experience at every interaction.**
>
> **Ryan Jones, CEO, Florence**

Educational Initiatives and Training: Provide comprehensive training to ensure that sites can fully utilize the technological tools, bridging the gap in digital literacy and maximizing the potential of these investments.

For Sites

Continue Investing in Technology: With the majority of sites adopting eISF and eConsent platforms, continue this trend by investing in technologies that boost operational efficiency and compliance.

Advocate for Effective Solutions: Proactively communicate with sponsors about the technology needs and challenges of your site. Your input can significantly influence the development of more effective solutions.

Emphasize Seamless Integration: Focus on adopting technologies that seamlessly integrate into your existing systems, minimizing disruption and maximizing efficiency.

Leverage Data for Decision Making: Use data insights to make informed decisions about technology adoption and utilization, ensuring that the tools you choose align with your operational objectives.

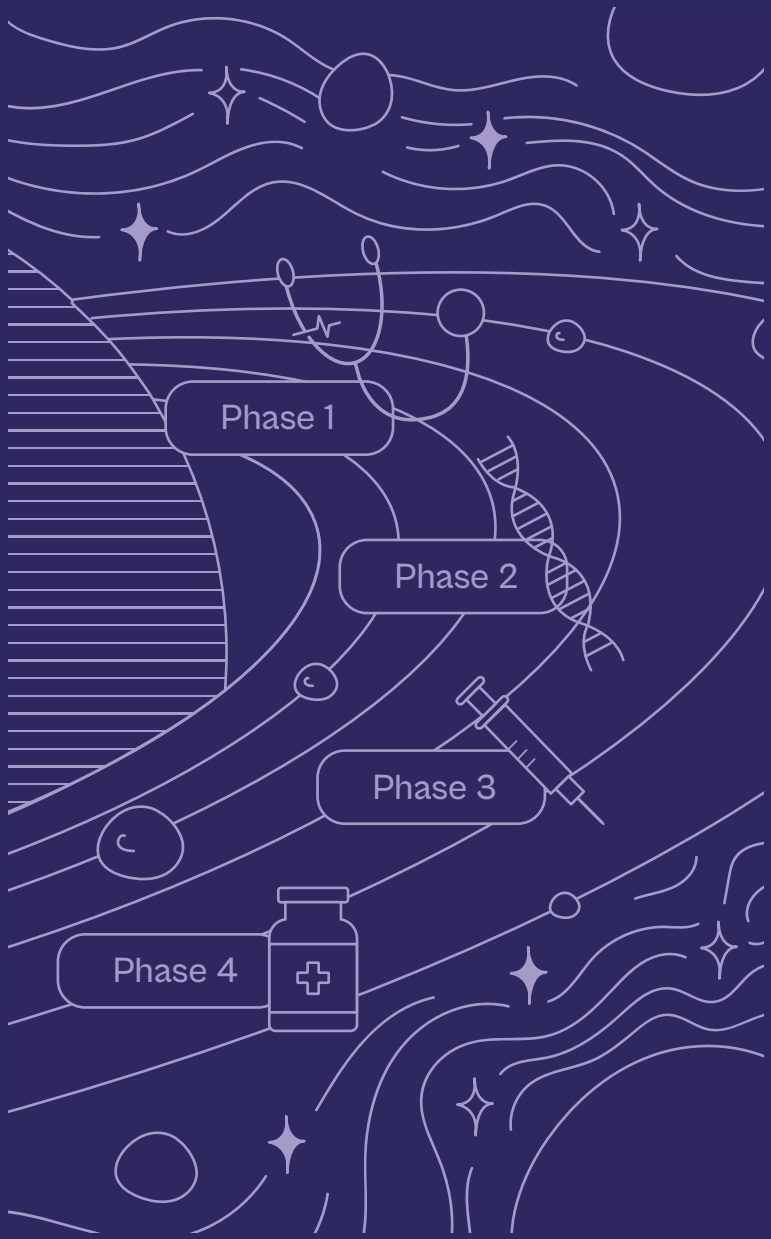
The path to successful clinical trials in 2024 is in embracing digital transformation with a focus on site enablement, effective eISF deployment, and seamless integration. Both sponsors and sites have pivotal roles to play in this journey.

By fostering collaboration, embracing innovation, and continuously adapting strategies, the clinical trials industry can achieve greater efficiency, compliance, and success in this era of digital transformation. This comprehensive approach will ensure that clinical trials not only meet the challenges of today but are also well-prepared for the opportunities of tomorrow.

Photo from Research Revolution 2023

An Introduction to Florence's Site Enablement Platform

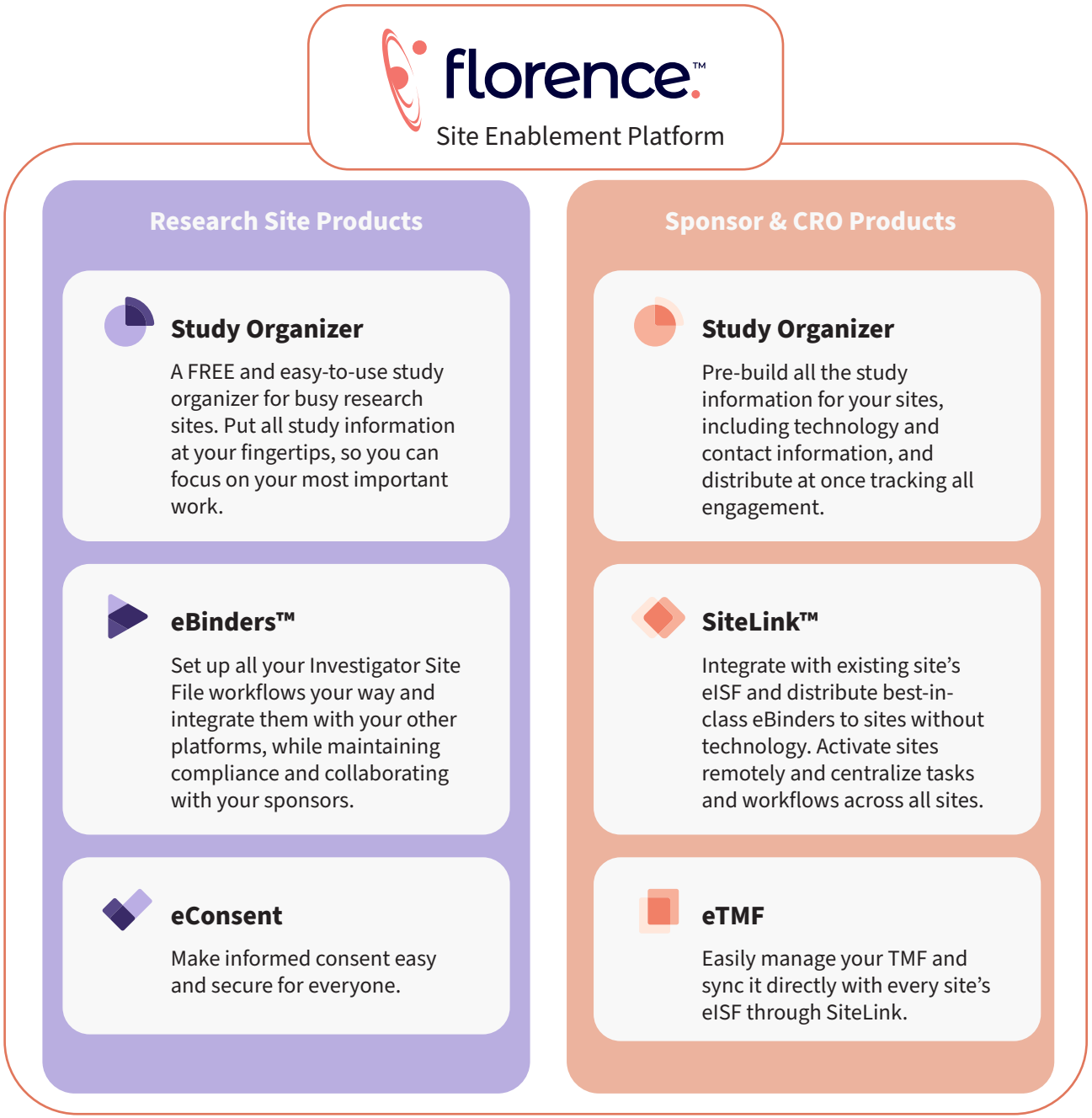
/ An overview of Florence's Industry Leading Site Enablement Platform Trusted by 18k+ sites and hundreds of sponsors and CROs across 50+ countries.



Collaborate With Any Site.

Anywhere, Anytime.

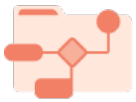
Florence's Site Enablement Platform brings real-time sponsor-site collaboration to life, allowing you to seamlessly integrate with every site's workflows across the full study life-cycle through Florence's SiteLink™.



Sponsor Product Highlight
SiteLink™

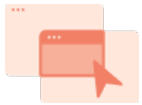
Deploy and Integrate to an eISF at Every Study Site

Florence's SiteLink is a complete solution for sponsors and CROs to remotely work with their research sites on a single unified document workflow platform without the disruption to sites caused by legacy shared portals and disconnected systems.



E2E Workflow Automation

Manage and automate all workflows in one place. Create, edit, sign, gather and review eISFs, eTMFs, and eBinders all within the platform.



Open Integrations

No need for sites to reinvent their workflows. We integrate with any system, so sites can work with you while continuing to use their own workflows.

Site Intelligence

Track compliance and performance with our reporting and analytics dashboard.

Site Activation Teams

On-boarding and adoption take just a few clicks with the help of our Site Activation Teams. Florence is rated #1 on G2 for usability and customer support.

Remote Monitoring

Monitor multiple sites around the world in real time -- all on one dashboard. Now, no protocol deviations, errors, or compliance issues go unnoticed.

Get an inside look at the Site Enablement Platform trusted by 3 of the top 5 Pharma, 2 of the top 3 CROs, and 18k+ research sites around the world.

florencehc.com
info@florencehc.com

95%
Of sites can be fully set-up on platform in weeks.

2x
Increase in the number of sites monitored per CRA.

40%
Faster site activation and startup document workflow timelines.

Site Product Highlight
eBinders™

Move Your Studies to the #1 Rated eISF

Digitize all of your study binder workflows with Florence eBinders and provide remote access for start-up, monitoring and source data review for your sponsors. eBinders is trusted by 18k+ research sites around the globe.

Digital from Start-up to Close

Create, edit, distribute, collect, sign and review all investigator site files, electronic logs and participant binders electronically within a single platform. Speed study start-up by as much as 40%.

Experience Flexible Workflows

Every site is unique and has custom workflows and standard operating procedures. Florence eBinders lets you set up your structures and workflows the way you need while maintaining regulatory compliance.

Use Digital Participant Binders

Our front-end integration with your EMR/EHR provides seamless source binder document collection, redaction, and storage. Provide monitors with secure remote access to source for review and verification.

Automate Compliance

Built-in compliance features include automated audit trails, version control, extensive user permission options and in-app redaction. Plus, your team is supported by our extensive compliance program.

Enable Remote Monitoring

Give monitors secure and compliant access to your eISF and redacted participant binder. Automate scheduling of remote visits, track monitor activity, and communicate with your monitor on follow-up items.

Gain Site-wide Visibility

Global dashboards and project milestones offer a single view of all your studies. Track expired documents, missing signatures, and outstanding tasks in one central location.

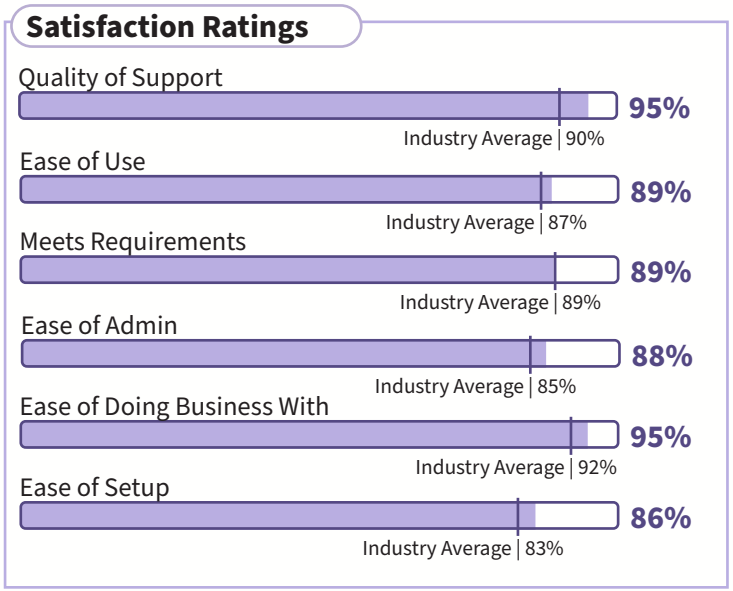
Enjoy an Easy-to-Use Interface

Florence is rated the #1 clinical trial workflow platform on G2 for ease of use and customer support. Even the most paper-loving PI will enjoy moving to Florence eBinders.

Customizable Electronic Logs

Improve patient safety, increase study speed, and ensure data quality with electronic clinical trial logs on Florence. Customize workflows for any log you need.

Florence is Loved by Sites in 50+ Countries



See more independent reviews by finding Florence on G2.com.

Read 80+ Reviews by Searching Florence on G2.com

"Easily accessible and organized and HELP is always available. There are also great resources available."

"I enjoy the simplistic design and how the features allow for a range of regulatory abilities"

"Game changer for our organization!"

"Florence makes collecting and organizing confidential source documents a breeze."

"A win for all users, with new options and improvements for end users regularly!"

"Fast implementation and quick system to start using!"

Start your Site Enablement Journey with Florence

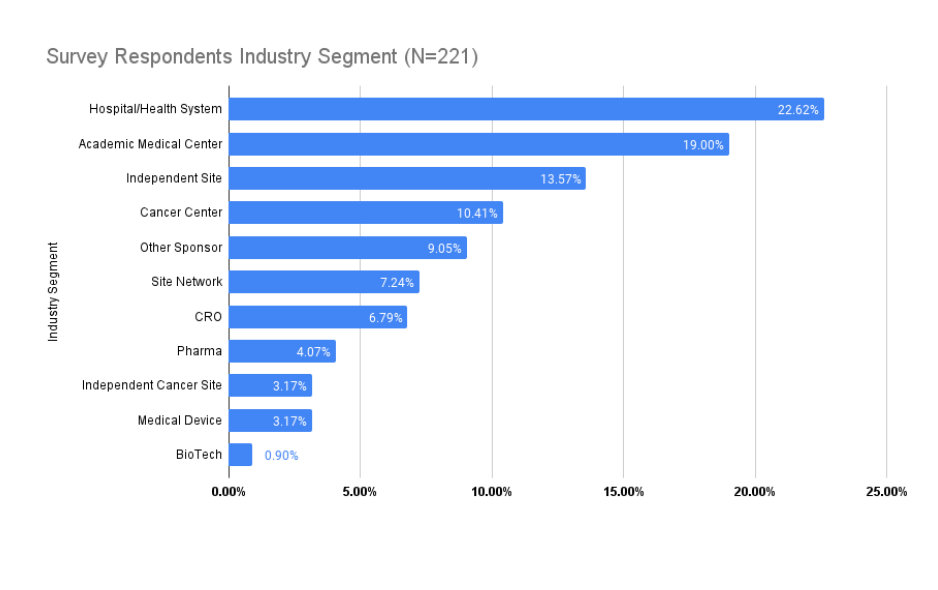
Connect with a Site Enablement expert to dig into how to transform your clinical trial operations with technology in 2024 and beyond.

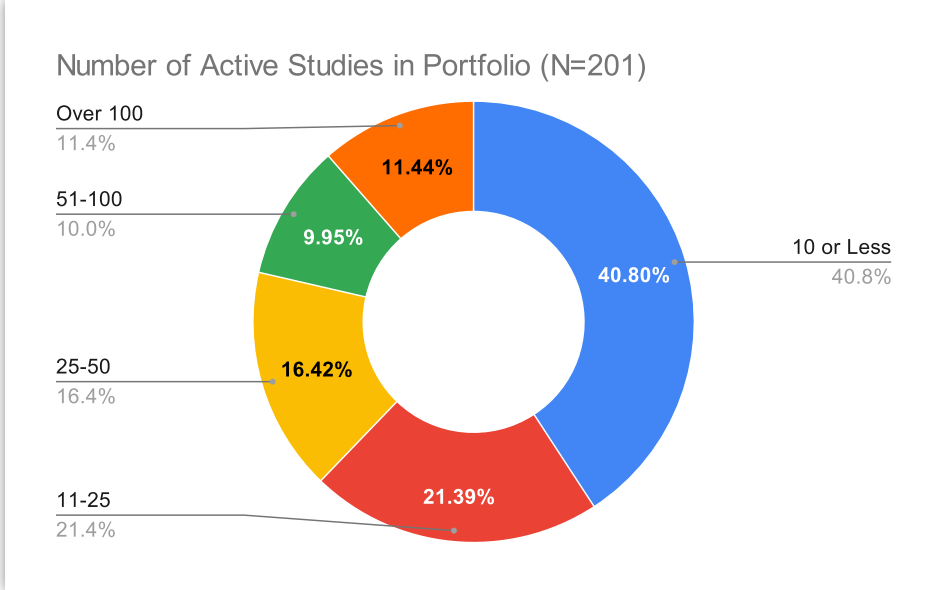
Connect at Florencehc.com

Email us at info@florencehc.com

Survey Data Results

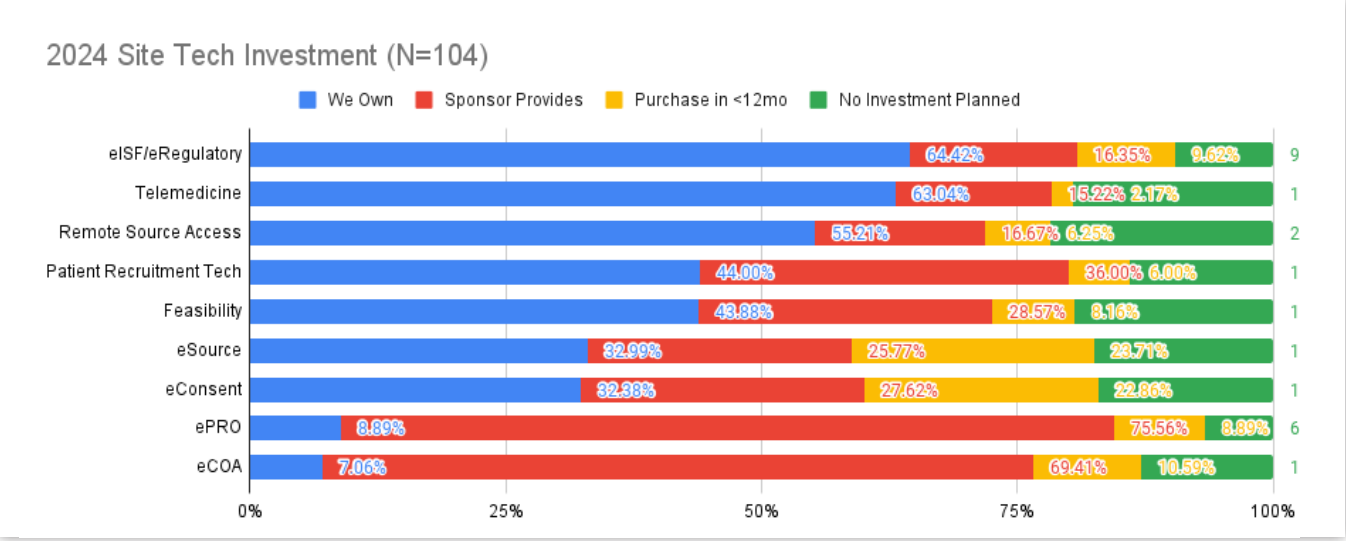
Survey Demographics

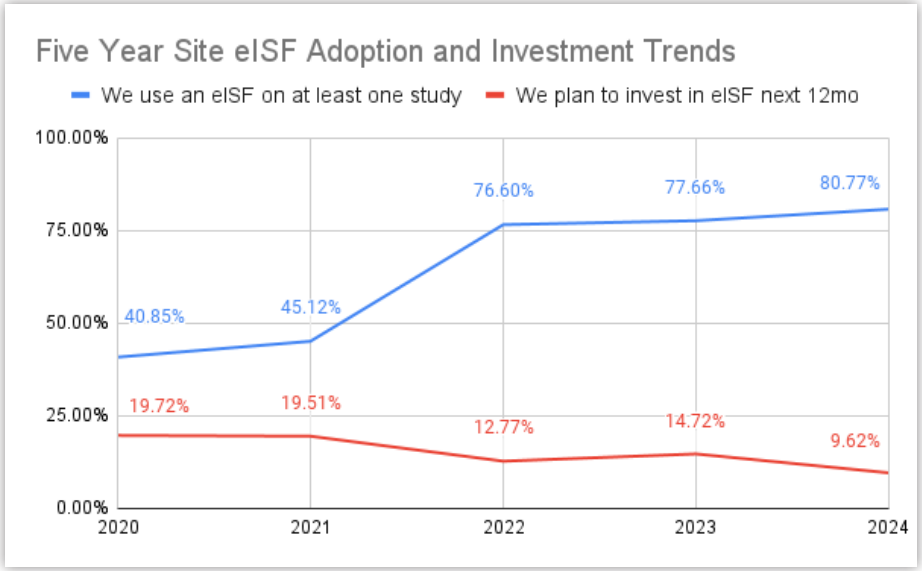


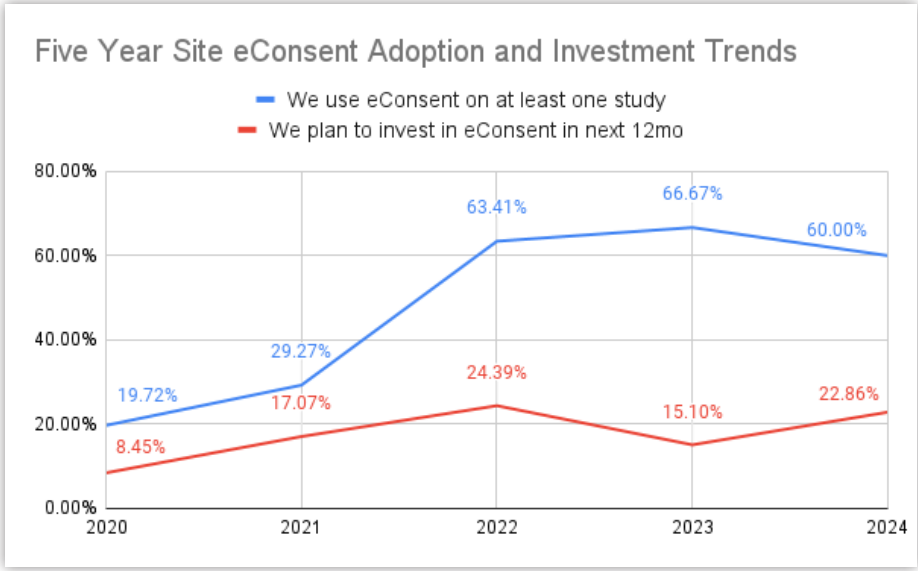


Site Survey Data Results

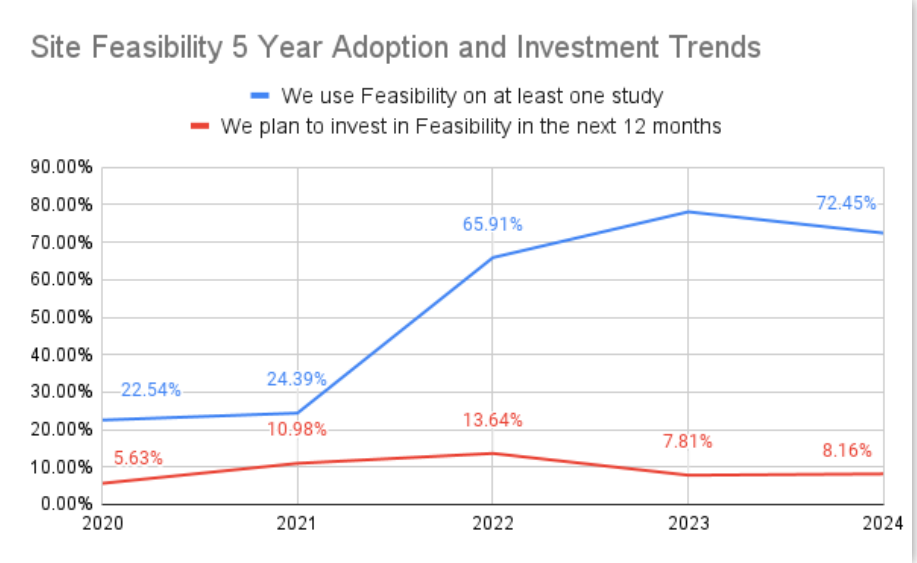
Site Data Results

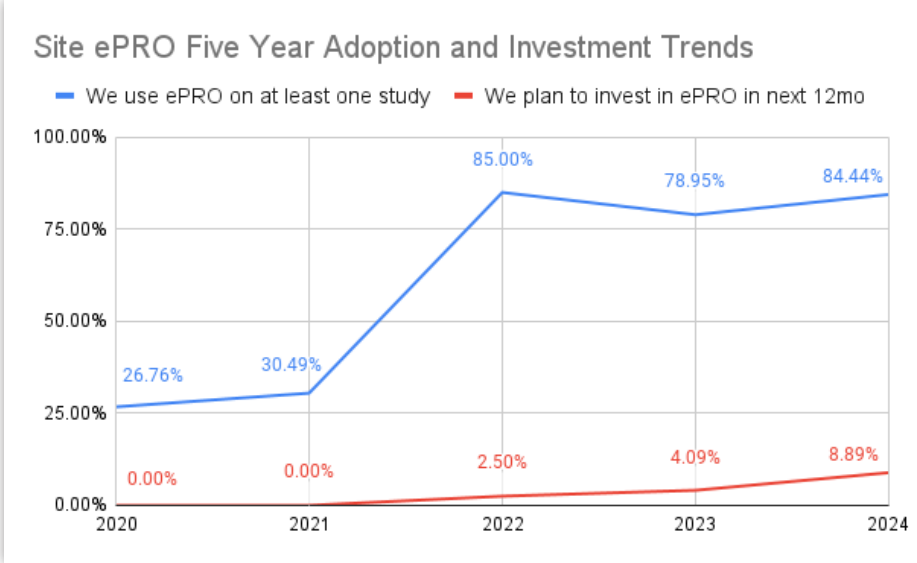


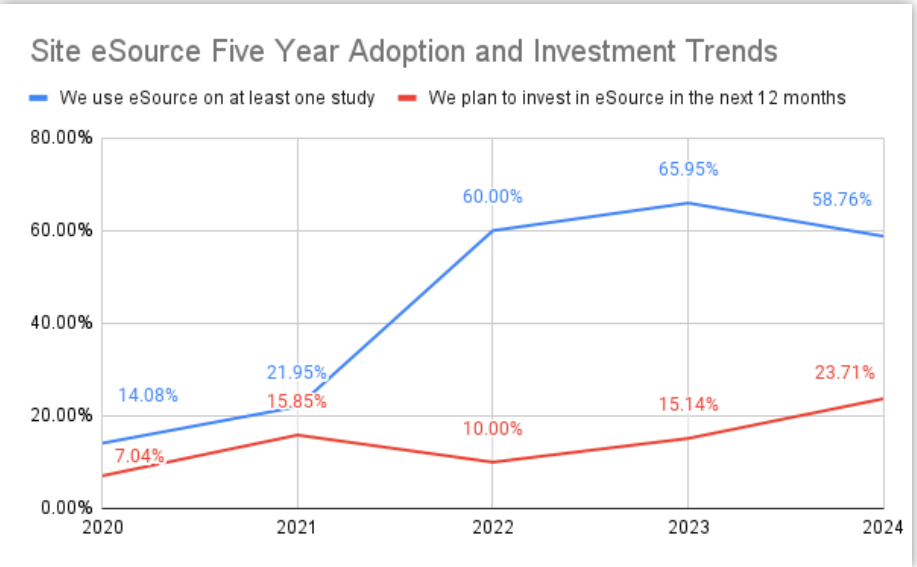




Site Data Results







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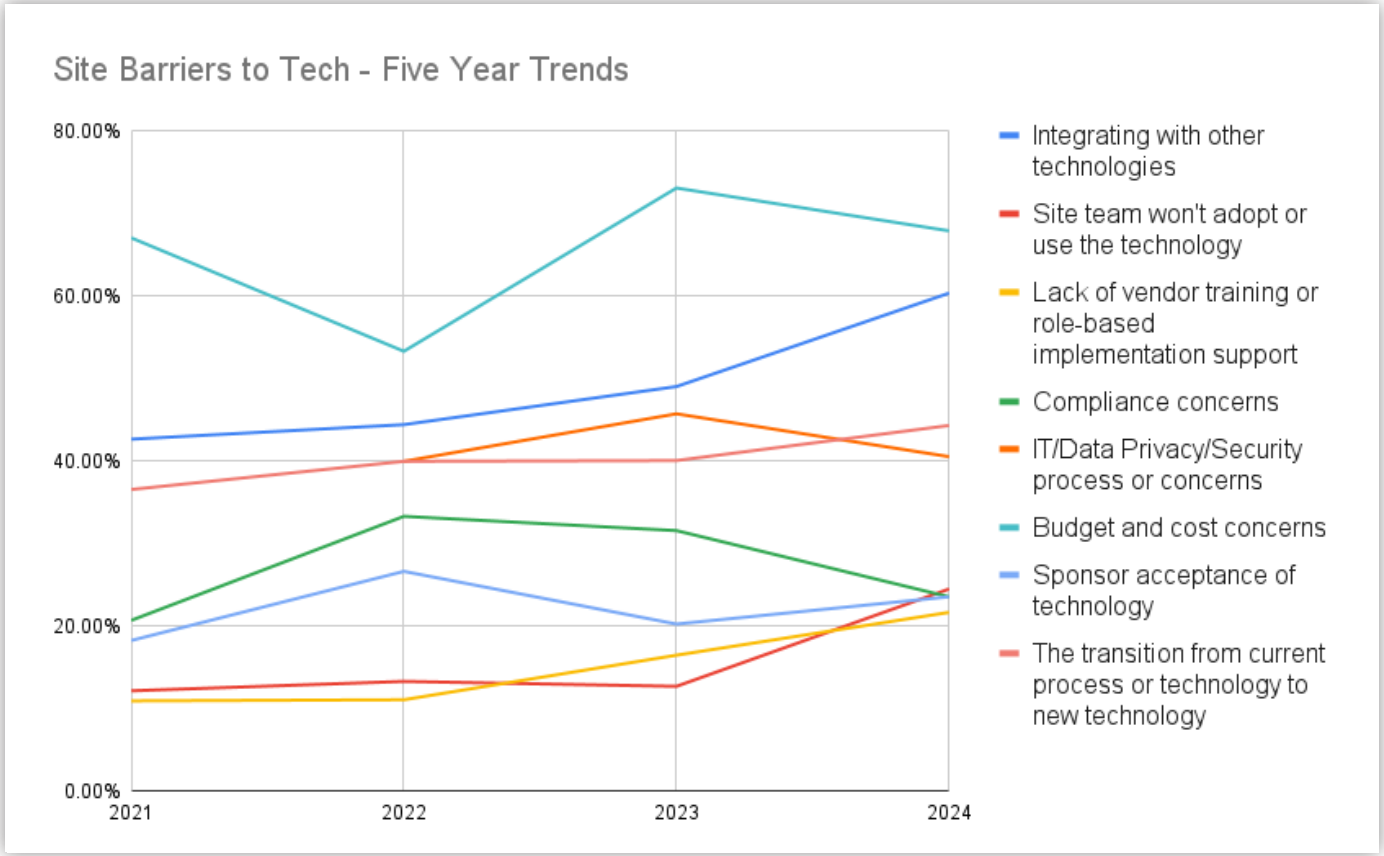

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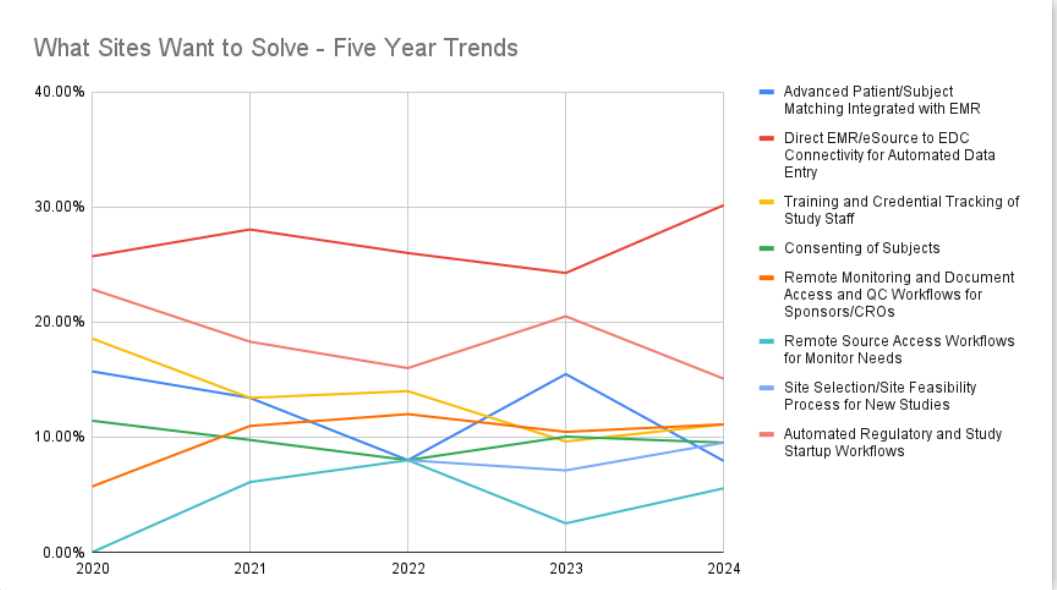

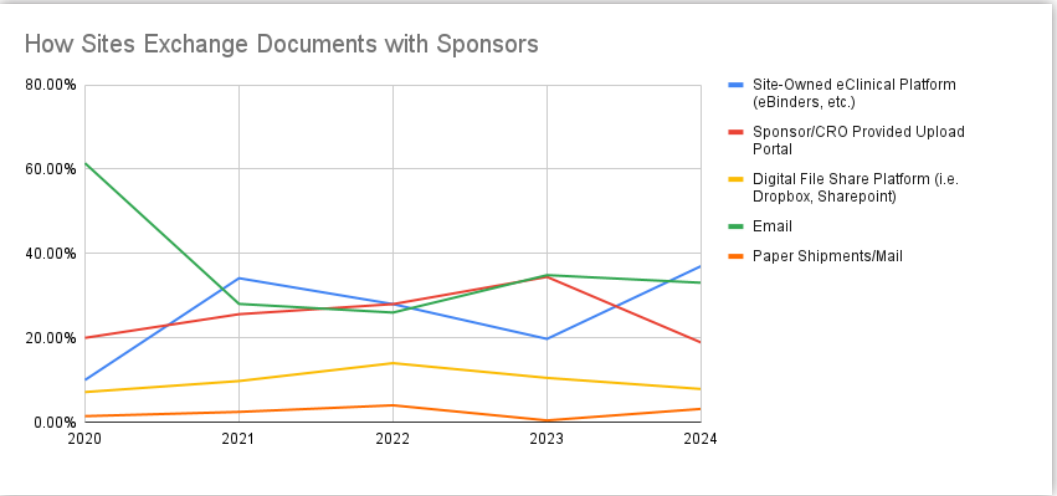

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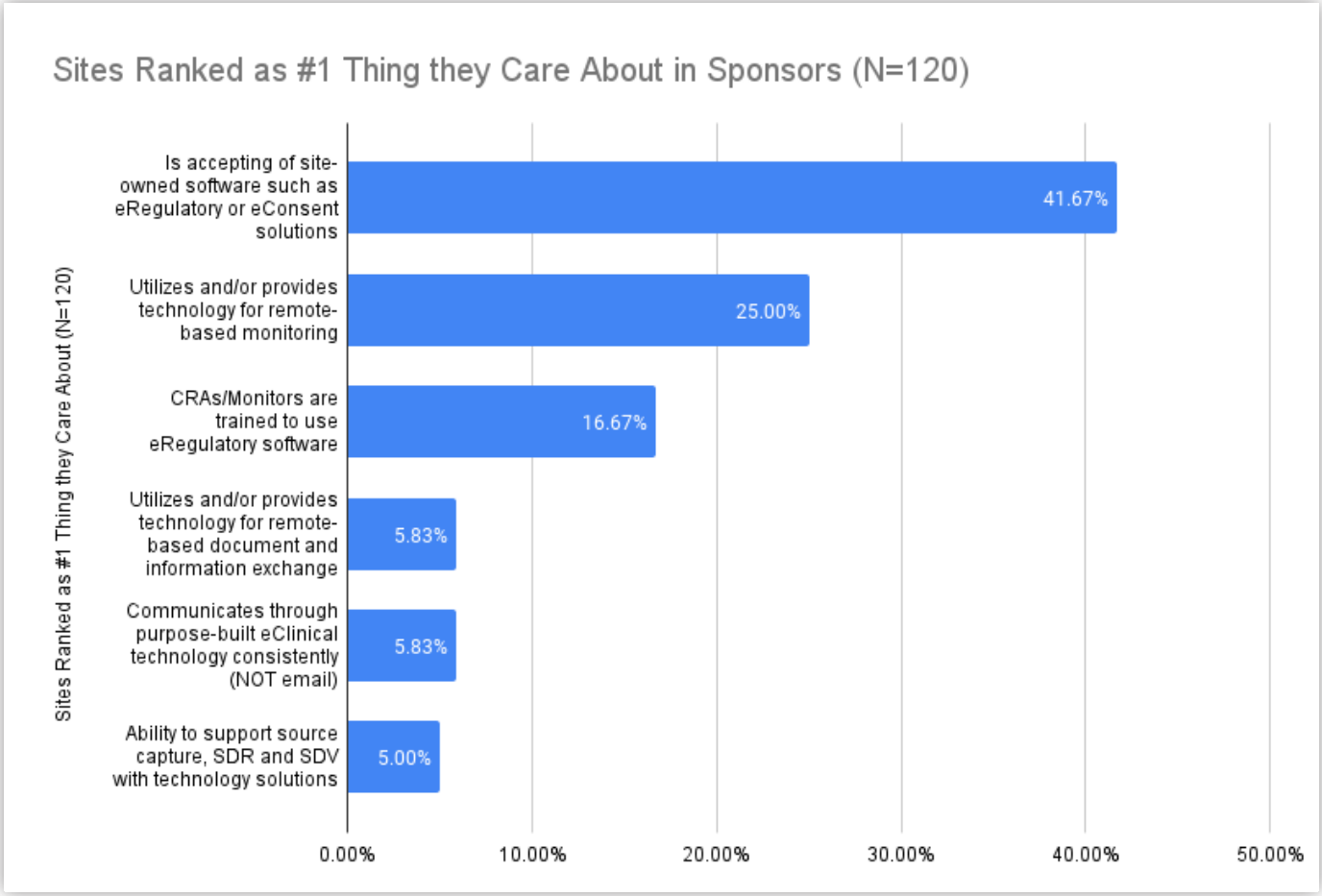

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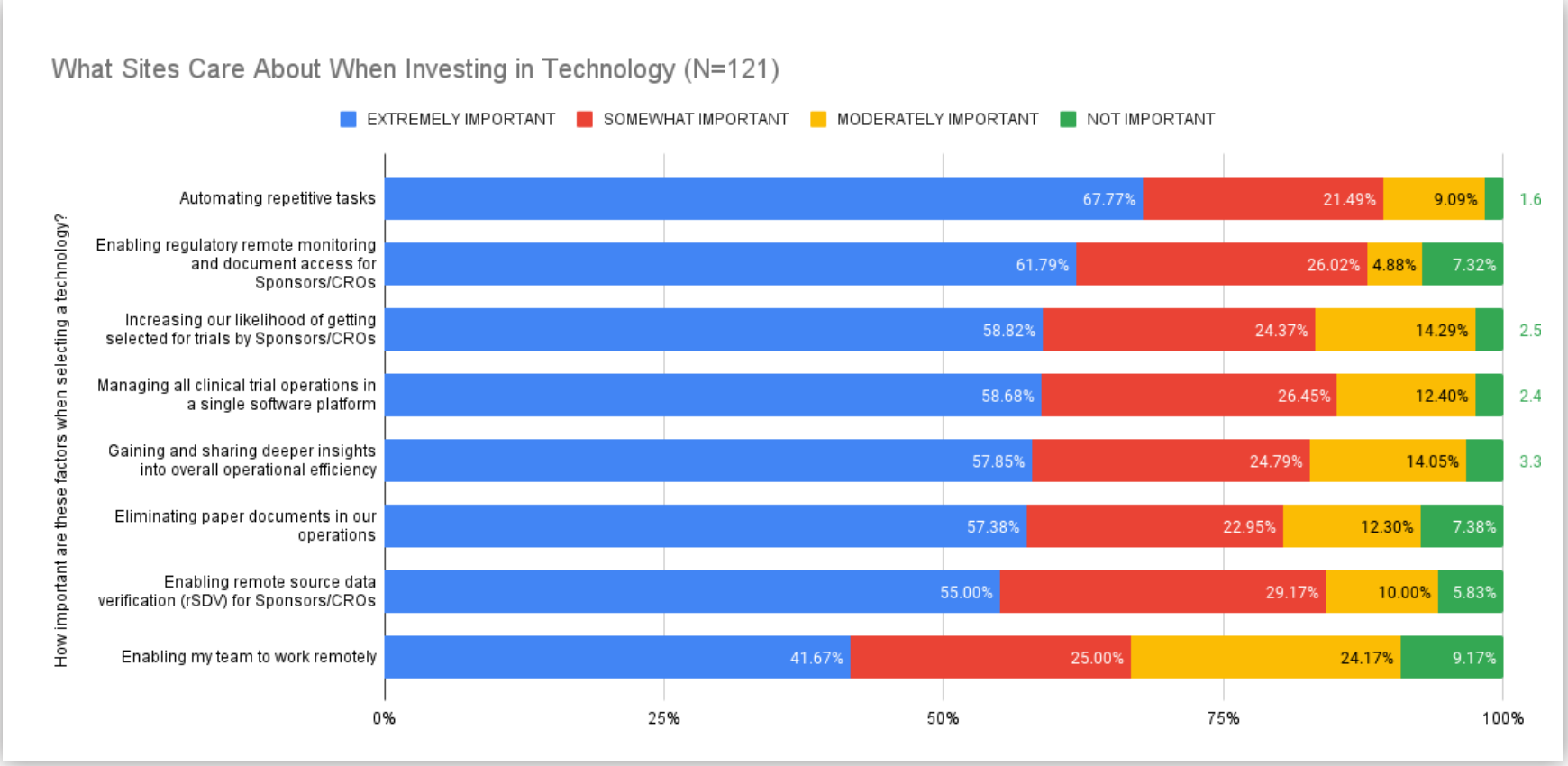
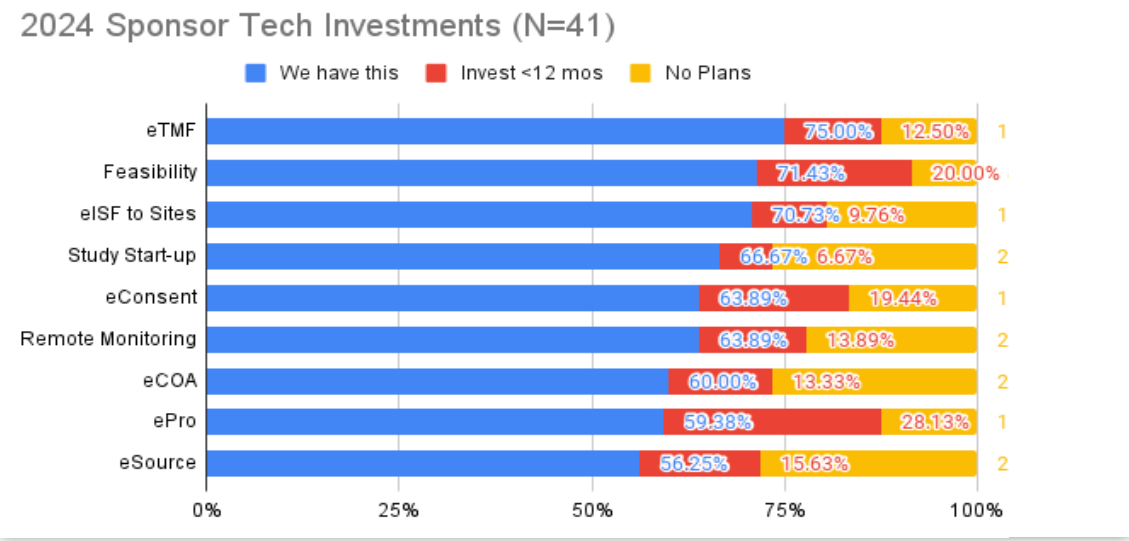
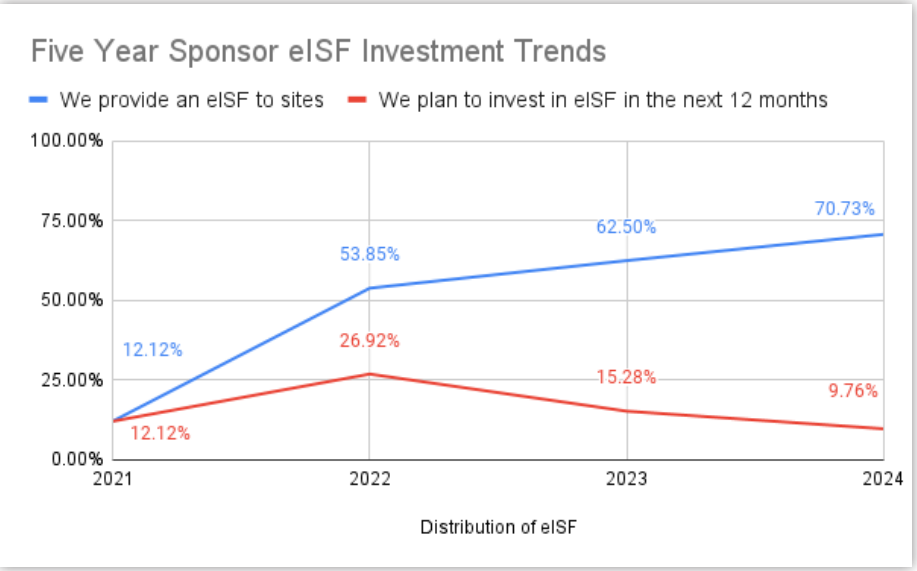
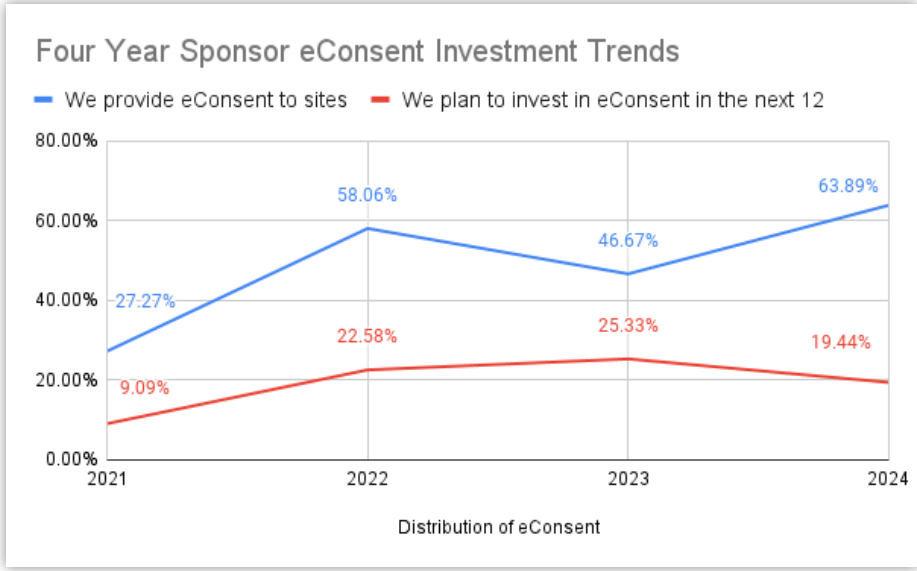


Sponsor and CRO Survey Data Results

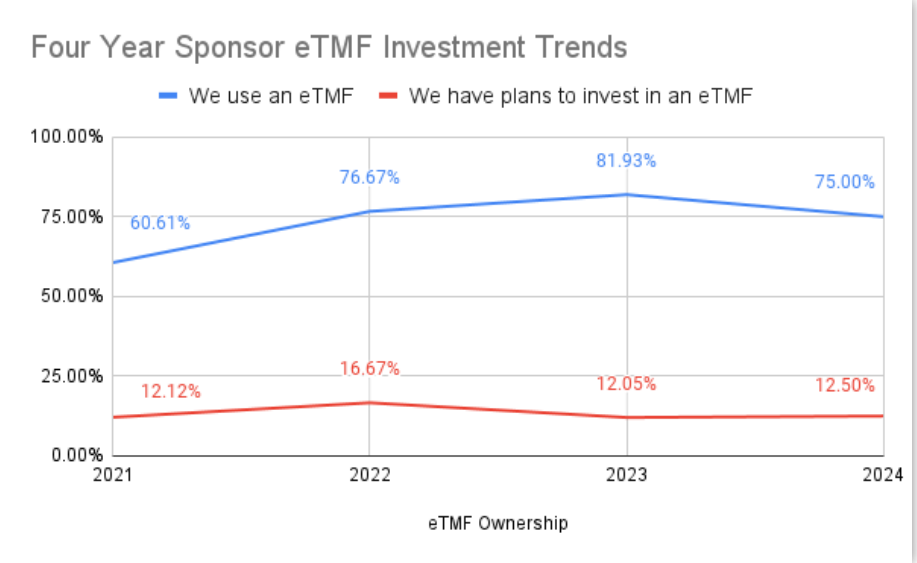
Sponsor/CRO Survey Results

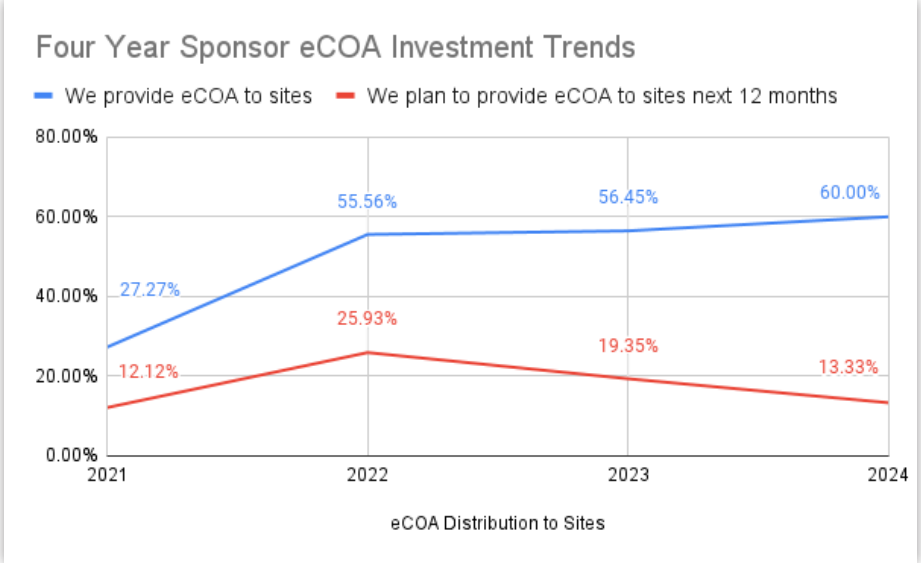


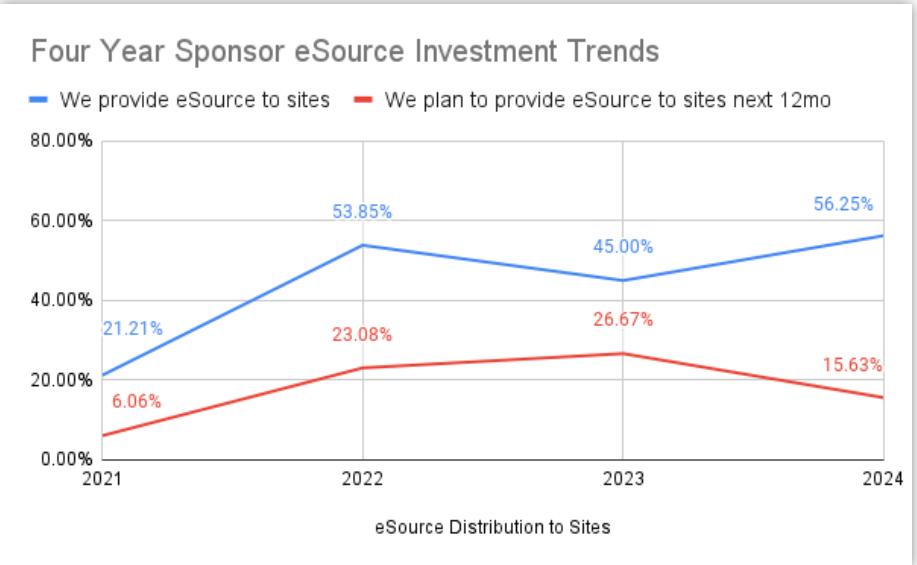


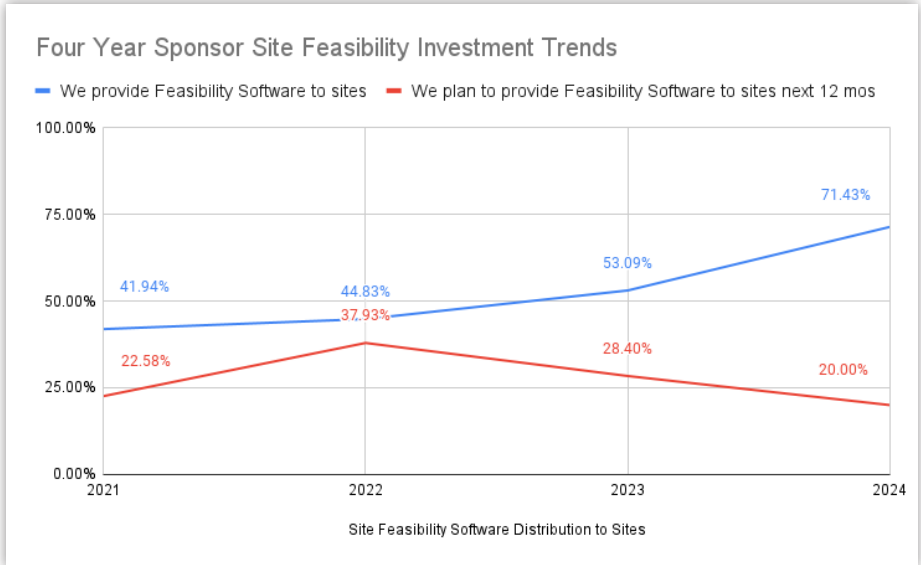


Sponsor/CRO Survey Results

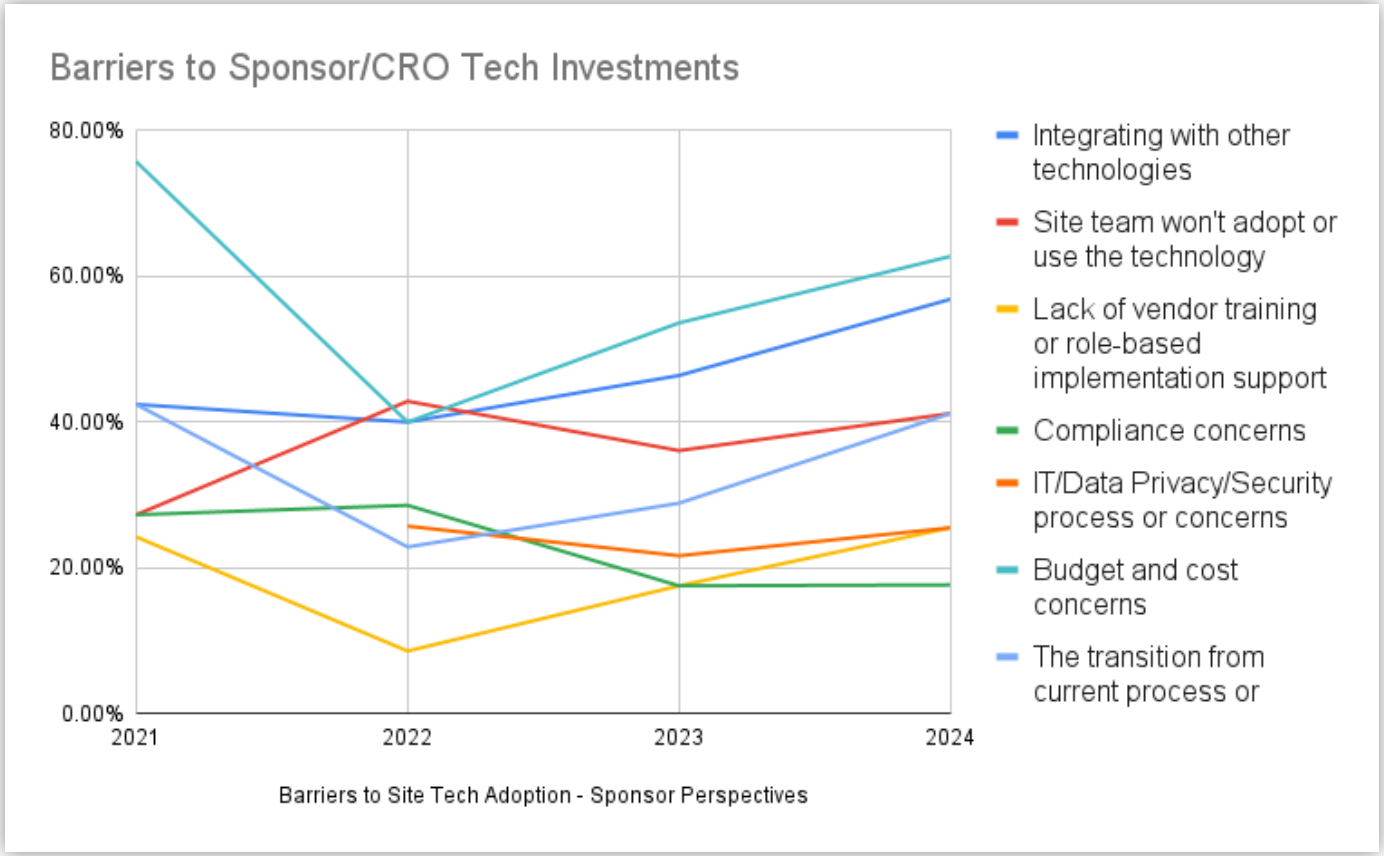








Sponsor/CRO Survey Results



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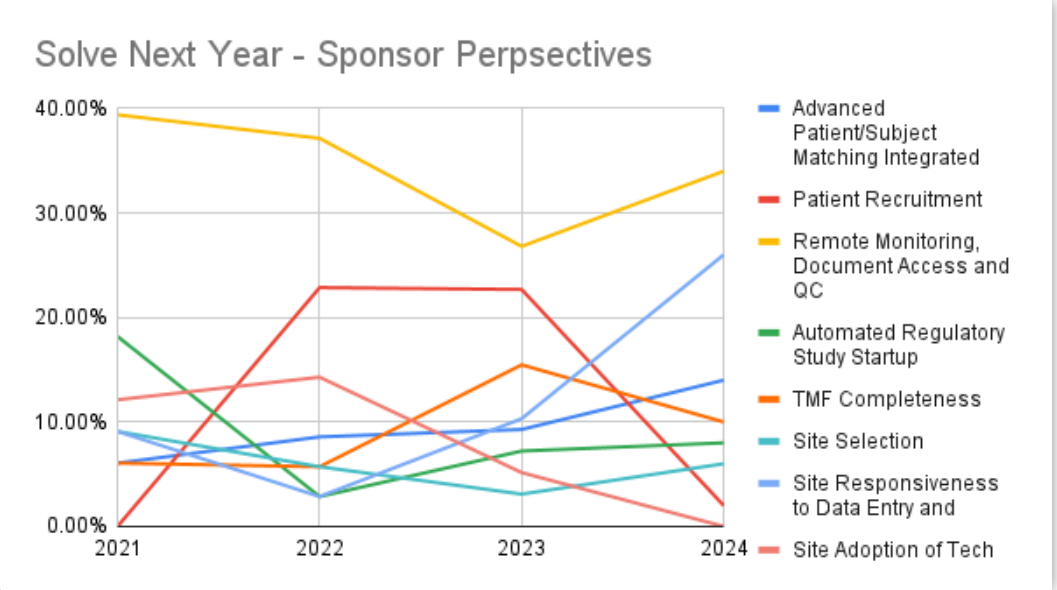

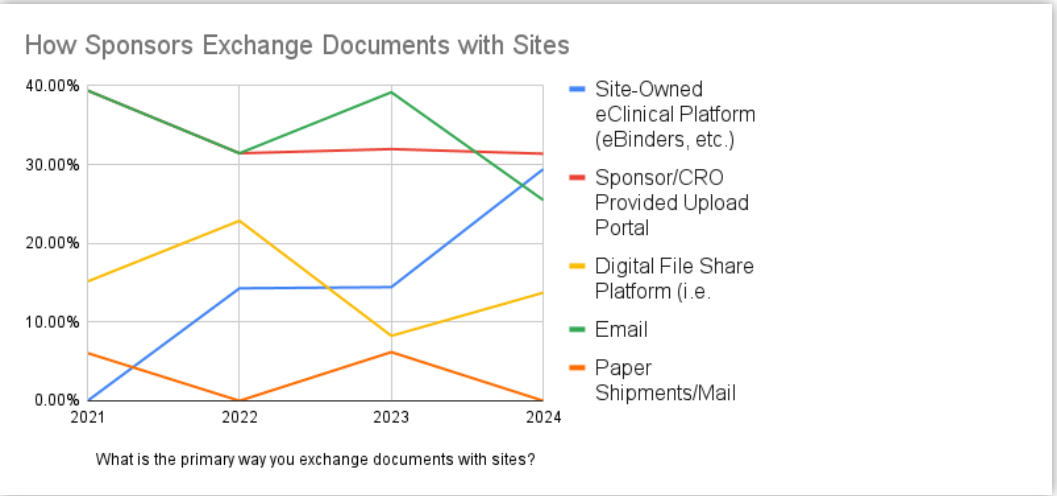

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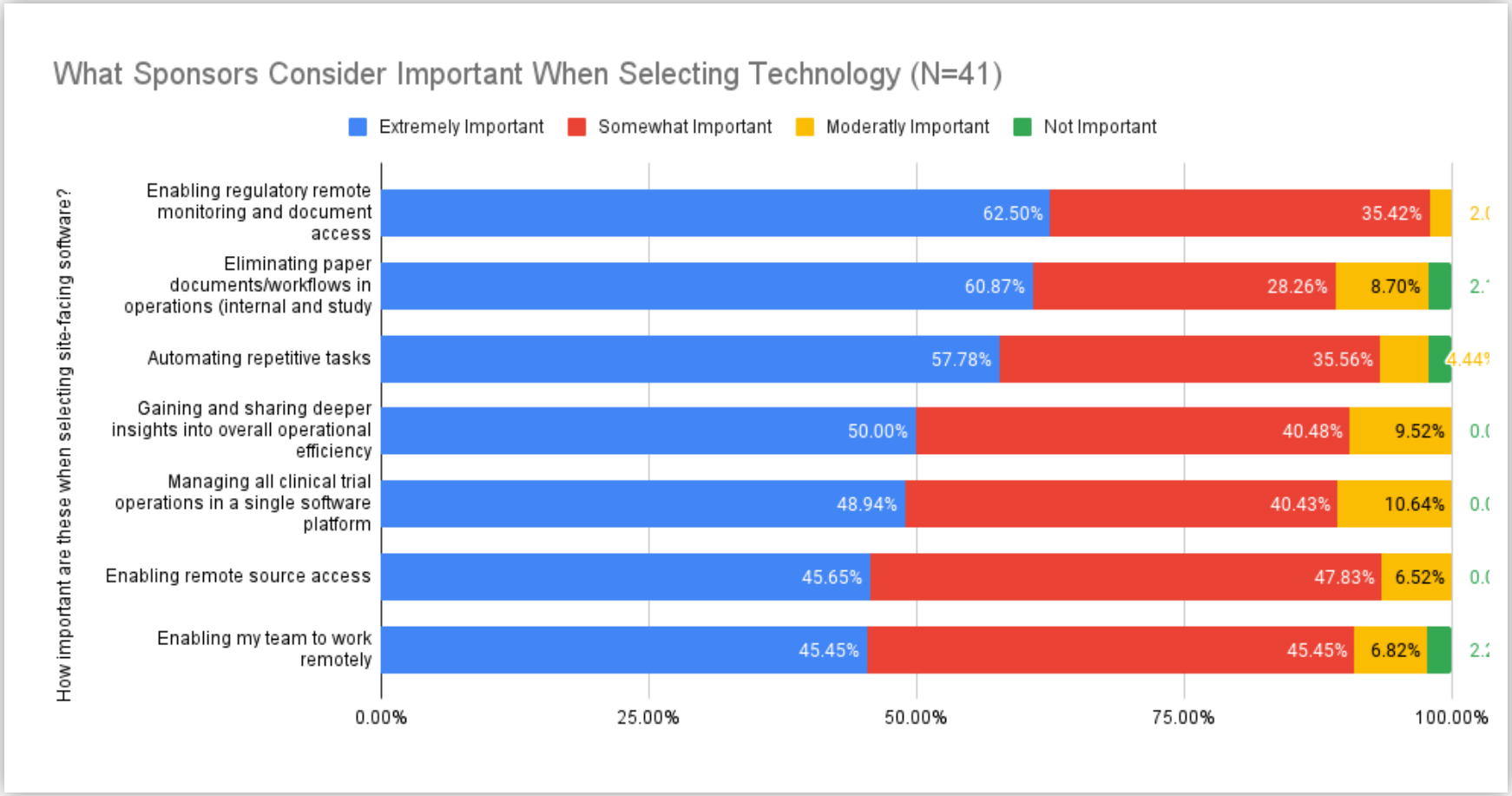

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